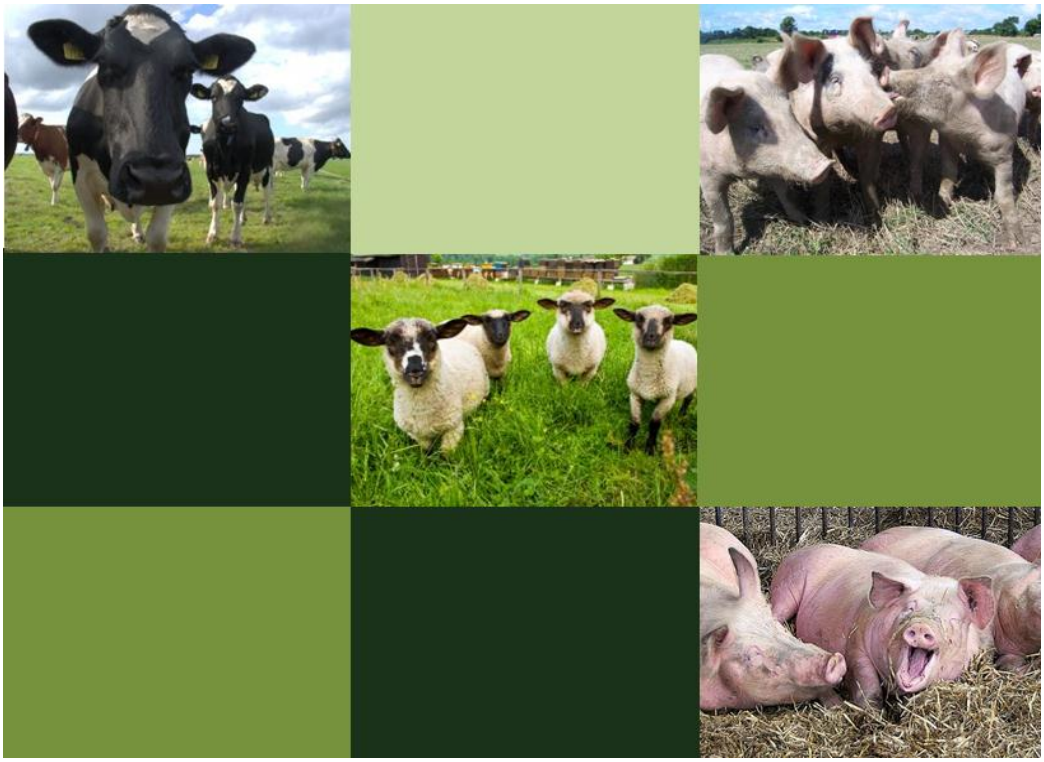

Impact in the EU and third countries of EU measures on animal cloning for food production

Final report to DG SANCO: Main Text

6 December 2012

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Final report to DG SANCO

Main text

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A set of annexes to this report are bound separately.

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Glossary of terms

Term	Definition/interpretation
Clone	An animal produced by means of cloning.
Compliance costs	The sum of the one-off costs associated with changing existing systems (e.g. traceability systems) to meet the requirements of the specified packages and the additional on-going costs of operating those extended systems as incurred by competent authorities and the supply chain.
Descendant	An animal produced by a traditional breeding technique, for which neither of its parents is a clone but its ancestor was a clone (i.e. 2nd and subsequent generations).
Direct revenue impacts	The direct effect of packages on revenues (sales) of operators, most often as a consequence of placing additional constraints on the business or withdrawal of products.
Learning costs	'Learning costs' are the staff time and advisory costs incurred by directly affected operators as they familiarise themselves with the new legal requirements. This is a one-time impact.
Measure	An intervention proposed by the Commission for consideration in this study, (e.g. traceability of live clones).
Offspring	An animal produced by a traditional breeding technique, for which at least one of its parents is a clone (i.e. 1st generation).
Operating costs	A category of compliance costs: the incremental cost of running the new, modified or extended systems to meet requirements of the packages including activities undertaken by operators and by competent authorities.
Package	A combination of policy measures.
Reporting and inspection costs	Reporting and inspection costs are incurred as breeders, livestock producers and food business operators respond to information requests (i.e. reporting).
Reproductive materials	Semen, embryos and ova.
System development costs	Cost incurred to extend the scope and/or scale of systems for identification, traceability etc. to meet package requirements.
Trade-mediated impacts	Impacts on operators that arise through the conditions placed by packages on trade between the EU and third countries, such as a requirement for provision of information on whether animals, reproductive materials, or food products are (or are derived from) clones, clone offspring or clone descendants.

Key messages

- Cloning is a copying process that avoids the mixing of genes associated with the conventional sexual reproduction process; an animal with desirable attributes can be replicated, but the technique cannot be used to acquire or refine desirable traits. Cloning of animals for food production is most commonly used to replicate high value breeding animals. The technique is more expensive than other common breeding techniques and has a high failure rate so is used selectively.
- The use of the cloning techniques has been criticised on ethical and animal welfare grounds. The majority of cloned embryos do not develop to term and more die during or shortly after birth from a variety of causes. Surrogate cattle dams have problems including late gestational loss and more difficult delivery. Studies have shown that survival of offspring and descendants of clones is similar to the survival of conventionally bred animals.
- There is no evidence that commercial cloning of animals for food production is taking place in the EU and consultations suggest it is unlikely to be established before 2020. Commercial cloning of animals for food production is practised in some of the EU's trading partners, most commonly with bovine animals though there is some use with porcine animals. It is also used for equine animals bred for sport and leisure. Under current legislation there is, in principle, the potential for offspring and descendants of clones to be produced in the EU through importation of reproductive materials from clones or of their offspring or descendants, and (though this is uncommon) importation of live animals. Food products derived from such animals could also be imported.
- Animal cloning for food production could be regulated without major disruption to the EU food chain or its consumers through suspension of the technique (and suspension of marketing of clones) in the EU or introduction of traceability requirements for clones, subject to common-sense arrangements being put in place to exclude or trace clone imports. Suspension of the use of clone reproductive materials or requiring their traceability is also feasible if existing supply chain mechanisms for excluding such materials from imports from North America are recognised and extended to other trading partners as needed. The impacts would be small.
- Extending the scope of controls beyond clones to clone offspring and clone descendants (and their reproductive materials) creates the risk of negative indirect effects on the EU livestock breeding sector and also to livestock producers, especially the dairy sector, through interruption to trade in reproductive materials. Requiring identification of the clone status of individual animals and their traceability would impose large additional costs on the EU livestock sector and competent authorities in the development and operation of new systems. There would be very few clone offspring or clone descendants in the market and such costs would not be proportionate.
- The reliability of claims made for the clone status of descendants could not, in most instances, be verified. Systems would be reliant on documentary controls and prone to fraud and accidental error (e.g. mis-attribution of offspring to parent). Market incentives (e.g. higher cost, lower value) may not encourage compliance.
- Food products derived from clone offspring or clone descendants are not currently identified as such by the EU's trading partners. Suspending such products or requiring their identification and traceability is likely to reduce or halt imports in affected product categories, with negative impacts on EU consumers and the supply chain, when exporters are unwilling or unable to comply with the EU's evidential requirements.
- Labelling products as derived from clones, clone offspring or clone descendants is likely to increase the drive to exclude such products from the market. Labels would be no more reliable than the traceability systems that sit behind them. Clones are very unlikely to find their way into food products and traceability systems for clone offspring and descendants would be costly and unreliable. Few, if any, products are likely to be brought to the market.
- A requirement for premarket approval for food from clones is also likely to have a limited impact within the EU because supply chain sentiment is unlikely to see many (if any) products registered, though a requirement for premarket approval for food from offspring or descendants of clones would represent an additional barrier to trade with the EU for operators in third countries.

Executive Summary

Introduction

This is a summary of a study commissioned by DG SANCO of the European Commission from ICF GHK to inform and support development and appraisal of proposals to regulate animal cloning in the EU. It provides a feasibility and impact assessment of four possible approaches to regulation of animal cloning for livestock in the EU. It includes a description of the use of and concerns about the technique and the outlook for livestock cloning to 2020. It then compares the expected impacts of various measures, specified by the European Commission, through which the four approaches would be implemented. The appraisal covers feasibility, administrative burdens, induced costs, trade-mediated impacts, employment effects, and then impacts on consumers, SMEs and the environment.

There is currently a lack of inter-institutional agreement between the Commission and the Parliament regarding the regulation of animal cloning in the EU. A Roadmap was developed in February 2012 to address this issue. This study will assist the Commission as it prepares an impact assessment of the five options set out in the Roadmap. The four approaches assessed here are:

- A suspension or ban on animal cloning in the EU, including use of the cloning technique, marketing of reproductive materials from clones, marketing of live clones, and marketing of clone offspring, descendants, and the reproductive materials of offspring and descendants.
- Traceability for clone reproductive materials, live clones, their offspring and descendants, their reproductive materials and derived food products.
- Labelling requirements for food products derived from clones, their offspring and descendants, in addition to the traceability requirements.
- Premarket approval requirements for food products derived from clones, their offspring and descendants, in addition to the traceability requirements.

The scope of work includes bovine, porcine, ovine, caprine and equine animals and spans the full breadth of the food supply chain from production to consumption. The study considers the impacts of the four approaches on both the EU and third countries. It does not consider cloning for research purposes, pharmaceutical production or other commercial uses, including sport and leisure or conservation of endangered species or breeds.

ICF GHK acknowledges with thanks the support given to the study by many stakeholders who participated in the consultation and research process.

Context to the study - livestock cloning in the EU and third countries

Scientific and social context of livestock cloning

Commercial cloning is a form of assisted reproductive technology and may be used to replicate ‘high quality’, high value breeding animals. It can increase the number and therefore the availability of animals with superior genetics. Cloning can multiply the number of such animals, but it is not a breeding technique— an animal with desirable attributes can be replicated, but the technique cannot be used to acquire or refine desirable traits.

Commercial cloning is most common in sectors where assisted reproductive technologies are already widely used and where breeding animals carry a particularly high value. Cloning is currently considered to be of greatest benefit in the dairy industry, where larger numbers of high quality animals could increase overall herd milk yield, the availability of stock with disease resistance and other desirable traits associated with milk quality.

Cloning has been used for bovine, porcine, ovine, caprine and equine animals. Its use has been mostly limited to dairy cattle and horses, however, largely due to their high value as breeding animals. Cloning is relatively expensive and has a high failure rate, making it viable only where the prospective returns are worth the investment. The overall success rate of the cloning procedure is less than 10 per cent in bovine animals and between 5 and 17 per cent in pigs. Its use in equine animals is limited to sport horses. Little use of the technique is made for ovine, caprine and porcine animals.

There are animal health and welfare concerns associated with cloning, particularly the higher mortality rate of clones compared with sexually produced animals. A majority of cloned embryos do not develop to term and of those that do, another proportion die during or shortly after birth from a variety of causes. Surrogate cattle dams also have problems including late gestational loss and more difficult delivery. Studies have shown that survival of offspring and descendants of clones is similar to the survival of conventionally bred animals.

Studies carried out on in the EU and third countries on the safety of food products derived from clones, their offspring and descendants conclude that there are no additional risks associated with consuming these products and that there is no increased risk compared to food products derived from conventionally-bred animals.

Nonetheless, research suggests that EU citizens and consumers are concerned about animal cloning, and oppose its use for livestock. The supply chain does not generally perceive investment in cloning to be worthwhile at this time due to consumer concerns, coupled with high costs to use the technique and availability of other assisted reproduction techniques.

A joint statement on animal cloning issued in 2010 by the governments of Argentina, Brazil, New Zealand, Paraguay and the United States observes that regulatory approaches to agricultural technologies should be 'science based' and should not restrict trade more than necessary to fulfil 'legitimate objectives'. It states that there is no basis to differentiate offspring or descendants of clones from other sexually reproduced animals. New Zealand is the only country that currently regulates cloning activity. No third country identifies or tracks the offspring or descendants of clones.

Current use of animal cloning and the outlook to 2020

The research suggests that there is currently no commercial cloning of livestock animals in the EU and none is expected before 2020. Commercial cloning of bovine animals is happening in a small number of third countries, particularly in North America and Argentina. Cloning is also being applied to porcine, ovine and caprine animals in third countries, but to a much lesser extent. Commercial cloning is concentrated in the US, Canada and Argentina, although there is some activity in New Zealand, Australia, Chile, China and South Korea.

Commercial cloning of beef and dairy cattle is likely to continue in third countries. It is expected to become more efficient and less expensive, but remain limited to high value breeding animals. Commercial pig cloning may also become more widespread by 2020. Its application to ovine and caprine animals is expected to remain limited.

The most likely route for clones, clone offspring and descendants or their reproductive materials to come into the EU is as reproductive materials from bovine animals, and possibly porcine animals from North America, and beef products from Argentina. Offspring of bovine dairy clones have been produced in the EU from imported reproductive materials from North America (two such animals entered the UK food chain in 2010). It is possible, if unlikely, that equine clones produced for sport could enter the EU food chain when the animals reach the end of their working life or through equine meat imports from third countries.

Supply chain and trade profile

The supply chains that may be affected by the proposed approaches to regulation of animal cloning reach from 'farm to fork', including the breeding sector, producers, markets, slaughterhouses, cutting plants, meat and dairy processors, wholesalers, retailers, as well as importers of live animals, reproductive materials and food products. Species-specific information is available on the number of enterprises involved in animal breeding and production, as well as for imports of live animals and their reproductive materials. Beyond these points in the supply chain the available data only provide aggregate numbers of enterprises across the different sectors.

The policies potentially affected a very large number of businesses – relatively few firms in the breeding sector but very many producers, processors and retailers. There are fewer than 10 companies operating in the EU that could conduct cloning activities (none are known to be doing so). Approximately 300 AI companies operate in the EU livestock breeding sector. There are an estimated 120 importers of reproductive materials. Almost all the importers of live animals deal in equine animals, though there are a few importers of bovine, porcine, ovine and caprine animals. The EU has

nearly 8 million producers of bovine (3.3 mil), porcine (2.7 mil), ovine (1.2 mil) and caprine (0.7 mil) animals. The total number of markets, slaughterhouse and cutting plants is unknown, though there are an estimated 15,000 of these operations for bovine animals. Further down the supply chain there are around 82,000 processors / manufacturers, 83,000 wholesalers, and 624,000 retailers of meat and dairy products. There are around 715 importers of meat and dairy products.

The measures assessed could affect trade, particularly imports into the EU. At present:

- Parts of the EU livestock sector are heavily reliant on imported reproductive materials, particularly from US and Canada. Commercial cloning activities occur in both countries, but the proportion of materials sourced from clones, their offspring and descendants is unknown.
- A small number of live bovine, ovine and caprine animals and a larger, but still relatively small number of porcine animals are imported to the EU each year. Due to the high transportation costs, these are all expected to be high value breeding animals, which the EU livestock sector also considers to be important to the breeding industry. A relatively large number of equine animals imported into the EU each year (11,000 in 2011), but these are all expected to be for sport and leisure purposes rather than food production.
- The EU is a net importer of beef and veal worth around €1.7 billion per year. Sheep meat imports are valued at approximately €1 billion. Cheese and butter are worth more than half a billion euro, despite the EU being a net exporter of these products. 95 per cent of beef imports are sourced from eight countries, with 70 per cent coming from Argentina, Brazil and Uruguay. Milk and dairy products are sourced primarily from Switzerland, New Zealand, and Ukraine and Belarus. The EU is self-sufficient in pig meat though there is small volume of pig offal imports from Switzerland and of pig meat, mainly from US and Chile. Sheep and goat meat is primarily sourced from New Zealand and Australia. Around 70% of equine meat is sourced from Argentina, Brazil, Uruguay and Mexico, most of the remainder is sourced from Canada and the US.

Feasibility and impacts of the four approaches

The individual measures provided are not, with a few exceptions, viable in isolation so for the purposes of analysis were combined into coherent 'packages' of measures. In some cases, different strategies have also been modelled to explore the implications of alternative possible interpretations of the stated policy objectives. For example, for traceability, one strategy looks at the impacts assuming that best use is made of existing traceability systems, another looks at the impacts of implemented full traceability of every individual animal, and another looks at whether the objectives could be achieved via voluntary approaches.

The feasibility and impact assessment process therefore involved, for each approach: specifying the packages of measures; mapping these packages onto the supply chain; defining the obligations that the packages place on different sectors and the systems required to achieve the objectives of the different approaches; assessing the feasibility of each package; analysing the impacts on operators and competent authorities arising from the packages, including impacts on SMEs, EU competitiveness, consumers and the environment. The feasibility and impacts of the four approaches have been considered comparatively and progressively through the supply chain, from packages that focus on live animals and their reproductive materials through to food products.

Feasibility

The feasibility assessment considered the issues involved in the construction and operation of systems that could be developed to deliver on each of the four approaches. It focused on technical feasibility, that is, whether a compliant system could be constructed, as well as the strengths and weaknesses of each package of measures.

Feasibility of packages focused on live animals – clones

The suspension of the cloning technique in the EU and marketing of clones and traceability of live clones by adapting existing traceability systems are both feasible (measure S1 / package S-A, measureT1 / package T-A). Use of the cloning technique requires specialist expertise and technology not widely available. Clones are high-cost animals that would be used for breeding purposes. As such, they are highly identifiable since operators involved in breeding such high-value animals tend to

keep detailed records of the animals. With few firms to regulate, domestic cloning would be relatively easy for competent authorities to control. Imports are more problematic, but there are only a small number of animals to control. Imported live animals can be controlled relatively easily through risk-based surveillance of trade focusing on the main sources of food production animals with the highest levels of cloning activity.

Feasibility of packages focused on reproductive materials from clones

Suspension of the marketing of reproductive materials from clones (package S-B) and traceability of reproductive materials from clones (package T-B) under all traceability strategies are feasible without significant adjustment to existing EU (or third country) systems. The production of reproductive materials is already a highly regulated industry in the EU and in the third countries from which the EU sources imported materials. Individual identification and traceability is already enabled in the EU for all semen and embryos. There is no known domestic production of clone reproductive materials for bovine, porcine, ovine or caprine animals. Private sector agreements also already identify cloned reproductive materials from bovine and equine animals originating in the US and Canada. There is no known trade in reproductive materials from clones of the other species.

Feasibility of packages focused on live animals – offspring and descendants

Suspension of the marketing of clone offspring and descendants (packages S-C, S-D), and the traceability of clone offspring and descendants (packages T-C, T-D) using existing infrastructure are both feasible, but would require considerably more adjustment to existing systems than controls that applied only to clones. These packages are more vulnerable to fraud than those covering only clones and clone reproductive materials; third countries are unlikely to change their traceability systems to ensure that imports of live animals into the EU conform to EU requirements. Together, these issues put packages related to clone offspring and descendants at risk of not meeting their objectives.

Domestically produced offspring of clones are identifiable due to agreements with North American operators to identify reproductive materials from clones. The offspring produced from these reproductive materials are most likely to be high-value breeding animals and therefore, records will be kept of these animals' parentage. Identifying domestically produced descendants will be complicated by the record keeping required. As descendants become part of multiplication herds, parentage information may not be fully reliable due to mixing of animals on farm. Incentives may not encourage compliance, especially if operating the system entails additional cost and identification of animals as clone descendants has an impact on their market value.

Few live animals of the species covered here are imported into the EU and those that are imported are 'high value' animals whose heritage would normally be documented. Offspring of clones will be relatively easy to identify since parentage records are kept for these high-value animals for at least the previous generation. Identifying clone descendants is much more complicated than for clone offspring because current systems in third countries do not require traceability of clone offspring or descendants. Assuming that the EU requires documentary evidence at the point of import, this package would therefore require countries exporting to the EU to establish new systems that identify each clone offspring and descendant. These systems would need to incorporate trade in animals and reproductive materials amongst third countries to be comprehensive. It seems unlikely adequate systems would be built.

Information on the pedigree status of reproductive materials would be needed to implement these packages; such documentation is not currently required. Systems in place in North America to identify clone reproductive materials do not extend to reproductive materials from clone offspring or descendants. Additional steps would need to be taken by operators to identify these reproductive materials as derived from clone offspring or descendants.

'Legacy' presence of clone offspring and descendants in the EU is a potential problem and a source of additional regulatory costs for suspension and traceability packages covering descendants because identifying all such animals could be difficult and expensive. A decision would be needed on how to treat these animals. One option would be to accept a low level legacy presence of clone offspring and descendants in the food chain and focus efforts on excluding new sources.

Feasibility of packages that require identification of the status of all animals or batches of animals/reproductive materials

Packages covering traceability of clone offspring (T-C, Strategy 1 – ID all animals or batches and Strategy 2) and descendants (T-D, Strategy 1 - ID all animals or batches and Strategy 2) are technically feasible, but would require major changes to the systems for some species, even where there is likely to be little, if any, cloning activity.

A traceability strategy that requires identification of the 'clone status' of all animals or batches of animals will require adjustment to all existing traceability systems to enable an indication to be provided as to whether or not the animal is a clone, clone offspring or descendant, or batch of animals contains animals that are clones, clone offspring or descendants. At present, this should be straightforward for porcine, ovine and caprine animals, since cloning activity for these species is very limited. Bovine animals are more complicated because offspring and descendants may be produced in the EU. There is also an issue of 'legacy' bovine offspring and descendants in the EU.

Traceability approaches that require individual animal identification and traceability will require significant adjustments to existing traceability systems and may require new systems where existing systems cannot cope with identifying the number of new animals that require traceability. Third countries are unlikely to implement new traceability systems in the absence of evidence on human health or safety risks.

Feasibility of packages focused on food products

The greatest challenge to feasibility of packages covering food products arises from imports. Confirmation of the status of these food products as being derived from clones, clone offspring or clone descendants would need to rely on traditional documentary methods used in supply chain traceability systems. This kind of documentation is not currently required for imported food products. International trade in reproductive materials will make it difficult to be certain that the animals, and thus food products, from a country that does not use the cloning technique were not actually derived from reproductive materials from clones, their offspring or descendants obtained in another country. Extension of traceability requirements into processed food products would not be feasible in most instances.

Suspending the marketing of food products derived from clones (S-E) is the most feasible of the packages covering food. The number of potential EU suppliers is small. Proportionate systems for suspension of clone imports are also technically feasible through working with trading partners. The risk of clones being used systematically for food in the next few years is low as clones are uncommon and very valuable, though there is a theoretical risk of such animals entering the food chain at the end of their working lives as breeding animals. Nonetheless, demonstrating and documenting that foods are free of clones would require systems that do not currently exist. Third countries that export to the EU would require appropriate traceability systems or segregated supply chains, unless a pragmatic agreement was reached with third countries to exclude clones from exports to the EU. Verification of claims would not be possible. Moreover enforcing the suspension of use of clones in imported food products would be a significant challenge due to the high volume of EU meat product imports, especially bovine products.

Constructing a system that can exclude clone offspring (S-F) and descendants (S-G) is less feasible than one covering clones alone. Trading partners would need to either identify and trace all clone offspring as live animals and then trace them through the food chain to demonstrate that exports to the EU did not contain products derived from clone offspring, or to establish fully segregated 'clone-free' supply chains. The feasibility of the system for all animals would depend on the specification of the evidential requirements applied by the EU to imports under the new EU 'cloning' legislation.

Traceability packages for clone offspring and clones descendants (T-F, T-G) face the same challenges as suspension packages for food products derived from clone offspring and clone descendants – identification and traceability beyond clones themselves is difficult, if not impossible, without completely segregated supply chains. The EU's trading partners (and those countries' other trading partners) will need to adapt their traceability systems. It seems unlikely they will do so.

Feasibility of labelling and premarket approvals for food products derived from clones, their offspring and descendants.

Labelling and premarket approval approaches for food products derived from clones (package L-A, P-A), their offspring (package L-B, P-B) and descendants (package L-C, P-C) are feasible only to the extent to which the underlying traceability systems are feasible. The limitations of traceability described above are thus also present for labelling and premarket approvals. Where it is difficult or impossible to confirm that a food product contains clones, their offspring or descendants (e.g. mixed meat products), then it will be difficult to label these products, for example, and there are likely to be more errors in identification.

A labelling approach that requires 'positive' labelling (e.g. "contains products derived from descendants of clones") is likely to prompt the industry to exclude products from the supply chain that would be required to carry the positive label. This is due to the negative perception of the cloning technique by consumers and supply chain operators' concern about negative responses of consumers to any label referring to cloning. A labelling approach that required food products to be labelled with information telling the consumer that they may be derived from clone offspring or descendants could be used in a context where food exports to the EU were unable to provide full traceability. This would enable imports to continue in a way that would not be possible if declaration of clone status was a formal requirement for import into the EU.

A labelling approach that is voluntary and 'negative' (e.g. "produced without cloning technology") is likely to be appealing to some operators. A certification approach could be used in which sufficient documentary evidence would confirm that the process used involved sufficient effort by the supply chain to exclude these animals, even if the product is not verifiable. Even so, there is a risk that the two labelling packages covering food products from clone offspring (L-B) and descendants (L-C) would not achieve their objectives because of difficulties in confirming the claims made for imported food products derived from offspring and descendants.

Impacts

Given that little or no commercial cloning is expected in the EU in the period to 2020, virtually all of the impacts arising from the proposed approaches assessed in this study arise from the development of systems to control activities and products that are not present in the supply chain or, in the case of bovine animals, present only at very low levels. Direct and indirect effects are expected on the EU supply chain. The imposition of new requirements that exporters in third countries may be unwilling or unable to satisfy poses a risk of causing interruption to trade, especially for packages that cover clone offspring and descendants, and food products. These trade-mediated effects could negatively impact the EU's animal breeding at one end of the supply chain, and affect choice and price of food for consumers at the other. Some packages are also expected to cause a large number of businesses to spend time (and thus incur cost) understanding the implications of the new legislation for their operations, even in circumstances where they would not be expected to encounter any animals or products regulated (under that legislation). This is a form of additional deadweight cost.

By making products derived from clones, clone offspring and clone descendants more 'visible', the interventions are likely to reinforce a drive towards exclusions of such animals and products from the supply chain. Labelling requirements, which makes clone status visible to consumers, are likely to further reduce demand for livestock animals produced from the use of cloning technology and their introduction into the EU supply chain. Mandatory 'positive' labelling is likely to result in downward pressure on upstream operators by retailers and manufacturers to exclude clones, their offspring and descendants from the supply chain. Operators will face additional costs to take measure to exclude these animals.

Fully segregated supply chains are feasible in some cases, such as for milk, but due to the lack of market demand for products formally recognised as being derived from clones (or clone offspring / descendants), operators are unlikely to invest in those operations.

Direct burdens

The direct burdens on EU operators will vary significantly depending on the approach taken, the information requirements of the approach and the compliance, reporting and enforcement strategy of competent authorities (sections 7.4 and 8.4).

'Learning costs'

'Learning costs' are the staff time and advisory costs incurred by directly affected operators as they familiarise themselves with the new legal requirements (sections 7.4.2 and 8.4.2). Under the suspension and traceability (Strategy 1) approaches such costs are likely to be modest where packages focus on breeders and the 'upstream' parts of the supply chain operators (estimated at less than a €100,000 for packages S-A and T-A due to the small number of directly affected operators, and approximately €1 million for packages S-B to S-D and T-B to T-D). Most of the costs under these packages are borne by the AI industry.

Learning costs increase significantly where packages include regulation of food products. Under the suspension packages (S-F to S-G) meat food importers will also be directly affected, increasing costs by more than €5 million. Under traceability packages (T-E to T-G) costs could increase by approximately €200 million under each package as other 'downstream' operators in the EU supply chain (slaughterhouses, markets, food importers, processors, manufacturers, wholesalers, and retailers) are required to learn about the new requirements (Table 7.5 and Table 8.9).

Learning costs for breeders / holdings can vary from relatively modest (a couple of million euro) where packages focus only on identification and traceability of clones themselves to hundreds of millions of euro where all holdings must learn about new requirements related to traceability under Strategy 1 if all animals/batches of animals must be identified as a clone (or not) and under Strategy 2 if all individual animals must be identified and traced. This is because the scope of the regulation changes from focusing only on those operators handling animals that may be clones, offspring or descendants to all operators raising livestock animals in the EU. Even if each of these operators only needs a minimal amount of time to learn about the new requirements, there are nearly eight million operators that may be directly affected under these scenarios.

Reporting and inspection costs

Reporting and inspection costs are incurred as breeders, livestock producers and food business operators responses to requests for information (i.e. reporting) and/or inspections from competent authorities (CAs) (sections 7.4.2 and 8.4.3).

CAs' approach to regulation will determine the precise burdens on operators. If CAs take a risk-based approach that focuses on EU organisations capable of conducting cloning and targeted checks on imports, then regulatory costs can be reduced. If CAs implement a comprehensive monitoring and reporting framework then the costs will be far higher. In all cases, the costs increase as the packages involve more of the supply chain, and particularly for those that cover food products.

Annual reporting burdens under the suspension approach and (the less ambitious, Strategy 1) traceability approach will be modest where packages focus on clones. For example, traceability costs are estimated at approximately €2,000 per year for packages focusing on clones (T-A and T-E). Estimated annual reporting burdens grow to approximately €32,000 under traceability packages that cover clone offspring and clone descendants (packages T-B, T-C, T-D, T-F, T-G) (Table 7.7 and Table 8.13). Additional annual reporting burdens could be zero to negligible for breeders/holdings under traceability Strategy 1 where positive ID is required only for clones, their offspring and descendants (sub-strategy (a)) but more than €100 million per year if all animals require individual identification where this is not already a requirement under EU legislation (Strategy 2) (Table 8.15).

Compliance costs

The traceability approach will impose additional costs on competent authorities and businesses, including livestock producers. The costs to CAs include one-off costs for changing paper-based documentary and IT based traceability systems to achieve compliance with the new rules and on-going costs for operation of the expanded system (section 8.4.4).

If the traceability approach focused on making best use of existing traceability infrastructure (Strategy 1) consultations with selected MS representatives suggest that these changes could be made through minor adjustments to existing systems. Sub-strategy (a) requires identification only of clones, their offspring, descendants, reproductive materials and derived food products, which would also keep costs low given the small number of animals in the system. Sub-strategy (b) would impose much higher costs since it would require an indication of the status of all animals or batches of animals, and derived products (i.e. clone, offspring, descendant 'yes' or 'no').

If each animal had to be individually identified for all species without derogations (Strategy 2) much larger investments in databases and associated systems would be required. Countries with large populations of porcine, ovine and caprine animals would need to have systems that could accommodate individual ID of all of these animals (potentially millions of additional animals and many millions of animal movements). New systems are likely to be needed to record this information. The costs of adjusting or creating new systems under Strategy 2 would likely run into millions of euros in total across the EU.

There would also be large additional capital and operating expenses for the livestock sector to work to the new system in which individual animal ID and traceability is required. That change would involve removing the derogations put in place under current traceability legislation. There would be additional costs in acquiring and maintaining equipment (such as ear tags, and modifying readers). The requirement to identify the clone status of each small ruminant would require more than 50 million animals to be tagged each year at a cost to breeders and producers in tags and other equipment estimated at €37million to €98 million/year. The cost for porcine animals would be higher because many more porcine animals are produced each year (approximately 260 million) than ovine/caprine animals (approximately 89 million), and most are currently batch-identified. The cost is estimated at between €193 and €510 million each year (section 8.4.4.3). Added to this would be the cost of time taken by operators to administer the system. The inputs required for an accurate estimation of additional costs are not all available but the incremental cost of recording clone status on an individual animal basis is estimated at €24 million for ovine and caprine animals and €71m/year for porcine animals (Table 8.20).

The suspension approach would not impose additional compliance costs on the EU. But it would require compliance expenditure by third countries that would be required to develop segregated supply chains or traceability systems sufficient to demonstrate that their exports to the EU of animals were not clones, their offspring or descendants, and exports of reproductive materials and food products were not derived from such animals, much as would be needed under the traceability approach (section 7.4.1). These systems do not exist at present.

The labelling and premarket approval approaches would impose further compliance costs on operators and competent authorities. These include:

- Costs for labelling changes: operators that need to adapt or redesign product labels in order to accommodate new labelling requirements will incur additional costs that are expected to range from as little as €100 to as much as €13,000 per stock keeping unit depending on the requirements (Table 9.3). The incremental costs will be lower where changes can be integrated into the labelling 'lifecycle' and included during the regular 'refresh' of a product label.
- Costs for premarket approval: the expected costs to industry of approvals are less than €30,000 per product for a purely administrative approval mechanism. Toxicological tests are unlikely to be required, but if they were, the costs could be more than €300,000 for testing and detailed risk assessment (section 10.4.2). The designated authority will also incur costs to establish the approval system. The assumptions made about evidence required are illustrative for this appraisal only.

The total expected costs on the supply chain are small because it is expected that relatively few products would be labelled or brought to the market. The detail of the labelling requirements (e.g. whether they specify a note in the list of ingredients or a prominent front of pack label) would influence impacts.

In a scenario where imported foods were required to be labelled as potentially derived from clones, clone offspring or clone descendants (i.e. "may contain"), there would be impacts on exporters in third countries. This route would however enable food imports to continue in circumstances where third countries are unable (or unwilling) to establish robust traceability systems for such animals and derived products.

Trade-mediated effects

Many of the measures assessed risk disrupting EU import trades, with the potential for impacts across the supply chain, from the artificial insemination and elite breeding sectors all the way through to consumers. Imports of reproductive materials are of direct importance to the EU breeding and

livestock production sector and benefit the rest of the supply chain indirectly. If the EU imposes conditions relating to clone status that exporters are unable or unwilling to satisfy, €3.67 billion worth of annual imports of meat and other animal-derived food products are at risk of interruption (sections 7.5.3 and 8.5.2). Given the international trade in reproductive materials, animals and food, to achieve traceability or exclusion of products of clone offspring and descendants from the EU supply chain would demand that the other trading partners of the EU's direct trading partners have adequate traceability systems for clone status – in effect a global traceability system. The feasibility and reliability of such a system is in doubt.

The size of such trade-mediated contingent risks varies depending on the scope of the legislation. The precise impacts will also depend on the behavioural responses by the EU supply chain and by actors in third countries. The analysis has therefore estimated trade and jobs 'at risk' rather than specifying definitive losses. The value of trades and the number of businesses at risk are set out in Table E.1. Both short-run effects (e.g. loss of access to South American beef) and long-run effects (e.g. impacts on EU dairy breeding strategies and productivity if EU breeders are denied access to elite genetic materials from North America) are anticipated.

EU requirements to trace or excludes products based on a clone status add cost and complexity for operators exporting to the EU and for EU importers. Evidential requirements under all scenarios are expected to be harder to meet, and therefore entail additional costs.

Premarket approvals (PMAs) could also create issues for importers of meat and other products into the EU if importers cannot be sure that imported products are free of animal clones, offspring and descendants because they will not be able to place them on the EU market. PMA requirements risk triggering trade disruptions to meat and other animal product imports. Generic authorisations could reduce the problem. Even under a generic system, issue remains until the first authorisation is granted Authorities could provide for a transitional period for PMA to allow food products that may be derived from clone offspring and descendants to continue to enter the market without approval until end of the transition period. A PMA requirement would create an additional barrier for exporters to the EU over and above that posed by traceability requirements.

Impacts on competitiveness

In addition to direct economic impacts and indirect trade-related effects on EU and third country operators and competent authorities, there may be impacts arising from the proposed approaches related to competitiveness, including cost competitiveness, capacity to innovate and international competitiveness. These are each considered in turn below.

Table E.1 Summary of potential trade-mediated impacts arising from suspension and traceability approaches

Issue	Package	Number of businesses at risk	Value of trade at risk (€m/yr)	Significance of impacts if full cessation of trade
Cloning technique is unavailable in EU	All suspension packages (S-A to S-G)	LOW – no known food-related companies conducting cloning in the EU	**N/A**	LOW – potential limited impact to 2020 in the dairy sector
Imports of live animals cease	All suspension and traceability packages (S-A to S-G and T-A to T-G)	LOW - small numbers of live animals imported	LOW - 2.3	MEDIUM – small numbers of animals, but important to EU breeding sector
Imports of reproductive materials cease	S-B to S-G and T-B to T-G	MEDIUM – 120 companies may go out of business; 294 AI companies may be affected	MEDIUM - 14	MEDIUM - HIGH The EU breeding industry is heavily reliant on imported reproductive materials, especially for bovine animals

Issue	Package	Number of businesses at risk	Value of trade at risk (€m/yr)	Significance of impacts if full cessation of trade
Imports of food products cease	S-F, S-G and T-F, T-G[1]	MEDIUM – 715 companies may go out of business; effects greatest for bovine, ovine and equine meat importers	HIGH - 3,667	LOW – caprine food imports MEDIUM – porcine, ovine and equine food imports HIGH – bovine food imports

Cost competitiveness

Packages that extend beyond control of cloning are expected to have negative impacts on the cost competitiveness of EU businesses. It is not clear that EU controls on use of cloning would confer an advantage in export markets that would help to offset the additional costs. In the EU domestic market the negative impacts of the additional administrative burdens would be mitigated by an increase in demand for domestically production if access to imports was reduced.

The largest direct cost impact domestic producers is triggered by a requirement for individual animal traceability in the porcine and ovine/caprine sectors; many producers in those sectors already exist on low margins and it is unlikely that the incremental costs could be passed in full down the supply chain. The packages that impose additional traceability and reporting burdens would make these sectors less competitive. Indirect effects may be greater than the direct effects, particularly where trade losses occur due to third countries not being able or willing to meet traceability requirements. If trades are halted, input costs could rise in the EU, for example, in the breeding sector.

Table E.2 Cost competitiveness

Packages	Direct effects	Indirect effects
Control of cloning and use of clone reproductive materials S-A, S-B & T-A, T-B	None as no commercial cloning expected in the EU in the baseline (business as usual) scenario	Some additional administrative costs to meet requirements Risk of loss of access to imports of live animals and RM which could raise input costs, if existing private schemes are not recognised and extended
Controls on clone offspring and descendants S-C, S-D & T-C, T-D	Negative impacts on farmers and importers of animal genetics for bovine species Where all animals require ID, significant additional administration and equipment costs in porcine and ovine/caprine sector would negatively impact cost competitiveness of these sectors	Potential trade losses where third countries do not meet traceability requirements to allow importers to meet requirements of suspension or traceability approach in the EU –could raise input costs in the EU
Controls on food S-F, S-G & T-F, T-G	Increased compliance and reporting costs	Risk of widely distributed negative impacts due to loss of imports Some negative impacts may be offset if imports are restricted from third countries due to lack of compliance with traceability requirements and EU producers benefit from loss of competition

Impacts on EU's capacity to innovate

The indirect (and uncertain) trade-mediated effects have the potential to immediately impact on innovation and thus productivity growth in the livestock sector in the EU, particularly for bovines. If trading partners cut off trade with the EU in live animals and reproductive materials, it would also affect Europe's access to high quality genetics in key breeds and thus the sector's ability to improve the quality of the EU breeding stock. Suspension measures which prohibit use of cloning technologies

[1] Food products derived from clones are highly unlikely since clones are scarce and expensive and, it is assumed, could be excluded through pragmatic measures without putting EU trade as a whole at risk.

risk inhibiting the EU's capacity to innovate in this area, though the short-term impacts of the approach on cloning research and innovation are expected to be small.

International competitiveness

Traceability and suspension packages that reach beyond regulation of clones and clone reproductive materials risk having a negative impact on the EU's international competitiveness. Packages that result in lack of access to high quality genetic materials from third countries could, especially over the longer term, negatively impact on competitiveness in price-sensitive export markets. The additional administrative burden imposed on the food chain would be expected to reduce the competitiveness of the affected sectors. This is particularly true of the more ambitious traceability strategy which could have negative impacts for porcine, ovine, caprine and equine animal industries due to significantly higher costs imposed on operators.

There would potentially be some benefits for EU domestic producers in-so-far as:

- Packages that interrupt imports could reduce domestic producers' exposure to competition in the EU market, which could improve their competiveness in the domestic EU market;
- Suspension, traceability, and labelling approaches that enable 'clone free' status for EU products, could have a positive impact on demand for those products in third countries if this is seen as a premium attribute by consumers; and
- Competitiveness impacts arising from the labelling and premarket approval approaches are expected to flow predominantly from the traceability systems underlying them.

Impacts on SMEs

The four approaches as specified do not provide an exclusion from the requirements for SME businesses. The food chain contains large numbers of SMEs, from the farming sector through to manufacturing and retail. All four approaches therefore have the potential to impact on SME growth. The impacts on SMEs are likely to vary depending on the approach and strategy chosen, as well as information requirements. Indicative likely impacts are described in Table E.3.

Table E.3 Expected scale, distribution and type of impacts on SMEs

Package	Sectors	Principal impacts expected	Comments	Significance
Control of cloning S-A & T-A	Live animal importers	Risk of loss of market in live animal imports	Aggregate value of trade is small	High for affected businesses
			Few businesses rely on trade in live animals to the EU, but important to those few businesses	Low overall
			Animals are high-value and therefore likely to be traceable with modest effort	
Clones plus clone reproductive materials S-B	Importers of RM	Materials will need to be identified as derived from clones and excluded (S-B) from EU market	Existing system can and does already screen out clone RM where required	Low
Clones plus clone reproductive materials T-B	Importers of RM	Materials will need to be identified as derived from clones and traced in EU market	Materials are already traceable and identifiable in major exporting countries as derived from a clone	Low
As above plus offspring and descendants S-C, S-D & T-C, T-D	Importers of RM	Risk of loss of access to imported RM leads to loss of business for importers where exporters cannot or will not identify RM from	Existing 'screening' system does not extend to offspring and descendants of clones	High

Package	Sectors	Principal impacts expected	Comments	Significance
		clone offspring/ descendants		
	Breeders	Loss of access to high quality Holstein/other genetics would negatively affect breeding programmes	Some Member States are heavily dependent on AI and imported RM for breeding programmes	High in select MS Low in other MS
As above, plus food S-E, S-F, S-G & T-E, T-F, T-G	Food importers, processors, manufacturers, retailers etc.	Risk of loss of access to imported meat and dairy suppliers Import substitution from domestic supply should raise prices/profitability for EU suppliers	Higher input prices likely Some businesses rely entirely on imports Food products derived from clones (T-E) are highly unlikely and could be excluded through pragmatic measures without the negative impacts expected from T-F and T-G.	High/critical for businesses dependent on imports General negative impact from higher input prices

Social (employment) impacts

Few EU jobs are currently sustained by commercial livestock cloning so suspension will have little direct impact on employment in the breeding sector. The more substantial employment impacts expected are:

- Employment losses prompted by the additional administrative burdens place on livestock producers and other food business operators (FBOs); and
- The risk to jobs in EU livestock sector and supply chains created by requiring third countries to comply with traceability conditions that they may be unable or unwilling to meet.

Direct and indirect (trade-mediated) employment impacts of the suspension and traceability approaches, as well as labelling and premarket approvals are summarised in Table E.4.

Impacts on consumers

The suspension and traceability approaches that reach beyond control of cloning and clone reproductive materials could result in negative impacts on EU consumers. These may include both price effects (i.e. price changes in consumer markets) and choice effects (i.e. changes in the availability of goods and services available to consumers). Short run impacts are likely to be highest for packages that include food products, mainly because of the potential trade-related impacts on food imports. These could limit the availability of certain products and increase prices where alternatives must be sourced from other trading partners or supplemented by domestic production. Traceability Strategy 2 may also increase the production costs for operators, and these costs may be passed to consumers, increasing costs to purchase these products.

Table E.4 Social (employment) impacts

	Direct impacts	Indirect (trade-mediated impacts)
Suspension	Negligible for all packages – few if any EU jobs sustained by commercial cloning in the food chain	Potential high negative impacts; suspension puts jobs at risk in businesses importing products and in downstream supply chains – impacts expected in the EU and third countries, especially for packages related to food products (S-E, S-F, S-G)
Traceability – Strategy 1	Negligible for live clones (T-A) and their reproductive materials (T-B) – few EU jobs sustained by commercial cloning; reproductive materials are already traceable and the status of the RM is easy to determine	May have negative impacts for domestic and third country operators for reproductive materials from clone offspring (T-C) and descendants (T-D) – third countries unlikely to implement required systems to enable

	Direct impacts	Indirect (trade-mediated impacts)
		traceability. Packages related to food products (T-E to T-G) could produce significant employment impacts in sectors currently sustaining thousands of jobs in the EU and third countries if traceability requirements results in a cut-off in trade of these products
Traceability – Strategy 2	Direct impacts for live bovine animals, and RM of all species (T-A, T-B) expected to be the same as under Strategy 1 EU jobs would be created for live porcine, ovine, caprine and equine animals to produce tags, equipment, computer systems for individual ID and to implement the systems (T-A, T-C, T-D)	Impacts for food products of all species (T-E to T-G) expected to be the same as under Strategy 1. Employment gains through expanded traceability for porcine, ovine, caprine and equine animals likely to be offset by employment losses caused by additional administrative burdens place on livestock sectors and supply chain.
Labelling	Few products likely to be brought to market under 'positive' labelling Voluntary labelling may result in creation of a small number of jobs in administration of requirements, inspections, etc.	Impacts are expected to be related to the underlying traceability systems, rather than labelling itself
Premarket approval	No measurable employment impacts expected – demand for approvals likely to be zero	Primary impacts are expected to be related to traceability rather than the PMA itself; though PMA would present an additional barrier to trade if / once the traceability issues had been overcome.

Table E.5 Potential consumer impacts

Package	Price effects	Choice effects
S-A, S-B & T-A, T-B (Strategy 1, positive ID only)	None expected	None expected
S-C, S-D & T-C, T-D (Strategy 1, positive ID only)	Price effects in dairy markets if dairy sector loses access to imported reproductive materials Marked short run effects may occur in MS with high dependence on imported RM and heavy use of AI Price effects in meat and meat products sector if meat production sector loses access to imported RM	Limited, except as a consequence of product scarcity
T-A, T-C, T-D (Strategy 1 and 2, ID all animals/batches)	Negative price effects if all animals must be identified	None expected
S-F, S-G and T-F, T-G (Strategy 1 and 2)	Price effects in dairy markets if imports of dairy products cease Potentially significant price effects in meat and meat products sector if imported meat products cease (primarily bovine, as well as ovine meats)	Product-specific and seasonal due to loss of access to specific brands/types of dairy product. Significant for bovine meat and meat products Significant for ovine and caprine meat products Limited for porcine and equine meat products

Environmental impacts

The evidence suggests that the negative welfare impacts are concentrated in the cloning process itself. The incremental animal welfare benefits are thus highest for the measures and packages that focus only on cloning (measure S1, package S-A; measure T1, package T-A). As the scope of the packages increases to cover offspring, descendants and food, the additional animal welfare benefits decline while the additional economic impacts, and risks, increase.

There is uncertainty about the impacts of use of cloning on genetic diversity in domesticated species, but the most likely outcome is a reduction in the genetic diversity of the gene pool, and potentially further concentration in the use of a small number of breeds. The EU's exposure to these impacts is likely to be indirect, mediated through the use of genetic materials imported from North America. Regulating the use of cloning could reduce the risk of this loss of diversity, though it could also deny EU breeders access to high quality genetics from North America that are used to supplement 'domestic' genetics. If, *in extremis*, imports of reproductive materials ceased then EU breeders in the dairy sector and elsewhere would be denied access to the global 'pool' of genetic resources used in animal breeding and would need to develop alternative strategies for the same breeds or turn to other domestic EU breeds.

Conclusion

The analysis suggests that controls that were limited to the use of cloning in the EU in the period to 2020 would not have a significant economic impact, partly because little or no commercial cloning is expected even without regulation. Suspension of, or requiring traceability for, clone reproductive materials is feasible and would not have a large economic impact if existing supply chain arrangements can be recognised, formalised and extended. However, as the scope of the packages increases beyond cloning to cover offspring, descendants and food, the incremental animal welfare benefits decline while the additional economic impacts, and risks, increase. Packages also become progressively less feasible. The key issues are:

- The costs associated with traceability requirements imposed on the EU supply chain under the traceability approach, and the exact specification of those traceability requirements;
- The systems or documentary evidence that entities exporting animals, reproductive materials and to the EU will be required to have to support declarations on whether those goods are clones, clone offspring and clone descendants, or derived from such animals; and
- How to foster a system that is robust and reliable in a context where claims of the clone status of animals and products will not (with few exceptions) be verifiable except by documentary evidence, where mistakes as to parentage are easily made (e.g. through mixing of young animals and parents in extensive systems), and where incentives in the supply chain may not encourage compliance (e.g. higher costs, lower market value).

The proportionality of the actions represented by many of the packages evaluated is doubtful given the absence of commercial cloning in the EU and that commercial cloning for food production in third countries is largely confined to bovine animals.

1 Introduction

1.1 This report

This is the final report of a study on the impacts in the EU and third countries of measures on animal cloning for food production that could be adopted by the EU. The study was commissioned by the Health and Consumer Protection Directorate General (DG SANCO). The work has been carried out by ICF GHK working with the support of three external experts[2].

1.2 Context to the study

The purpose of the study is to supply evidence that will inform the further development and appraisal of proposals from the Commission to regulate animal cloning.

In January 2008 the Commission tabled a legislative proposal for the revision of Novel Food Regulation (EC) n° 258/97 to streamline the authorisation procedure while maintaining the principle of a premarket approval for novel foods. The use of the cloning technique emerged in the inter-institutional discussions on this proposal. At first and second European Parliament reading, all the Member States in Council were in favour of the inclusion of food from the offspring of clones (1st generation) in the Novel Food scope while the Commission was of the opinion that it should only cover food from clones as is the case under the current regime.

The European Parliament was against the principle of a possible authorisation of food from clones and their offspring under the Novel Food Regulation (as reflected in its Resolution of January 2008). The Parliament favoured a total ban of the use of the cloning technique in the EU and the placing on the market of food from clones themselves and their offspring (first and subsequent generations).

In October 2010 the Commission adopted a report to the European Parliament and the Council on animal cloning which suggested a number of possible measures on cloning:

- Temporary suspension of the use of the cloning technique in the EU for the reproduction of all food producing animals; the use of clones; the import of clones and the marketing of food from clones; and
- Setting up a mandatory traceability system for the imports of semen and embryos from clones to allow farmers and industry to develop data bank(s) of offspring in the EU.

The lack of inter-institutional agreement at second reading triggered a Conciliation procedure. A final agreement could not be found and the Ordinary Legislative Procedure was stopped by end of March 2011.

A Roadmap was developed in February 2012 as a response to the call from the European Parliament and the Council to address the issue of cloning. Five options are elaborated in the Roadmap. The present study will inform the Commission's impact assessment of the five options by analysing the impacts of four different approaches to addressing animal cloning, as discussed in the following section.

[2] Dr Ann Bruce, Research Fellow, Innogen, United Kingdom;
Professor Keith Campbell, University of Nottingham, United Kingdom; and
Dr Diogo M. de Souza Monteiro, Kent Business School, United Kingdom.

1.3 Terms of reference

The study provides an assessment of the economic, social and environmental impacts, as well as a feasibility assessment of approaches that would introduce:

- ***A suspension or ban on animal cloning in the EU***. This includes the cloning technique, marketing of reproductive materials from clones, marketing of live clones, their offspring and descendants (and reproductive materials from offspring and descendants), and marketing of food from clones, their offspring and descendants;
- ***A traceability system*** for reproductive materials from clones, live clones, their offspring and descendants (and reproductive materials from offspring and descendants), and food derived from clones, their offspring and descendants;
- ***Labelling requirements, in addition to traceability***, on food derived from clones, their offspring and descendants; or
- ***Premarket approval, in addition to traceability and labelling***, for food derived from clones, their offspring and descendants.

Within each of these approaches there is a set of discrete measures that can be applied individually or in combination with each other. These measures are defined in the study terms of reference and reproduced in Annex 1. In most instances individual measures, as defined, are not viable when introduced on their own (for example, traceability of food derived from offspring of clones is not viable unless there is also traceability of clone offspring). Instead they would need to be applied in combination with one or more of the other given measures. Such combinations of measures are, for the purposes of this paper, described as 'packages'. The packages assessed in this paper are described in the chapter corresponding to each approach.

The study considers the socio-economic and environmental impacts of the different cloning measures on the EU food chain, on EU consumers and on international trade (imports and exports). The social impact refers to the potential reduction in activity and employment in the farming sector and meat and milk industry which may result from the adoption of the cloning measures, and to the potential impact on consumers in terms of prices and expectations. The environmental impact refers to the potential consequences on biodiversity, the EU gene pool for the species concerned, animal health and welfare and food safety.

The study has required definition of:

- A set of packages based on a schedule of measures provided by the Commission;
- The systems required to implement the packages; and
- The obligations the packages would place on the food chain;

The feasibility of the packages has been assessed and the direct and indirect impacts identified and, wherever possible, quantified.

The scope of work:

- Covers bovine, porcine, ovine, caprine and domestic soliped (equine) species.
- Spans the full breadth of the affected supply chains, that is:
  - The breeding sector, including the artificial insemination industry;
  - EU livestock farmers;
  - The meat industry (slaughterhouses, cutting plants and meat processors);
  - The milk and milk products industry;
  - Butchers and retail/distribution sector;
  - Traders (imports and exports);
  - National Competent Authorities (administrative burden and costs); and
  - Consumers.
- Includes EU countries and the EU's main third countries trading partners.

The study is limited to consideration of cloning for food production and does not cover the use of the cloning technique for all other purposes such as research, production of pharmaceuticals, sport or other commercial uses, or the conservation of endangered species or breeds. All references to animal cloning in this document refer only to cloning of livestock used in the production of food, unless stated otherwise. Where the analysis relate to food it focuses on meat, milk, meat and milk products and derived processed products such as gelatine and caseins.

The analysis does not include use of macro-econometric models to assess the economic implications of the barriers to trade that the packages could potentially introduce. The Joint Research Centre of the European Commission has been appointed to carry out such an assessment.

1.4 Structure

This report is structured as follows:

- Chapter 2 provides an overview of issues related to cloning livestock animals;
- Chapter 3 describes the current use of and outlook for animal cloning in the food chain;
- Chapter 4 provides a summary of the supply chain and trade profiles for the five animal species covered in this study;
- Chapter 5 summarises the approach to the impact assessment;
- Chapter 6 provides an overview of existing traceability systems in the EU and third countries;
- Chapter 7 details the feasibility and impacts appraisal of the suspension approach;
- Chapter 8 details the feasibility and impacts appraisal of the traceability approach;
- Chapter 9 details the feasibility and impacts appraisal of the labelling approach; and
- Chapter 10 details the feasibility and impacts appraisal of the premarket approval approach;
- Chapter 11 provides an assessment of potential environmental impacts arising from use of livestock cloning; and
- Chapter 12 synthesises and summarises the feasibility and impacts of the four approaches.

Annexes cover:

- The study terms of reference (Annex 1);
- EU legislation relevant to animal cloning for livestock animals (Annex 2);
- The measures appraised under each of the four approaches (Annex 3);
- Specification of the suspension (Annex 4), traceability (Annex 5), labelling (Annex 6) and premarket approval (Annex 7) packages;
- The regulatory cost model used to assesses the administrative burdens arising from the four approaches (Annex 8);
- Supplementary information on livestock sectors (baseline data) (Annex 9);
- Supplemental data and other information to support the baseline (Annex 10);
- Stakeholders consulted for the study (Annex 11); and
- References (Annex 12).

2 The cloning of livestock animals

This chapter provides a brief explanation of what animal cloning involves, why there is commercial interest in the technology, and the health, ethical and environmental debates that have been prompted by its use. The purpose of this section is to provide some information on the scientific and social context to this study. The commentary is not intended to be exhaustive but instead to help the lay reader understand the background issues.

2.1 Cloning as a technique for animal breeding

Animal cloning is emerging from the research laboratory and into commercial practice, although commercial cloning is not yet widespread anywhere in the world. The main commercial driver for adoption of cloning techniques is their potential to produce larger numbers of reproductive materials from particularly 'high quality' breeding animals, that is, to increase the number, distribution, and availability of animals with superior genetics.

Cloning is a technique that facilitates the replication of animals. It is, by definition, a copying (i.e. multiplication) process - cloned animals have the same DNA sequence as the animals from which they are produced. Cloned animals carry a copy of the entire nuclear DNA of the original animal, rather than a mix of genes from male and female parents.

Cloning therefore enables the replication of an existing genotype that has favourable traits which breeders wish to see retained. This contrasts with breeding techniques - both traditional selection processes and, more recently, engineered genetic modification - that are used for the acquisition or refinement of desirable traits.

Cloning is a form of assisted reproductive technology. The most common cloning procedure, somatic cell nuclear transfer (SCNT), involves removing all DNA from the nucleus of an egg, inserting replacement nuclear DNA from the animal that is being cloned, and stimulating the egg to develop into an embryo. The embryo is implanted in a surrogate female animal and goes through gestation to normal term. Embryo splitting and embryonic cell cloning are also used.

Cloning is being introduced into livestock breeding sectors that already use assisted reproductive technologies. Artificial insemination (AI), which enables dissemination of the genetics of superior male animals, is the most common type of assisted reproductive technology. AI has been used for more than 200 years. It has been widely adopted for dairy cows and, to a lesser extent, in the beef industry and for porcine animals. Sexed semen were introduced in recent years to control the gender of the offspring produced using AI (Butler and Wolf, 2010).

Embryo transfer is another assisted reproductive technology which has enabled an increase in the average number of calves per year produced by superior cows. *In vitro* fertilisation (IVF) utilises embryo transfer and offers more flexibility in the mating of sires to the same cow. IVF is a complex procedure, however, and has not been broadly adopted (Butler and Wolf, 2010).

Genomic selection is a technique that allows breeders to optimise strategies for identifying and selecting elite animals, thereby, for example, reducing the generation intervals required to produce breeding animals with desired traits. This is in contrast to cloning, which can only *replicate* animals that already have a preferred trait. Cloning is not used to *develop* elite animals with a preferred trait but it is potentially useful in *multiplying* such animals and so accelerating the rate at which their traits can be introduced to the wider herd.

Cloning is currently considered to be of greatest benefit in the dairy industry, where the availability of more animals with higher quality genetics could increase overall herd milk yield, the availability of stock with disease resistance, and increased availability of stock with desirable genetic traits associated with milk quality (Butler and Wolf, 2010).

2.2 The economics of animal cloning

Cloning is a higher cost procedure and has a lower success rate than traditional reproductive techniques for pedigree or other high value animals. Cloning can be a commercially attractive proposition where the expected income from the clone is more than sufficient to cover the costs of its production. The value of reproductive materials obtained from cloning a 'high quality' breeding animal over its lifetime can more than justify the initial expenditure on the cloning process. Clones of elite animals could be used as sires for multiplication of beef cattle and dairy cattle with desirable characteristics since the high cost of their production is more than offset by their market value. Cloning is also seen as potentially useful as 'insurance' whereby breeders may seek to protect themselves from the premature injury or death of highly valuable animals by creating and storing somatic cell lines of those animals.

Information on the economics of the process is relatively scarce due mainly to the relative infrequency of its use, but some information has been gathered during this study. For example:

- TransOva, a US cloning company estimates that it costs between USD18,000-20,000 (approximately €15,000-16,000) to produce a clone. This range is likely to be competitive elsewhere in the world. Typically, clones are used as breeding animals due to their high cost. A clone can generate on average USD60,000 in semen/embryo sales in the first year of production.
- Consultation with EU industry association COPA-COGEGA indicates that the cost of producing a clone for research purposes in the EU is approximately €12,000-15,000 (i.e. similar to the TransOva estimate). Embryos of cloned bulls sold at auction in the US have fetched USD10,000-20,000 (€8,000-16,000), which is the same price as embryos from an animal from a 'non-cloned' high-value embryo line.
- A cloned sport horse can fetch USD800,000 on the market, based on auction prices in Buenos Aires in 2010 for a cloned polo horse (Carroll, 2011). Cryozootech, a French horse cloning company sells a dose of semen from a cloned horse for between €450 and €700 depending on the clone.
- To produce the first cloned fighting bull, the Spanish breeders group May spent around €30,000. The family which owns the bull could expect to make around €1.5 million from selling the bulls that the clone fathers naturally during his lifetime (Kanter, 2010).
- A simulation exercise to analyse the economic feasibility of cloning conducted by Butler and Wolf (2010) suggests that, 'the revenues generated by increased growth in milk production per cow were substantial and that producers may be willing to invest in such a technology'. Nonetheless, Butler and Wolf assume that the technical difficulties of the cloning technology have been overcome in this scenario, which is currently a limiting factor as it results in high production costs.

2.3 Health, safety and environmental aspects of cloning

Healthy clones have been produced which appeared to have no differences compared to conventional animals. However, not all animals involved in the production process survive and the health, welfare, ethical and environmental implications of animal cloning have prompted discussions regarding this technology and, based on survey evidence, are matters of concern for some citizens and consumers.

2.3.1 Animal health and welfare aspects of cloning

There are a number of animal health and welfare considerations related to animal cloning. The mortality rate of clones is considerably higher than in sexually produced animals. EFSA (2008 and updated 2010) reported that a majority of cloned embryos do not develop to term. Where embryos do develop to term, a proportion dies during or shortly after birth. The main causes of death include cardiovascular failure, respiratory problems, liver or kidney failure,

immune deficiencies or musculoskeletal abnormalities. Available data indicate that the overall success rate of the cloning procedure (measured as the percentage of live clones born from the number of embryos transferred) is less than 10 per cent in bovine animals and between 5 and 17 per cent in pigs. Full welfare impacts are unknown because they depend on the use to which the cloning technique is put—in some cases, there may be benefits such as disease resistance or better adaptation to difficult environments.

A proportion of the surrogate cattle dams have problems that include late gestational loss and more difficult delivery (dystocia). Offspring may be larger than average, with associated health problems occurring in both cattle and sheep but not pigs. Other problems, including musculoskeletal conditions, may develop later in the animal's life.

Studies undertaken outside Europe have shown that the survival of the offspring or descendants of clones does not differ to any significant extent from the survival of conventionally bred animals (around 85 per cent) (EC, 2010). Adverse health effects have not been observed in the offspring of clones, although studies have not been conducted for their entire lifespans (USFDA, 2008a; CRS, 2010). Information on clone offspring remains limited, especially in cattle with long generation intervals. A study of the characteristics of 39 cattle clone offspring (which were compared both to clones themselves and to AI controls born and raised in the same experimental farm) confirmed that the first generation offspring did not have any of the pathologies observed in clones (Heyman et al., 2009).

2.3.2 Ethical considerations

There is a basic ethical argument that animals warrant respect and that humans' responsibilities to animals include not allowing them to suffer unnecessarily. Some European countries have incorporated these aspects into national law. For example, Norwegian and Danish law emphasise respect for, 'animal integrity as an independent value that goes beyond welfare' (Gamborg, Gunning and Hartlev, 2005). In that context, a case has been made by some stakeholders that the suffering and health problems experienced by surrogate dams and clones make it difficult to justify cloning animals for commercial uses (EGE, 2008).

2.3.3 Environmental impacts

One argument that has been made against animal cloning is that it will further decrease genetic diversity. The loss of genetic diversity is a problem because it is irreversible. When a breed disappears, its unique adaptive attributes held in its genetic resources are lost forever (FAO, 2007).

More than 7,600 breeds were listed in FAO's Global Databank for Animal Farm Genetic Resources 15 years ago. 190 have now disappeared. Since 2002, at least 60 breeds of cattle, goats, horses, pigs and poultry have become extinct (FAO, 2007). This trend was reinforced and facilitated in the last years because of the development of assisted reproductive technologies (Bulfield, 2000); artificial insemination is perceived as one of the main causes of genetic loss in livestock by Basrur & King (2005).

Cloning can be used commercially to duplicate elite breeding animals and therefore reduce the number of animals used in breeding programmes. This could contribute to the further loss of genetic diversity (EFSA, 2008). Breeding programmes utilising only a few bloodlines also may increase the susceptibility of an animal population to risk factors such as infection by disease and climate change (EFSA, 2008).

EFSA (2008) reports that, where used appropriately and with suitable management measures, these adverse effects can be avoided. While EFSA foresees no 'new or additional' environmental risks from cloning, the data are limited (2008). This was confirmed in the updated EFSA 2012 statement (EFSA, 2012).

Animal cloning can also be used to replicate rare indigenous breeds of livestock (Wells et al., 1998) or individual animals within a breed which possess unique characteristics (Westhusin et al., 2007). Cloning can also be used to 'improve the safety and cost-

effectiveness of *in vitro* conservation', as some tissues may be easier to preserve than embryos (FAO, 2007). Such uses would help slowing the shrinking of animal genetic diversity.

2.3.4 Food safety

Research has been carried out in recent years to assess the safety of food derived from clones and their offspring, in the United States, Japan, Australia, New Zealand and Europe. All of the evaluations undertaken conclude that no hazards have been identified concerning the consumption of food originating from healthy clones for bovine and porcine animals, and found no increased risk compared to food products originating from conventionally-bred animals (NZFSA, 2009; USFDA, 2008a; EFSA, 2012).

The New Zealand Food Standards Agency (NZFSA) states that products derived from pig, sheep, goat and cattle clones are edible. The US FDA makes a similar claim, but observes that data are scarce for bovine, caprine and porcine animals, and insufficient for sheep to conclude that the products derived from them are edible (US FDA, 2008a). EFSA (2012) limits the results on the safety of food products to bovine and porcine animals due to limited data availability.

The evaluations undertaken by government bodies rely on scientific publications which test chemical and physical characteristics of food products (mostly from bovine animals) in laboratories. For example, a number of studies compared the chemical composition of milk produced by cloned cows to that of milk produced by non-cloned cows; no differences were observed (Walsh et al., 2003; Norman and Walsh, 2004 in NZFSA, 2009; Ito and al., 2011). The same procedure was undertaken for meat from beef cattle and the parameters examined fell within the industry standards (Tian et al., 2005; Ito and al., 2011). No difference was observed concerning the protein digestion rate and the allergenicity of the products (Ito and Watanabe, 2011; Heymann et al., 2007).

The US FDA also anticipates that most of the food products developed from the use of cloning technology will be from the offspring or descendants of clones rather than from the clones themselves. It has stated that there are no human food or animal feed risks associated with the offspring of a clone for a species traditionally consumed for food, 'that are not present in other sexually-reproduced animals of the same species' (US FDA, 2008a).

2.4 Attitudes to animal cloning

Evidence suggests many EU citizens and consumers are concerned about animal cloning and reject the idea of it being used for livestock. Due to consumer and citizen concern, as well as the high costs of cloning and effective use of other breeding techniques in the EU, the EU supply chain does not on the whole perceive investment in cloning to be worthwhile at this time.

Third countries where there is cloning activity have concluded that there are no food safety risks arising from the consumption of food from clones or their offspring or descendants, and, with the exception of New Zealand, have opted not to regulate commercial cloning activity in their domestic markets.

2.4.1 Consumer perspectives on cloning

Citizens' and consumers' attitudes to the cloning of animals that then enter the food chain are very important to the analysis presented in this study. Information on the strength of consumers' preferences for, or against, use of cloning and the consumption of products derived from animal clones, their offspring or descendants helps in the definition of assumptions about market demand and supply chain responses to the measures considered in this analysis and the policies' ultimate impacts.

Survey evidence (e.g. Eurobarometer, 2010) suggests a majority of EU citizens are concerned about animal cloning and most do not accept it for livestock animals. There is support for labelling and traceability systems that enable information about products derived from clone offspring to be made available to consumers.

These views are supported by a Eurobarometer study commissioned by DG SANCO of the European Commission in 2008 on European consumers' attitudes towards animal cloning (The Gallup Organization 2008), which found that:

- Almost a quarter of EU citizens (23 per cent) indicated that animal cloning to preserve endangered animals would be justifiable without constraints and 44 per cent would accept it under certain circumstances. Similar proportions reported that they would accept animal cloning to improve robustness against animal diseases;
- Animal cloning was less acceptable to consumers: 58 per cent indicated that cloning livestock would never be justified;
- A majority of EU citizens indicated that it was unlikely they would buy meat or milk from cloned animals; of these, 43 per cent said it was 'not at all likely' that they would buy such products;
- More than 80 per cent of EU citizens indicated that special labelling should be required for food products from the offspring of cloned animals, if they became available in shops.

A 2010 consumer study commissioned by DG Research found similar results: EU citizens did not view animal cloning as having benefits, and also expressed concerns that cloning is unsafe, inequitable and worrying (Gaskell et al., 2010). In only two countries - Spain and the Czech Republic - did public support for animal cloning for food products reach 30 per cent. Average support across the EU was only 18 per cent (Gaskell et al., 2010).

A study by Gray (2011) found that European consumers are less accepting of food products derived from cloned animals than their American counterparts. The reasons why European consumers reject cloned products are also different from those expressed by American consumers. Europeans are concerned about cloning from an 'ethical and moral perspective' whereas Americans cite food safety concerns.

2.4.2 Supply chain perspectives on cloning

Interviews conducted for this study with organisations involved in food and farming in the EU suggest that the main barrier to further development and use of the cloning technique in Europe is consumer acceptability. Stakeholders also stated that the high costs and low efficiency, relative to alternative breeding techniques, constitute barriers to the use of cloning.

EU traders of reproductive materials and live animals interviewed for this study take care to avoid import of materials and animals produced using cloning technology because they are concerned about consumer reactions. Representative associations for breeders, producers, slaughter and cutting, trade, manufacturing and retail interviewed for this study all cite lack of demand for food produced from clones, clone offspring and clone descendants amongst clients and consumers. Importers of reproductive materials cite an accepted industry practice which prevents US reproductive materials derived from clones from being imported. Breeding companies for porcine and bovine animals argue that cloning is not only expensive and difficult but it also limits the potential for further genetic improvement in the sense that a clone is a copy of a previous generation and it is therefore no better than a traditional descendant.

Nonetheless, the breeding and farming sectors support further development of cloning technology in Europe, where the techniques and products meet legal and food safety requirements (for example: BAB, 2012; EDA, 2012; EFFAB, 2010). The European breeding industry is particularly concerned that its long term viability is at risk where it does not have

access to new technologies that are available and unrestricted elsewhere in the world (EFFAB, 2010).

2.4.3 Third country perspectives

A joint statement on animal cloning for livestock production was issued in 2010 by the governments of Argentina, Brazil, New Zealand, Paraguay and the United States (Joint Statement, 2010).

The statement observes that regulatory approaches related to agricultural technologies should be 'science-based' and should not restrict trade more than is necessary 'to fulfil legitimate objectives'. It also repeats the findings of expert scientific bodies which have concluded that there is no evidence of a food safety concern arising from the consumption of food from clones or their offspring or descendants. Moreover, there is no basis to differentiate the offspring or descendants of clones from other sexually reproduced animals of the same species.

The governments of these countries are concerned that restrictions targeting the food from the offspring or descendants of clones could have a negative impact on international trade, and that there would be difficulties in implementing audit and enforcement measures for clone offspring or descendants, and significant additional burdens would be placed on livestock producers. The US FDA has determined that because food from clones and the offspring of clones from any species traditionally consumed as food are safe and no different than food from conventionally bred animals, there is no basis to require labelling of food products from clones or their offspring or descendants.

3 The use of and outlook for animal cloning in the food chain

3.1 Introduction

In an impact assessment the impacts of the proposed interventions are assessed by comparison to outcomes in a reference scenario – a projection that defines expectations of 'how things will be' if none of the policies under consideration are adopted and life continues on a business-as-usual basis. This chapter explains that reference scenario for the current study. It is based on desk research and stakeholder consultations. It considers:

- The current scale and distribution of commercial cloning activity on the species of interest and the outlook for that activity in the period to 2020;
- Evidence on consumer attitudes to cloning and their propensity to purchase foods derived from animal clones, their offspring or descendants; and
- The EU's principal external trades and trading partners in products of interest to this assessment now and the outlook to 2020.

The analysis presented here summarises more detailed information that is provided in Annex 9 and Annex 10.

3.2 The use of cloning techniques for multiplication of animals for the food chain

Research suggests that:

- Commercial cloning for use in the food chain is not known to be occurring within the EU at this time and is not expected to start (on a business-as-usual basis) before 2020.
- Cloning is being carried out on bovine animals in a small number of countries. Products from bovine clones, and also from their offspring and descendants, have entered the food chain in the US. They are also likely to have done so in Argentina, although this has not been confirmed through consultation with Argentinian stakeholders. The most likely channel for import into the EU of animals, reproductive materials and food products covered by the measures being evaluated are bovine reproductive materials from the US and Canada, and beef products from Argentina.
- Cloning is also being applied to porcine, ovine and caprine animals, albeit to a much lesser extent. Based on the presence of cloning companies in key trading partner countries, the most likely entry route for clones, clone offspring and descendants, their reproductive materials and derived food products for these species is pig reproductive materials from the US.
- Equine cloning is being undertaken for equine animals for sport purposes in the EU, the US, South America and other parts of the world and is expected to continue. It remains a niche practice used for very high value animals rather than for animals bred for food purposes. TRACES statistics suggest that 6,530 live horses were exported from the US to the EU in 2011 and an average of 2,500 to 3,000 horses in previous years.[3] Most of the US horses meant for slaughter are transported by truck to Canadian and Mexican slaughterhouses (Stull, 2012). Transporting live animals for slaughter in Europe (by boat or by plane) would be too expensive; it is more profitable to export horse meat once it has been processed. This is confirmed by the statistics of horse meat producers in the EU, which do not mention any imports of live animals from the US (IFCE, 2011). No explicit data were found relating to the final destination of these animals, though many of these are expected to be competition/racing horses that do not remain in the EU.

[3] Final destination of these animals to be confirmed.

3.2.1 Commercial cloning in the EU

3.2.1.1 Current activity

Research for this study suggests that in Europe there are currently no commercial cloning activities focused on livestock used for food production. One company based in France produces equine clones and their offspring for sporting purposes (source: DG SANCO survey to Member States and third countries regarding cloning activity, 2012; interviews with stakeholders contacted by ICF GHK for this study confirmed the responses reported in the DG SANCO survey). May, a breeding company based in Spain, produced the first cloned fighting bull in 2010; the bull is expected to spend its life in a stud, siring other fighting bulls (Kanter, 2010).

Denmark is the only EU country that has banned cloning for food outright though no clones themselves are known to have entered the food chain in Europe to date. No premarket approval requests have been submitted under the Novel Foods Regulation.

Offspring of clones have been produced in the EU; for example, Holstein UK reports approximately 100 offspring of cloned bovine animals in the United Kingdom. Offspring from cloned cattle are known to have entered the food chain in the UK in 2010 through the slaughter of two sires for dairy cattle. No other such activity has been reported in the EU or EFTA countries, although the EU does not currently regulate the import of reproductive material from clones.

3.2.1.2 The outlook to 2020

The consultations conducted for this study thus far suggest that there is little prospect of commercial cloning activity for livestock developing in Europe in the period to 2020, or at least not at any significant scale, unless there is a significant change in consumer attitudes. These attitudes are related to the (lack of) perceived positive consumer benefit from use of cloning techniques as well as other concerns, including animal welfare.

3.2.2 Commercial cloning of food animals beyond the EU

Commercial cloning is present and expanding in many of the EU's principal trading partners. International trade in reproductive materials, live animals and food products could lead to animal clones, their offspring, descendants, their reproductive materials and food products derived from such animals being imported in the EU.

3.2.2.1 Current activity

Commercial cloning activity in third countries is concentrated in a small number of countries. The countries with the most well-developed commercial cloning sectors are the US, Canada, and Argentina. New Zealand, Australia, Chile, China and Korea are also undertaking commercial cloning for livestock species.

Bovine animals: commercial cloning activity for livestock is best developed in bovine animals. Cloning technology is being applied to cattle in the US, Canada, Argentina and Australia (source: DG SANCO survey to Member States and third countries regarding cloning activity, 2012). It may also be undertaken in Brazil, New Zealand, Chile, China and Uruguay based on the presence of cattle cloning companies in these countries. Milk and meat from the offspring or descendants of cloned bovine animals have entered the food chain in the US and may have done so in Argentina; these are the products most likely to continue to enter human food chains in the near future. The Swiss government says that 'several hundred' second or third generation descendants of clones are in Switzerland. This represents a very small proportion of the country's 1.5 million head of cattle (Kanter, 2010).

Porcine animals: consultations with the US cloning industry suggests that there is some commercial cloning for pigs in that country and that it is becoming more common. It may also be undertaken in New Zealand and China based on the presence of pig cloning companies in these countries.

Ovine and caprine animals: consultation with industry stakeholders in the EU and a survey undertaken by DG SANCO (2012) of third country Competent Authorities indicate that commercial cloning of ovine or caprine animals outside the EU is uncommon. Some commercial cloning of these animals is on-going in the US, but at very small scale.

Equine animals: consultation with industry stakeholders in the EU and a survey undertaken by DG SANCO (2012) of third country Competent Authorities indicate that there is no livestock cloning activity currently being conducted outside the EU for equine animals. Sport cloning is being undertaken in North and South America. The first cloned horse in Latin America was produced by Bio Sidus in 2010. By 2015, cloned foals are expected to be ready for competition in Argentina (Carroll, 2011). Companies are producing cloned sport horses in the United States (ViaGen), Brazil and South Korea.

3.2.2.2 *The outlook to 2020*

Commercial cloning for beef and dairy cattle is likely to continue to 2020. It is expected to become more efficient and less expensive, but remain a practice limited in application to only the highest value animals.

Commercial pig cloning may also become more widespread by 2020. The use of AI is becoming more commonplace in commercial pig production but there is a relatively low supply of semen from high merit boars (Suk *et al*., 2007). Consequently, boars in a commercial AI stud farm may be from the top 10–20 per cent of the breeding population, as compared to the top one per cent or better possible through cloning. Calculations by Suk *et al*. indicate that cloning offers a good potential return on investment to pig producers.

Consultations with industry suggest that the commercial cloning activity for ovine and caprine animals is likely to be limited. This is due to the high costs of cloning and the low margins on ovine and caprine animal production.

Interviews with the industry suggest that use of the cloning technique for sport horses is expected to remain low due to the high cost of producing the clones. The technique will only be used in special cases when a horse has an exceptionally high value and particularly where a high value horse is unable to reproduce (e.g. due to sterility or castration). These animals are unlikely to enter the food chain. Commercial equine cloning as livestock is unlikely to develop in the period to 2020 due to the low market value of a food animal and limited market for these meat products.

4 Supply chain and trade profile

4.1 Introduction

The purpose of this section is to provide a short description of the supply chains that would potentially be affected by measures that control use of cloning and the marketing of derived animals and products. It covers EU domestic production, processing and retail sector and the EU's external trade.

4.2 Employment and enterprise baseline

Determination of the number of enterprises potentially affected by measures is an important part of the impact assessment. Standard data sets do not support full profiling of the supply chain by sector and species. Table 4.1 provides the best available information, drawn together from multiple sources, on the number of enterprises in each part of the supply chain.

4.3 EU import trade profile

Adoption of some of the combinations of measures examined in this report has the potential to affect EU trade. The trade baseline is thus important information for the impact assessment.

4.3.1 Reproductive materials and live animals

Parts of the EU livestock sector are now heavily reliant on reproductive materials imported from outside the EU. For example, while imported bovine semen represents only 2.5 per cent of the semen used in artificial insemination in the EU, the breeding sector considers access to this genetic material as essential to the continued viability of the industry (EC, 2010; ICF GHK consultation with breeding industry representatives).

Reproductive materials for all species are primarily sourced from the US and Canada, both countries known to undertake commercial cloning activities (although the proportion of reproductive materials from clones or their offspring or descendants is unknown).

Approximately 99 per cent of the 1.8 million units of bovine semen imported into the EU since 2008 were sourced from either the US or Canada. The US and Canada are also dominant in the markets for genetic materials of porcine, ovine and caprine animals. In addition, over 99 per cent of EU imports of equine semen come from the US.

Additional information on imports for each of the five potentially affected species is highlighted below. Further information and supporting data can be found in Annex 10 and Annex 11.

4.3.1.1 Imports of live bovine animals and reproductive materials

Approximately 99 per cent of the 1.8 million units of bovine semen imported into the EU since 2008 came from either the US or Canada. The proportion of materials sourced from animal clones, their offspring or descendants is unknown (EC, 2010).

The market value of international trade in livestock genetics as a whole is relatively small. US and Canadian exports of bovine semen to the EU from 2006-11 were worth an average of €21 million and €17 million respectively. A 2008 USDA report indicates that 'the largest U.S. export in livestock genetics is bovine semen' (USDA, 2008a).

Few live bovines are imported into the EU. In 2011, only 45 live bovines were imported from countries beyond EU jurisdiction, with a total trade value of less than €1 million. Of these 45 animals, 42 were sourced from Canada and three from New Zealand.

Table 4.1 Economic operators in the EU by sector and species (*indicative*)

Sector	All species	Bovine	Porcine	Ovine	Caprine	Equine
Companies that could conduct cloning activities	7	4	1	0	0	2
AI companies	294	*150*	*50*	*10*	*5*	[79 studs]
Producers	7,852,710	3,334,210	2,662,310	1,189,480	666,710	Unknown
Markets & assembly centres	Unknown	5,644*	Unknown	Unknown	Unknown	Unknown
Slaughterhouses	Unknown	9,847*	Unknown	Unknown	Unknown	Unknown
Processing / manufacture of meat and dairy	81,993	Unknown	Unknown	Unknown	Unknown	Unknown
Of meat:	*59,794*	Unknown	Unknown	Unknown	Unknown	Unknown
Of dairy:	*23,196*	Unknown	Unknown	Unknown	Unknown	Unknown
Wholesale of live animals, meat and dairy product	82,801	Unknown	Unknown	Unknown	Unknown	Unknown
Of live animals:	*16,823*	Unknown	Unknown	Unknown	Unknown	Unknown
Of meat specialists:	*22,715*	Unknown	Unknown	Unknown	Unknown	Unknown
Of dairy [and egg] specialists:	*14,464*	Unknown	Unknown	Unknown	Unknown	Unknown
Retailers of food and specialist retailers of meat and meat product	623,812	Unknown	Unknown	Unknown	Unknown	Unknown
Of meat and meat product specialists:	*110,693*	Unknown	Unknown	Unknown	Unknown	Unknown
Importers: reproductive materials**	120	53	12	2	2	51
Importers: live animals	1667	3	12	5	2	1645
Importers: meat	715	280	40	374 (sheep and goat)		21

Sources: Eurostat Structural Business Statistics (2009), extracted on 18/07/12; and TRACES data

**FCEC (2009), pp. 71, Slaughterhouses (9,847); Markets and Assembly Centres (5,644)*

*** NB: only embryos are imported for bovine animals; and only semen is imported for the other species*

Notes on importers:

AI companies, breeders and producers are often involved directly in the import of reproductive materials and live animals. Manufacturers and wholesalers of meat are often directly involved in the import of meat. Alongside those making direct use of the imported reproductive materials, live animals and products, there also exist a number of specialist import/export trading companies

4.3.1.2 *Imports of live porcine animals and reproductive materials*

Porcine semen is seldom traded since freezing results in 'significant losses' (USDA, 2008). The scale of trade in porcine reproductive materials is therefore much smaller than that of bovine reproductive materials. The US and Canada are dominant in the markets for genetic materials of porcine animals, accounting for over 99 per cent of the 245 units of porcine semen imported by the EU in 2011. In 2011, all of the 845 live pigs imported into the EU were sourced from Canada.

4.3.1.3 *Imports of live ovine and caprine animals and reproductive materials*

The US and Canada dominate the EU's imports of reproductive materials of ovine and caprine animals, accounting for 82 per cent of the 1,441 units ovine and caprine semen imported in 2011. A small number of sheep (29) and goats (11) were imported into the EU in 2011; the majority came from New Zealand (five goats were imported from Croatia).

4.3.1.4 *Imports of live equine animals and reproductive materials*

Trade in equine semen is thought to mainly serve the horse racing sector and other equine recreational sectors. Over 99 per cent of EU imports of equine semen come from the US. The market size changes significantly from year to year, with peaks of over 175 thousand and 260 thousand units in 2007 and 2011, respectively.

While the EU markets for live cattle, pigs, sheep and goats are relatively small, the EU market for live equine imports is more substantial. In 2011, nearly 11,000 equine animals were imported into the EU. This market is also valuable; each horse is on average valued at approximately €10,000.[4] Imported animals are mainly used for racing and other recreational purposes.

At least one company is importing cloned horses into the EU (source: company interview). These horses are born in the US and imported as foals. In the next five to ten years, cloned horses may also enter the EU from South America.

4.3.2 Food products

The EU is a net importer of beef and veal. Beef imports are forecast to increase. The trade in beef products could reach half a million tonnes by 2020. Table 4.2 shows the top three import trades for relevant products. Market effects (e.g. price changes) are more likely to be observed where measures have an impact on these trade flows.

Table 4.2 EU imports of beef, veal, dairy products and sheep meat are worth €3310 million/yr

Species	Product	Approximate Total Annual Value	Summary
Bovine	Beef and veal products[5]	€ 1.7 billion	The EU is a net importer of bovine meat products and the third largest importer in the world; the net trade imbalance is expected to grow to 2020
	Cheese and butter	€ 610 million	The EU imports considerable quantities of cheese and butter despite being a net exporter of these products
Ovine	Sheep meat	€1 billion	The volume of imported sheep meat is equivalent to over a quarter of domestic EU production; 85 per cent was supplied by New Zealand; the EU is a net importer of sheep meat

Top three import trades for relevant products: 2006-2011

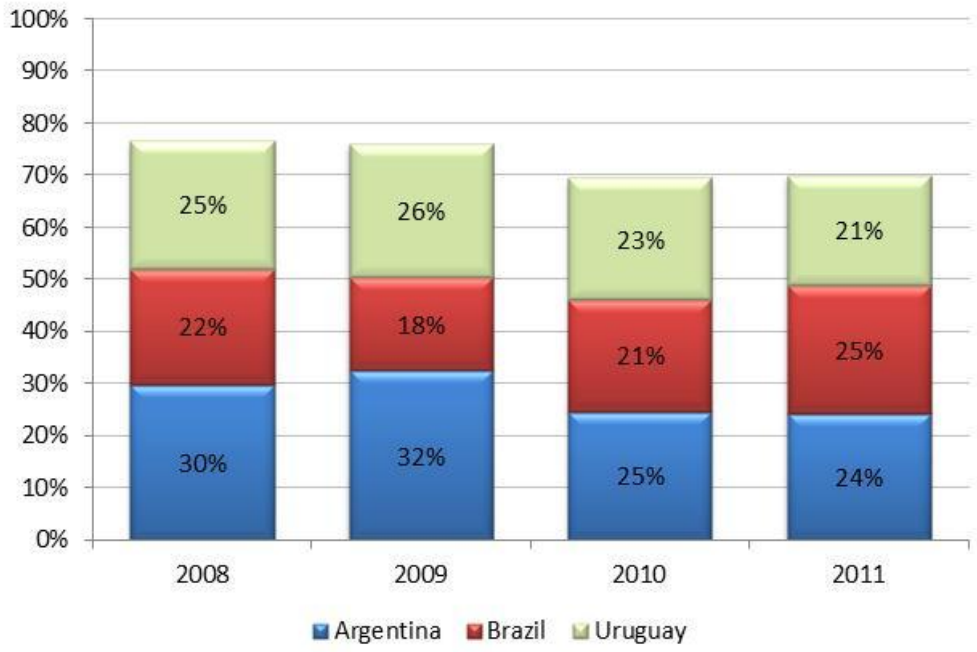
[4] This figure is arrived at by dividing the total value of EU imports of live equine from COMEXT (excluding Switzerland) by the number of equine imports recorded in the TRACES database.

[5] Value includes all fresh, frozen, chilled, prepared and preserved bovine meat, offal and derived products including gelatine

4.3.2.2 *Imports of bovine products*

In 2011, approximately 350,000 tonnes of bovine meat products worth over €1.7 billion were imported into the EU. More than 95 per cent of these imports came from eight countries. Argentina, Brazil and Uruguay accounted for approximately 70 per cent of the total trade volume in 2011 (Figure 4.1).

Figure 4.1 Most of the EU's beef imports come from Argentina, Brazil and Uruguay- Top 3 partners for EU bovine product imports as a share of the total trade volume, 2008-11



Source: Eurostat, data extracted on 22/06/2012, supporting data available in Annex 10.

In recent years, Australia, New Zealand, Paraguay, Namibia and the US all increased their bovine product exports to the EU. By 2011 these five countries together accounted for 27 per cent of total trade, up from five per cent in 2006.

EU beef and veal imports are forecast to increase by 10 per cent from 2011 to 2020 according to the latest projections (OECD-FAO, 2012). Globally, the EU is the third largest importer of beef and veal behind Russia and Japan.

4.3.2.3 *Imports of dairy products*

The EU is largely self-sufficient in dairy products. It is a net exporter but still imports considerable quantities of cheese from third countries and, to a lesser extent, butter. These two product groups accounted for almost 90 per cent of the €610 million average annual value of EU dairy imports from 2006-2011.

Over half of all EU imports of cheese in 2006-11 were purchased from Switzerland, representing 70 per cent of the total value of EU cheese imports (€1.79 billion). In this period, a further 150,000 tonnes of cheese worth €348 million were shipped to the EU from New Zealand. In the same period, New Zealand was also the source of 88 per cent of all EU butter imports, at the average annual value of €110 million from 2006-2011.

Imports of milk proteins and caseinates were also significant over this period, with the EU on average importing €178 million each year from 2006-11. Of this total amount, 80 per cent was sourced from just three countries: New Zealand, Ukraine and Belarus.

4.3.2.4 *Imports of porcine products*

The EU is self-sufficient in pig meat and consequently imports relatively little (an average of 30,000 to 40,000 tonnes per year from 2006-11). It accounts for less than one per cent of global imports. In 2011, the EU imported just 14,000 tonnes of pig meat, and a further 18,000 tonnes of offal at a total value of €61 million. 99.9 per cent of pig offal was imported from Switzerland; over 80 per cent of imported pig meat came from the US and Chile. Total annual EU imports of gelatine are relatively stable, with 20,000 tonnes imported annually over the period 2006-11, valuing at approximately €76 million per year.

In addition, the EU also imports relatively high quantities of low value prepared pig meat and offal products such as ham and sausages. On average, the EU imported 126,000 tonnes of such products at an approximate value of just €18 million per year from 2006-11.

4.3.2.5 *Imports of ovine and caprine products*

Imports from New Zealand and Australia are the most important trades for ovine and caprine products**.** From 2006-2011, EU imports of sheep meat were valued at just over €1 billion per year (averaging 200,000 tonnes per year). Of the total volume imported into the EU over this period, 85 per cent of total sheep meat imported was supplied by New Zealand at an average of 178,000 tonnes each year. A further eight per cent of EU sheep meat imports were sourced from Australia. Though these figures are relatively low, it is notable that the volume of imported sheep meat is equivalent to over a quarter of domestic EU production.

4.3.2.6 *Imports of equine products*

In 2011 the EU imported 28,000 tonnes of horse meat, valued at €94 million. The volume of imported horse meat is equivalent to over half of domestic EU production. From 2006-2011, the EU imported a total of €592 million worth of horse meat, 71 per cent of which was sourced from Latin America (Argentina, Brazil, Uruguay and Mexico) and a further 27 per cent from Canada and the US.

4.4 EU export trade profile

4.4.1 Bovine export markets – live animals, meat and reproductive materials

EU exports of bovine meat, and live animals declined in 2006, but have since 2010 recovered and grown rapidly. In 2010 alone, EU bovine exports increased in volume by 125 per cent from 2009 levels. More than four fifths of the recent growth in EU bovine meat exports is accounted for by growth in exports to Russia and the development of a Turkish export market. In 2011, these markets represented more than 62 per cent of the total EU bovine meat exports by value and volume.

Past trends suggest that the destination of exports shifts year-on-year even when the size of EU bovine meat export market is relatively unchanged overall. This can be attributed to the natural changes in relative prices across markets (DG AGRI Short Term Outlook, 2011).The recent upsurge in EU exports of live bovine animals is driven by increased exports to Algeria, Lebanon, Morocco, Syria and Turkey. These five markets alone represent 62 per cent of the volume of EU bovines.

Globally, the main markets for trade in bovine semen are the EU, the US, Canada and Latin America. On average, the EU exports bovine semen worth €25 million each year, based on 2006-2011 COMEXT data. EU exports of bovine semen to the US, Canada and Latin America represent less than half of this total export value from 2006-2011. A further quarter of this trade is to neighbouring countries, particularly Turkey and Switzerland, while more modest amounts are exported to Australia, China and Japan.

In 2011, based on US[6] and Canadian[7] import data, EU exports to these respective markets represented 21 per cent and 23 per cent of the total value of their imports of bovine semen.

4.4.2 Dairy products export markets

Total volumes of EU exports of milk and milk products steadily increased over the period 2006-2011. By 2011, exports of milk and cream accounted for over half of total dairy exports, with cheese and curd accounting for a further quarter. In total, the export of milk and dairy products was worth over €8 billion in 2011, an increase of €3 billion from 2009 levels.

Major markets for EU dairy products are Russia, the Middle East, North Africa, and South East Asia. Of these, markets in South East Asia and Russia have exhibited the strongest growth in recent years. The size of these main EU export markets varies considerably for different individual products.

For milk and cream, the majority of EU exports are purchased by North Africa and the Middle East. Russia and Iran are the two major importers of EU butter. In 2011, over 30 per cent of all EU exports of cheese and curd were purchased by Russia. The next major importers of EU cheese and curd are the US, Switzerland and Japan. The market for whey is more geographically concentrated, with roughly two thirds of EU exports consumed in South East Asia from 2006-11.

EU export markets for milk proteins and caseinates are annually valued at €394 million, based on 2006-11 data. The main markets for EU milk proteins are based in North America and South East Asia. The US market is the most valuable overall, worth a total of €140 million annually.

4.4.3 Porcine export markets – live animals, meat and reproductive materials

EU porcine exports experienced year-on-year growth from 2006-2011, and as a result the EU exported more than 2.7 million tonnes of porcine meat, and meat products in 2011, valued at over €5.3 billion. Over this period, exports of pig offal represented roughly 35 per cent of total porcine product exports in each year. Export volumes of live pigs are relatively small.

In recent years more than half of all EU pig meat and offal exports have been to the Far East. Most goes to just three countries: China (including Hong Kong), Japan, and South Korea. Russia is the destination of an additional 20 per cent of EU pig meat and offal exports. These patterns have been relatively stable over time. Mainland China and Hong Kong account for roughly three quarters of pig offal exports.

The EU exports approximately 28,000 tonnes of gelatine derived from pigs each year. These exports are valued at €131 million per year from 2006-11. The US, Japan and Switzerland are the three major importers of EU gelatine and together absorb more than half of total EU gelatine exports.

Data on the export of porcine genetic materials are not collected so cannot be reported.

4.4.4 Ovine and caprine export markets – live animals, meat and reproductive materials

EU exports of sheep and goat meat are relatively minor, and the volumes of trade are small compared to that of exports of bovine and porcine meat and meat products. Exports of live sheep doubled from 2010 to 2011 (46,000 tonnes) of which 83 per cent of the annual growth can be attributed to increased demand for live sheep from Turkey. In 2011, the value of EU sheep meat exports increased by 156 per cent, from €39 million to €99 million. Overall, from 2006-11, the EU exported an annual average of 7,000 tonnes of sheep meat valued at €34

[6] http://www.fas.usda.gov/gats/default.aspx

[7] http://www5.statcan.gc.ca/cimt-cicm/

million per year. Data on the export of ovine and caprine genetic materials are not collected so cannot be reported.

4.4.5 Equine export markets

EU exports only small quantities of horse meat. Export volumes are dwarfed by those of other species.

4.5 EU market outlook

4.5.1 EU bovine export market outlook

The OECD-FAO Agricultural Outlook (2011) forecasts that EU exports in beef and veal will fall steadily year-on-year from 2010 to 2020, dropping by an estimated total of 41 per cent over the period. EU beef accounts for only three per cent of global beef and veal exports. The marginal role of the EU in these markets is expected to continue to 2020. Major third country beef exporters include Australia, Canada, India, the US, and the South American countries of Brazil, Argentina and Uruguay. Brazil, Uruguay and Australia are also major global suppliers of live bovine animals, exporting to the EU's main markets in North Africa and the Middle East.

4.5.2 EU dairy export market outlook

The EU is a major player in international dairy markets. It accounted for 24-30 per cent of world dairy exports from 2005-2010. The big four dairy producers in order of their market share are New Zealand, the EU, Australia and the US.

While the global market situation has recently been favourable, DG AGRI (2011) reports that expectations for the next two years depend on the extent of increased milk production both in the EU and in the main supplying countries (e.g. New Zealand, Australia, and the US) and the sustainability of strong demand on the world market led by China and other countries of South-East Asia as well as by the Near and Middle East.

The OECD-FAO Agricultural Outlook (2011) projects that global imports of dairy produce will rise by a million tonnes from 2010 to 2020. Despite this growth in the market the EU's share of global dairy products is forecast to fall below 20 per cent in this period. This is largely as a result of competitive pressure from New Zealand.

4.5.3 EU porcine export market outlook

EU pig meat accounted for roughly a quarter of total world pig meat exports from 2005 to 2010. Pork exports from the US and Canada accounted for a further quarter each in this period; Brazil is the fourth largest pork exporter.

EU pig meat exports are forecast to decline year on year to 2020, with the EU seeing its share of the market fall to 20 per cent (OECD-FAO 2011). This decline is likely to occur in the context of global growth in the volume of pig meat exports (likely to be sustained by demand in Japan, Russia, Ukraine and other East Asian markets), which is forecast to be mostly captured by US pig exporters. There is also growing import demand for pig meat in markets where EU exports currently have less market presence such as Mexico, the US and Australia.

4.5.4 EU ovine and caprine export market outlook

Looking ahead to 2020, EU exports of sheep meat are forecast to increase but still account for just two per cent of global sheep meat exports (OECD-FAO 2011). Australia and New Zealand together account for over three quarters of this trade. The EU is the world's biggest importer of sheep meat, taking 25 per cent of global sheep imports in 2010. Saudi Arabia, the US and China are the next biggest markets for sheep imports. The volume of EU imports of sheep meat is forecast to decline by 22 per cent from estimated 2010 levels.

4.6 Internal EU trade and animal movements

An impact assessment of Regulation (EC) No 1/2005 on the protection of animals during transport provides the most comprehensive data available on internal movements of animals (Baltussen, Gebrensbet and de Roest, 2011). The reported data cover the period 2005 to 2009. The study found that by volume, intra-community trade in meat is more important than trade in live animals. Total intra-community trade represents approximately 20 to 30 per cent of total meat slaughtered (similar across species). Of this, intra-community trade in live animals represents about 15 per cent of total heads of cattle slaughtered, 10 per cent of total heads of pig slaughtered and 5-12 per cent of total heads of sheep slaughtered.

Table 4.3 Intra community trade in live animals as percentage of slaughtering in EU-27

	2005	2006	2007	2008	2009
Bovine	N/A	15	15	14	16
Pigs	N/A	9	8	9	12
Sheep	N/A	5	12	7	9

Source: Baltussen, Gebrensbet and de Roest (2011); insufficient data available for horses; no data provided on goats

5 The approach to the impact assessment

5.1 Introduction

This chapter explains the approach adopted for the impact assessment and how the analysis presented in the next chapters is structured. It considers:

- The approach to assessing the feasibility of the different packages of measures;
- The approach to identifying and quantifying impacts for the different packages of measures; and
- The 'behavioural' responses expected in the supply chain when packages are introduced.

5.2 The approach

The approach used to determine feasibility and to identify and quantify impacts involved a stepwise process that comprised:

- The specification of a set of packages built from measures listed in the study terms of reference;
- The mapping of these packages onto the supply chain, definition of the obligations that they will place on different sectors and the systems required to achieve the objectives of those packages;
- An assessment of the feasibility of each package and, as far as practicable, the constituent measures;
- An assessment of the likely behavioural responses that may occur under different packages;
- Modelling the impacts on businesses and competent authorities for each package, including those associated with:
  - (i) Understanding the implications of the changes ('learning' costs);
  - (ii) Reporting and inspection costs incurred by operators in meeting competent authorities' compliance regime;
  - (iii) Additional costs associated with meeting traceability, labelling and other new obligations (as applicable), including both one-off investment in new equipment and systems and extra operating costs;
  - (iv) Other impacts, such as trade-mediated effects and additional requirements imposed by the supply chain;
  - (v) SMEs, consumers, SMEs and competitiveness.
- Consideration of the environmental impacts of the four approaches; and
- A comparative analysis of the different approaches and packages, covering feasibility of each and associated impacts, and a commentary on the constituent measures.

5.3 Step 1: Definition of packages

The Commission tasked the project team with determining the feasibility and appraising the impacts of four approaches, each of which is defined through a set of individual measures. The first step in the assessment process was to develop a set of internally coherent 'packages' from different combinations of these measures. The set of packages defined for each approach varies in scope (in terms of the activities and products regulated) and in the 'footprint' that they have on the supply chain. The packages are described in the assessment for each approach (chapters 7-10).

5.4 Step 2: Definition of systems and appraisal of their feasibility

The second step was to define the system(s) that would be required to achieve the objective(s) of each package, and then to appraise its feasibility. The policy measures given in the terms of reference define the capabilities required (e.g. traceability of clone offspring) but the precise nature of the policy-makers' objectives and requirements determine what kind of system is needed. System definitions are provided under each of the approaches in chapters 7-10.

The analysis takes as its starting point the existing import controls, traceability systems and other measures that operate in the EU and international farming sector and food supply chain. These are summarised in chapter 6.

The feasibility assessment considers the issues involved in the construction and operation of the defined systems. It focuses primarily on the technical feasibility (whether a compliant system could be constructed). The text also provides a brief commentary on the strengths and weaknesses of the system envisaged for each package. This explores issues such as access to mechanisms for verifying the claims made for the clone status of animals or products, and general resilience to fraud, malpractice or undetected 'leakage' of animals/products with clone status into the food chain. An overall feasibility assessment is provided, as well as detailed consideration of variance by package and by animal species.

5.5 Step 3: Modelling

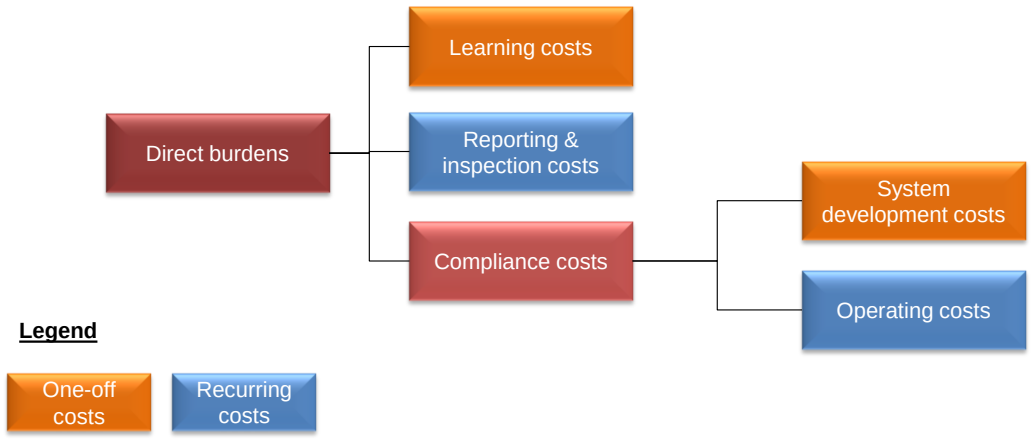
5.5.1 Direct burdens

Direct burdens are considered as:

- Costs incurred by operators in familiarising themselves with the requirements of the legislation and its impacts on their business (termed 'learning costs' in the text);
- Compliance costs associated with the establishment and operation of additional systems and processes required to achieve compliance with the new law (e.g. enhanced traceability systems and databases, addition requirements to tag animals and record their movements); and
- Reporting and inspection costs triggered by competent authorities' oversight of the new legislation.

A schematic representation of this is shown in Figure 5.1.

Figure 5.1 Schematic representation of the categories of direct burdens potentially created by the legislation



Cost estimates are provided for each of the packages under the four approaches: suspension, traceability, labelling and premarket approval:

- Under the ***suspension approach***, the costs are calculated for seven different packages under a simple suspension strategy;
- Under the ***traceability approach***, costs are calculated for seven different packages according to three different implementation strategies;
- Under the ***labelling approach***, costs are calculated for three different packages. Labelling costs are additional to the costs of the traceability approach and are independent of the traceability strategy adopted; and
- Similarly, under the ***premarket approval approach***, costs are calculated for three different packages. These costs are additional to the costs of the traceability approach and are not affected by which traceability strategy is adopted.

At a minimum, all approaches will require new legislation and/or amendments to existing legislation. Preparatory actions by operators and CAs will be necessary for these actors to become familiarised with the new rules. These costs are assumed to occur in the first six months to a year that the new legislation takes effect and are therefore one-off costs.

Variable costs are quantified, wherever possible, through application of a modelling approach in which:

- New information obligations are identified;
- Time required for each operation is identified;
- Cost per operation per affected business is estimated based on hourly cost factors; and
- Total burden is estimated based on business population data.

The fixed costs are expressed in terms of the lump sum investment required. Indications of the scale of fixed cost investment and the likely annual cost once operational are provided. Costs are expressed in 2012 euros.

The net impacts are estimated by reference to the baseline scenario described in chapter 4. The distribution of impacts (i.e. who is affected) are clearly stated. Impacts are monetised where possible. Where there is insufficient information to quantify impacts, indicators of relative scale / significance are used.

5.5.2 Indirect effects (market responses)

The response of the market (consumers, EU supply chain, and third countries) to the approaches considered in this study is a key determinant of the policies' impacts. For instance, the supply chain impacts of a given policy extend beyond, for example, labelling costs if consumers' choices will change when products derived from animal clones are labelled (the policy will trigger effects that shift patterns of demand and supply in the market). The issue of expected demand must be considered where the costs (or benefits) to sectors vary according to the quantity of the affected product sold on the market.

The specific impacts arising for each package are considered in the chapters that follow. The summaries below describe the strategic assumptions made about demand for each approach.

5.5.2.1 Suspension

Under the suspension approach, the expressed demand for regulated products will be zero because the products covered by the suspension package will, in effect, be banned and will not be available in the market. The scope of that suspension ('ban') varies by package and by animal species. There will be knock-on effects on trade, and on consumption patterns (consumer choices). These effects are described in chapter 7.

5.5.2.2 Traceability

Organisations interviewed for this study suggest that the main barrier to development and use of the cloning technique in Europe is consumer acceptability. The traceability requirements specified in the different packages make the animals / products / materials derived from clones more 'visible' to the supply chain. **The balance of evidence from consultations suggests that supply chain actors would seek to 'edit out' the products covered by the measure from the supply chain once they become visible.**

Research conducted on the current EU situation suggests that there is no commercial animal cloning in the EU so there will be no 'domestic' supply of clones, their reproductive materials or derived products to trace. EU-produced animals and products would, however, be affected if they were derived from imported animals or products that were derived from clones. Imports of animals or products derived from clones would be directly affected by supply chain 'choice editing'.

The key issue is the specification of the requirements that the EU places on importers and how the businesses (and authorities) in those third countries respond. The traceability requirement may, for instance, lead to a situation in which third countries invest in setting up a 'clone-free' supply chain to the EU. Alternatively, it could lead to trade disruption if exporting countries are unable or unwilling to put in place systems that match EU requirements.[8] These issues and complexities are explored in more detail in chapter 8.

5.5.2.3 Labelling

As in the traceability scenario, the changes in demand will be focused on imports in cases where third countries comply with measures and continue to supply the EU with food products derived from clones, offspring and descendants. In both situations, changes in demand are likely to lead to a 'clone-free' supply chain from third countries, or an end to the trade in question. These issues are explored in detail in chapter 9.

5.5.2.4 Premarket Approval

For premarket approval the market response is seen first in the number of applications submitted for approval.

5.6 Step 4: Impacts

The final step involves determining the impacts associated with each package.

The impact analysis includes a combination of quantitative and qualitative assessments of the four approaches. These include:

- The direct burdens and indirect supply chain effects (as discussed above);
- Trade-mediated effects;
- Impacts on SMEs;
- Impacts on competitiveness;
- Social (employment) impacts;
- Environmental impacts.

The impact analysis for each approach is set out in the next four chapters—one for each approach—and concludes with a summary chapter that aggregates and compares the impacts across approaches.

The expected **direct burdens** associated with each approach, strategy, and package) are assessed by modelling the estimated, anticipated regulatory costs for operators in different sectors that may be affected by the measures and for competent authorities. A description

[8] The potential form and scale of retaliatory action from trading partners is not covered in this study.

of the model and details regarding its implementation are provided in Annex 8. Tables provided in the following chapters summarise the results.

The assessment also provides information on expected ***indirect supply chain effects*** and the ***trade-mediated effects***, including social (i.e. employment) and competitiveness impacts that may result from implementation of the four approaches. Anticipated internal and trade-mediated effects are presented primarily as a qualitative assessment, supported by quantitative data where these are available.

Impacts on SMEs, consumers and competitiveness are examined. Finally, the assessment addresses potential ***environmental impacts*** that may arise from implementation of the four approaches. These are presented as a primarily qualitative assessment in chapter 11.

6 Traceability systems in the EU and third countries

The traceability of clones, clone offspring and clone descendants, their reproductive materials and derived food products is important to all the approaches examined in this study. This section summarises the existing general traceability arrangements in place in food chain in the EU and in third countries, and the systems in place already specifically for the traceability of clones, their offspring and descendants, and for reproductive materials from animals with clone heritage.

6.1 EU traceability systems for live animals

Live animal traceability systems have been set up in the EU that would be helpful in the implementation of the approaches examined in this study. These systems have been constructed mainly to support food safety, human health and animal health objectives. They contain a number derogations and exclusions which, while appropriate to a risk-based approach to those objectives, would leave some gaps in coverage if the systems were to be co-opted for use in tracing clones, clone offspring or clone descendants. Subsequent chapters show how closing the gap between the current systems and the requirements of policy packages would require additional investment in system development, for example, in removal of derogations and application of individual traceability where current systems work on a batch basis.

Individual animal traceability is already in place in the EU for bovine and equine animals and some porcine, ovine, and caprine animals (mostly breeding animals). Most porcine, ovine and caprine animals are not individually identified, but instead identified on a batch basis. Most of the EU's trading partners have individual bovine and equine animal traceability systems in place. The US does not have individual bovine traceability. In most countries, porcine, ovine and caprine species do not have individual traceability. Table 6.1 summarises the traceability requirements under existing EU regulations for bovine, porcine, ovine, caprine and equine animals. At present:

- All bovine animals in the EU are individually identifiable to the point of slaughter;
- Bovine animals imported into the EU are individually identified from the point of entry into the EU;
- Individual porcine breeding animals and porcine animals transported between Member States are individually identifiable to the point of slaughter;
- The vast majority of porcine animals are identified on a batch basis (no individual identification);
- All ovine and caprine animals born after 1 January 2010 must be electronically and individually identified, except by derogation in MS in which the ovine population is fewer than 650,000 animals. High value breeding animals must also be identified individually as of 1 January 2010;
- The vast majority of ovine and caprine animals are identified on a batch basis (animals under the age of 12 months sent straight to slaughter); and
- Under EU legislation most equine animals are required to be individually traceable. Imported equine animals are also individually identifiable. Equine animals produced in the EU that are intended for slaughter, however, are not required to be individually identified.

Table 6.1 Regulatory baseline – the existing traceability arrangements for live animals

Species	ID	Track/Trace	System	Status
Bovine	Individual animal	Individual animal	Ear tag identification, passport & movements database organised at MS level	In force (legal requirement)
Porcine	Most porcine animals identified on a batch basis. Individual breeding and some other animals	Holding of origin	Ear tag identification, tattoos, & movements database organised at MS level	In force (legal requirement)
Ovine / caprine	Batch (animals sent to slaughter before the age of 12 months) Individual for all other animals (except for countries with sheep pop<650,000)	Holding of origin Individual animal	Electronic identification & movements database organised at MS level	In force (legal requirement) since January 2010
Equine	Individual animal, except for animals of wild or semi-wild populations or for animals sent to slaughter before 12 months	Individual animal	Electronic transponder (containing Universal Equine Life Number) & identification document or passport Central database not compulsory	In force (legal requirement)

Current EU law requires the recording of the dam but not the sire on the bovine animal ID database (BSE is transmitted via the maternal line). The percentage of breeders who currently record the parentage of offspring is as high as 60-70 per cent for dairy animals in some Member States (e.g. France). In other Member States, only 20 per cent of a herd is recorded in a performance recording system. EU law does not require parentage recording at all for porcine, ovine, caprine, or equine animals.

Consultation with the AI industry in the EU indicates that pedigree information, including DNA information, is currently kept in databases for bovine breeding animals in the AI sector; these data are kept by the national herd books (source: consultation with DE, DK, ES, FI, FR, NL, SE, and UK AI firms, UK herdbook, DE cattle breeding association). This allows full traceability through the supply chain for individual pedigree bovine animals produced from their reproductive materials until slaughter in the EU.

Pure line porcine breeding animals are also individually identified, and the semen doses collected from them are traceable. This individual traceability is maintained at the nucleus level for breeding pigs but is lost when the pig becomes part of a 'batch' at the multiplier stage through mixed weaning of all litters. Information about individual breeding and multiplier animals is also held in private (commercial) databases in some Member States. There is a national database in France for individual porcine breeding animals, but it only contains data from a small number of firms.

DNA databases for porcine breeding animals are currently being implemented in the Netherlands; all of these animals will eventually have their DNA registered and available. A French porcine breeding company currently carries out DNA testing for all male breeding animals to verify parentage. The DNA is kept by the lab which conducted the test and in a company database (not nationally held). There is no formal pedigree certificate information for porcine animals in the UK, but paper records are retained; there are no routine DNA parentage tests for porcine animals in the UK.

A DNA test is a prerequisite to obtain a breed certificate in Germany (these are issued by the Association of German meat and cattle breeders and owners - Bundesverband Deutscher Fleischrinderzuchter und –halter e.V.) (Consultation with an AI company based in DE). DNA tests are typically outsourced by EU firms to a small number of companies operating in the EU (located in the Netherlands, Ireland and UK) and the US.

6.2 Traceability for reproductive materials

Reproductive materials from bovine, porcine, ovine, caprine and equine animals are individually identifiable and traceable under EU law (Annex 2 provides a list of relevant legislation). Traceability of imported reproductive materials is enabled through registration and approval of semen collection centres and information supplied on health certificate submitted at the border. Table 6.2 summaries the regulatory requirements for reproductive materials.

Table 6.2 Regulatory baseline – the existing traceability arrangements for reproductive materials

Species	ID	Track/Trace	System	Status
Bovine	Individual	Individual (donor for semen; parents for embryo)	Health certificate & international code (at EU level)	In force (legislative requirement)
Porcine	Individual	Individual (donor for semen; parents for embryo)*	Health certificate & indication of origin on the packaging containing the dose of semen or embryos	In force (legislative requirement)
Ovine / caprine	Individual	Individual (donor for semen; parents for embryo)*	Health certificate & indication of origin on the packaging containing the dose of semen or embryos	In force (legislative requirement)
Equine	Individual	Individual (donor for semen; parents for embryo)*	Health certificate & indication of origin on the packaging containing the dose of semen or embryos	In force (legislative requirement)

**Consultation with AI companies indicated that the traceability of reproductive materials did not seem to be systematic in practice, especially when semen doses are mixed*

6.3 Traceability for food products

Food products derived from all five animal species are identified entirely on a batch basis; the batch is traceable back to a group of slaughtered animals. The batch may contain animals from different holdings. Traceability enables identification of the holdings from which a particular batch of food products was derived. Imported food products must be accompanied by a health certificate submitted at the border. The baseline is summarised in Table 6.3.

Table 6.3 Regulatory baseline – the existing traceability arrangements for food products

Species	ID	Track/Trace	System	Status
Bovine	Slaughterhouse batch	Individual animal or group of animals slaughtered reference number	Supply chain documentation Batch + slaughterhouse + cutting hall numbers on labels	In force (legal requirement)
Porcine	Slaughterhouse batch	Group of animals slaughtered reference number	Health certificates Batch number labelling or site specific approval number on label (referring to slaughterhouse, cutting plant, processor or producer)	In force (legal requirement)

Species	ID	Track/Trace	System	Status
Ovine / caprine	Slaughterhouse batch	Group of animals slaughtered reference number	Health certificates Site specific approval number on label (referring to slaughterhouse, cutting plant, processor or producer)	In force (legal requirement)
Equine	Slaughterhouse batch	Group of animals slaughtered reference number, which can be related to the individual identification numbers of the animals (slaughterhouse level)	Health certificates Depends on the country. No standardised process. Site specific approval number on label (referring to slaughterhouse, cutting plant, processor or producer)	In force (legal requirement). Not equally implemented in all countries. For example: very advanced in France, not at all in Germany; Spain and Belgium are implementing it slowly, unreliable in Northern Ireland

6.4 Traceability for clones, their offspring and descendants in the EU

There are a few systems in the EU or third countries that support traceability specifically for clones, their offspring and descendants. For example:

- Bovine clone offspring are registered in the UK through Holstein, UK (see box below);
- Consultation with a horse cloning company indicates that some clone (sport) horses are identified as such in their passports, but this practice is not standardised; and
- Reproductive materials from clones of bovine animals are excluded from import into the EU where required by EU importers through a private supplier-based system in the US and Canada.

Registration of Holstein clone offspring in the UK

Registration of the offspring and descendants of clones is accepted in the UK (Holstein, UK). The UK population of clone offspring is estimated to be fewer than 100 bovine animals. Embryos from offspring of clones are produced in the US (but not in the UK). On arrival in the UK the embryos are sent to embryo transfer (ET) labs. Two sets of forms are completed in cooperation with these labs: the importing company has to complete an ET1 form after the embryo implantation and an ET2 form after the birth of the animal.

When the animal is born it is given an ear tag and 14 pieces of information are provided to Holstein UK. Holstein UK is in charge of registering the animal and an electronic request is automatically sent to the British Cattle Movement Scheme (BCMS). When this request is accepted, the animal receives a registration certificate and a passport. The information about clones is already included in the pieces of information. The animals are registered as ETN if they come from a cloned dam, ET otherwise.

This system enables tracking for descendants of clones within pedigree herds. Traceability is carried further along the supply chain using cattle passports. If the animal is kept in a pedigree herd/milk recording herd, tracking for the clone descendants can continue using

the passport information. If the animal is sold to a non-pedigree herd, the BCMS could be used to transmit the information further down the supply chain to the point of slaughter.

When US clone offspring entered the UK food chain in July 2010 it took no longer than 3-4 hours to locate the offspring and send letters to the operators they were supplied to; the animals were removed from the food chain within 24 hours (Holstein UK).

6.5 Traceability of clone reproductive materials imported from third countries

AI companies consulted for this study indicated that there are currently systems in place in the US and Canada to ensure that reproductive materials derived from clones are not exported to the EU. Consultees have a high degree of trust in the system. This is an accepted industry practice and there are no controls at the EU border because suppliers carry the burden of clone identification/segregation for their products.

6.6 Traceability of clones in New Zealand, Canada and the United States

New Zealand has a clone registry in operation under a regulatory control scheme implemented in 2010; it is the only country that does so. Some Canadian livestock breed registries have provisions to identify animal clones through a supplemental designation on the registration documents, to differentiate animal clones from the animals which were derived through conventional breeding. The animal registration process is voluntary. For example, Holstein Canada established special protocols for recording clones to ensure they can be uniquely identified and distinguished on Certificates of Registration. The US had an industry-led voluntary clone registration system in place for several years but it has been discontinued (see box below for a description of the system).

6.7 The scope for use of DNA databases in verification

Physical verification of claims made for imports would be possible if samples from the exported products could be compared to a DNA database. This would require a record of the DNA of the clones (and offspring and descendants under some policy packages) as well as standard administrative data (registration number, etc.). This would allow testing of samples from animals to determine if they were present on the registry. It would not be possible to confirm that an animal has clone heritage if its parent was not on the database.

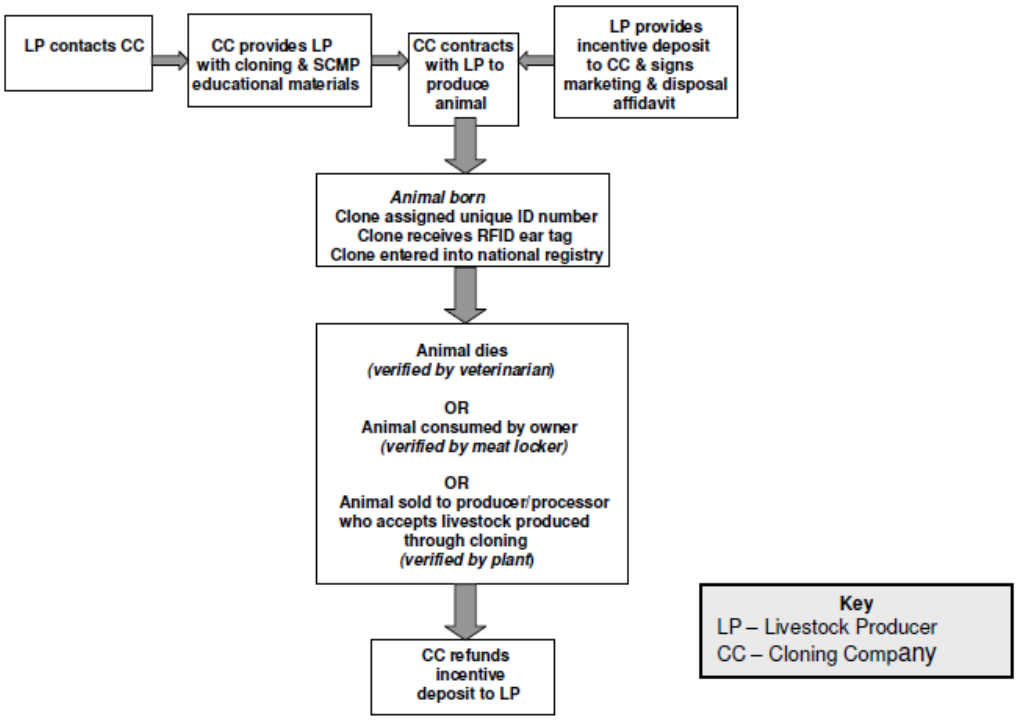
In practice, use of DNA testing is limited depending on the type of food products covered (e.g. meat or milk) and the stage of the food supply chain controls where testing is used. Further details are provided in Annex 9.

Supply chain management for clones in the US

A paper-based supply chain management programme for verification of clones was set up in the US but has since been discontinued. It was implemented voluntarily in the US for clones (but not their offspring or descendants) and reached to the point of slaughter. The system was developed by the largest US livestock cloning companies, ViaGen and Trans Ova Genetics.

The Supply Chain Management Program (SCMP) involved a registry system that followed livestock clones from birth to death and carcass disposal. The key components of the program were education, a national clone registry, affidavits, and incentives (Figure 6.1).

Figure 6.1 US Livestock Cloning Supply Chain Management Program Overview



Source: http://www.clonesafety.com/documents/SCM_How.pdf

The Colorado based company, AgInfoLink, managed the database of animals identified with an Animal Identification Number. The system was designed to manage only cloned animals, not their offspring. Consultation with the cloning industry in the US indicates that the SCMP system was operational for five years but that it was discontinued because there was no demand for it, neither from consumers nor from companies. No claims for labelling of cloned pedigrees were submitted.

The program functioned as follows:

- Cloning company contracts to produce animal following owner education.
- Owner signs an affidavit committing to proper marketing or disposal of animal or milk products.
- Owners get refunded an incentive deposit they had previously paid to the cloning company when they notify the company of animal death (verified by a veterinarian), consumption by owner (verified by the meat locker) or sale to a packer/processor who accepts livestock produced through cloning (verified by a signed statement from the packer/processor).
- The incentive deposit was based on a value higher than market value for a similar animal.

7 Approach appraisal: suspension

7.1 Introduction

This chapter examines the feasibility and impacts of a suspension (or ban) approach to regulation of animal cloning. It is assumed that the suspension or ban would be introduced through new EU legislation and that the control would be temporary, in force until 2020.

The analysis considers the suspension measures defined in the study terms of reference. Most of those measures are not viable in isolation but instead must be introduced in combination with other suspension measures. As an example, suspension of the marketing of descendants of clones is very unlikely without suspension of the marketing of clones and clone offspring. The assessment has therefore considered different combinations of measures that provide coherent 'packages' of intervention. The analysis shows the estimated cost for each package and also the incremental cost associated with the application of each additional measure.

7.2 Definition of the suspension packages

The suspension measures provided by the terms of reference and considered in this appraisal are listed in Table 7.1.

Table 7.1 Suspension measures

	Measure description
S1	Suspension of the cloning technique for all food production animals and use of clones
S2	Suspension of the marketing of food from clones
S3	Suspension of the marketing of reproductive materials of clones
S4	Suspension of the marketing of live offspring (1st generation) & their reproductive materials
S5	Suspension of the marketing of live descendants of clones (2nd and subsequent generations) & their reproductive materials
S6	Suspension of the marketing of food from offspring of clones (1st generation)
S7	Suspension of the marketing of food from descendants of clones (2nd and subsequent generations)

Other than measure S1 (suspension of the cloning technique for all food production animals and use of clones) no measure is viable on its own so they have been combined into a set of internally coherent packages, labelled S-A to S-G, as described by Figure 7.1.

The packages are described in more detail in Annex 4. They vary in scope from covering only the suspension of use of the cloning technique through to suspension of marketing of all clones, clone offspring and clone descendants, all reproductive materials obtained from such animals, and all derived food products. As the scope varies, so does the number of business sectors potentially affected. Table A4.3 shows which business sectors are affected by each package of measures.

Figure 7.1 Representation of the scope of the suspension packages S-A to S-G

		Cloning activity	Reproductive material from clones [imported]	Reproductive material from clones [EU]	Live offspring from clones (first generation) [imported]	Live offspring from clones (first generation) [EU bred]	Live descendants from clones (all generations) [imported]	Live descendants from clones (all generations) [EU bred]	Food from clones [EU material]	Food from clones [imported material]	Food derived from offspring from clones (first generation) (i) imported	Food derived from offspring from clones (first generation) (ii) EU bred	Food derived from descendants from clones (all generations) (i) imported	Food derived from descendants from clones (all generations) (ii) EU bred
S-A	1													
S-B	1 + 3													
S-C	1 + 3 + 4													
S-D	1 + 3 + 4 + 5													
S-E	1 + 2													
S-F	1 + 2 + 3 + 4 + 6													
S-G	1 + 2 + 3 + 4 + 5 + 6 + 7													

*"Live offspring from clones (first generation) [imported]" and "Live offspring from clone (first generation) [EU bred]" also cover reproductive materials of clone offspring. Live descendants from clones (all generations) [imported]" and "Live descendants from clones (all generations) [EU bred]" also cover reproductive materials of clone offspring.

7.3 Feasibility assessment

This section provides a classification of, and commentary on, the feasibility of the suspension approach. It considers both technical feasibility and the extent to which the approach is robust against false claims.

7.3.1 Summary of the feasibility analysis

All packages are technically feasible for EU production (and require no significant change to existing systems) but for imported animals, reproductive materials and food products there are issues as to how compliance would be confirmed. There is a risk that all packages that cover more than clones and reproductive materials would not achieve their objectives. This is due to the expected difficulties in confirming the claims made for imported animal clones, their offspring or descendants, derived reproductive materials and food products, and the lack of any means of empirical verification of those claims. The risk is influenced by the EU's evidential requirements and the extent to which these provide scope for a proportionate, risk-based approach. It is difficult to see conditions in which measures that extend the scope of controls into clone descendants and food products derived from clone descendants are feasible.

There are few companies in the EU capable of carrying out cloning so domestic cloning activity is relatively easy for competent authorities to regulate. If animal cloning is suspended within the EU and effective controls are applied at the EU's borders then clones will be excluded from the EU food chain. There is therefore no need for additional traceability capability within the EU itself. The same principle applies for packages that cover clone offspring and descendants, derived reproductive materials and derived food products –exclusion at the border and suspension of cloning within the EU negates the need for additional traceability systems in the EU. In this sense suspension is straightforward to implement for the domestic food supply chain. The challenges posed by this approach arise at the border, where imports into the EU will need to be screened for compliance with the suspension law. The EU's requirements for 'proof' of the clone status of imports, and the response of third countries to those requirements are very important to the feasibility of the suspension approach.

The analysis suggests that suspending the use of the cloning technique for livestock animals is the most feasible of the packages evaluated. Systems for suspension of clone imports are also technically feasible. Suspending the marketing of clone reproductive materials should be feasible for domestically produced and imported reproductive materials. Packages that cover clone offspring and descendants (and their reproductive materials) are likely to be challenging to implement, particularly for imports. Packages that extend to food products will be very challenging, both for domestically produced and imported products.

The feasibility of suspension changes with the scope of the legislation and the standards of proof that the EU will demand on imports. Feasibility increases if the EU is prepared to recognise private traceability systems in third countries, national cloning moratoriums in third countries, and other systems and measures in place that restrict clone production or record their movements and the movements of their reproductive materials, etc. If the EU took a proportionate approach, the evidential requirements would also recognise the variation in commercial cloning activity for food production across species and in different parts of the world. A uniform approach that does not recognise those differences may well impose demanding evidential requirements to trade for species (and derived products) for which there is little or no commercial cloning activity and with countries that have little or no access to such technologies (e.g. some developing countries). An approach that required documentary evidence from official traceability systems tracking clone offspring and clone descendants and derived food products that reached across global supply chains is unlikely to be feasible.

7.3.2 Suspension of cloning within the EU domestic supply chain should be straightforward

If cloning of animals is stopped within the EU and effective controls are applied at the EU's borders then clones will be excluded from the EU food chain. There are few companies in the EU capable of carrying out cloning so domestic cloning activity is relatively easy for competent authorities to regulate. There is no need for additional traceability capability within the EU itself. A simple suspension strategy can be implemented faster than the other approaches considered in this report as it requires new legislation but no new substantive systems within the EU.

The same principle applies for packages that cover clone offspring and descendants, derived reproductive materials and derived food products – exclusion at the border and suspension of cloning within the EU negates the need for additional traceability systems in the EU. In this sense suspension is straightforward to implement for the domestic supply chain. The challenges posed by the suspension approach occur at the border, where imports into the EU will need to be screened for compliance with the suspension law.

7.3.3 Imports are a key issue for the feasibility of the suspension approach

In most cases confirmation of the status of animals, reproductive materials and food products would depend on traditional documentary methods used in supply chain traceability system. Currently, this kind of documentation is not required for imported live animals and is only included in a small number of cases. No such documentation is provided for imported food products. Under existing systems, the claims made under packages that cover clone offspring or descendants and any clone-derived food products cannot be verified, as the status of the offspring, descendants and food products cannot currently be traced back to the individual animal of origin in any third country. Supplementing documentary evidence with DNA evidence (while recognising the limitations of DNA comparisons in this context) would not be possible without new investment as trading partners do not have comprehensive registries against which to compare DNA of animals or reproductive materials.

International trade in reproductive materials will make it difficult to be certain that the animals or food products obtained from a country that does not use the cloning technique were not actually derived from reproductive materials from clones, their offspring or descendants obtained in another country. There would be specific issues for imports from countries that are known to have populations of clone offspring or descendants (e.g. Switzerland) if all such animals could not be identified and excluded from the EU supply chain.

The EU's requirements for 'proof' of the clone status of imports, and the response of third countries to those requirements are, therefore, important to the feasibility of the suspension approach. The 'feasibility' of suspension (if this is defined as a system with which operators can comply) increases if the EU is prepared to make use of existing systems, policy commitments, etc. in third countries – for example, private traceability systems in third countries, national cloning moratoriums in third countries. For instance:

- If the EU requires full traceability of animal clones, their offspring and descendants; reproductive materials; and derived food products irrespective of the prevalence of regulated products in that country, then exporters to the EU would be able to demonstrate compliance with the suspension approach only where their country has such systems in place. Given that there is trade between third countries in animals, reproductive materials and food products, these systems may need to extend beyond the country that trades with the EU into other third countries. At present the EU's trading partners do not, with a few exceptions, operate systems that indicate whether animals are clone, clone offspring or clone descendants, indicate whether reproductive materials are obtained from such animals, or whether food products are derived from such animals. If the necessary investment in third countries does not take place, then exporters are unlikely to be able to comply with the suspension approach.

- If the EU requires verification of claims in addition to documentary evidence then third countries would need to build and operate comprehensive DNA databases for all animals in the food chain for each species covered by the EU suspension (with the caveat that even DNA matching does not necessarily provide certainty). This would involve new activities for third country operators as such databases are not in place.
- If the EU requires a declaration by the exporter, backed by private supply chain arrangements that could be subject to audit, then the system may be more feasible for operators in third countries and their trading partners in the EU. For example, the supply chain has already established a system for reproductive materials that is trusted within the industry. Nonetheless, the scale and complexity of the systems that would be required in third countries increases rapidly as the packages extend beyond clones and reproductive materials to clone offspring, descendants and food products.

Suspending the use of the cloning technique for clone animals used for food production is the most feasible of the measures evaluated. The number of potential EU suppliers is small; proportionate systems for suspension of clone imports are also technically feasible through working with trading partners. Suspending the marketing of clone reproductive materials should be also feasible for domestically produced and imported reproductive materials. There are existing private systems operated by the supply chain that help exclude reproductive materials from clones from EU imports. These could potentially be extended more widely, taking a risk-based approach.

If the EU took a proportionate approach, the evidential requirements would also recognise the variation in commercial cloning activity for food production across species and in different parts of the world. A uniform approach that does not recognise those differences may well impose demanding evidential requirements affecting trade:

- For species (and derived products) for which there is little or no commercial cloning activity; and
- With countries that have little or no access to such technologies (e.g. some developing countries).

7.3.4 The risk of the suspension approach failing is highest for bovine animals and derived products but low elsewhere due to the low level of commercial cloning of other species

Commercial cloning activity is concentrated in bovine animals and (non-food) equine animals. The probability of offspring and descendants of clones for porcine, ovine and caprine animals entering the food chain despite the suspension approach is very small. A risk-based approach to suspension that targets bovine animals and controls the introduction of sport horses into the food supply chain could be used to reduce the burden on operators working with other species, and the burden on competent authorities.

Imported food products present an enforcement challenge, particularly for bovine products (due to the large scale of trade and variety of sources). Equine meat comes from fewer countries. Ovine, caprine and porcine meat products come from a small number of exporting countries and may thus, in principle, be more easily controlled.

Food thresholds

As described in this chapter, prohibiting the marketing of foods derived from clones, clone offspring and clone descendants would present very significant challenges. The legislation would need to specify the thresholds at which the suspension would apply. For instance, would the suspension apply only to food products that are entirely derived from the regulated animals (e.g. milk, meat), or also to processed products? Inclusion of processed products would be difficult due the problems associated with traceability of ingredients across the EU and global food chain.

Table 7.2 Commentary on feasibility of the suspension measures

Package	Commentary on feasibility
Package S-A Suspension of cloning for all food production animals and use of clones *[Feasibility of measure S1]*	Could be implemented without significant adjustment to existing EU systems. EU companies with the capacity to clone animals for food would be identified and monitored by CAs. Animal genetics companies are the most likely candidates. Imports are more problematic but there are a small number of animals to control. Imported live animals can be controlled relatively easily through risk-based surveillance of trade focusing on the main sources of food production animals with the highest levels of cloning activity. Assessment of claims that an animal is not a clone is possible in the EU through oversight of companies that could conduct cloning activities; verification is not possible, however. Imported live animals would require documentation of the pedigree information for the animal to confirm that it is not a clone. This information should be relatively easy to confirm given the small number of operators that can produce a clone in third countries and EU operator awareness of the status of imported animals.
Package S-B S-A plus suspension of marketing for reproductive materials of clones *[Feasibility of measure S3 when applied in addition to Package S-A]*	Could be implemented without significant adjustment to existing systems. EU companies that produce and handle reproductive materials are already tightly regulated. The origin of reproductive materials would require oversight in third countries, but should be straightforward to control since few international companies are capable of producing clone reproductive materials. At a minimum, documentation of the pedigree or equivalent status of reproductive materials would be required. Currently, this kind of documentation is not required. There are, however, systems in place in North America that identify reproductive materials that are obtained from clones so that they can be excluded from exports to the EU. Risk-based surveillance of trade could be developed, recognising that the vast majority of reproductive materials imported into the EU are from the US and Canada (all species), with some imports from Australia and New Zealand (bovine, ovine / caprine / equine), the Far East (a small amount of ovine and caprine materials) and Latin America (a small amount of equine materials).
Package S-C S-B plus suspension of marketing for live offspring of clones (and their reproductive materials) *[Feasibility of measure S4 when applied in addition to Package S-B]*	Suspension of cloning within the EU and suspension of import of offspring of clones should prevent the presence in the EU of any clone offspring. The challenge is to apply the suspension to imports of live animals and reproductive materials of clones. Few live animals are imported to the EU and those that are brought in are often 'high value' animals whose heritage would be documented. An issue is thus whether the EU suspension legislation would regard such documentation as acceptable evidence of status and how the evidence would be used, whether the EU would accept an exporter's declaration on the health certificate, with the proviso that the original documentation could be requested by regulators. Pedigree status of reproductive materials would be required. Currently, this kind of documentation is not required. The systems in place in North America to identify clone reproductive materials do not extend to reproductive materials from the offspring of clones. Additional steps would need to be taken by operators to identify reproductive materials from clone offspring. Assuming that the EU required documentary evidence at the point of import, this package would require countries exporting to the EU to establish new systems that 'tagged' each clone offspring and all reproductive materials obtained from those animals. To be comprehensive

Package	Commentary on feasibility
	these systems would need to provide for trade in clones, clone offspring and clone reproductive materials amongst third countries (e.g. between the US and Canada). Debating, designing and constructing relevant systems in third countries would take time. This would impact on the speed with which the suspension of marketing of clone offspring could be introduced without disruption to trade and the supply chain (discussed further below). There would potentially be issues with 'legacy' presence of undocumented clone offspring in the system.
Package S-D S-C plus suspension of marketing for live descendants of clones (and their reproductive materials) *[Feasibility of measure S5 when applied in addition to Package S-C]*	If a viable solution to the problems posed by Package S-C is not found then package S-D is not feasible – clone offspring will not have been effectively excluded from the EU, may be present in the EU supply chain and used to generate clone descendants on EU farms. The concerns about imports of live animals noted for S-C apply equally to S-D. The main feasibility issue is, again, likely to relate to imports of reproductive materials. Current systems do not identify whether there was a clone amongst the parents of animals in previous generations from the animal from which reproductive materials were obtained. Assuming that the EU requires documentary evidence at the point of import, this package would therefore require countries exporting to the EU to establish new systems that identify each clone descendant (and thus each clone and clone offspring), and all reproductive materials obtained from those animals. To be comprehensive these systems would need to incorporate trade in animals and reproductive materials amongst third countries (e.g. between the US and Canada). These systems would be focused on the breeding sectors in these third countries. Detailed study would be required to specify the systems needed to meet EU requirements. Special provisions might be needed for rare breeds or non-commercial imports of reproductive materials and animals. Designing, building and commissioning such systems would take time. This would impact on the speed with which the suspension of marketing of clone offspring could be introduced without disruption to trade and the supply chain. There would potentially be issues with 'legacy' presence of undocumented clone descendants in the system.
Package S-E S-A plus suspension of marketing of food from clones *[Feasibility of measure S2 when applied in addition to Package S-A]*	Excluding EU-bred clones from use in food is straightforward, but imports are more problematic. The risk of clones being used systematically for food in the next few years is low as clones are uncommon and valuable and so are more likely to enter the food chain at the end of their working lives as breeding animals rather than be produced directly for food. Nonetheless, demonstrating and documenting that foods are free of clones would require systems that do not currently exist. Under this package third countries that export to the EU would in principle be required to have appropriate traceability systems or segregated supply chains though the EU ought to be able to agree a pragmatic solution (based around third countries undertaking to exclude clones from exports to the EU) that avoids creating barriers to trade given the scarcity of clones. If a pragmatic solution could not be found then enforcing the suspension of use of clones in imported food products is a significant challenge due to the high volume of EU meat product imports. Verification of claims would not be possible. The feasibility of the system would thus depend on the specification of the evidential requirements applied to imports under the EU legislation. A requirement for comprehensive official traceability systems for all food products is less feasible than a proportionate risk based approach under which, for instance, trading partners demonstrated that clones were not entering the food chain.

Package	Commentary on feasibility
Package S-F S-C plus suspension of marketing of food from clone offspring *[Feasibility of measure S6 when applied in addition to Package S-C]*	Construction of a system for S-F is less feasible because of the much larger number of animals that fall within scope and the difficulty of creating an equivalent 'pragmatic' solution. Trading partners would therefore need to either: (i) identify and trace all clone offspring as live animals and then trace them through the food chain (so as to demonstrate that exports to the EU did not contain products derived from clone offspring); or (ii) establish fully segregated 'clone-free' supply chains. Segregation may be the only practical option - as discussed in more detail elsewhere in this report, the traceability of food products at the individual animal level is feasible only in certain circumstances and would not be viable for many of the food products covered by the legislation. Again, the feasibility of the system would depend on the specification of the evidential requirements applied to imports under the EU legislation. A requirement for comprehensive official traceability systems for all food products is less feasible than, for instance, a certification and audit system for segregated supply chains. The observations on timing and thresholds (for ingredients) made above apply equally to S-F.
Packages S-G Package S-D plus suspension of marketing for food from descendants of clones *[Feasibility of measure S7 when applied in addition to Package S-D]*	The analysis applied for S-F above applies also to S-G, with the added complication that all animals and derived food products would potentially be in scope of the legislation. Effective control over clone reproductive materials should prevent the introduction into the supply chain of food products derived from clone offspring and their descendants where the supply chain for clone reproductive materials is entirely EU-generated. Trading partners would not be able to demonstrate that food products were not derived from clone descendants with current systems. The key issue, again, is the EU's evidential requirements. Third countries wishing to trade with the EU would need to establish fully traceability systems across all generations of animals that record whether the animal had a clone antecedent, and for all relevant food products. These systems would, in principle, need to reach across all other trading partners so as to control for the possibility of (for example) reproductive materials derived from clone offspring being imported and used to produce an animal whose products are then exported to the EU. In extremis this would in effect require a global traceability system for all species in scope and all food products that would potentially use regulated ingredients. The alternative would be a fully segregated food production system. In an environment where clones are becoming more common in breeding, this segregation would need to extend into the breeding sector. In the absence of a full traceability system, animals destined for the EU export market would need to be bred in a system genetically isolated from the rest of the sector in that country. The volume of meat products imported into the EU from third countries and difficulty ensuring oversight of the supply chain in each exporting country to exclude any clone-derived inputs complicates the task of enforcement. Proportionate, risk-based approaches that recognised the use of cloning in each trading partner for each species may alleviate some of the issues described above but it is difficult to see S-G as a feasible option.

7.3.5 The supply chain would need to be given time to prepare for the new obligations

As noted above, the suspension of cloning in the EU and imports of clones (measure S1 / package S-A) could be applied relatively quickly – there are few companies, no known commercial cloning activity in the EU, and no major system developments needed. The adoption of measures that required more significant development of systems or a supply chain transition in trading partners would require a longer lead-in period if disruption to the supply chain is to be avoided. In some cases that lead-in time could be substantial.

Implementation is likely to be most straightforward for operators upstream in the supply chain because they already have the most information about the clone status of the animals and products they handle, and because many fewer operators will be affected (see baseline information on the number of operators at each stage in the supply chain, Annex 8, Table A8.4). Packages that include measures further down the supply chain (i.e. for food products) not only affect many more operators overall, but also require operators to obtain information that they are unlikely to be already collecting voluntarily.

7.4 Impacts of the suspension approach

This section assesses the impacts that arise from the suspension approach. The obligations placed on operators and competent authorities by the packages are detailed in Annex 4, Table A4.3.

7.4.1 Summary of the economic impact analysis

Table 7.3 provides an overview of the impacts of suspension.

Table 7.3 Impact summary – by package

	S-A	S-B	S-C	S-D	S-E	S-F	S-G
Learning costs	89	1,123	1,123	1,123	89	3,212	3,212
Annual reporting burden € '000	10	128	128	128	10	367	367
	…plus inspection/compliance costs that will vary according to the specification of the legislation and competent authority strategies						
Other economic impacts	Negligible	Low	Risk of negative impacts triggered by interruption to trade		Risk trade impacts if pragmatic approach not agreed with partners	Risk of substantial negative impacts triggered by interruption to trade	
Trade at risk, €m/yr*	2.3	14	14	14	2.3	3,667	3,667
Impacts on consumers	None	None	Risk of dairy and meat price rises, especially over longer term		None if pragmatic approach agreed	Risk of price rises & reduction in choice	
Employment impacts	Negligible	Jobs at risk in imports of reproductive materials though losses would be offset to some degree by increase in domestic supply			Negligible if pragmatic approach agreed	Jobs at risk in food import supply chain Employment in domestic production would offset losses to some degree	

**Excludes equines, most of trade in which is not for food production*

The suspension legislation is expected to trigger one-off 'learning costs' for the supply chain as operators seek to understand the implications of the cloning suspension for their

businesses. The potential scale of these learning costs increases rapidly as the scope of controls extends down the supply chain and from clones to clone descendants. Packages that suspend marketing of food products affect many more enterprises and would also trigger higher learning costs. These costs are not easily quantified but, given the large number of farm and food enterprises, even a few hours of staff time spent by each enterprise leads to costs for the EU as a whole measured in the hundreds of millions of euros.

The reporting and inspection costs associated with suspending cloning in the EU (measure S-1 / package S-A) are expected to be modest (less than €10,000 per year if markets for leisure/sport horses can be excluded) because of the small scale of the cloning sector and the fact that the approach, as specified, does not require investment in and operation of new traceability and other regulatory systems. Beyond package S-A, the scale of the administrative burdens imposed on the food chain will be driven by the strategies of the competent authorities (CAs). If CAs take a risk-based approach that focuses on EU organisations capable of conducting cloning and targeted checks on imports, then regulatory costs would be contained (though would inevitably be higher for packages that cover food products). Inspections or monitoring of all importers would entail significant regulatory costs.

The direct short-run compliance costs to each individual EU business from suspending cloning are low in all cases because no commercial cloning is expected in the business-as-usual (reference) scenario. Prohibition of a scarce or non-existent activity changes little for EU operators. Suspension is, however, expected to impose additional costs:

- Through supply chain effects – by prompting enterprises to seek confirmation that suppliers (particularly of imports) are compliant with the suspension; and
- Through trade-mediated effects - by causing disruption to existing trade patterns, particularly where exporters to the EU are unable or unwilling to comply with the terms of the suspension.

The potential scale of these impacts varies according to the scope of the legislation. There is uncertainty about the scale of the impacts because they arise from behavioural responses by the EU supply chain and by actors in third countries. These responses cannot be predicted with certainty. The analysis therefore considers trade and jobs 'at risk' rather than specifying definitive losses.

Supply chain effects may arise if the suspension approach prompts retailers and producers to revise the specifications they give their suppliers to require verification that products are not derived from clones, their offspring or descendants. This could lead to additional costs for suppliers in seeking verification from further up the supply chain and additional costs for purchasers in auditing and control. The impacts would be expected to reach beyond the EU to suppliers and their supply chains in the EU's direct trading partners, and potentially beyond. Confirmation of compliance is expected to be less problematic for ovine, caprine and porcine species than for bovine species because there is little commercial use of cloning and verification would be easier to accomplish for imported products for these species (imports of live animals and reproductive materials for these species are small).

Suspension could trigger trade-related impacts on the EU due to operators in third countries being unable or unwilling to meet the EU's requirements for evidence of whether animals are clones, clone offspring or clone descendants, whether reproductive materials had been obtained from such animals and whether food products are derived from such animals. For the packages that include food products these impacts could affect the EU animal genetics and breeding sector, EU farmers (especially in the dairy sector), food importers, and consumers (through effects on both price and choice).

The value of the trades for animal products for food production (i.e. excluding equines) at risk ranges from €2 million/yr under packages that affect trade in reproductive materials for bovine, ovine and caprine, and porcine animals, to between €3,000 million/yr and €4,000 million/yr under packages that affect trade in food products.[9] The largest impacts would be

[9] It is assumed that a pragmatic solution would be found for food from clones so this threat arises principally in relation to food derived from clone offspring and clone descendants.

expected from interruption to imports of bovine semen from North America (under packages that suspend use of reproductive materials from clones, their offspring or descendants) and beef products, particularly from South America, and dairy products and sheep meat, particularly from Switzerland, Australia and New Zealand (under packages that suspend marketing of food products containing ingredients derived from clones, clone offspring or clone descendants).

Table 7.4 Summary of trade-mediated impacts potentially arising from suspension approach

Issue	Package	Number of businesses at risk	Significance of impacts if full cessation of trade
Cloning technique is unavailable in the EU	All packages	**LOW** – no known food-related commercial cloning in the EU	**LOW** – some impact to 2020 may arise in the dairy sector but likely to be limited
Imports of live animals cease	All packages	**LOW** – small numbers of live animals imported	**LOW** – few EU operators are reliant on imported live animals, but for those that are, impacts could be **HIGH**
Imports of reproductive materials cease	S-B to S-G	**MEDIUM** – 120 companies may go out of business; 294 AI companies may be affected	**MEDIUM** – **HIGH –** the EU breeding industry relies heavily on imported reproductive materials, particularly for bovine animals
Imports of food products cease	S-E to S-G	**MEDIUM** – 715 companies may go out of business; effects greatest for bovine, ovine and equine meat importers	**LOW** – caprine food imports **MEDIUM** – porcine, ovine and equine food imports **HIGH** – bovine food imports

Interruption to these trades would have significant impacts on EU importers and their supply chains. This could take the form of a 'shock' to the market and then gradual adjustment to a new equilibrium as alternative (EU or other) suppliers are found or alternative production methods adopted. Reductions in income and employment in import trades would be offset to some degree by growth in domestic EU production but the gains from trade would be lost. The potential for disruption is not limited to trade with countries that host commercial cloning companies because of the potential presence of clone offspring and descendants due to trade in live animals and reproductive materials between third countries, and international trade in food products (e.g. processed products manufactured in other third countries).

Any impacts arising from wider retaliatory trade measures adopted by trading partners would be in addition to the impacts of the EU's loss of access to imports. Retaliatory trade measures are not considered.

7.4.2 Direct burdens

Suspension of the cloning technique would not require any additional actions by EU operators beyond compliance with the suspension. Direct additional burdens on EU businesses would include:

- Staff time and advisory costs incurred by directly affected operators as they familiarise themselves with new legal requirements (learning costs); and
- On-going commitments in responding to requests and/or inspections from competent authorities during the period of the suspension (reporting and inspection costs).

The scale of the reporting and inspection costs imposed on the food chain in the EU will be driven by the strategies of the competent authorities (CAs). If CAs take a risk-based approach that focuses on: (i) EU organisations capable of conducting cloning; and (ii) targeted checks on imports, then regulatory costs would be contained (though will inevitably be higher for packages that cover food products). If CAs attempt to implement a

comprehensive monitoring and reporting framework involving (for example) all importers, then costs would be higher, especially for packages involving suspension of food products derived from clone offspring and descendants.

The costs incurred by competent authorities in monitoring and inspection will vary in the same way. Whether these end up as net costs to CAs (and require additional public expenditure) or additional burdens on industry depends on whether costs are recovered from industry or met from the general budget (practise on this varies across Member States). The EU suspension legislation could incorporate text on charging to ensure a consistent approach.

'Legacy' presence of clone offspring and descendants in the EU is a potential problem and source of additional regulatory costs for suspension packages covering descendants because identifying and locating all such animals could be difficult and expensive. A decision would be needed on how to treat such animals, for example, whether to accept a low level legacy presence of clone offspring and descendants in the food chain and focus efforts on excluding new sources.

Parts of the supply chain that are not directly regulated are likely to incur additional costs in learning about the legislation and its potential impacts on their own businesses. These are 'induced' rather than direct burdens. As an example, livestock farmers may spend time (i.e. incur costs) understanding and managing the consequences for their business of the suspension of marketing of semen derived from clone offspring.

The likely scale of these learning costs increases rapidly as the scope of controls extends down the supply chain and from clones to clone descendants. Given the number of indirectly affected operators under some packages, the aggregate learning costs are potentially large (Table 7.5). These costs are not easily quantified but, given the large number of farm and food enterprises, even a few hours of additional staff time spent by each enterprise leads to large aggregate costs for the EU as a whole. There are fewer than 10 companies in the EU capable of carrying out commercial cloning, fewer than 30 operators importing live bovine / ovine / caprine / porcine animals and around 70 importers of reproductive materials, but more than 7 million registered livestock holdings for the species covered by this study, more than 80,000 meat and dairy processors and manufacturers, and more than 100,000 retailers of meat and meat products. In this context it seems likely that learning about the new legislation could easily cost the supply chain tens or even hundreds of millions of euro in staff time.

Costs have been estimated for directly affected operators, including companies with the potential to conduct commercial cloning activities for food production, AI companies, importers of live animals, importers of reproductive materials and importers of food products. Others operators are indirectly affected as suspension should effectively cut off supply of clone-derived products to operators that are not directly capable of cloning activity within the EU or dealing with imported products from third countries that could include cloned materials. Table 7.5 and Table 7.7 set out the estimated one-time learning costs and estimated annual reporting costs for each package and the affected sectors, given the assumptions made. Table 7.6 and Table 7.8 provide a breakdown of the same costs by animal species and package. These figures do not represent the total economic impact of the packages – just the direct burdens on directly regulated businesses. Learning costs for other businesses are described above; other impacts are described in sections that follow.

Table 7.5 Estimated one-time learning costs by sector and package assuming that each operator incurs 70 hours of staff (or support) time understanding and preparing for the new legislations, '000 €

Sector	S-A	S-B	S-C	S-D	S-E	S-F	S-G
Companies with the potential / capacity to conduct cloning activities in the EU	€18	€18	€18	€18	€18	€18	€18
AI companies	-	€783	€783	€783	-	€783	€783
Importers of live animals	€71	€71	€71	€71	€71	€71	€71
Importers of reproductive materials	-	€251	€251	€251	-	€251	€251
Importers of meat food products	-	-	-	-	-	€2,089	€2,089
Approx. total, by package	**€89**	**€1,123**	**€1,123**	**€1,123**	**€89**	**€3,212**	**€3,212**

Notes: Whether these costs appear as net costs for CAs depends on cost recovery.

The basis of the calculations is described in Annex 8. Equines have been removed because evidence suggests that the large majority of equine transactions and trade are not related to the food chain.

Attributing burdens to individual measures is not straightforward because most measures are only viable when used in combination with others. Changes in aggregate cost occur when new groups of importers fall into the scope of the legislation – as triggered by measure S3 (reproductive material importers) in package S-B and by measure S6 (food importers) in package S-F. The figures below exclude the equine sector as the large majority of the equine business and trade is not food related.

Table 7.6 Estimate of learning costs per package and by animal species, '000 €

Package	Bovine	Porcine	Ovine & caprine	Total bovine, porcine, ovine & caprine	Equine*	Approx cost, all species
S-A, S-E	€24	€42	€23	€89	€5,304	€5,393
S-B, S-C, S-D	€763	€268	€92	€1,123	€5,777	€6,900
S-F, S-G	€1,606	€388	€1,217	€3,212	€5,841	€9,053

**Equines have been treated differently in this table because research suggests that most activity relates to horses used for leisure and sport rather than the food chain. If the legislation and enforcement regime can effectively exclude such animals the aggregate burden, and the disruption to an industry unrelated to food production, can be greatly reduced.*

On the basis of the analysis:

- Measures S1 and S2 trigger reporting costs estimated at €10,000 per year plus a €89,000 one-off learning cost to regulated entities, including five companies that could conduct cloning activities in the EU and 22 importers of live animals;
- Measure S3 triggers additional reporting costs estimated at €118,000 per year plus a €1 million one-off learning cost to regulated entities, including 215 AI companies and 69 importers of reproductive materials;
- Measure S4 triggers the same additional reporting cost as S3 but is not viable without S3, and with S3 already in place, its additional burden is zero;
- Measure S6 triggers additional reporting costs estimated at €239,000 per year plus a €2 million one-off learning cost to regulated entities, including 694 importers of meat food products;

- Measure S7 triggers the same additional reporting costs as S6 but is not viable without S6, and with S6 already in place its additional burden is zero.

Table 7.7 Indicative annual reporting and inspection costs by sector under each package incurred servicing competent authorities' requests, '000 €

Sector	S-A	S-B	S-C	S-D	S-E	S-F	S-G
Companies with the potential / capacity to conduct cloning activities in the EU	€2	€2	€2	€2	€2	€2	€2
AI companies	-	€89	€89	€89	-	€89	€89
Importers of live animals	€8	€8	€8	€8	€8	€8	€8
Importers of reproductive materials	-	€29	€29	€29	-	€29	€29
Importers of meat food products					-	€239	€239
Approx. total, by package	**€10**	**€128**	**€128**	**€128**	**€10**	**€367**	**€367**

Notes: Whether these costs appear as net costs for CAs depends on their approach to cost recovery.

An average of 8 hours has been estimated per operator for directly affected operators upstream in the supply chain. The basis of the calculations is described in Annex 8.

Equines have been removed because evidence suggests that the large majority of equine transactions and trade are not related to the food chain.

Table 7.8 Indicative annual reporting and inspection costs per package and by animal species, '000 €

Package	Bovine	Porcine	Ovine & caprine	Total bovine, porcine, ovine & caprine	Equine*	Approx cost, all species
S-A, S-E	€3	€5	€3	€11	€606	€617
S-B, S-C, S-D	€87	€31	€10	€128	€660	€788
S-F, S-G	€184	€44	€139	€367	€667	€1,034

**Equines have been treated differently in this table because research suggests that most activity relates to horses used for leisure and sport rather than the food chain. If the legislation and enforcement regime can effectively exclude such animals the aggregate burden, and the disruption to an industry unrelated to food production, can be much reduced. The small discrepancies as compared to Table 7.7 are rounding errors.*

7.5 Other economic impacts

7.5.1 Direct revenue impacts

This sub-section considers the direct impact of the suspension packages on operators' sales revenues.

The reference scenario presented in chapter 3 concluded that there is unlikely to be any commercial animal cloning operations in the EU in the period to 2020 for bovine, porcine, ovine and caprine species, and that the limited cloning of equine species was targeted at animals destined for racing rather than food production. Suspension of cloning activity within the EU would not, therefore, curtail existing business operations and the direct impact on operators' revenues of suspension of cloning by the EU is thus expected to be small in the period to 2020 in the EU and in trading partners.

Substantial indirect impacts on some operators' revenues are expected under suspension packages that go beyond the suspension of cloning in the EU via a series of trade-mediated mechanisms. These are discussed in section 7.5.3.

7.5.2 Induced costs in the supply chain

The introduction of cloning legislation in the EU may prompt retailers and producers to revise the specifications they give their suppliers to require that products are not derived from clones, clone offspring or clone descendants. This would lead to additional costs for suppliers in seeking verification from further up the supply chain, and additional costs for purchasers in auditing and control. The scope of supply chain action would not necessarily be limited to the scope of the legislation. Most of these induced costs would be incurred in the EU but given the global nature of supply chains some cost impact would be expected on suppliers beyond the EU's borders. This could lead to disruption and/or changes in sourcing strategies that reach further than the scope of the legislation that is adopted.

There is no known commercial cloning of ovine, caprine and porcine species (except in the US) so confirmation of compliance is expected to be less problematic for these species than for bovines. Imports of live animals and reproductive products for these species are also relatively uncommon, limiting the scale of the task. Providing confirmation to customers that food products are not derived from clones will be easier than providing confirmation that food products are not derived from clone offspring and/or clone descendants (ref S-F, S-G) because clones are comparatively scarce and produced for breeding rather than for food.

7.5.3 Indirect trade-mediated impacts

It was explained above that the feasibility of the suspension measures would be heavily influenced by:

- The evidence required by the legislation with regard to imports;
- The ease with which exporters/importers could supply such evidence; and
- The extent to which cloning technology is used in the livestock sector of trading partners.

The cloning legislation would add cost and complexity to the job of exporting to the EU by requiring additional information and supporting systems. This will impact negatively on businesses in the EU's trading partners, and potentially on businesses further down the supply chain in the EU. The EU legislation will pose more difficulties for exporters to the EU:

- When the evidential requirements specified are more demanding;
- If the supply chain struggles to find, finance and/or manage the required information; and
- Where the use of cloning technology grows and exclusion of regulated products consequently becomes more difficult (most imports of reproductive materials, live animals and food products for the five species come from countries where there is some commercial cloning activity, though most of that activity relates to bovines).

Individual exporters may be unable to satisfy evidential requirements even if they are willing to do so (e.g. if national supply chain traceability systems for clone descendants are not put in place by authorities, or third country governments are unwilling to cooperate). If the EU legislation does not take account of the prevalence of cloning in the trading partner's supply chain it could require costly systems that partners are unwilling or unable to build to trace clones, offspring or descendants that do not actually exist in their supply chains.

There are too many unknowns, and too many different sizes and types of producer and exporters in the EU's trading partners, for it to be possible to specify the cost impacts on a 'typical' exporter from an EU trading partner. There is also a lack of baseline studies from which to estimate the costs of 'upgrading' identification and traceability systems to capture and pass on information about whether animals are clones, clone offspring and clone descendants (see chapter 8). If the EU legislation recognises existing systems and policies in third countries – for example, existing supply chain arrangements, and national moratoriums - and takes a risk-based approach to border controls and enforcement then costs would be lower than if fully comprehensive identification and traceability systems are required.

Nonetheless, the analysis suggests a risk that import trades would come to a halt because of exporters being unwilling or unable to meet the conditions associated with the EU's

approach. This would administer a 'shock' to the markets concerned, triggering a set of direct and indirect impacts on the EU supply chain and also case-specific price and choice impacts on consumers. There would be short run impacts and then long term impacts as markets adjusted to the new situation. Table 7.11 provides details of the import trade 'at risk' for different animal products from key trading partner countries by package. The nominal value of a specific trade is not always a reliable indicator of the strategic importance of that trade to EU food production and producers as also explained in this section.

The analysis suggests that there is a risk that the suspension approach would result in (mainly) negative and potentially large economic impacts to EU food chain sectors through disruption to imports. The products and trading partners involved and the significance of the risk vary depending on which measures are adopted, as described further below. The disruption would be triggered by exporters in third countries being unable or unwilling to meet the EU's requirements for evidence of the clone status of animals and derived products in categories that fall within the scope of the suspension. The precise text of the legislation may influence whether, how and where these impacts are observed – for example, whether the law specifies who makes the declaration that imports are compliant with the terms of the suspension and whether/what supporting evidence is required. The challenge faced by exporters, for any given legislative requirement, would be smaller for clones and larger for clones descendant and foods derived from descendants.

The potential for the EU suspension approach to trigger retaliatory trade measures from third countries and the scale and impact of those measures are out of scope of this study. Any impacts arising from retaliatory trade measures adopted by trading partners would be in addition to the impacts of the EU's loss of access to imports.

7.5.3.1 Imports of live animals

The EU import trade in live animals for food production is fairly small. In 2011, 98 per cent of the €120m value of live animal imports for the species of interest here related to horses (generally originating in the US). Most, if not all, of these animals were destined for sport and leisure uses rather than food production (see Annex 10, section A10.2.5).

The majority of imports of bovine, porcine and ovine and caprine animals originate from third countries where cloning is not currently occurring and is not expected to occur before 2020. The potential for trade disruption would therefore be affected by: (i) the burden of proof required of exporters to the EU, and (ii) the degree to which animal clones, offspring and descendants are present in those third countries as a consequence of trade in reproductive materials and live animals.

Short run impacts: The short run economic impact of loss of access to imports of live animals is expected to be low. There are a small number of importers for bovine, porcine, ovine and caprine species. Consultations with the AI sector and animal breeding companies suggest that these importers are companies and farmers importing animals for specific purposes and they are not trading solely in live animals. To avoid incidental negative impacts on the horse industry, the suspension legislation would need to be drafted so as to exclude imports of horses where these are not to be used for food production.

Long run impacts: Consultation with AI and breeding companies suggests that live animals of the bovine, ovine/caprine and porcine species are imported for breeding purposes rather than for direct consumption. Although the numbers are not large these animals are important to EU breeding strategies.

If the suspension approach led to cessation of imports of high genetic quality animals EU companies' access to good genetic stock would decrease. The significance of the impact is likely to be relatively limited as most animal breeders and producers in Europe import reproductive materials rather than live animals. If, however, access to imported reproductive materials was also curtailed (see below) then loss of imports of live animals would have more significance.

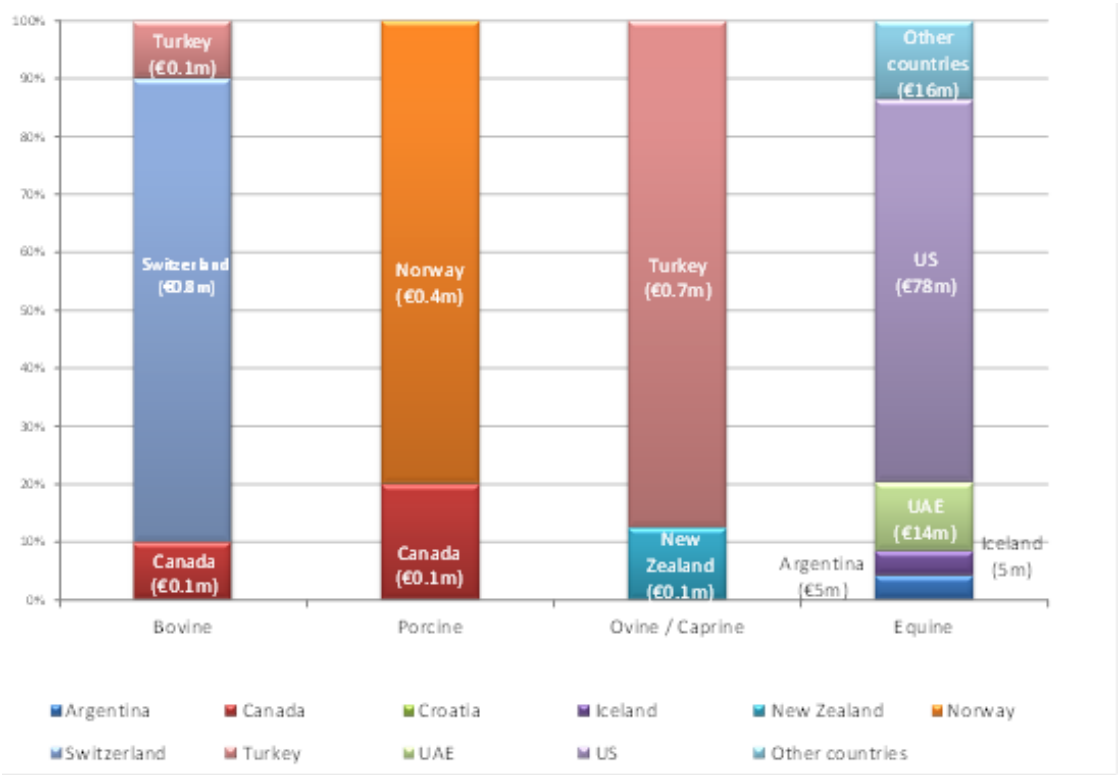
Table 7.9 Imports of live animals are not common; porcine animals are imported more often than bovines or ovines/caprines

Species	Number of imported live animals, 2009 data	Number of operators potentially affected, 2009 data
Bovine	45	3
Porcine	845	12
Ovine	40	2
Caprine		2
Equine*	10766	1645

Sources: Eurostat Structural Business Statistics (2009), extracted on 18/07/12; and TRACES data provided by DG SANCO (2009)

**Most if not all imported equine animals are destined for sport/leisure uses rather than food production*

Figure 7.2 Value of imports of live animals by country of origin, 2011



Source: Eurostat COMEXT 2011 data on trade in live animals and food products, extracted 22/06/12

7.5.3.2 Imports of reproductive materials

Some of the packages assessed here involve suspension of marketing of reproductive materials of clones (S-B onwards), clone offspring (S-C onwards) and clone descendants (S-D onwards). Disruption to the import trade in reproductive materials would have substantial impacts on the individual EU companies involved in the trade and associated supply chain, including farmers. It would also have wider and longer term systemic impacts on the EU farming sector.

The value of reproductive materials imported into the EU was €12.3m in 2011, the majority of which (93 per cent) was from bovine animals. Almost 100 per cent of imported reproductive materials originated from the US and Canada (where there is some commercial cloning). The dominance of the US and Canada suggests that the substitutability of reproductive materials from alternative countries is low. European dairy and beef farmers are importing high quality genetics of Holstein and other breeds from North America, for which equivalent alternative suppliers do not exist.

Large quantities of reproductive materials for equine animals are imported from third countries. Consultation with the horse breeding industry indicates that these materials are imported for sport purposes rather than meat.

Short run impacts: Reproductive material imports into the EU are managed by a small number of firms. These companies are likely to be negatively affected by lack of access to imported reproductive materials.

Long run impacts: If imports of reproductive materials ceased as a consequence of exporters being unable to demonstrate compliance with the EU's terms of suspension there would be negative impacts for the AI and breeding industry in the EU. There would be particularly significant effects on the bovine breeding sector, and downstream impacts on productivity and performance in the associated EU farming sectors (most notably dairy but also beef).

Table 7.10 Bovine reproductive materials are the largest component of the EU import trade in animal reproductive materials (2009)

Species	Number of imported units of semen	Number of imported embryos	Number of operators potentially affected
Bovine	1,878,621	4,062	53
Porcine	235	-	12
Ovine	1,441	-	2
Caprine		-	2
Equine*	261,145	-	51

Sources: Eurostat Structural Business Statistics (2009), extracted on 18/07/12; and TRACES data provided by DG SANCO (2009).

**Most, if not all, equine reproductive material imports are used in the production of animals destined for non-food uses.*

Animal breeding companies produce animals intended to improve the quality of herds in terms of, for example, animal health, longevity, fertility and feed conversion ratios. Imports of reproductive materials are important because they enable EU companies to increase the number of animals in the selection process. Companies breeding bovine animals in the EU rely to some extent on the import of reproductive materials to gain access to high quality bovine genetics. Reducing, or losing access to such genetic resources would have long term negative impacts on the quality of the EU herd. Certain bloodlines are very dependent on the trade in reproductive materials. For example, Angus breeders obtain 95 per cent of imported genetics from North America. Short-horn pedigrees are almost entirely reliant on imports from Australia, the US and Canada. The Holstein is the most important breed in the EU for dairy production. Breeders in the US and Canada have been selecting animals to improve the Holstein breed since 1870. The US and Canadian selection process is much more advanced than in Europe where this type of research has only been undertaken for the past 40 years. European producers would be significantly disadvantaged if they did not have access to imported genetics. There could be a positive impact to EU animal breeders in the short run as imports of semen would be replaced with domestically produced material but the decrease in the relative quality of the genetic material available to EU breeding companies could render them uncompetitive. Productivity growth would suffer and breeders of these animals would lose shares in their export markets. This might prompt new renewed interest

in other breeds, though that possibility was not raised by industry in the consultations undertaken for this study.

Lower productivity growth (as measured by changes in milk yields, feed conversion ratios, etc.) would decrease the competitiveness of EU herds over the long term, with impacts on the competitive of EU livestock products on domestic and international markets. Although the numbers of units of reproductive materials imported by breeding companies in the porcine, ovine and caprine sectors is much lower than the bovine sector, consultation with AI and breeding industry companies indicate that the impacts of a suspension of imports could be significant.

The equine breeding sector, including companies involved in AI for equine animals, could be caught up in the trade disruption unless the legislation was drafted in such a way as to clearly exclude horses not destined for food production from its scope. Without such an exclusion, there could be a significant negative impact on the EU equine breeding sector due to its reliance on imports of genetic materials from third countries. Over 99 per cent of imports of reproductive materials for equine breeding (worth around €0.8m in 2011) originate in the US. It is unlikely that EU reproductive materials would be of sufficient quality to ensure equine breeders remain competitive.

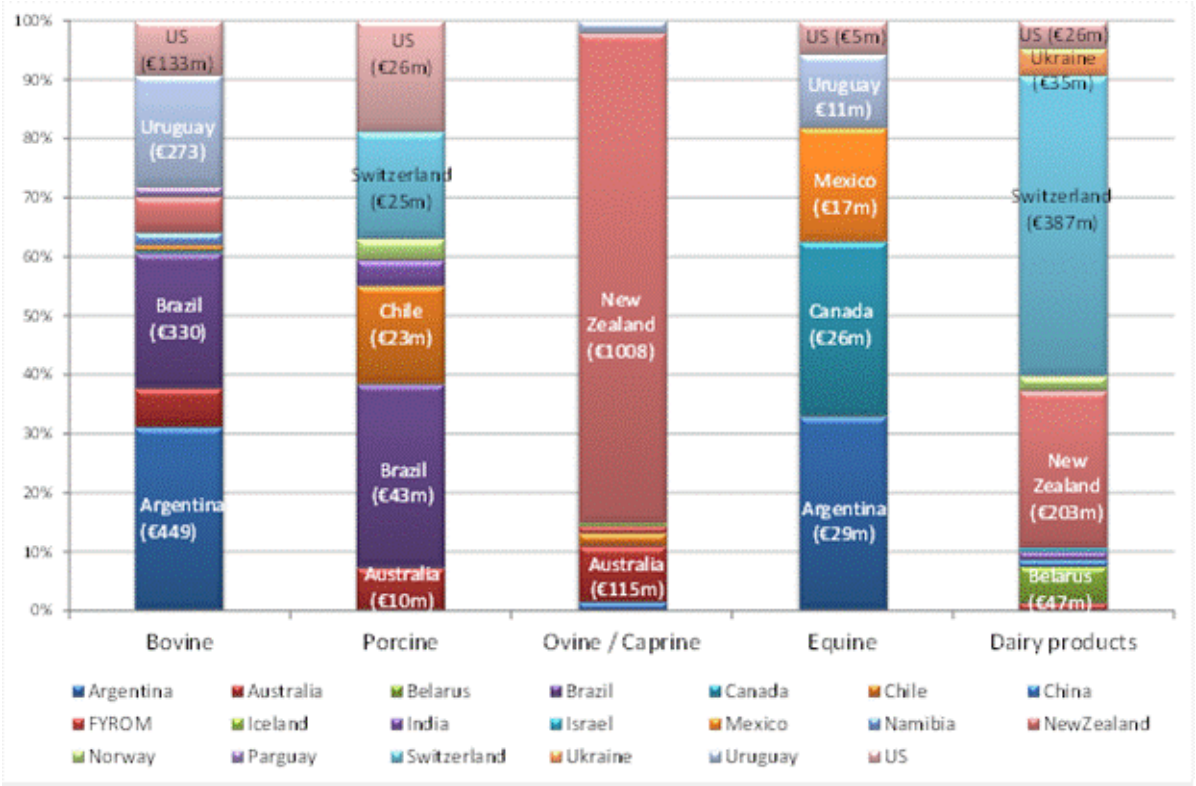
7.5.4 Imports of food products

The suspension packages that cover food products, especially the marketing of foods containing products derived from clone offspring and clone descendants, have the potential to trigger disruption in trade in related food categories. The trade at risk is substantial - approximately €3.7 billion worth of food derived from bovine, porcine, ovine, caprine and equine animals (including bovine dairy products) is imported to the EU each year. This includes: €1.5bn of bovine meat, €1.2bn of ovine / caprine meat, €137m of porcine meat, €94m of equine meat and €736m of dairy products.

Countries where cloning is currently undertaken (or thought to be undertaken) dominate EU imports in these categories. Over 70 per cent of imported meat and dairy products originates from these countries (Figure 7.3). The impact would be particularly significant for bovine, ovine and caprine meat imports: 94 per cent of bovine meat imports and 96 per cent of ovine and caprine meat imports originate from countries where cloning is undertaken (section 3.2.2).

It is conceivable that other countries could increase production to satisfy EU demand although the current dominance of countries where cloning is undertaken (or thought to be undertaken) indicates that this would take several years at least. And, due to trade in animals, reproductive materials and derived products, food products sourced from third countries might contain ingredients from countries with commercial cloning. If traceability systems or segregated supply chains were not in place then importers could not confirm that products meet the terms of the suspension.

Figure 7.3 Value of imports of food (meat and dairy) by third country, 2011



Source: Eurostat COMEXT 2011 data on trade in live animals and food products, extracted 22/06/12

Table 7.11 provides an estimate of the value of trade at risk by product under the suspension packages.

Table 7.11 Trade at risk, by species and trading partner

Package	Indicator	Species				
		Bovine	Porcine	Ovine / Caprine	Equine	Dairy products[10]
Live animals (all packages)	Value (€m)	1	0.5	0.8	118	Not applicable
	Quantity (t) – live animals	3000	1000	3000	32000	
	TRACES records:	45	845	40	10,766	
	By trading partner [& TRACES record]	Switzerland: €0.8m Turkey: €0.1m Canada: €0.1m [42] New Zealand: [3]	Norway: €0.4m Canada: €0.1m [845]	Turkey: €0.7m New Zealand: €0.1m [35]	US: €78m (6,530) Argentina: €5m (904) Croatia: (847) Iceland: €5m (561) UAE: €14m (473) [11]	

[10] Dairy products cannot be disaggregated by animal species source; the majority of dairy products, however, are derived from bovine animals. For Europe, in 2011, over 95 per cent of dairy products made in Europe are derived from cattle, with the remaining amount derived from sheep and goats' milk. (Source: Eurostat agriculture production data).

Package	Indicator	Species				
		Bovine	Porcine	Ovine / Caprine	Equine	Dairy products[10]
Reproductive materials (packages S-B to S-G)	Total estimated value (€m)	€11.5 m	< € 0.001 m/yr[12]	< € 0.01 m/yr[13]	> € 0.8 m/yr[14]	Not applicable
	Units of semen	1,878,621	235	1,441	261,145	
	Units of semen by trading partner	United States: 977,402[15] Canada: 898,107 Australia: 2,225 New Zealand: 803 Croatia: 84	Canada: 176 United States: 59	United States: 912 Canada: 267 Australia: 242 New Zealand: 14 South Korea: 6	United States: 260,772 Canada: 286 Brazil: 80 Australia: 3 New Zealand: 2 Morocco: 1	
	Number of embryos	4,062				
Food products (packages S-F, S-G)*	Meat & meat product value[16], € m	1,469	137	1,217	94	736[17]
	Meat & meat product value by product type	Meat: €1,456m Offal: €5m Gelatine: €8m	Meat: €53m Offal: €8m Gelatine: €76m	Sheep meat: €1,188m Goat meat: €5m Offal: €24m		Cheese: €412m Casein: €157m Butter: €148m Milk and cream: €24m Whey: €20m Buttermilk/yoghurt: €14m
	Meat & meat product quantity (t)	191,000	52,000	191,000	28,000	238,000
	Value by trading partner	Argentina: €449m Brazil: €330m Uruguay:	Brazil: €43m (100% gelatine) United States: €26m (55% gelatine)	New Zealand: €1,008m Australia: €115m Chile: €27m	Argentina: €29m Canada: €26m Mexico: €17m	Switzerland: €387m (87% cheese) New Zealand: €203m (50% butter, 25% casein)

[11] Also, Qatar: 156, Mauritius: 144, Russia: 141, Canada: 138, Morocco: 110, Turkey: 97, New Zealand: 95, Ukraine: 78, Brazil: 74, Uruguay: 69, Australia: 47 (€3m), Oman: 43, Serbia: 42, Saudi Arabia: 40, Belarus: 31, Japan: 16 (€1m)

[12] Estimate based on proportion of bovine to porcine units imported and value of bovine imports; estimate for porcine units likely to be an overestimate since units of porcine material are less valuable than bovine materials

[13] Estimate based on proportion of bovine to ovine & caprine units imported and value of bovine imports; estimate for ovine and caprine units likely to be an overestimate since units of ovine and caprine material are less valuable than bovine materials

[14] Estimate based on proportion of bovine to equine units imported and value of bovine imports; estimated value for equine units likely to be an underestimate since units of equine material are more valuable than bovine materials

[15] *$7.5m / € 6 m* - USDA, Foreign Trade Statistics; Canada est. € 5.5 m

[16] Includes fresh, chilled and frozen, bovine meat, offal and gelatine

[17] Includes milk, cream, buttermilk, yoghurt, whey, butter, cheese, casein and caseinates

Package	Indicator	Species				
		Bovine	Porcine	Ovine / Caprine	Equine	Dairy products[10]
		€273m United States: €133m Australia: €95m New Zealand: €87m Namibia: €31m Paraguay: €25m Chile: €14m Canada: €6m	Switzerland: €25m (60% gelatine) Chile: €23m (100% meat) Australia: €10m (100% meat) India: €6m (100% gelatine) Norway: €5m (80% meat)	Uruguay: €25m Argentina: €18m FYROM: €14m Iceland: €6m	Uruguay: €11m United States: €5m	Belarus: €47m (100% casein) United States: €36m (75% butter) Ukraine: €35m (100% casein) Norway: €19m (74% cheese) India: €10m (100% casein) China: €9m (100% casein) Australia: €10m (85% cheese) Israel: €5m (80% whey)

**Data for 2011 (unless otherwise specified). Note that some discrepancies between totals and country breakdowns are related to the cut-off values for inclusion of trade partners in table; Reproductive materials: No cut-off (all relevant trade included); Live animals: All live animal imports recorded in TRACES, & if not in TRACES – shown in table if imports valued at greater than or equal to €0.1m; Food products: Shown in table if imports valued at greater than or equal to €4.5m. Sources: Eurostat COMEXT 2011 data on trade in live animals and food products, extracted on 22/06/12; TRACES data on reproductive materials provided to ICF GHK by DG SANCO, 23/07/12. *Package S-E has been coded here on the basis that a pragmatic agreement would be struck with trading partners to exclude clones from exports to the EU without putting wider trade at risk.*

Table 7.12 The value of the annual trade relating to animals for food production at risk under suspension approach ranges from €2.3m/yr under package S-A to €3 billion/year under packages S-F and S-G - *Value of trade at risk, € million/ year*

Package of measures	Live animals		Repro. materials		Food products		Total	
	B,P,C,O	E	B	P,C,O	Meat	Dairy	Total, all species	Total exc. equines
S-A	2.3	118[18]					120.3	2.3
S-B	2.3	118	11.5	<0.01			132.6	13.8
S-C	2.3	118	11.5	<0.01			132.6	13.8
S-D	2.3	118	11.5	<0.01			132.6	13.8
S-E*	2.3	118	11.5	<0.01			132.6	13.8
S-F	2.3	118	11.5	<0.01	2917	736	3785	3667
S-G	2.3	118	11.5	<0.01	2917	736	3785	3667

*Sources: EU import data except for genetic materials where value is taken from US / Canadian export data. Eurostat COMEXT 2011 data on trade in live animals and food products, extracted on 22/06/12; Key: B= Bovine, P = Porcine, C = Caprine, O = Ovine, E = Equine. *S-E has been coded here on the basis that a pragmatic agreement would be struck with trading partners to exclude clones from exports to the EU without putting wider trade at risk.*

7.6 Social (employment) impacts

The expected 'direct' employment impacts of the suspension approach are negligible for all packages because few if any EU jobs are sustained by commercial cloning for the food chain

[18] Most (perhaps all) of these animals are not intended for food production and are unlikely to enter the food chain

(and associated products) in the reference scenario for the species of interest. The potential employment impacts arise through the induced and indirect effects of the legislation.

Supply chain efforts to confirm compliance with the suspension legislation would create employment in the supply of verification services but this growth would come at the expense of employment elsewhere (more supply chain resources would be channelled into compliance activities at the expense of core business).

The trade-mediated effects described above have the potential to create much larger (mainly negative) employment impacts. Suspension would put jobs at risk in businesses importing products within the scope of controls and in downstream supply chains. If the lost imports were replaced by EU production (rather than by compensating imports from other third countries) then the EU job losses may be partially offset by employment gains in related EU producer sectors.

A full survey of employment in the companies importing reproductive materials, live animals and food products, and macro-economic modelling of trade and employment impacts was beyond the scope of this study. It may safely be assumed that the €3 billion - €4 billion food import trade detailed at Table 7.11 will be sustaining thousands of jobs in the EU. This employment would be at risk if the packages that include food products derived from clone offspring and descendants were introduced. Losses would be offset to some degree by growth in employment in domestic suppliers as domestic output rises to offset the loss of imports. Jobs would also be at risk in exporting countries until such time as replacement markets were found. For example, Argentinian data suggest that around 1.73% of the country's total beef production is exported to Europe; 1.73% of employment in beef production equates to more than 8,000 jobs.[19] A full modelling exercise would be required to properly estimate the gross and net changes in employment.

In summary, the employment impacts of package S-A are expected to be very low (especially if a proportionate system is put in place to regulate clone imports). The packages (S-F, S-G) that include food products from clone offspring and clone descendants could potentially put thousands of EU jobs at risk in the import-related supply chain. Package S-E would pose the same risk if a pragmatic agreement to exclude clones from exports to the EU could not be reached with trading partners. For packages that would regulate reproductive materials and live animals the jobs directly at risk are more likely to be in the hundreds than the thousands. Employment in domestic production would be expected to rise as EU producers expanded output to meet the demand previously serviced by imports. As the (negative) productivity impacts of trade cessation occur, EU producers would be expected to become less competitive in international markets for the affected species (e.g. beef, dairy products), with negative long run effects on employment in that sector.

7.7 Impacts on consumers

This section considers potential impacts on consumers arising from the suspension packages. It considers:

- Price effects – that is, where the package may change the prices in consumer markets; and
- Choice effects – that is, where the package may change the variety of goods and services available to consumers.

Short run impacts on consumers are expected to be highest (and negative) for the packages that include food products. This is because of the risk of loss of meat, dairy and other related food imports, and the associated effects on both price and choice. Packages for which there is a risk of loss of access to reproductive materials have some potential for triggering short run shocks to the market, but also would have long run (negative) effects on consumers if the lack of access to high quality genetics resulted in reduced pace of productivity and

[19] Total beef production in Argentina (2011): 2,6 Mio tonnes (Argentinian Institute for the Promotion of Bovine Meat); total bovine meat exports to the EU (2011): 44790.5 tonnes (Comext – Eurostat); total employment bovine farming (2002): 467 000 (Ministry of Economy and Public Finance - National Statistics and Censuses Institute).

quality improvements in the meat and dairy sector, as well as higher prices. Table 7.13 provides a summary of the expected consumer impacts arising from the suspension packages.

Table 7.13 Potential impacts on consumers arising from suspension packages

Package	Price effects	Choice effects
S-A	None expected	None expected
S-B	None expected	None expected
S-C & S-D	Price effects in dairy markets if dairy sector loses access to imported reproductive materials. Marked short run effects may occur in MS with high dependence on imported reproductive materials and heavy use of AI Price effects in meat and meat products sector if meat production sector loses access to imported reproductive materials	Limited, except as a consequence of product scarcity
S-E	None expected	None expected
S-F, S-G	Price effects in dairy markets if imports of dairy products cease Potentially significant price effects in meat and meat products sector if imported meat products cease.	Product-specific and seasonal: potential loss of access to specific brands/types of dairy product (e.g. New Zealand butter, Swiss cheeses). There is a seasonal element to supply of some products (e.g. New Zealand lamb sold when domestic fresh lamb is not available) that could exacerbate the impacts. **Significant** for bovine meat and meat products: EU imports significant amount of bovine meat and meat products. **Significant** for ovine and caprine meat and meat products: EU imports significant amount of ovine and caprine meat. Impacts, for example, on the seasonal availability of lamb. **Limited** for porcine meat and meat products: the EU is largely self-sufficient in pork products **Limited** for equine meat and meat products: the EU is not a major consumer of horse meat (and imports 25 per cent of meat consumed)

7.8 Impacts on SMEs

This section considers impacts of the suspension approach on SMEs. The approach, as specified, does not provide an exclusion from the suspension requirements for SME businesses. The food chain contains large numbers of SMEs, from the farming sector through to manufacturing and retail. The approaches therefore have the potential to impact on SME growth.

The expected impacts on SMEs mirror the expected impacts on EU businesses as a whole. Trade-mediated impacts dominate. Expected impacts on the farming sector (which has a high concentration of SMEs) are mixed, with the potential (in packages S-F, S-G) for higher prices as the market seeks to compensate for the loss of meat and dairy imports being offset by the risk of loss of access to imported reproductive materials having short run impacts on breeding plans for some businesses and the potential for longer run impacts on productivity growth for the sector as a whole.

Table 7.14 Expected scale, distribution and type of impact on SMEs

Package	Sectors where impacts will be concentrated	Principal impact expected	Significance
S-A S-E	Live animal imports	Risk of loss of market in live animal imports	High for affected businesses but aggregate value of the trade is small
S-B	Importers of reproductive materials (RMs)	Requirement to ensure clone reproductive materials are not imported	Low (existing system screens out clone RMs)
S-C	Importers of reproductive materials	Risk of loss of access to imported reproductive materials leads to loss of business for importers	High - existing 'screening' system does not cover clone offspring
	Breeders	Loss of access to high quality Holstein/other genetics would negatively affects breeding programmes	High High in Member States with high dependency on AI & imported RM
	Dairy/beef farmers	Farmers need to find alternative RM suppliers to maintain output	
S-D	Importers of reproductive materials	Risk of loss of access to imported reproductive materials leads to loss of business for importers	High - existing 'screening' system does not cover clone descendants
	Breeders	Loss of access to high quality Holstein/other genetics would negatively affects breeding programmes	High
	Dairy/beef farmers	Farmers need to find alternative RM suppliers to maintain output	High in Member States with high dependency on AI & imported RM
S-F, S-G*	Importers of reproductive materials	Risk of loss of access to imported reproductive materials leads to loss of business for importers	High - existing 'screening' system does not cover clone descendants
	Breeders	Loss of access to high quality Holstein/other genetics would negatively affects breeding programmes Farmers need to find alternative RM suppliers to maintain output	High
	Dairy/beef farmers	Risk of loss of access to imported meat and dairy suppliers	High in Member States with high dependency on AI & imported RM
	Food importers, processors, food manufacturers, retailers and food service companies	Import substitution from domestic supply should raise prices / profitability for EU suppliers	High/critical for specific businesses that have import dependency. General negative effect arising from higher input prices. Uncertain (ref JRC modelling)

**A solution for S-E to exclude clones from food supplies is more feasible than for S-E and S-F on clone offspring and descendants, which are more numerous and not traced.*

7.9 Impacts on competitiveness

This section considers the expected impacts of suspension on competitiveness.

7.9.1 Cost competitiveness

The suspension of cloning in the EU in itself is not expected to have direct effects on companies' cost competitiveness; there is expected to be no commercial cloning activity for food production in the business as usual baseline to 2020. Impacts on cost competitiveness are expected to arise through:

- Additional administrative costs incurred in assuring that inputs meet the terms of the suspension package adopted (e.g. private compliance mechanisms established in supply chains); and
- The contingent risk of loss of access to imports of live animals, reproductive materials and food (depending on the package adopted) which would be expected to raise input costs in the market.

In summary, the impacts on cost competitiveness are expected to be neutral for packages S-A, S-B and S-E, and negative for other packages S-C, S-D, S-F and S-G. Negative impacts on cost competitiveness are concentrated in farming and for importers of animal genetics in packages S-C and S-D, and distributed more widely across the rest of the food chain in packages S-F and S-G. EU producers (especially in the bovine meat/dairy and ovine sectors) would benefit from loss of competition from imports in scenarios where exports from third countries to the EU are disrupted or lost.

7.9.2 Capacity to innovate

The potential (albeit uncertain) trade-mediated effects of suspension on the mainstream animal breeding sector are expected to have more significant effects on the EU's capacity to innovate than the direct effects on the cloning and biotech sector. The trade-mediated effects described above have the potential to have immediate impacts on innovation and thus productivity growth in the livestock sector in Europe, particular for bovines. If trading partners were unable or unwilling to comply with EU requirements with regard to trade in live animals and reproductive materials it would have the effect of cutting off Europe's access to high quality genetics in key breeds. An example is the Holstein breed, which is important for the dairy sector and for which North America is the principal source of new high quality genetics for Europe. There would be new challenges for the increasingly globalised animal breeding sector (including EU companies in the sector) in managing breeding programmes and the movement of genetic material into Europe.

Measures that prohibit access to and use of new technologies risk inhibiting the EU's capacity to innovate. The suspension of cloning would stop the commercial use of the technology in the context of food production (though not in other applications). The net innovation impacts of the approach on cloning research and innovation are expected to be small in the short term – the evidence suggests that EU industry would not be investing in commercial cloning for food production even in the absence of new measures. Suspension could have longer and indirect effects on the allocation of innovation investments in industry and upstream research funding by signalling explicitly that market prospects for the technology are not positive in Europe. Organisations looking to invest in the development of such technologies may be more inclined to place their investments elsewhere.

7.9.3 International competitiveness

The potential impacts of the suspension approach on international competitiveness are mixed and complex. The following impacts have been identified:

- Packages that resulted in interruption to imports would reduce the exposure of domestic producers to competition in the EU market and would be expected to increase their relative competitiveness / market share. This could result in EU market share in third countries declining as a larger part of domestic output is absorbed by domestic demand. For example, bovine semen that the EU currently exports might be used for domestic production and North America would be likely to replace the EU in its current markets (typically South America);

- Packages that resulted in loss of access to high quality genetic materials could have short and long run impacts on output and on productivity, both of which could negatively impact on competitiveness in price-sensitive export markets; and
- Suspension could have positive impacts on demand for EU products in third countries if its 'clone free' status was perceived as a premium attribute by consumers. A search for information on consumer attitudes to cloning for food production in Japan, Korea and other third country markets has not yielded enough information to determine how or whether this might occur. The acceptability of meat from clones, clone offspring and clone descendants for different religious faiths could also be relevant to the market prospects for EU products in such circumstances.

There is thus some uncertainty about the scale and direction of the net effect on the EU's international competitiveness. The potential for international competitiveness to be reduced through loss of market access due to retaliatory trade measures introduced by third countries is out of defined scope of this analysis.

8 Approach appraisal: traceability

8.1 Introduction

This chapter examines the feasibility and impacts of applying a traceability approach to the regulation of animal cloning, introduced through new EU legislation. It also considers the potential for voluntary approaches to traceability led by industry.

The analysis considers the traceability measures defined in the study terms of reference. Most of those measures are not viable in isolation but instead must be introduced in combination with other traceability measures. As an example, traceability of offspring of clones relies on traceability of the clones themselves. The assessment has therefore considered different combinations of measures that provide coherent 'packages' of intervention. The analysis shows the estimated cost for each package and also the incremental cost associated with the application of each additional measure.

The packages can be implemented in different ways depending on policy-makers' precise objectives and requirements. These choices are modelled in three different traceability 'scenarios', defined below. Feasibility and impacts are assessed for each strategy with a discrete assessment of each package of measures under each of the three strategies.

8.2 Definition of the traceability packages and implementation strategies

8.2.1 Definition of the traceability packages

The traceability measures provided by the terms of reference and considered in this appraisal are listed in Table 8.1.

Table 8.1 Traceability measures

	Measure description
T1	Traceability for live clones
T2	Traceability for food from clones
T3	Traceability for reproductive materials of clones
T4	Traceability for live offspring of clones (1st generation) & their reproductive materials
T5	Traceability for live descendants of clones (2nd and subsequent generations) & their reproductive materials
T6	Traceability for food from offspring of clones (1st generation)
T7	Food from descendants of clones (2nd and subsequent generations)

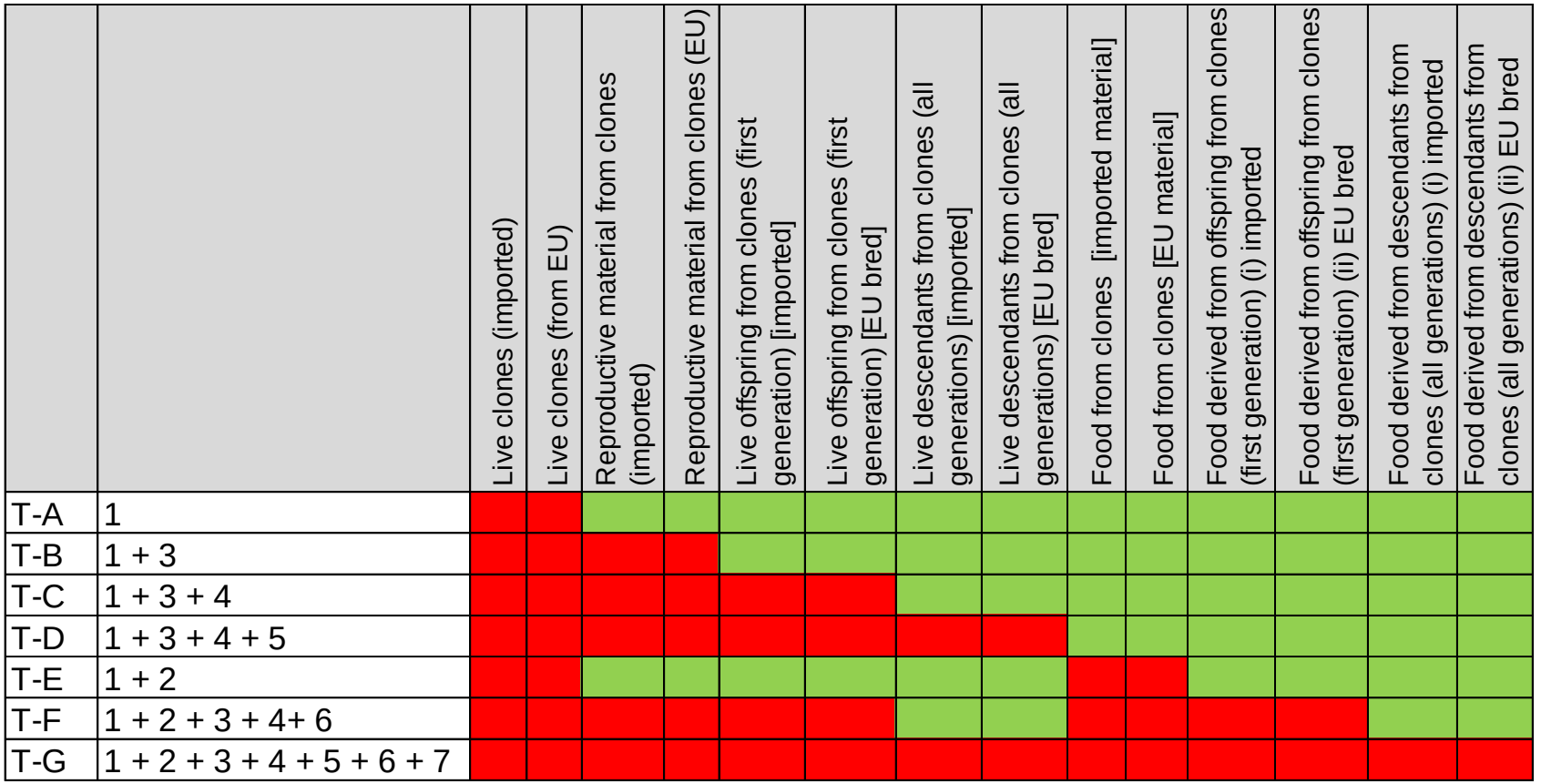
Other than measure T1 (traceability for live clone animals), no measure is viable on its own; the measures have to be combined into a set of internally coherent packages, labelled T-A to T-G, as described by Figure 8.1.

8.2.2 Definition of the implementation strategies

8.2.2.1 Traceability requirements depend on the information requirements of the policy-maker

In the study brief the traceability requirements are stated at a high level, that is, traceability for clones, their reproductive materials, their offspring and descendants and food products derived from clones, offspring or descendants. The precise interpretation given to these high level requirements determines what system is needed to implement the traceability approach, and what further investments are needed to supplement the arrangements already in place in the food chain. Impacts can only be determined once that interpretation has been agreed and the associated systems have been specified. In general terms, as the policy-makers' demands become more detailed, more precise and require more verification, so the system required becomes more sophisticated and comprehensive. Examples of how policy-makers' requirements determine the system that is needed are provide in Table 8.2.

Figure 8.1 Representation of the scope of the traceability packages T-A to T-G



* “Live offspring from clones (first generation) [imported] and [EU bred]” also covers reproductive materials of clone offspring. Live descendants from clones (all generations) [imported] and [EU bred]” also cover reproductive materials of clone offspring and descendants.

Table 8.2 The system required varies according to the precise policy objective

Policy-makers' requirement	System capability required
Ability to identify an individual animal	Individual identification of animals with tag and database
Ability to identify an individual animal as a clone, F_1 offspring, or F_x descendant and verify its clone status.	Individual ID on documentary system plus best available verification system. The verification system could potentially be a database containing a DNA sample of each clone, F_1 offspring and F_x descendant, with parentage tests for new registrations, though even DNA databases have flaws and limitations.
Ability to identify a batch of animals as containing clones / F1 offspring / Fx descendants	Batch identification system for animals
Ability to identify a food product as being wholly or partially derived from animals with clone status	Fully segregated supply chain needed for milk and for many other products (e.g. processed meat products) Other products: animal identification and traceability, either on a batch or individual basis
Ability to identify all of an animal's descendants or antecedents (e.g. in order to remove all descendants of a clone from the supply chain)	Individual animal identification and traceability Recording of dam/sire of each animal, possibly with DNA sampling
Ability to trace reproductive materials / animals / products through the supply chain (up/down)	Obligations on supply chain to retain one up / one down documentation

8.2.2.2 Three alternative traceability 'strategies' have been considered

In this assessment three different 'strategies' for implementation of the traceability approach are examined. The purpose of introducing these strategies is to illustrate the type and distribution of impacts expected to arise from the traceability approach, their potential scale (and significance), and how those vary as the precise specification is modified.

All three strategies recognise and make full use of existing traceability systems in the food chain. The strategy specifications are set out in detail in the tables that follow but they can be summarised as follows:

- Strategy 1 makes best use of existing identification and traceability systems, involves use of documentary approaches to meet the policy objectives, and use of exporter declarations to manage import risks. Two sub-strategies provide for a choice between: (a) identification and traceability of clones/offspring/descendants only or (b) identification and traceability of all animals as either 'conventional' or a clone/offspring/descendant.
- Strategy 2 also recognises and uses existing traceability systems but meets a more demanding set of policy-makers' requirements. It involves the further development of identification and traceability systems to ensure individual traceability for all animal species so that operators can determine and provide evidence regarding the status of individual animal clones, offspring and descendants, their reproductive materials and derived food products. Imports are restricted to cases where exporters in third countries operate using identification and traceability systems that mirror EU systems.
- Strategy 3 looks at the conditions under which identification and traceability objectives could be met through voluntary measures adopted by the supply chain, and where public intervention would be needed to enable effective voluntary action.

Strategy 2 would satisfy a very demanding set of objectives from policy-makers whereas Strategy 1 is a closer fit to the design and capabilities of existing identification and traceability systems. The two strategies therefore provide an indication of the upper and

lower bounds on the potential impacts arising from such system designs. Strategy 3 appraises the scope for, and limits to, voluntary action and where government intervention could action to be taken by the supply chain but through systems developed by operators rather than built by public authorities.

8.2.2.3 Traceability Strategy 1 – adapt existing identification and traceability systems

Strategy 1 requires operators to identify clones, their offspring and descendants, associated reproductive materials, and their presence in food products. Existing traceability systems will be adapted to capture that information. The strategy involves use of documentary approaches to meet the traceability objectives. Importers will rely on exporter declarations to manage import risks.

Within Strategy 1, there are two sub-strategies:

- Sub-strategy (a) requires information only for those animals, materials and products that are cloned or derived from clones. This will result in a system whereby only those operators handling clones, their offspring and descendants, reproductive materials or food products will need to take additional action to ensure traceability.
- Sub-strategy (b) requires information indicating the status of the animals, materials or products regardless of whether it is a clone or derived from a clone; that is, documentation must indicate clone/offspring/descendant 'yes' or 'no'. This will result in a system whereby all operators handling live animals, reproductive materials or food products of the five species will need to take some additional action to ensure traceability.

The various elements of the Strategy are described in Table 8.3.

Table 8.3 Traceability Strategy 1 – adapt existing identification and traceability systems

Element	Description
Identification & traceability – legislation requiring: For live animals: ■ Adjustments to existing identification and traceability systems to enable identification of a live animal as a clone, clone offspring or clone descendant. ■ Operators to register live animals on existing identification systems and to identify a live animal as a clone, clone offspring or clone descendant. For reproductive materials: ■ Adjustments to existing traceability systems to enable identification of reproductive materials as derived from a clone, clone offspring or clone descendant (where this is not already done). ■ Operators who place reproductive materials on the market to indicate on existing traceability systems that the materials are derived from a clone, clone offspring or clone descendant. For food products: ■ Adjustments to existing traceability systems to identify that a food product is derived from a clone, clone offspring or clone	Current traceability legislation for all animal species is amended. The revised legislation requires that existing identification and traceability systems capture information that indicates whether: ■ Live animals are clones, clone offspring or clone descendants; ■ Reproductive materials have been obtained from clones, clone offspring or clone descendants; and ■ Food is derived from such animals. This information is not required under existing legislation. The approach adopted for most porcine / ovine / caprine animals works with current traceability systems such that identification of a clone, offspring, or descendant is attached only to batches containing animals that fall within the scope of the adopted legislation. Under this strategy those remain as batch-based systems. Two possibilities for information requirements: 1. No additional information requirements are attached to 'normal' animals, reproductive materials and food products (i.e. those animals, materials and products that are not cloned or derived from clones). 2. All animals, reproductive materials and food products, whether an individual animal or

Element	Description
descendant. ■ Operators who place food products on the market to indicate on existing traceability systems that the products are derived from a clone, clone offspring or clone descendant.	batch, must have an indication of its status (e.g. clone / offspring / descendant 'yes' or 'no').
Import control – legislation requiring: ■ Modification of import control systems to obtain and retain information about whether a given imported live animal is a clone, clone offspring or clone descendant, reproductive materials are derived from clones, their offspring or descendants, or a food product is derived from clones, their offspring or descendants. ■ Operators importing live animals to identify that an imported live animal is a clone, clone offspring or clone descendant, reproductive materials are derived from clones, their offspring or descendants, or a food product is derived from clones, their offspring or descendants.	Modifications are made to current import controls to solicit and record information that indicates whether: ■ Live animals are clones, clone offspring or clone descendants; ■ Reproductive materials have been obtained from clones, clone offspring or clone descendants; and ■ Food is derived from such animals. This is information that is not required under existing legislation. Under this strategy an exporters' / importers' declaration at the border is sufficient evidence of the status of the product. The systems (in 3rd countries) that enable exporters to make such declarations are not stated or specified in the revised legislation.
Enforcement – legislation requiring: CAs to monitor compliance	Competent authorities will be required to establish and implement compliance monitoring.

8.2.2.4 *Traceability Strategy 2 – fully comprehensive individual identification and traceability*

Traceability Strategy 2 demonstrates the implications of policy-makers specifying a more demanding set of requirements than under Strategy 1. Specifically, it involves a system that:

- Provides identification and traceability at the level of the individual animal for all animal species to ensure individual traceability for all animal species so that operators can determine and provide evidence regarding the status of individual animals, their reproductive materials and their offspring and descendants;
- Provides the facility to identify and locate antecedents and, where required, offspring and descendants; and
- Places a more restrictive set of requirements on imports, requiring exporters in third countries to use identification and traceability systems that mirror EU systems.

Current traceability systems already provide for and require individual identification of all bovine animals, and for reproductive materials of all species as described in chapter 6. As a result, the approach applied under the first strategy will be the same under this strategy for:

- Live bovine animals;
- Reproductive materials of all species; and
- Food products, since individual animal identification of meat products is only possible in a limited number of cases (i.e. for whole bovine cuts), as discussed in chapter 6.

Under Strategy 2:

- All porcine animals will require individual traceability, and so information systems that currently provide batch identification will need to be converted so that they provide individual identification;
- Derogations in the legislation for ovine and caprine animals will need to be removed so that all such animals are individually identified; and
- The derogation for equine animals intended for slaughter will need to be removed from the existing legislation so that all animals are individually identified.

Table 8.4 The constituent elements of Strategy 2 are described in Table 8.4. Traceability Strategy 2 – fully comprehensive individual traceability

Element	Description
Legislation requiring full traceability of clones / offspring / descendants, their reproductive materials and derived food products, at the individual animal level throughout the EU supply chain, including traceability across generations so that, for instance, all offspring and descendants of an individual clone can be located.	The revised legislation on identification and traceability requires that systems capture information on the status of each individual animal, dose of reproductive materials and food products (i.e. whether it is, or is derived from, a clone, clone offspring or clone descendant). This would require extension of systems that are currently batch based, as well as the capture and transmission of information that is not required under current legislation (e.g. whether it is a clone, clone offspring or clone descendant, their reproductive materials, or associated food products). Amend existing identification and traceability legislation to require the capture of parentage information on clones / clone offspring / clone descendants.
Legislation requiring: imports to meet the same standards of traceability as those applied within the EU.	Amend existing legislation to specify that: ■ The EU will only accept imports from countries that have systems equivalent to those established in the EU for traceability of clones, their offspring and descendants, reproductive materials and derived food products. ■ The entire supply chain for the animal/material/product must be covered by such systems, including parts of the supply chain that reach beyond the EU's trading partners into additional third countries (e.g. where clones, offspring or descendants, their reproductive materials or food products are imported by a third country trading partner before reaching the EU). Systems will be required in countries that export to the EU covering: (a) that fraction of their production that serves the export market, where such production is fully segregated from other production and (b) their entire production base, in cases where production for export to the EU is integrated with other production.
Requirement on CAs to monitor compliance	Competent authorities will be required to establish and implement compliance monitoring.

8.2.2.5 Traceability Strategy 3 – voluntary, operator-led identification and traceability

Traceability Strategy 3 looks at whether identification and traceability objectives could be met through voluntary measures adopted by the supply chain, and where public intervention would be needed to enable effective voluntary action.

8.3 Feasibility assessment

This section provides a classification of, and commentary on, the feasibility of the traceability approach according to the three strategies set out in section 8.2. All of the strategies rely on documentary approaches; verification through empirical means alone is not possible since clones cannot be distinguished from the original animal using only a DNA test, and accordingly DNA tests cannot be used to verify offspring, descendants, reproductive

materials or food products without at least some documentary measures in place. DNA testing is infeasible as a verification method for many of the packages under consideration here (e.g. to verify food products). As such, the systems considered are only as robust as the documentation underlying them.

8.3.1 Summary of the feasibility analysis

All packages are feasible for EU production of live animals and their reproductive materials, but infeasible for food products that are not whole cuts and without segregated supply chains. Claims for imported live animals and reproductive materials are likely to be difficult to confirm, but there are systems in place amongst EU and third country operators to trace clones and reproductive materials. These could be used as the basis for a system that supplies evidence on the clone status of these products.

Importers are not currently required to identify whether imported food products are derived from clones, clone offspring or descendants. No third countries have systems to identify and track food products on the basis that they are derived from clone offspring or descendants. New Zealand is the only country known to keep a clone registry and this does not extend to offspring or descendants. Traceability of clone offspring and descendants in food products is largely infeasible.

There are few companies in the EU capable of carrying out cloning. EU law requires individual traceability for at least some animals of all the species considered in this study (e.g. animals older than 12 months). Individual identification is therefore possible for this subset of animals using existing systems and with minor adjustments to the system these animals could be identified as clones if necessary. As a result, identifying clones and ensuring their traceability (measure T1, package T-A) is feasible under all of the proposed traceability strategies.

There is no known domestic production of clone reproductive materials for bovine, porcine, ovine or caprine animals. Individual identification and traceability is already enabled in the EU for all semen and embryos. Health certificates indicate parents for embryos and the donor for semen. International trade in cloned reproductive materials is highly regulated; private operator agreements also already identify cloned reproductive materials from bovine and equine animals originating in the US and Canada.[20] There is no known trade in the reproductive materials of cloned porcine, ovine or caprine animals. Identifying reproductive materials derived from clones and ensuring their traceability (measure T3, incorporated into package T-B) is thus feasible under all of the proposed traceability strategies, on the assumption that existing private agreements are given formal recognition and, where necessary, extended to other trading partners.

Identification and traceability for the offspring of clones (measure T4, incorporated into package T-C) is more complicated, but feasible with some amendments to existing bovine identification and traceability systems. Identification and traceability becomes more complicated with each additional generation of descendants (measure T5, incorporated into package T-D), however, because extensive records must be kept of the lineage of all animals in order for operators to identify and provide evidence of the status of their animals. Herd books could facilitate this for many bovine animals, but many animals are not recorded, and the scope for (and likelihood of) errors increases with each successive generation.

Although the total number of imported bovine animals per year is small and they come from a limited number of countries there is also a risk that clone offspring and descendants are imported from third countries and are not identifiable as such because no third country currently traces clone bovine offspring or descendants. Live animals imported into the EU are typically high value animals and these would have their heritage documented, which should enable traceability for offspring, but may not provide sufficient evidence for descendants.

[20] Approximately 99 per cent of all imported reproductive materials to the EU of both species comes from the US and Canada.

It is unlikely that any porcine, ovine and caprine clone offspring or descendants will be produced in the EU in the period to 2020. In these circumstances traceability systems for such animals would not be needed for the domestic food supply chain where the complete supply chain originates in the EU (including reproductive materials). EU production of offspring and descendants of sports horse clones is expected and further development of existing systems would be needed to facilitate their traceability if and where they enter the food supply chain. There would be advantages to ensuring that measures introduced for the food chain do not inadvertently impact on the sport and leisure horse breeding sector.

Identification and traceability for food products produced from clones (measure T5, incorporated in package T-E) would be feasible assuming that a pragmatic solution could be achieved based on exclusion of clones from the EU supply chain (including imports) to avoid the need for additional traceability infrastructure.

Identification and traceability for food products produced from clone offspring and descendants (measures T6 and T7, incorporated in packages T-F and T-G) is difficult for some products and infeasible for others without completely segregated supply chains. *Individual* animal traceability is only possible for whole cuts of meat. Existing traceability systems in the EU only require *batch* identification to enable traceability to the holdings from which the products originated. EU systems would need to be adjusted to indicate whether food products are derived from clones, their offspring or descendants, and would likely require segregated systems for clones, their offspring and descendants.

More problematically, clones, their offspring and descendants for all species may enter the food supply chain in third countries and derived food products may enter the EU food chain through trade without being identifiable as such because there are no traceability systems that reach through the entire supply chain for clones in most countries and none for offspring and descendants in any third country. Third countries would need to develop entirely new systems in most cases in order to ensure that EU importers could comply with traceability requirements for food products. For these reasons, traceability for food products derived from clones, their offspring or descendants is infeasible, except in a limited number of cases (e.g. for whole cuts of meat produced through segregated supply chains originating in the EU).

8.3.1.1 *Summary of strategy 1 - adapt existing identification and traceability systems*

Strategy 1 is:

- Feasible for clones themselves and their reproductive materials (T-A, T-B);
- Feasible, but challenging, for domestically produced offspring and their reproductive materials (T-C); infeasible for imported offspring (T-C) and descendants and their reproductive materials (T-D); and
- Feasible for food products produced from clones (package T-E) (though clones are expensive to produce and therefore very unlikely to be used for food production) but increasingly difficult for offspring and descendants (T-F and T-G). This applies only where a segregated slaughter line is used and/or for whole cuts of meat. It would be more sensible to exclude clones from the food chain than establish new traceability systems for a very small number of animals that are unlikely to find their ways into food.

8.3.1.2 *Summary of strategy 2 - fully comprehensive individual identification and traceability*

Strategy 2 is:

- Feasible for clones and their reproductive materials (T-A, T-B and also T-E if an exclusion agreement is reached), but would require major changes to existing systems (e.g. for bovine traceability), and potentially the complete overhaul/change of other systems (e.g. for porcine, ovine and caprine traceability);
- Theoretically feasible for offspring and descendants (T-C, T-D) and their reproductive materials in contained systems, but feasibility is lower in traditional and extensive farming systems where identification of parentage can be problematic and error rates are

high. Incentives on FBOs may not encourage compliance if status as a clone descendant results in higher operating cost and lower market value;

- The same as Strategy 1 for food products (T-F, T-G): that is, infeasible for most food products produced in the EU and infeasible for all food products produced in third countries without major modifications to existing systems and creation of new systems. Feasible for a limited number of food products but would require significant changes to existing systems (segregated supply chains).

8.3.1.3 Summary of strategy 3 – voluntary, operator-led identification and traceability

Strategy 3 is:

- Feasible for clones and their reproductive materials (voluntary action is already being undertaken for bovine animals by some operators in the EU and third countries);
- Theoretically feasible but likely to be difficult to implement for clone offspring and their reproductive materials, and likely to be very difficult, if not impossible, to implement and sustain reliably for clone descendants; and
- Feasible for food products only where traceability is in place 'upstream', i.e. for live animals.

8.3.2 Traceability Strategy 1 – adapt existing traceability systems

Under Strategy 1 existing traceability legislation for all animal species is amended. The revised legislation requires that existing identification and traceability systems capture and pass on information that indicates whether:

- Live animals are clones, clone offspring or clone descendants;
- Reproductive materials have been obtained from clones, clone offspring or clone descendants; and
- Food is derived from clones, their offspring or descendants.

This is information that is not required under existing legislation, neither for sub-strategy (a) nor (b). Existing traceability systems will be adapted to capture that information. Strategy 1 involves use of documentary approaches to meet the objectives of the various traceability measures. Importers will rely on exporter declarations to manage import risks.

8.3.2.1 Traceability Strategy 1 applied to clones and their reproductive materials within the EU domestic supply chain should be straightforward; traceability will be more difficult for offspring, descendants and infeasible for most derived food products.

The traceability systems are already in place for the five animal species under consideration would provide 'one-step-forward and one-step-back' traceability of clones or clone-derived products in the supply chain on an individual or batch basis. All bovine and equine animals are individually identified; some porcine, ovine and caprine animals are also individually identified, but most are not. Food products derived from all five animal species are identified only on a batch basis.

Adjusting current systems to identify clones and reproductive materials from clones under sub-strategies (a) and (b) would be straightforward. There are few (if any) clones to identify in the EU and therefore, little (if any) reproductive material from clones that may be used to produce offspring and descendants. Traceability for clone offspring produced through an entirely domestic supply chain is more complicated, but minor adaptations to existing traceability systems could enable identification of the few (if any) domestically produced clones.

Traceability of clone descendants becomes more complicated with each additional generation of descendants. Detailed records must be kept of the lineage of all animals in order for operators to identify and provide evidence of the clone status of their animals. Herd books could facilitate this for most bovine animals, but the lineage of many animals is not recorded, and the scope for errors increases with each successive generation (e.g. a lamb

may be attributed to the wrong ewe). Lineage records for porcine, ovine and caprine animals are even less comprehensive than for bovine animals, making it even more difficult to accurately record the descendants of clones for these species. Operators would need to develop new or more comprehensive recording systems to record the lineage of their animals in order to comply with traceability requirements.

Providing a system with the near-zero error rate required to underpin credible and defensible claims on clone status is likely to be very difficult. Incentives on FBOs may not encourage the development of a complete and reliable system, for example, if an animal's status as a 'clone descendant' results in higher operating costs and a lower market value.

Identification and traceability of food products produced from clones, offspring and descendants is difficult for some products and infeasible for others without having completely segregated clone-based supply chains. Existing traceability systems in the EU only require batch identification to enable traceability to the holdings from which the products originated. Identifying the status of food products would be possible (e.g. 'batch may contain'/'does not contain clone derived material') but traceability would only allow identification of the holdings from which the batch originated.

Identification and traceability of live animals, reproductive materials and food products regardless of whether they are clones or derived from clones under sub-strategy (b) would require all operators handling these animals/materials/products to provide information on their status ('yes' or 'no'). This would entail additional activities for many more operators in the EU (i.e. all operators involved in the supply chain for the five species of interest versus a very small number or none under sub-strategy (a)).

Consultation with operators across the supply chain for this study suggests that the incentive to exclude clones from the main supply chain would be strong. This suggests that any production from clones would occur in fully segregated supply chains.

8.3.2.2 Traceability Strategy 1 is feasible for clones and their reproductive materials imported from third countries, but not for offspring, descendants and derived food products

EU food law requires countries that trade with the EU to have traceability systems in place for the range of species and products in question. Very few live animals are imported by the EU each year, and cloning companies are easily identifiable, so it should be relatively easy to trace any imports of live clones to the EU with some modest adaptation to existing systems. Similarly, reproductive materials from clones are easily identifiable because there are only a few companies and only a small number of third countries that provide these materials, so clone reproductive materials should also be easily traceable using existing systems, again with some modest adaptation to existing systems. Existing identification and traceability systems are already in place amongst private operators to identify and trace reproductive materials from clones that enter the EU, facilitating an approach that relies on minimal adaptation of already existing traceability systems.

Providing traceability for imported live clone offspring and clone descendants would be more difficult than for clones. No third country currently traces clone bovine offspring or descendants through the supply chain, although the total number of live animals imported each year is small and they come from a limited number of countries. For the EU's policy objective to be achieved third countries would need to adapt their own systems to capture information about clone status for animals exported to the EU. This is an unlikely scenario but not impossible given the very low numbers of live animals imported to the EU, the small number of countries from which they originate and the limited extent of cloning worldwide.

Current documentation does not, however, indicate whether imported food products are derived from clones, clone offspring or clone descendants. Such products cannot be identified in most countries under existing systems as there is limited traceability for clones in a small number of countries and none in most. There are no traceability systems that reach through the entire supply chain for clone offspring and descendants in any third country. Traceability of food products derived from clones, their offspring and descendants is essentially infeasible at present and current evidence suggests that the necessary investments are unlikely to be made by any third country in which cloning is taking place.

Without investment from third countries, exporters will not be able to comply with traceability requirements for food products.

Also, as noted in Chapter 7 (suspension approach), international trade in reproductive materials makes it difficult to be certain that the animals or food products obtained from a country that does not use the cloning technique were not actually derived from reproductive materials from clones, clone offspring or clone descendants obtained from another country. This trade aspect means that the EU policy objectives could only be met in full by a traceability system for clones, clone offspring and clone descendants that covered the entire global livestock production and trading system.

There would be specific issues for imports from countries that are known to have populations of clone offspring or descendants (e.g. Switzerland) if all such animals could not be identified and excluded from the EU supply chain.

As for domestic operators, identification and traceability of live animals, reproductive materials and food products regardless of whether they are clones or derived from clones under sub-strategy (b) would require all third country operators handling these animals/materials/products to provide information on their status ('yes' or 'no'). This would entail additional activities for many more operators in third countries.

8.3.3 Traceability Strategy 2 – fully comprehensive traceability

Traceability Strategy 2 demonstrates the implications of policy-makers specifying a more demanding set of requirements than under Strategy 1. Specifically, it involves a system that:

- Provides traceability at the level of the individual animal for all animal species so that operators can determine and provide evidence of the status of their products for individual animals, their reproductive materials and their offspring and descendants;
- Provides the facility to identify and locate parents and, where required, offspring and descendants; and
- Places a more restrictive set of requirements on imports, requiring exporters in third countries to use identification and traceability systems that mirror EU systems.

Current traceability systems already provide for and require individual identification of all bovine animals, and for reproductive materials of all species as described in chapter 6. As a result, the approach applied under the first strategy will be the same under this strategy for:

- Live bovine animals;
- Reproductive materials of all species; and
- Food products.

Therefore, the feasibility assessment set out under Strategy 1 applies equally to bovine animals and reproductive materials of all species under Strategy 2. Individual animal identification of meat products is only possible in a limited number of cases and will face the same challenges as under Strategy 1.

8.3.3.1 Traceability Strategy 2 may be expensive for domestic operators, but is feasible for live animals that are not already individually identified under EU law

Strategy 2 requires that all porcine animals are individually identifiable and traceable. In the EU, most pigs are batched identified; systems providing batch identification will be converted to provide individual identification. Similarly, derogations for ovine and caprine animals and for equine animals intended for slaughter will need to be removed from existing legislation so that all animals are individually identified.

It is feasible to convert batch identification systems to individual identification, although it is likely to be costly to do so. Individual identification is already required under EU law for some porcine, ovine, caprine and equine animals. Where animals are produced in controlled environments, young animals can be individually identified more easily; this is complicated in systems where animals are reared in more 'natural' environments, for example, in hill

farming systems where young animals may be reared by an animal that is not its mother, complicating identification of parentage[21].

Traceability for offspring and descendants of clones supported by individual animal identification is much more complicated than for clones themselves and will require extensive record-keeping of parentage by operators. This is not common practice and, based on limited research evidence, is not always reliable in a working farm context, especially in extensive livestock systems. Segregated production for clones and their offspring and descendants would also be expensive, but feasible, and would facilitate accurate animal identification and therefore traceability.

8.3.3.2 Traceability Strategy 2 will require the development of completely new systems for animal identification and traceability in many third countries

Few live animals are imported into the EU and the cloning technique is not widely applied to porcine, ovine and caprine animal species. Individual traceability for these species is not common in third countries, however. Completely new systems will be required in most countries, which would be expensive. It is doubtful whether they would be built, making this approach largely infeasible for imported live animals.

8.3.4 Traceability Strategy 3 – voluntary, supply chain-led traceability

The appraisal of Strategy 1 and 2 shows that achieving the given policy objectives through public policy interventions is potentially difficult, especially for food products. It is useful to consider whether the same outcomes could be achieved through voluntary action within the supply chain, perhaps with lower cost and disruption.

Research has shown that operators in the EU supply chain have already taken steps to identify reproductive materials of clones and to exclude clones from food products. Examples include arrangements to identify reproductive materials of bovine clones that are imported from North America, the registration system established for certain clone offspring in the UK, and statements by retailers that their meat products are not obtained from clones (statements would require certain supply chain commitments).[22]

The evidence suggests that voluntary identification and traceability arrangements are feasible in the upper reaches of the supply chain – that is, amongst importers of animals, importers of reproductive materials, cloning companies and specialist animal breeders. The objectives of measures T1 (traceability for live clones), T3 (traceability for reproductive materials of clones), T5 (traceability for food from clones) and potentially also T4 (traceability for live offspring of clones and their reproductive materials) appear achievable on a voluntary basis. The challenge would be to construct a process and governance arrangements that ensured those arrangements were comprehensive, covering all domestic production and imports.

Pressure for the identification of clones (and their reproductive materials and offspring) at present comes mainly from those seeking to avoid buying the animals and the derived products (in which circumstances none of the relevant products then enter the EU food system and so there is nothing to trace). Livestock producers that see an advantage in using clones but are concerned about market reaction to use of such stock may be less keen on adopting a traceability system that makes those animals (and their products) more 'visible'. In effect, a voluntary system is least likely to happen where it is most useful.

Building a coalition for a comprehensive voluntary system may therefore be difficult. If the entire food chain is convinced that such animals and products are better excluded from the supply chain then voluntary measures are more straightforward. Agreements may be easier to reach in sectors (e.g. caprines) with no commercial cloning activity, but if there are no

[21] Studies reported in Kilgour & Dalton (1984) suggested that 6 - 18% of lambs can be stolen from their dam by another ewe. This would result in the wrong dam being recorded and probably the wrong sire.

[22] For example, UK retailer Morrisons claims that it 'does not accept products from cloned…animals'; see Morrisons policy on genetic modification at: http://www.morrisons.co.uk/Corporate/Policy/Genetic-Modification-GM/ (viewed 2 Nov 2012).

clones or related material in the food system anyway then such agreements have little added value. Though the proposition has not been tested with stakeholders, it seems more likely to hold for clones and potentially also for their offspring than for clone descendants which are several generations removed from the cloning process.

A voluntary approach to traceability for clone offspring is theoretically feasible but the same challenges apply in extending a system across each EU livestock sector. The extension of the model to descendants is theoretically feasible but is likely to be very difficult to sustain across the generations.

A voluntary approach to traceability of clone offspring and clone descendants in food products is, in practical terms, infeasible if there is not also traceability 'upstream' for live animals and reproductive materials. A voluntary approach to identification of clone status and traceability for food products would not be feasible for bovines if the 'coalition' did not reach out into the EU's trading partners as well.

If traceability is mandated by law for live animals (i.e. clones, clone offspring and clone descendants) and their reproductive materials then the upstream barriers to a voluntary approach to traceability for food products are removed and a voluntary system becomes feasible, at least for supply chains that are not using imported products and inputs.

It is not clear that market drivers would encourage operators to establish such systems. Based on the research evidence, it seems more likely that the information on clone status would be used to exclude some or all of the products derived from such animals from the lower parts of the food chain. Mandatory 'upstream' identification and traceability enables retailers and manufacturers to exercise that choice more easily.

8.3.5 A risk-based approach to control of clones, clone offspring and clone descendants in the food chain would focus on bovine animals

Commercial cloning activity is concentrated in bovine animals and (non-food) equine animals. The probability of offspring and descendants of clones for porcine, ovine and caprine animals entering the food chain before 2020 is very small. Moreover, farm size and type of operation varies significantly across the EU, from large-scale production using the latest technology to small-scale holdings with a few animals managed in a traditional way. A risk-based approach to traceability that targeted bovine animals and farming operations most likely to utilise clones, their reproductive materials and/or their offspring and descendants for breeding purposes, and controlled the introduction of sport horses into the food supply chain could be used to reduce the burden on small-scale operators and those working with other species, as well as the burden on competent authorities.

Imported food products present an enforcement challenge, particularly for bovine products (due to the large scale of trade and variety of sources). Equine meat comes from fewer countries. Ovine, caprine and porcine meat products come from a small number of exporting countries and may thus, in principle, be more easily controlled.

Where identification and traceability of food products is desired, it is unlikely to be met through voluntary action alone. Operators 'downstream' in the supply chain are more likely to develop requirements that their suppliers completely exclude clones, their offspring and descendants than risk obtaining incorrect information on the products' status.

For packages covering food products, operators downstream in the supply chain (such as retailers) are likely to need reassurance of upstream traceability (rather than voluntary action alone) to ensure that identification and traceability is more reliable for food products. Government intervention is likely to be required from an early stage in the supply chain (i.e. for live animals and their reproductive materials) in order to give confidence to operators working with food products, allowing them to identify and trace derived food products as well.

Table 8.5 Commentary on feasibility of the traceability measures

Package	Commentary on feasibility
Package T-A Traceability for live clones *[Feasibility of measure T1]*	■ **Strategy 1**: Could be implemented with minor adjustment to existing EU and third country systems under sub-strategy (a). Sub-strategy (b) is feasible in the EU and potentially in third countries if third countries are willing to require new information to be provided by all operators handling clones in order to ensure EU imports include an indication as to their status. Assessment of claims is possible due to evidential requirements of animal parentage. Import verification through operator declarations can be trusted due to straightforward identification of cloning companies in third countries and existing relationships between EU and third country operators to identify clones. ■ **Strategy 2**: Requires substantial adjustment to existing EU systems for porcine, ovine, caprine and equine animals intended for food Production; requires new or major changes to existing third country systems for these animals as well; third countries are unlikely to implement new traceability systems for these species without recognised human health or safety risks. But, where individual traceability is enabled for these animals, clones should be easy to identify and trace within the system. ■ **Strategy 3**: Systems in place in the EU and third countries could be adapted to identify and trace clones as explained under Strategy 1.
Package T-B T-A plus traceability for reproductive materials of clones *[Feasibility of measure T3 when applied in addition to Package T-A]*	■ **Strategy 1**: Could be implemented without substantial adjustment to existing EU systems or systems operating in third countries under sub-strategy (a). Sub-strategy (b) is feasible in the EU and potentially in third countries if third countries are willing to require new information to be provided by all operators handling reproductive material from clones in order to ensure EU imports include an indication as to their status. Assessment of claims is possible due to evidential requirements of animal parentage; import verification through operator declarations can be trusted due to straightforward identification of cloning companies in third countries and already existing relationships between EU and third country operators to identify clone status of reproductive materials. ■ **Strategy 2**: Individual animal traceability is already enabled in the EU for reproductive materials of all species. This strategy, as Strategy 1, could be implemented without substantial adjustments to existing EU systems or systems operating in third countries. ■ **Strategy 3**: Systems in place in the EU and third countries could easily be adapted by private operators to identify and trace clone reproductive material as explained under Strategy 1; voluntary systems already exist for bovine animals.
Package T-C T-B plus traceability for live offspring of clones (and their reproductive materials) *[Feasibility of measure T4 when applied in addition to Package T-B]*	■ **Strategy 1**: Feasible with some amendments to existing identification and traceability systems for bovine animals under sub-strategy (a). Sub-strategy (b) is feasible in the EU and potentially in third countries for bovine animals if third countries are willing to require new information to be provided by all operators handling live offspring of clones in order to ensure EU imports include an indication as to their status. More difficult for other species where heritage records are less comprehensive than for bovine animals. There are likely to be very few if any offspring of these other species produced from clones to 2020, however. There are also few live animals brought into the EU each year, and these are 'high value' animals for which parentage records would be available for at least the previous generation, which could help to identify the clone parent(s). ■ **Strategy 2**: Requires substantial adjustment to existing EU systems for porcine, ovine, caprine and equine animals intended for food Production; requires new or major changes to existing third country systems for these animals as well; third countries are unlikely to implement new traceability systems for these species without recognised human health or safety risks. ■ **Strategy 3**: As described under Strategy 1, traceability for domestically produced clone offspring is feasible and already enabled voluntarily for bovine animals in the UK, but will require additional systems to be put in place to capture this information across the EU supply chain.

Package	Commentary on feasibility
Package T-D T-C plus traceability for live descendants of clones (and their reproductive materials) *[Feasibility of measure T5 when applied in addition to Package T-C]*	■ **Strategy 1**: Traceability for domestically produced descendants will be complicated by the record keeping required. Parentage information may not be fully reliable due to mixing of animals on farm. Incentives may not encourage compliance under sub-strategy (a) or (b), especially if operating the system has a cost and identification as clone descendants impacts market values. Traceability for animals imported to the EU may be feasible where these high-value animals are accompanied by sufficient information to identify the clone parents but current systems do not require this and third countries are unlikely to make this a new requirement. Traceability for clone descendants is much more complicated than for clones themselves or their offspring, and will require extensive record-keeping of parentage by operators, which is not common practice. ■ **Strategy 2**: Requires substantial adjustment to existing EU systems for porcine, ovine, caprine and equine animals intended for food production; requires new or major changes to existing third country systems for these animals as well; third countries are unlikely to implement new traceability systems for these species without recognised human health or safety risks. Traceability for descendants supported by individual animal identification is much more complicated than for clones themselves or their offspring and will require extensive record-keeping of parentage by operators, which is not common practice. ■ **Strategy 3**: Traceability for domestically produced descendants will be complicated by the record keeping required. A voluntary approach may be technically feasible for the first generation of EU clone descendants but is likely to be more difficult to sustain with each additional generation. The costs of compliance and incentives for non-compliance may undermine the system, especially if clone status has a negative impact on market values. Traceability for imported descendants will only be as strong as the accompanying heritage information.
Package T-E T-A plus traceability for food products derived from clones *[Feasibility of measure T2 when applied in addition to Package T-A]*	■ **Strategy 1**: Identification and traceability for food products derived from clones is difficult for some products and infeasible for others without completely segregated supply chains. The risk of clones being used systematically for food in the next few years is low as clones are uncommon and valuable. They are more likely to enter the food chain at the end of their working lives as breeding animals rather than be produced directly for food. Nonetheless, traceability for foods derived from clones would require new systems. Third countries that export to the EU would need appropriate traceability systems or segregated supply chains. Verification of claims would not be possible. ■ **Strategy 2**: *Individual* animal traceability is only possible for whole cuts of meat. Existing traceability systems in the EU only require *batch* identification to enable traceability to the holdings from which the products originated. ■ **Strategy 3**: The same issues arise under Strategy 3 as under Strategy 1. Operators would struggle to obtain sufficient evidence of the clone status of imported food products. Voluntary systems upstream in the supply chain are unlikely to be sufficient to give downstream operators dealing with food products sufficient confidence in product status. Government action is likely to be required for this package.
Package T-F T-C plus traceability of food products derived from clone offspring *[Feasibility of measure T6 & T2 when applied in addition to Package T-C]*	■ **Strategy 1**: Identification and traceability for food products produced from clone offspring is difficult for some products and infeasible for others without completely segregated supply chains for clones and their offspring. Developing an effective system in the EU would be less feasible than for package T-E due to the much larger number of animals that fall within scope. Trading partners will need new traceability systems or completely segregated supply chains. ■ **Strategy 2**: *Individual* animal traceability is only possible for whole cuts of meat. Existing traceability systems in the EU only require *batch* identification to enable traceability to the holdings from which the products originated. ■ **Strategy 3**: The same issues arise under Strategy 3 as under Strategy 1. Operators would struggle to obtain sufficient evidence of the clone status of imported food products. Government action is likely to be required for this package.

Package	Commentary on feasibility
Packages T-G Package T-D plus traceability of food products derived from descendants of clones *[Feasibility of measure T6, T2 & T7 when applied in addition to Package T-D]*	■ **Strategy 1**: Identification and traceability for food products produced from clone descendants is difficult for some products and infeasible for others without completely segregated supply chains for clones, their offspring, and their descendants. Construction of an effective system in the EU would be less feasible than for T-F due to the much larger number of animals that fall within scope, and record keeping challenges. Trading partners will need new traceability systems or completely segregated supply chains. ■ **Strategy 2**: *Individual* animal traceability is only possible for whole cuts of meat. Existing traceability systems in the EU only require *batch* identification to enable traceability to the holdings from which the products originated. ■ **Strategy 3**: The same issues arise under strategy 3 as under strategy 1. Operators would struggle to obtain sufficient evidence of the clone status of imported food products. Government action is likely to be required for this package.

8.3.6 The supply chain would need to be given time to prepare for the new obligations

Traceability for clones and their reproductive materials (measures T1 and T2 / packages T-A and T-B) could be applied relatively quickly – there are few companies, no known commercial cloning activity in the EU, and no major system developments needed. The adoption of measures that required more significant development of systems or a supply chain transition in trading partners would require a longer lead-in period if disruption to the supply chain is to be avoided. In some cases that lead-in time could be substantial.

Implementation is likely to be most straightforward for operators upstream in the supply chain because they already have the most information about the clone status of the animals and products they handle, and because many fewer operators will be affected (see baseline information on the number of operators at each stage in the supply chain, Annex 8, Table A8.4. Packages that include food products affect many more operators and also require operators to obtain information that they are unlikely to be collecting voluntarily today.

8.4 Direct burdens

This section assesses the impacts that arise from the traceability approach for each of the three strategies. The obligations placed on operators and competent authorities by packages are detailed in Annex 5, Table A5.2.

8.4.1 Summary

The traceability approach will impose direct burdens on EU businesses that include:

- Staff time and advisory costs incurred by directly affected operators as they familiarise themselves with new legal requirements ('learning' costs);
- Compliance costs associated with the operation of the extended traceability requirements, both in initial investment and then in on-going operating costs; and
- On-going commitments in responding to requests and/or inspections from competent authorities, estimated to 2020 ('reporting and inspection costs').

These are considered below. The estimates for livestock producers draw on EU data on the number of holdings for each species. No derogations have been assumed for the numerous 'back-yard' holdings with just a few animals that are prevalent in some Member States, for example. Commentary is provided elsewhere in this chapter on how a risk-based approach would lead to a focus on particular species and activities, and in so doing reduce overall burdens.

Direct burdens arising from the traceability approach will vary depending on the information requirements (i.e. strategy chosen) and point in the supply chain. Upstream and downstream operators[23] (excluding breeders/farmers) are expected to incur reporting and inspection costs (on the order of hundreds of thousands of euro in total). Direct burdens will be negligible for breeders/farmers where traceability focuses only on clones and their offspring and descendants (sub-strategy (a)), but the scale of impacts will increase significantly where all animals or batches of animals must be identified (potentially reaching a total of more than a million euro annually) (sub-strategy (b)).

Traceability requirements are likely to trigger one-off learning costs as operators seek to understand the implications of the traceability requirements for their businesses. The scale of these costs increases rapidly as the scope of controls extends through the supply chain from package T-A to T-G (with the exception of T-E, tracing food from clones).

[23] Upstream operators refer to those businesses involved primarily in the import and production of reproductive materials and in breeding activities that precede multiplication for slaughter; downstream operators refer to those businesses involved in food production, from slaughter to retail.

Table 8.6 One-off learning costs by traceability package (€'000) – assuming upstream operators each spent 1 hour on familiarisation if action is required to identify animals under Strategy 1 and 5 hours under Strategy 2

Sector	Strategy	#Operators	Hours / operator*	T-A	T-B	T-C	T-D	T-E***	T-F	T-G
Feasibility (see section 8.3)				**Feasible**	**Feasible**	**Feasible**	**Difficult & doubtful reliability**	**Feasible**	**Infeasible**	**Infeasible**
Companies that could conduct cloning activities	All strategies	5	70	€18	€18	€18	€18	€18	€18	€18
AI companies	All strategies	215	70		€783	€783	€783		€783	€783
Importers of live animals	All strategies	22	70	€71	€71	€71	€71	€71	€71	€71
Importers of reproductive materials	All strategies	69	70		€251	€251	€251		€251	€251
Breeders/ holdings**	S1 (ID clones only)	0	1	€0				€0		
	S1 (ID offspring, descendants only)	>1	1		>€0	>€0	>€0		>€0	>€0
	S1 (ID all animals and/or batches)	>7 million	1	€0	<€119,243	<€119,243	<€119,243	€0	<€119,243	<€119,243
	S2 (ID all animals)	>7 million	5	€0	<€382,826	<€382,826	<€382,826	€0	<€382,826	<€382,826
Slaughterhouses / markets / assembly centres	S1 (ID clones only)	0	1					€0		
	S1 (ID offspring, descendants only)	>1	1						>€0	>€0
	S1 (ID all animals and/or batches)	15,491	1					€0	€713	€713
	S2 (ID all animals)	15,491	5					€0	€3,563	€3,563
Importers of food products	S1 (ID clones only)	0	1					€0		
	S1 (ID offspring, descendants only)	>1	1						>€0	>€0
	S1 (ID all animals and/or batches)	694	1					€0	€30	€30
	S2 (ID all animals)	694	5					€0	€149	€149

Processors / manufacturers	S1 (ID clones only)	0	1	€0			
	S1 (ID offspring, descendants only)	>1	1		>€0	>€0	
	S1 (ID all animals and/or batches)	81,993	1	€0	€3,772	€3,772	
	S2 (ID all animals)	81,993	5	€0	€18,858	€18,858	
Wholesalers	S1 (ID clones only)	0	1	€0			
	S1 (ID offspring, descendants only)	>1	1		>€0	>€0	
	S1 (ID all animals and/or batches)	82,801	1	Some learning costs expected			
	S2 (ID all animals)	82,801	5	Some learning costs expected			
Retailers	S1 (ID clones only)	0	1	€0			
	S1 (ID offspring, descendants only)	>1	1		>€0	>€0	
	S1 (ID all animals and/or batches)	623,812	1	Some learning costs expected			
	S2 (ID all animals)	623,812	5	Some learning costs expected			

**Assumed time taken per operator on familiarisation with the requirements of the legislation.*

*** An equal average time is assumed for all EU livestock producers are treated equally; no adjustment is made for 'backyard' holdings on the basis that there will be no derogations in Strategy 2.*

**** It is assumed here that a pragmatic solution reached to exclude clones from food chain avoids need to engage slaughterhouses, processors and manufacturers.*

Table 8.7 Estimated compliance costs by traceability package, €

Component	Sector	Strategy	T-A	T-B	T-C	T-D	T-E*	T-F	T-G
			Feasible	Feasible	Feasible	Difficult & doubtful reliability	Feasible	Infeasible	Infeasible
System development costs (one-off investment)	Competent Authorities	S1	Limited impact						
	Breeders & livestock producers`	S1	Minor modification to existing systems						
	Slaughterhouse to retail	S1					Segregated supply chains required		
	Competent Authorities	S2	Development of ID + traceability systems estimated at millions of euro						
	Breeders & livestock producers	S2	Upgrading equipment & systems for individual animal identification (non-bovines)						
	Slaughterhouse to retail	S2						Upgrading equipment & systems for individual identification (non-bovines)	
Annual additional operating costs to record status and parentage	Breeders & livestock producers, AI sector *Recording status and parentage*	S1 (ID clones only)	€0				€0		
		S1 (ID offspring and descendants only)		>€0	>€0	>€0		>€0	>€0
		S1 (ID all animals and/or batches)	€0	€9m/yr	€9m/yr	€9m/yr	€0	€9m/yr	€9m/yr
		S2 (ID all animals)	€10m/yr -100m/yr in additional time costs €37m/yr-€98m/yr for additional ear tags for ovine and caprine individual animal ID €193m/yr-€510m/yr for additional ear tags for porcine individual animal ID						
	Slaughterhouse to retail		No added costs						

**It is assumed here that pragmatic solution reached to exclude clones from food chain avoids need to engage slaughterhouses, processors and manufacturers.*

Table 8.8 Estimated annual reporting and inspection costs by traceability package (€'000) – assuming all operators spend 2 hours on reporting if action is required to identify animals under Strategy 1 and 4 hours is required to report under Strategy 2

Sector	Strategy	#Operators	Hours / operator*	T-A	T-B	T-C	T-D	T-E*	T-F	T-G
Feasibility (see section 8.3)				**Feasible**	**Feasible**	**Feasible**	**Difficult & doubtful reliability**	**Feasible**	**Infeasible**	**Infeasible**
Companies that could conduct cloning activities	All strategies	5	2	€0.4	€0.4	€0.4	€0.4	€0.4	€0.4	€0.4
AI companies	All strategies	215	2		€22	€22	€22		€22	€22
Importers of live animals	All strategies	22	2	€2	€2	€2	€2	€2	€2	€2
Importers of reproductive materials	All strategies	69	2		€8	€8	€8		€8	€8
Breeders/ holdings	S1 (ID clones only)	0	2	€0				€0		
	S1 (ID offspring, descendants only)	>1	2		>€0	>€0	>€0		>€0	>€0
	S1 (ID all animals and/or batches)	>7 million	2	€0	<€238,486	<€238,486	<€238,486	€0	<€238,486	<€238,486
	S2 (ID all animals)	>7 million	4	€0	<€476,972	<€476,972	<€476,972	€0	<€476,972	<€476,972
Slaughterhouses / markets / assembly centres	S1 (ID clones only)	0	2					€0		
	S1 (ID offspring, descendants only)	>1	2						>€0	>€0
	S1 (ID all animals and/or batches)	15,491	2					€0	€1,426	€1,426
	S2 (ID all animals)	15,491	4					€0	€2,852	€2,852
Importers of food products	S1 (ID clones only)	0	2					€0		
	S1 (ID offspring, descendants only)	>1	2						>€0	>€0

Sector	Strategy	#Operators	Hours / operator*	T-A	T-B	T-C	T-D	T-E*	T-F	T-G
Feasibility (see section 8.3)				**Feasible**	**Feasible**	**Feasible**	**Difficult & doubtful reliability**	**Feasible**	**Infeasible**	**Infeasible**
	S1 (ID all animals and/or batches)	694	2					€0	€60	€60
	S2 (ID all animals)	694	4					€0	€120	€120
Processors / manufacturers	S1 (ID clones only)	0	2					€0		
	S1 (ID offspring, descendants only)	>1	2						>€0	>€0
	S1 (ID all animals and/or batches)	81,993	2					€0	€7,544	€7,544
	S2 (ID all animals)	81,993	4					€0	€15,088	€15,088
Wholesalers	S1 (ID clones only)	0	2					€0		
	S1 (ID offspring, descendants only)	>1	2						>€0	>€0
	S1 (ID all animals and/or batches)	82,801	2					€0	>€0	>€0
	S2 (ID all animals)	82,801	4					€0	>€0	>€0
Food retailers	S1 (ID clones only)	0	2					€0		
	S1 (ID offspring, descendants only)	>1	2						>€0	>€0
	S1 (ID all animals and/or batches)	623,812	2					€0	>€0	>€0
	S2 (ID all animals)	623,812	4					€0	>€0	>€0

*Note: Reporting and inspection costs are a function of competent authority strategies so **figures provided here are illustrative.***

**It is assumed here that pragmatic solution reached to exclude clones from food chain avoids need to engage slaughterhouses, processors and manufacturers.*

There would be additional operating expenses for the livestock sector in working to the new system. This would include the costs of acquiring and maintaining the equipment, and increased administrative burdens. Additional costs will be larger under Strategy 1, sub-strategy (b) than under sub-strategy (a) because it will require action to be undertaken by many more operators. Additional costs would be much larger under Strategy 2 than under Strategy 1 for non-bovine species as individual animal identification and traceability is required without derogation.

Packages that require traceability for clones (T-A) and clone reproductive materials (T-B) of porcine, ovine and caprine animals are unlikely to have any direct economic impact in the EU beyond the imposition of administrative burdens. For equines, indicating their clone status with a simple adjustment to the passports used for these animals would make them traceable with negligible economic impact. Requiring traceability for the reproductive materials of bovine and equine clones would have little impact providing the systems that already exist to trace these materials in North America are formalised and extended to other countries as required.

The live animals imported into the EU are high value breeding animals and traceable, so in principle their status as the offspring or descendant of a clone (T-C, T-D) could be specified. But no third country has systems in place to trace these animals on the basis of their clone ancestry and it is unclear whether third country operators would be willing or able to do so, especially if the obligation extended to descendants of clones without limit to the number of generations. If third countries cannot or will not provide this information beyond the first generation, the possibility of small scale, high impacts on particular businesses in the import trade and breeding sector cannot be excluded.

The traceability approach will impose additional operating costs for Competent Authorities, both on an on-going basis and one-off costs for making changes to the document and IT-based systems that Member States have built to comply with current traceability legislation. For Strategy 1, consultations with a small number of Member States suggest that the requirements could be accommodated with adjustments to their existing databases and other recording systems. Strategy 2 would involve much more significant investments in databases and associated communication systems. Countries with large numbers of pigs, sheep and goats would need systems capable of recording many more animals and handling many (potentially millions) more movements as existing derogations are removed and individual identification and traceability is introduced. This is likely to require new systems and additional processing and administrative capacity. The costs to Competent Authorities would be substantial - many millions of euros in total across the EU.

Traceability requirements for the reproductive materials of clone offspring and descendants may be possible for at least the first few generations with minor modifications to existing ancestry records used for breeding purposes. But once the genetics of these animals are sufficiently dispersed through the population, such that descendants are produced expressly for slaughter rather than for breeding, the type of recording keeping that could support identification of the status of the reproductive materials for these animals is likely to disappear. Since no third country currently traces reproductive materials from clone offspring or descendants and is unlikely to do so, a requirement to do so could result in an end to exports to the EU for these materials.

A requirement to trace food products derived from clones (T-E) should impose no direct economic impacts for the EU supply chain dealing in domestic food products of bovine, porcine, ovine or caprine origin - no clones of these species are expected to be produced in the EU before 2020. The most pragmatic solution is to seek agreement with trading partners to exclude clones from the EU food chain.

Requiring, for imports, traceability of food products derived from the offspring and descendants of clones (T-F, T-G) is likely to be infeasible without the EU's trading partners developing completely segregated supply chains – fully segregated systems would be required. Segregated systems for imported food products would be required because (a) if clones of a given species are produced in a country, then the only way to ensure that food products are not derived from these animals is to maintain a separate supply chain and (b) if

there is no cloning in a country that is exporting to the EU but the EU still requires a traceability system, then a segregated system will be required to provide this traceability.

Establishment of segregated systems for milk production and milk products is likely to mean farms 'converted' over to production based on, for instance, clone offspring. The milk purchaser would need to schedule tanks to keep the milk from clone offspring separate from other milk. All products and by-products would need to be sold into 'clone' markets. In a context where margins in the milk sector are under pressure and much of the liquid milk supply is sold into major retailers supply chains it seems unlikely that such a segregated system would become established given the supply chain's perceptions of consumer attitudes to clone products.

There is a significant risk that import trades worth several billions of euro a year would be reduced or halted because exporters in third countries are unwilling or unable to meet the requirements of the EU's approach. This would have negative impacts on food importers and other EU food business operators downstream in the supply chain. Impacts on consumer markets (prices and choice) are likely if the major trades, such as beef imports, cease.

Traceability requirements would add cost and complexity to the job of exporting to the EU by requiring additional information and supporting systems, with negative impacts for businesses in the EU's trading partners. Under Strategy 1 the scale of those negative impacts on third country operators increases as the information requirements and scope of the packages increases. The impacts are higher under Strategy 2 (in which individual animal traceability is required) than Strategy 1.

8.4.2 'Learning' costs

Directly regulated businesses will incur costs in understanding the implications of the new requirements for their operations. These learning costs have been estimated for directly affected operators, including companies with the potential to conduct commercial cloning activities for food production in the EU; AI companies and importers of reproductive materials; EU producers and importers of live animals; EU slaughterhouses, markets and assembly centres, and processors, manufacturers, retailers and importers of animal food products.

Parts of the supply chain that are not directly regulated are likely to incur additional costs in learning about the legislation and its potential impacts on their own businesses. These are 'induced' rather than direct burdens. The scale of these induced costs will increase rapidly as the scope of controls extends down the supply chain from clones to descendants. Chapter 7, section 7.5.1, provides examples of these costs.

8.5.1.1 Learning costs for upstream operators and food importers

For operators upstream in the supply chain, and for importers of food products, learning costs are expected to be the same under the traceability approach for both Strategy 1 and Strategy 2. This cost equivalence occurs because these operators are most likely to be involved in transactions that involve cloned animals, their offspring and descendants, and derived reproductive materials. It will take these operators more time than most to understand the implications of the traceability approach on their businesses. Table 8.9 provides the indicative magnitude of such learning costs by sector under each traceability package, with the given assumptions about time inputs and cost of time. Table 8.10 shows the learning costs for each package by animal species.

Table 8.9 Estimated learning costs by sector under each package, excluding equines, '000 €

Sector	T-A	T-B	T-C	T-D	T-E	T-F	T-G
Companies with the potential / capacity to conduct cloning activities in the EU	€18	€18	€18	€18	€18	€18	€18
AI companies	-	€783	€783	€783	-	€783	€783
Importers of live animals	€71	€71	€71	€71	€71	€71	€71
Importers of reproductive materials	-	€251	€251	€251	-	€251	€251
Approx. total / package	**€89**	**€1,123**	**€1,123**	**€1,123**	**€89**	**€1,123**	**€1,123**

An average of 70 hours has been estimated per operator to familiarise themselves with the new law. The basis of the calculations is described in Annex 8. Equines have been removed because evidence suggests that the large majority of equine transactions and trade are not related to the food chain.

Learning costs will be zero for upstream operators and food importers under Strategy 3. Packages T-F and T-G covering food products are likely to require government intervention. In these cases, the learning costs are likely to be similar to those under Strategy 1 and Strategy 2.

Table 8.10 Estimate of learning costs per package and by animal species, '000 €

Package	Bovine	Porcine	Ovine & caprine	Total bovine, porcine, ovine & caprine	Equine*	Approx. cost, all species
T-A, TE	€24	€42	€23	€89	€5,304	€5,393
T-B, T-C, T-F, T-G	€763	€268	€92	€1,123	€5,777	€6,900

**Equines have been treated differently in this table because research suggests that most activity relates to horses used for leisure and sport rather than the food chain. If the legislation and enforcement regime can effectively exclude such animals the aggregate burden, and the disruption to an industry unrelated to food production, can be greatly reduced.*

8.4.2.2 Learning costs for breeders / holdings

Breeders / holdings will incur learning costs under packages covering live animals (T-B, T-C, T-D) and food products derived from clone offspring and descendants (T-F, T-G). These costs vary by livestock species involved and by strategy. Table 8.11 provides an indication of the step change in costs incurred by these operators, by strategy and by species, in a context where there were (in 2010) approximately 3.3 million holdings rearing bovine animals; 2.3 million holdings rearing porcine animals; and 1.9 million holdings rearing ovine and caprine animals in the EU. This illustrates the order of magnitude of costs if each operator spends 1 hour understanding the implications of the new requirements and time is valued at an average EU skilled agricultural wage rate[24].

[24] There are some methodological issues associated with valuation of time of family farms where the principal will generally not receive a wage. The given labour cost is used as a shadow wage rate. More details are provided in Annex 8.

Table 8.11 Estimated learning costs for animal breeders/ holdings affected by species and strategy, '000 €

Sector	Bovine		Porcine		Ovine & caprine	
	No of entities ('000)	Total cost (€'000)	No of entities ('000)	Total cost (€'000)	No of entities ('000)	Total cost (€'000)
Strategy 1 (positive ID only clones)	0	0	0	0	0	0
Strategy 1 (positive ID only offspring/ descendants)	>1*	>0*	0	0	0	0
Strategy 1 (ID all animals or batches)	3,334	53,347	2,262	36,197	1,856	29,699
Strategy 2 (individual animal ID, all animals)	3,334**	53,347**	2,262	180,984	1,856	148,495

Source: Estimated number of operators in the EU per species - Eurostat, Structural Business Statistics (2009), data extracted on 18.7.2012.

An average of 1 hour has been calculated per operator where traceability is required under Strategy 1 (sub-strategy (a) and (b)), since there will be an adjustment to an already existing system, and affected operators will need to make some changes; 5 hours have been estimated per operator where individual animal traceability is required, but is not already implemented because operators will also need to learn about the new traceability requirements. The basis of the calculations is described in Annex 8.

Data on equine breeders/holdings are not available.

**A very small number of bovine offspring and descendants of clones are known to exist in the UK (approximately 100 animals). Therefore, there are a small number of operators (>1) that are likely to be affected by a requirement to ID these animals (total cost >0). An estimate cannot be made because an estimate of the number of operators that may be affected is not available.*

***The number of affected entities and therefore the total learning costs will be the same for those operators dealing with bovine animals under both Strategy 1 sub-option (b) and Strategy 2 because individual animal ID and traceability is already provided for all animals in the EU. There will be no changes under Strategy 2.*

8.4.2.3 'Learning' costs for downstream operators

Learning costs will be incurred by operators downstream in the supply chain if traceability requirements are extended to food products (T-F, and T-G[25]). These costs are likely to differ by livestock species involved, but the available data do not provide information on the proportion of operators in each sector dealing with only with bovine, porcine, ovine, caprine and equine meat products or a combination of these. As a result, the overall learning costs for upstream operators are estimated in aggregate according to the number of operators in each potentially affected sector. 0 provides an indicative measure of the potential learning costs for downstream operators where food products are covered under packages T-F and T-G on the assumption that each operator in the sector spends one hour researching and understanding the implications for their business under Strategy 1 and five hours under Strategy 2.

[25] T-E is assumed to be excluded from this for reasons previously cited.

Table 8.12 Estimated learning costs for operators downstream in the supply chain - food products (packages T-F and T-G), '000 €

Sector	S1 (ID clones only)		S1 (ID offspring, descendants only)		S1 (ID all animals and/or batches)		S2 (ID all animals)	
	#operators	Learning costs	#operators	Learning costs	#operators	Learning costs	#operators	Learning costs
Importers of meat food products	0	€0	>0	>€0	694	€30	694	€149
Slaughterhouses/ markets/ assembly centres	0	€0	>0	>€0	15,491*	€713	15,491*	€3,563
Processors/ manufacturers	0	€0	>0	>€0	81,993	€3,772	81,993	€18,858
Wholesalers	0	€0	>0	>€0	82,801 operators in the EU, but only a small number likely to be affected Some learning costs expected**			
Food retailers	0	€0	>0	>€0	623,812 operators in the EU, but only a small number likely to be affected Some learning costs expected**			

**Number of slaughterhouses/markets/assembly centres for bovine animals only; does not include operators for porcine, equine or ovine/caprine animals. Number of operators is therefore a significant underestimate of total operators affected.*

***Wholesalers and food retailers are only likely to be affected by a traceability requirement if they further process meat products; data on the number of such businesses as a subset of the total number of wholesalers and retailers is unknown.*

An average of 1 hour has been estimated per operator to familiarise themselves with the new law under Strategy 1 and 5 hours under Strategy 2. The basis of the calculations is described in Annex 8.

8.4.3 Reporting and inspection costs

As under the suspension approach, the scale of reporting costs (i.e. reporting to the regulator on activity and dealing with regulators' inspections, as distinct from day-to-day operation of traceability systems) imposed on the food chain in the EU will be driven by CA strategies. If CAs take a risk-based approach under Strategy 1 that focuses on organisations capable of conducting cloning and targeted checks on imports, then regulatory costs could be contained. If CAs attempt to implement a comprehensive monitoring and reporting framework involving all potentially affected operators, then costs would be far higher, especially where food products are included.

Monitoring costs incurred by competent authorities will vary in the same way. These may be net costs that require additional public expenditure or the burden may be passed to industry depending on whether cost recovery occurs from industry or is met from the general budget. EU legislation could incorporate text on charging to ensure a consistent approach. Section 8.4.3 provides reporting and inspection cost estimates incurred by regulated businesses.

8.4.3.1 Reporting and inspection costs for upstream operators and food importers

For operators upstream in the supply chain, and for importers of food products, reporting and inspection costs are expected to be the same under the traceability approach as under the suspension approach for both Strategy 1 and Strategy 2. As with learning costs, this cost equivalence occurs because these operators are most likely to be involved in transactions that involve cloned animals, their offspring and descendants, derived reproductive materials or imported food products. Table 8.13 provides the estimated reporting and inspection costs by sector under each traceability package. Table 8.14 shows the indicative costs for each

package by animal species. Under an assumption of a 'light touch' regulatory regime that requires an additional two hours of compliance time for each operator costs are low.

Reporting and inspection costs will be zero for upstream operators and food importers under Strategy 3 where it is entirely voluntary. Packages T-F and T-G covering food products are likely to require government intervention. In these cases, the costs are likely to be similar to those under Strategy 1 and Strategy 2.

Table 8.13 Indicative annual reporting and inspection costs by sector under each package, '000 €

Sector	T-A	T-B	T-C	T-D	T-E	T-F	T-G
Companies with the potential / capacity to conduct cloning activities in the EU	€0.4	€0.4	€0.4	€0.4	€0.4	€0.4	€0.4
AI companies	-	€22	€22	€22	-	€22	€22
Importers of live animals	€2	€2	€2	€2	€2	€2	€2
Importers of reproductive materials	-	€8	€8	€8	-	€8	€8
Approx. total, by package	**€2**	**€32**	**€32**	**€32**	**€2**	**€32**	**€32**

Notes: Whether these costs appear as net costs for CAs depends on cost recovery.

An average of 2 hour has been estimated per operator for directly affected operators upstream in the supply chain. The basis of the calculations is described in Annex 8.

Equines have been removed because evidence suggests that the large majority of equine transactions and trade are not related to the food chain.

Table 8.14 Indicative annual reporting and inspection costs per package and by animal species, '000 €

Package	Bovine	Porcine	Ovine & caprine	Total bovine, porcine, ovine & caprine	Equine*	Approx. cost, all species
T-A, T-E	€0.3	€0.6	€0.3	€1	€76	€77
T-B, T-C, T-D, T-F, T-G	€11	€4	€1	€16	€83	€99

**Equines have been treated differently in this table because research suggests that most activity relates to horses used for leisure and sport rather than the food chain. If the legislation and enforcement regime can effectively exclude such animals the aggregate burden, and the disruption to an industry unrelated to food production, can be much reduced.*

8.4.3.2 *Reporting and inspection costs for breeders/holdings*

There will also be reporting and inspection costs for breeders/holdings that vary by livestock species involved and by strategy. Table 8.15 provides an indication of the step-change in costs involved for these operators. These costs are driven by legislative requirements and Competent Authorities' strategies. A proportionate, risk-based strategy could reduce the burdens significantly.

Table 8.15 Indicative annual reporting and inspection costs for animal breeders/ holdings affected by species and strategy, '000 €

Sector	Bovine		Porcine		Ovine & caprine	
	No of entities ('000)	Total cost (€'000)	No of entities ('000)	Total cost (€'000)	No of entities ('000)	Total cost (€'000)
Strategy 1 (positive ID only clones)	0	0	0	0	0	0
Strategy 1 (positive ID only offspring/ descendants)	>1*	>0*	0	0	0	0
Strategy 1 (ID all animals or batches)	3,334	106,694	2,262	72,394	1,856	59,398
Strategy 2 (individual ID, all animals)	3,334**	106,694**	2,262	144,788	1,856	118,796

Source: Estimated number of operators in the EU per species - Eurostat, Structural Business Statistics (2009), data extracted on 18.7.2012.

An average of 2 hours has been calculated per operator where traceability is required under Strategy 1 (sub-strategy (a) and (b)) to report on these new requirements;4 hours have been estimated per operator where individual animal traceability is required, but is not already implemented, because operators need to report on the new traceability requirements as well as the number of animals with clone status as under Strategy 1. The basis of the calculations is described in Annex 8.

Data on equine breeders/holdings are not available.

**A very small number of bovine offspring and descendants of clones are known to exist in the UK (approximately 100 animals). Therefore, there are a small number of operators (>1) that are likely to be affected by a requirement to ID these animals (total cost >0). An estimate cannot be made because an estimate of the number of operators that may be affected is not available.*

***The number of affected entities and therefore the total learning costs will be the same for those operators dealing with bovine animals under both Strategy 1 sub-option (b) and Strategy 2 because individual animal ID and traceability is already provided for all animals in the EU. There will be no changes under Strategy 2.*

8.4.3.3 Reporting and inspection costs for downstream operators

There will be reporting and inspection costs for operators further down the supply chain where traceability requirements extend to food products (T-F and T-G[26]). These costs are likely to differ by livestock species but the available data do not provide information on the proportion of operators in each sector dealing separately with bovine, porcine, ovine, caprine and equine meat products or a combination of these. As a result, the overall reporting costs for upstream operators are provided in aggregate according to the number of operators in each potentially affected sector. Table 8.16 provides an indication of the potential costs associated with reporting for downstream operators where food products are covered under packages T-F and T-G, under an assumption in which each operator spends, on average across the sectors, an additional two hours of staff time on its annual compliance activity under Strategy 1 and four hours under Strategy 2. Again, the specification of requirements by CAs has the potential to reduce this burden or increase it significantly.

Table 8.16 Estimated annual reporting and inspection costs for operators downstream in the supply chain - food products (packages T-F and T-G), '000 €

Sector	S1 (ID clones only)		S1 (ID offspring, descendants only)		S1 (ID all animals and/or batches)		S2 (ID all animals)	
	#operators	Learning costs	#operators	Learning costs	#operators	Learning costs	#operators	Learning costs
Importers of meat food products	0	€0	>0	>€0	694	€60	694	€120
Slaughterhouses/ markets/ assembly centres	0	€0	>0	>€0	15,491*	€1,426	15,491*	€2,852
Processors/ manufacturers	0	€0	>0	>€0	81,993	€7,554	81,993	€15,088
Wholesalers	0	€0	>0	>€0	82,801 operators in the EU, but only a small number likely to be affected Some learning costs expected**			
Food retailers	0	€0	>0	>€0	623,812 operators in the EU, but only a small number likely to be affected Some learning costs expected**			

**Number of slaughterhouses / markets / assembly centres for bovine animals only; does not include operators for porcine, equine or ovine / caprine animals. Number of operators is therefore a significant underestimate of total operators affected.*

[26] T-E is assumed to be excluded from this for reasons previously cited.

***Wholesalers and food retailers are only likely to be affected by a traceability requirement if they further process meat products; data on the number of such businesses as a subset of the total number of wholesalers and retailers is unknown.*

An average of 1 hour has been estimated per operator to familiarise themselves with the new law under Strategy 1 and 5 hours under Strategy 2. The basis of the calculations is described in Annex 8.

8.4.4 Compliance costs

The traceability approach will impose additional costs on operators:

- Acquiring the equipment and supplies needed to operate more extensive traceability systems and/or recording information about the clone status of animals and producers;
- Administering those systems and fulfilling the given information obligations.

There will also be new burdens on competent authorities:

- Building new systems and adjusting existing systems to capture the information required;
- Administering those extended systems on an on-going basis.

The additional activities required under Strategy 1 are set out in Table 8.17 (for live animals), Table 8.18 (for reproductive materials), and Table 8.19 (for derived food products).

Strategy 2 requires changes to existing traceability systems for porcine, ovine and caprine, and equine animals to provide individual animal identification and traceability for all animals. This will require major changes to existing systems and the creation of entirely new systems.

In Strategy 3, operators voluntarily record information to capture the status of an animal or product. This is likely to result in similar costs as under Strategy 1. Under packages T-E, T-F and T-G, government intervention is likely to be required. Expected costs are likely to be similar as under Strategy 1.

These figures do not represent the total economic impact of the packages – just the burdens on directly regulated businesses. Other impacts are described in later sections. Estimated operating costs associated with these additional requirements are provided in sections 8.4.4.2.1 and 8.4.4.2.2.

8.4.4.1 System development costs

The traceability approach will require changes to the document and IT based systems that Member States have built to comply with current legislation. For Strategy 1 these changes would include a facility to add a marker to an animal's electronic or paper record to indicate that it is a clone or has clone ancestry. Consultations with a small number of Member States suggest that the requirements of Strategy 1 could be accommodated with adjustments to their existing databases and other recording systems. For example, the Danish CA estimates that making adjustments to the existing traceability system in Denmark to introduce information about cloned animals (cattle, sheep, goats, pigs and horses) into their central database would cost less than €200,000. This would include changes in:

- The database itself, to change information on individual cattle and on herds (batches) of other animals;
- User interfaces, including the forms used by authorities, the website (glr-chr.dk) where information is provided, the website (webdyr.dk) where information on individual cattle are registered and the website (landbrugsindberetning.dk) where information on herds is registered;
- Accompanying documents, including changes to cattle passports, horse passports and movement documents for sheep and goats;
- Reports; and
- Other web services.

Costs would be expected to vary significantly by Member State depending on the size of the animal populations involved and the extent to which the MS systems are fully computerised. The Danish system is likely to fall at the less costly end of this spectrum.

Problems may arise when animals are traded across internal EU borders; consultations suggest that interoperability of Member State systems is potentially an issue if the animal's status is added as a marker in the animal records.

Significant changes to existing electronic identification systems, such as ear tags, would be problematic and expensive but options may be available using existing systems. Taking the system for sheep and goats as an example, the transponder code structure is defined in an ISO standard that is referenced in the corresponding EU legislation. The structure of the animal identification code is fixed (the number string could not be changed from the existing 12 digits to 13 or more). There are, however, two unused digits within the existing string that could potentially be used to indicate clone status if a request was accepted by ISO and the EU legislation modified[27]. The clone identifier would need to be provided to the transponder supplier. There would be issues with the readers currently in use – a software change is likely to be required before they could read the additional data and some reader screens may not have enough space to show the extra information.

Strategy 2 would involve the same tag / transponder / reader issues as Strategy 1 but also require much more significant investments in databases and associated communication systems. Countries with large numbers of pigs, sheep and goats would need systems capable of recording many more animals and handling many (potentially millions) more movements as existing derogations are removed and individual identification and traceability is introduced. This is likely to require new systems and additional processing and administrative capacity. The costs to Competent Authorities would be substantial, many millions of euros in total across the EU. There would also be additional expense for the livestock sector in acquiring and maintaining the equipment needed to operate to the new system.

8.4.4.2 *Operating costs - time*

In addition to one-time system development costs to adapt or create new traceability systems, there will also be on-going costs such as:

- Time to add a 'flag' or other indicator of status to the database or other record keeping system for live animals and reproductive materials (domestic production and imports);
- Time to register the sire number for bovine animals, parents for other species, and donor for semen doses (domestic production and imports);
- Transfer of the 'flag' or other status indicator information to the importing MS's database at internal EU borders when animals are traded within the EU

These costs will occur under Strategy 1 and Strategy 2, but the overall costs will be considerably larger as the information requirements increase from recording only the status of a clone or its offspring, descendants, reproductive materials (and where possible, food for all animals or batches of animals and products (Strategy 1, sub-strategy (a)) to recording the status of all individual animals (Strategy 1, sub-strategy (b) and Strategy 2).

This section considers the indicative administrative costs involved in making step changes from one set of information requirements to another.

8.4.4.2.1 *Administrative cost to record and transmit clone status*

There will be administrative costs for breeders/producers and importers of live animals of bovine, porcine, ovine, caprine, and equine animals to record the status of the animal or batch of animals. Table 8.20 illustrates the step change in likely costs to record this information for domestically produced and imported live animals.

[27] Advice given to the contractor is that bits 10-15, providing 2 digits, are currently unused, reserved for future applications. ISO 11784 sets out the transponder code structure for the identification of animals. Regulation (EC) No. 21/2004 specifies that transponders must comply with ISO 11784.

Information necessary to make similar estimates for recording the status of reproductive materials is not available. But the same step-change in cost can be expected to record the status of these materials, from zero or negligible for strategies that focus only on positive identification to millions of euro each year to record the status of every unit or batch of these materials produced in the EU and imported.

8.4.4.2.2 Administrative cost to record parentage

Costs will also be incurred by breeders/producers and importers of live animals to record the parentage information of the animal necessary to keep records and therefore identify those animals that are clones, their offspring or descendants. Sire information will need to be added to existing systems for bovine animals, for example, since this information is not already recorded. If batch identification systems are converted to individual identification under Strategy 2, both parents will need to be recorded for all porcine, ovine, caprine and equine animals.

Table 8.17 Live animal identification requirement under Traceability Strategy 1 – Packages T-A, T-C, T-D

Species	Identification requirement under existing legislation	Identification approach under Traceability Implementation Strategy 1	Additional activity / obligation
Bovine	Identification and traceability for individual animals. Ear tag identification, passport and movements database organised at MS level Information on clone status not required.	Existing system, plus ■ A 'flag' or 'marker' in the movements database that indicates the clone status of the animal ■ Registration of sire number Full traceability of imported live animals under systems that meet the criteria specified by the EU that includes recording details of clone status	■ Modification of existing information systems to capture clone status ■ Time to add 'flag' indicating clone status to the database ■ Time to register sire number ■ Transfer of 'flag'/'marker' information to importing MS's database at internal EU borders when animals are traded within the EU ■ Import declarations and documentation on clone status ■ System developments in 3rd countries
Porcine	Most porcine animals are identified on a batch basis. Individual breeding and some other animals Ear tag identification, tattoos, and movements database organised at MS level Information on clone status not required	Individual identification of each porcine animal that falls within scope of the legislation. Movements register that records movements of such animals. Full traceability of imported live animals under systems that meet the criteria specified by the EU that includes recording details of clone status	■ Modification of existing information systems to capture clone status ■ Time to tag the animals ■ Cost of ID tag ■ Time to record clone status of batches in movements records ■ Transfer of 'flag'/'marker' information to importing MS's database at internal EU borders when animals are traded within the EU ■ Import declarations and documentation on clone status ■ System developments in 3rd countries
Ovine and caprine	Batch (animals sent to slaughter before the age of 12 months) Individual for all other animals (except for countries with sheep population of less than 650,000) Ear tag identification & movements database organised at MS level Information on clone status not required	In countries with sheep populations >650,000, animals with clone status will need to be individually identified + 'flag' or 'marker' in the movements database + registration of parents Full traceability of imported live animals under systems that meet the criteria specified by the EU that includes recording details of clone status An additional ear tag will indicate that animal has clone status.	■ Modification of existing information systems to capture clone status ■ Time to tag the animal ■ Cost of ID tag ■ Time to record clone status of batch in movements records (batch system) ■ Time to record the ID information (clone status + parentage) and register the animal (individual system) ■ Import declarations and documentation on clone status ■ System developments in 3rd countries
Equine	Individual animal, except for animals of wild or	Passport must include indication of	■ Modification of existing information systems to capture

Species	Identification requirement under existing legislation	Identification approach under Traceability Implementation Strategy 1	Additional activity / obligation
	semi-wild populations or for animals sent to slaughter before 12 months Electronic transponder (containing Universal Equine Life Number) & identification document or passport Central database not compulsory Information on clone status not required.	clone status + record of parentage (dam + sire)	clone status ■ Time to add clone status and parentage record to passport ■ Import declarations and documentation on clone status ■ System developments in 3rd countries

Table 8.18 Reproductive material identification requirement under Traceability Strategy 1 – Packages T-B, T-C, T-D

Species	Identification requirement under existing legislation	Identification approach under Traceability Implementation Strategy 1	Additional activity / obligation
Bovine	Individual (donor for semen; parents for embryo) Health certificate and international code (at EU level) Information on clone status not required.	Health certificate must indicate clone status + record parents for semen donor Health certificate and indication of origin on the packaging containing the dose of semen or embryos	■ Modification of existing information systems to capture clone status ■ Time to register clone status ■ Time to register parents for semen donor
Porcine	Individual (donor for semen; parents for embryo) Health certificate and international code (at EU level) Information on clone status not required.	Health certificate must indicate clone status + record parents for semen donor Health certificate and indication of origin on the packaging containing the dose of semen or embryos	■ Modification of existing information systems to capture clone status ■ Time to register clone status ■ Time to register parents for semen donor
Ovine and caprine	Individual (donor for semen; parents for embryo) Health certificate and international code (at EU level) Information on clone status not required.	Health certificate must indicate clone status + record parents for semen donor Health certificate and indication of origin on the packaging containing the dose of semen or embryos	■ Modification of existing information systems to capture clone status ■ Time to register clone status ■ Time to register parents for semen donor
Equine	Individual (donor for semen; parents for	Health certificate must indicate clone	■ Modification of existing information systems to capture clone status

Species	Identification requirement under existing legislation	Identification approach under Traceability Implementation Strategy 1	Additional activity / obligation
	embryo) Health certificate and international code (at EU level) Information on clone status not required.	status + record parents for semen donor Health certificate and indication of origin on the packaging containing the dose of semen or embryos	■ Time to register clone status ■ Time to register parents for semen donor

Table 8.19 Food product identification requirement under Traceability Strategy 1 – Packages T-E, T-F, T-G

Species	Identification requirement under existing legislation	Identification approach under Traceability Implementation Strategy 1	Additional activity / obligation
Bovine	Individual animal or group of animals slaughtered reference number Supply chain documentation Batch + slaughterhouse + cutting hall numbers on labels Information on clone status not required.	Supply chain documentation must indicate clone status + slaughterhouse batch or individual animal reference number or other indication of clone status required	■ Modification of existing information systems to capture clone status ■ Time to transmit clone status for food products from slaughter/cutting plant to retailers
Porcine	Group of animals slaughtered reference number Health certificates Batch number labelling or site specific approval number on label (referring to slaughterhouse, cutting plant, processor or producer) Information on clone status not required.	Slaughterhouse batch reference number or other indication of clone status required. For imports, health certificates must indicate clone status.	■ Modification of existing information systems to capture clone status ■ Time to transmit clone status for food products from slaughter/cutting plant to retailers
Ovine and caprine	Group of animals slaughtered reference number Health certificates Site specific approval number on label (referring to slaughterhouse, cutting plant,	Slaughterhouse batch reference number or other indication of clone status required. For imports, health certificates must indicate clone status.	■ Modification of existing information systems to capture clone status ■ Time to transmit clone status for food products from slaughter/cutting plant to retailers

Species	Identification requirement under existing legislation	Identification approach under Traceability Implementation Strategy 1	Additional activity / obligation
	processor or producer) Information on clone status not required.		
Equine	Group of animals slaughtered reference number, which can be related to the individual identification numbers of the animals (slaughterhouse level) Health certificates Depends on the country. No standardised process. Site specific approval number on label (referring to slaughterhouse, cutting plant, processor or producer) Information on clone status not required.	Slaughterhouse batch reference number or other indication of clone status required. For imports, health certificates must indicate clone status.	■ Modification of existing information systems to capture clone status ■ Time to transmit clone status for food products from slaughter/cutting plant to retailers

Table 8.20 Indicative administrative costs to record clone status – live animals (based on new animals born per year)

Species		Domestic production				Imports		
		Only clones	Only offspring/ descendants of clones	Clone status of animals to be identified on a batch or individual basis as per existing systems (status Y/N)	The clone status of all individual animals to be identified (status Y/N)***	Only clones	Only offspring / descendants of clones	The clone status of all individual animals to be identified (status Y/N)
		(strategy 1, sub-strategy (a))	(strategy 1, sub-strategy (a))	(strategy 1, sub-strategy (b))	(strategy 2)	(strategy 1, sub-strategy (a))	(strategy 1, sub-strategy (a))	(strategy 2)[28]
Bovine	Number *	0	>1	29 mil	29 mil	0	>1	<100
	Cost**	€0	>€0	€8 mil	€8 mil	€0	>€0	>€0
Porcine	Number *	0	0	All batches of animals sent to slaughter, est. avg. 4 mil	260 mil	0	Likely 0	<1,000
	Cost**	€0	€0	€1 mil	€71 mil	€0	Likely €0	>€0
Ovine & caprine	Number *	0	0	Unknown (data unavailable)	89 mil	0	Likely 0	<100
	Cost**	€0	€0	-	€24 million	€0	Likely €0	>€0

Sources: Bovine and porcine: USDA FAS, 2012. Reference year: 2012; Ovine and caprine: Eurostat, data extracted on 23/10/2012. Reference year: 2011 or most recent year for which data are available for Czech Republic, Denmark, Estonia, Latvia, Luxembourg, Slovenia and Finland. Data not available for Belgium; Equines have been treated differently in this table because research suggests that most activity relates to horses used for leisure and sport rather than the food chain. If the legislation and enforcement regime can effectively exclude such animals the aggregate burden, and the disruption to an industry unrelated to food production, can be much reduced.

The basis of the calculations is described in Annex 8.

**Number of animals or batches of animals that would require information capture on clone status*

***Cost assumes that all affected operators will require a minimum of one minute's time to record animal status for traceability purposes; an average cost of €16 per hour for a breeder/farmer or €0.27 for one minute's time per animal or batch of animals requiring information capture on clone status (domestic production); an average cost of €43 per hour for an animal importer or €0.72 for one minute's time per animal*

****Number of calves, piglets, lambs and kids estimated to be born each year and thus require identifying information over the period 2014-2020 (7 years)*

[28] All imported live animals are individually identified; Strategy 1, sub-strategy (b) and Strategy 2 have the same indicative costs for imports.

Indicative costs are expected to be similar to those for recording and transmitting information about clone status. The time required to record status and parentage for each animal is small (approximately one minute, estimated by breeders consulted for this study), but the number of animals for which this information must be recorded increases from zero or very small numbers to millions or hundreds of millions of animals depending on the strategy chosen and the species involved. The same holds for recording the donor for semen and the parents for embryos, depending on the species and the strategy.

8.4.4.2.3 Administrative cost to record parentage

Costs will be incurred to transfer information between Member States in case of internal trade. There are insufficient data to estimate the costs for each species. There is indicative information, however, that the time to transfer information between MS for all species will be minimal where systems are computerised and compatible between MS (though consultations suggest that this is unlikely to be the case between most MS).

8.4.4.3 Operating costs - materials

Under Strategy 2 livestock producers will have to purchase tags for individual animals. Additional costs will be involved.

- It is estimated that **it will cost the ovine/caprine sector an additional €37 million and €98 million per year to employ Strategy 2** because more than 50 million animals each year will require upgraded tagging. This is on the basis that individual identification for small ruminants cost from €1.03 for two conventional tags to €2.25 for a standard ruminal bolus and a conventional ear tag; this compares to €0.29 per animal for a slaughter lamb with only a holding tag. Tag/bolus costs to operators will thus increase by between €0.74 and €1.96 per animal to move from batch-based identification to individual identification under Strategy 2. Sixty per cent of these animals are estimated to be batch-identified under Article 4(3) of Regulation (EC) 21/2004 (animals intended for slaughter before the age of 12 months).
- It is estimated that **it will cost the porcine sector an additional €193 million and €510 million[29] per year to employ Strategy 2** if the same basic assumptions hold for the increased costs for tags applied to ovine/caprine animals above. Converting to individual identification for porcine animals will be much more costly than for ovine and caprine animals because most porcine animals are currently batch-identified in the EU and there are many more piglets born in the EU each year (approximately 260 million) than kids and goats (approximately 89 million).

8.4.5 There may be alternative, more proportionate, means of implementing some measures

The strategies developed here flow from the measures defined in the terms of reference and are based on an extension of existing identification and traceability systems. The cost of the changes is disproportionate to the scale of the regulated activity – for most of the species covered there is no commercial cloning activity in the EU.

There may be an alternative, more proportionate, approach that involves legislating for the same outcome (i.e. the identification and traceability of such clones, clone offspring and clone descendants as exist in the system) but leaves the means (the specification, development and operation of systems) to the supply chain. The law could, for instance, place a duty on:

- Livestock producers:
  - If they are producing clones, clone offspring or clone descendants, to participate in a recognised compliance scheme that maintains records of such animals;

[29] This cost estimate is based on the assumption that the majority of piglets born in the EU each year are batch identified (approximately 260 million piglets) and that tag/bolus costs to operators may increase by a similar amount as for small ruminants (between €0.74 and €1.96 per animal) to move from batch-based to individual identification

  - To identify any clone / clone offspring / clone descendants they produce;
  - To pass information on that animal's clone status when the animal is sold;
- Other FBOs further down the supply chain to capture and pass on information on the clone status of any animals they acquire.

This could enable the development of systems that are only developed and 'switched on' where they were needed.

Such approaches are, however, unlikely to be feasible for food products where imports are significant, such as in the bovine sector. In the reproductive materials sector, where imports are relevant but there are comparatively few suppliers, there would be a need for formalisation and extension of agreements with third countries to ensure reproductive materials are 'tagged' as having been derived from a clone, clone offspring or clone descendant where that is the case.

8.4.6 Indirect impacts arising from administrative burdens

The additional costs incurred by producers to implement traceability requirements would have negative indirect impacts on the industry for each species, especially under scenarios that cover all operators (i.e. under Strategy 1 if all animals or batches must include an indication of their status (clone/offspring/descendant = yes/no) and under Strategy 2 where all animals must be individually identified). In particular, Strategy 2 sets new traceability requirements for all porcine, ovine, caprine and equine animals. The administrative burden is expected to be high for industry operators for these species. There is a likelihood that some operators will cease trading as a result of these new requirements and the resultant pressure on profit margins. For example:

- Operators may not be able to pass additional costs on down the supply chain and so will have to absorb them in a context where operating margins are often already low;
- If increased production costs are translated into higher consumer prices, consumers may substitute red meat with lower cost poultry meat, reinforcing current trends (USDA FAS, 2012b).
- Production of EU beef and veal decreased by 4.8 per cent in 2012 compared to 2011. This trend is projected to continue in 2013, with a further 0.5 per cent decrease (DG AGRI Short Term Outlook, 2012). A total 1.3 per cent reduction in beef and veal production is projected over the period 2011-2020 (DG AGRI, 2011c). Gross margins for EU beef producers are positive, although generally not high.
- More favourable production trends are observed in the EU milk and dairy sector: over the period 2009 - 2020, EU milk production is expected to grow by 7 per cent, fresh dairy products by 6 per cent, and cheese by almost 10 per cent (DG AGRI, 2011c). Producer income is unstable, however. Margins for milk producers decreased significantly over the period 2007 - 2009: gross margins fell by 44 per cent, from 149 to 83 €/tonne. This is largely due to a 23 per cent price drop occurred in 2009. Gross margins showed a partial recover in 2010, reaching 115 €/tonne (DG AGRI, 2011b).
- The number of operators in the pig breeding industry has been falling due to volatility in feed prices, reduced consumer expenditure both in domestic and export markets and new environmental and animal welfare requirements which come into force in 2013. In some Member States prices have been below production costs. It is estimated that, average producer losses at EU level amount to €20-30 per pig, and the total losses for the EU pig industry are between €120 and €130million per week (BPEX, 2011). Forecasts suggest that 2013 will see an improvement in production, with record pig production levels. Per capita consumption of pig meat is foreseen to increase by 0.9 per cent over the period 2010-2020 (DG AGRI, 2011c). Introducing new traceability requirements could set back the sector's recovery.
- There has been a sharp decline in sheep and goat numbers in the EU over the last year. In 2012, production has decreased by an estimated 1.6 per cent and is expected to decrease by an additional 1.5 per cent in 2013. Additionally, EU consumption of sheep

and goat meat is expected to decline by around 5.6 per cent in 2012 and by 0.8 per cent in 2013 (DG AGRI Short Term Outlook, 2012). An overall decline of 3.6 per cent is foreseen between 2010 and 2020 (DG AGRI, 2011c).

- The trends affecting the cost structure of ovine and caprine production are similar to those observed in the pig sector, particularly with regard to increasing feed prices. For example, UK estimates suggest that sheep farmers faced a 6.6 per cent increase in production costs between 2010 and 2012, with significant cost increases for feed, power and machinery repairs (EBLEX, 2011).
- The market for horse meat is smaller than that of other sectors. In 2007, 55.5 million tonnes of horses, asses, mules or hinnies were slaughtered, accounting for less than 0.2 per cent of total slaughter for bovine, porcine, ovine, caprine, and equine animals.[30] In 2007, the yearly EU average consumption of horsemeat was 0.4 kg per capita (Dobranić, 2008). The number of animals slaughtered in the EU declined by 22 per cent between 2006 and 2010, and the quantity of horsemeat produced declined by 20 per cent over the same period according to FAO statistics.[31] Producer prices showed different trends in European Member States over this period: some countries, like Spain and Slovenia, registered an increase ranging between 10 and 25 per cent, while other countries registered a significant reduction: for example, a 29 per cent decrease occurred in Belgium.[32] Increased production costs due to traceability measures are also likely to affect horse meat production, adding up to other effects like the increase in feed prices.

8.5 Other economic impacts

8.5.1 Direct revenue impacts

This section discusses the direct impact of the packages on operators' revenues (i.e. sales). Such impacts arise through constraints on how operators conduct their normal business, and are distinct from the impacts on operating costs discussed above. Indirect trade-related impacts on sales that may arise as a result of the evidence requirements placed on imports are discussed in section 8.5.2 below.

Traceability requirements that focus only on clones are unlikely to have any direct revenue impact on operators in the EU because there are no known clones of bovine, porcine, ovine and caprine species in the EU or imported from third countries and none expected in the period up to 2020. The direct impacts on sales of traceability requirements on equine clones produced domestically and imported are also expected to be negligible. A simple adjustment to the equine passport for these animals to indicate their clone status would make them traceable where herd books are not already identifying the animals as clones.

No direct impacts are expected if traceability requirements were imposed on domestic food products derived from clones because there are no bovine, porcine, ovine or caprine clones in the EU or expected up to 2020. Production of food from equine clones is expected to be negligible or non-existent.

No direct revenue impacts on EU livestock producers are expected if traceability requirements were imposed on food products derived from the offspring or descendants of cloned porcine, ovine or caprine animals because there will be none to trace. Domestic EU production of clones and use of imported reproductive materials derived from such clones is not anticipated and thus neither offspring nor descendants of these species are expected to be produced in the EU to 2020.

Imposition of traceability requirements may have a direct impact on sales of the small number of livestock producers that have bovine offspring and descendants of clones on their holdings. Systems used to identify and trace such animals in the UK could be adopted in other MS as needed, such that entry of these animals into the food supply chain would also

[30] Source: Eurostat , extracted on 25/10/2012.

[31] FAOSTAT database, Livestock primary, extracted on 25/10/2012

[32] FAOSTAT database, Producer prices, extracted on 25/10/2012

be traceable. It is possible that retailers will prefer to exclude rather than have to identify and trace food products derived from these animals, in which case there would be a direct impact on the small number of operators who have these animals on their holdings. The vast majority of operators, however, are not expected to be affected.

There is a small number of equine offspring and descendants of clones bred for sport purposes. These are highly traceable due to the extensive pedigree records kept for these animals. Small adjustments would be required to identify these animals using equine passports, which would accompany the animal to slaughter. Any entry of these animals into the food supply chain would therefore be traceable.

8.5.2 Indirect trade-mediated impacts

Feasibility of the traceability measures for imports depends heavily on:

- The evidence required by the legislation with regard to imports;
- The ease with which exporters/importers could supply such evidence; and
- The extent to which cloning technology is used in the livestock sector of trading partners.

Requiring traceability for bovine and equine reproductive materials derived from clones is not expected to have a direct impact if the EU formalises existing industry systems operating between EU and North American operators and that model is extended to other countries as needed. No direct impacts are expected in relation to the other species.

The direct impacts on sales of exporters and importers arising from a traceability requirement covering live clone offspring and descendants are not easily estimated. The number of live bovine, ovine and caprine animals imported into the EU each year is small; a larger number of porcine animals are imported each year (approximately 1,000), but the figures are still relatively small. These animals are expected to be high-value breeding animals and as such, will have a high degree of traceability since knowing their lineage is essential for the breeding sector. Third country operators will need to adjust their systems in order to record the status of the animal if it is the offspring or descendant of a clone, but this should not be difficult. The possibility of significant impacts on a small number of businesses cannot be excluded, however, if third countries cannot or will not provide this information beyond the first generation.

It is expected to be infeasible to trace food products derived from the offspring and descendants of bovine clones produced in third countries and imported to the EU. There could be significant impacts on the sales of food importers and other EU operators downstream in the supply chain if these products cannot be traced.

Traceability requirements would add cost and complexity to the job of exporting to the EU by requiring additional information and supporting systems. This will result in negative impacts for businesses in the EU's trading partners. The EU legislation will pose difficulties for exporters to the EU:

- Under Strategy 1 (sub-strategies (a) and (b)) where third country operators cannot ensure traceability for supply chains in which clones/offspring/descendants, reproductive materials or derived food products may be present (e.g. for species and/or in countries where commercial cloning is prevalent).
- Under Strategy 1 (sub-strategy (b)) where the requirements for identifying animals extend to providing information (yes or no) on the status of an animal, reproductive materials or food product.
- Under Strategy 2 where requirements for identification and traceability are extended to individual identification of all porcine, ovine, caprine and equine animals.
- Under all strategies, evidential requirements are expected to be harder to meet for packages related to offspring and descendants of clones (including their reproductive materials and derived food products) because no third country currently traces these animals in the supply chain.

In summary, negative impacts increase for third country operators as the informational requirements and degree of comprehensive coverage increases under Strategy 1 (identifying and tracing only a subset of animals/batches under sub-strategy (a) to identifying all animals/batches under sub-strategy (b)). Negative impacts increase again from Strategy 1 to Strategy 2 (traceability requirements covering all individual animals).

There is insufficient baseline information (e.g. existing studies) to estimate the costs of 'upgrading' identification and traceability systems in third countries. Use of existing systems, such as those for exports of reproductive materials to the EU in place in the US and Canada between private operators, would significantly reduce the costs involved. But for countries that export significant quantities of meat products to the EU, the impact could be high if their traceability systems are not compliant with the EU's requirements. For example, in February 2008, the EU banned Brazilian beef imports because of deficiencies in the Brazilian traceability system. This cost the Brazilian economy an estimated $NZ430 million (€275 million) by mid-March of that year (MAF 2009).

No third country currently identifies or traces offspring or descendants of clones in the supply chain. Tracing these animals, reproductive materials and food products would require new systems to be put in place even under the most basic strategy (i.e. for Strategy 1,sub-strategy (a), packages T-C, T-D, T-F, T-G: identify only those animals that are offspring/descendants of clones, their reproductive materials and derived food products). Systems will need to cover those third countries that trade with EU trading partners. If the EU legislation recognises existing systems and polices in third countries, and takes a risk-based approach to border controls and enforcement, then costs will be lower than for fully comprehensive systems.

Implementing packages upstream in the supply chain is expected to result in less extreme negative impacts than in those downstream.

Nonetheless, the analysis suggests a risk that import trades would be significantly reduced or halted because exporters are unwilling or unable to meet the requirements of the EU's approach. Chapter 7, section 7.5.3 summarises the import trade 'at risk' for different animal products from key trading partner countries by package and species involved.

8.6 Social (employment) impacts

8.6.1 Summary

The principal employment impacts of the traceability approach are:

- Employment losses created by the additional administrative burdens placed on livestock producers and other FBOs; and
- The risk to jobs in food import and associated EU supply chains created by requiring third countries to comply with traceability conditions that they may be unable or unwilling to meet.

The picture is again complex; expected employment impacts can vary by species, package and strategy. For instance:

- Measures that impose traceability on clones and reproductive materials from clones would have negligible direct employment impacts in the EU and third countries if current industry arrangements are formally recognised and extended;
- Requiring traceability for reproductive materials obtained from offspring and descendants of clones risks negative impacts on employment in the breeding sector in the EU and in third countries, and may ultimately have negative impacts on the EU livestock sector;
- Packages that require traceability of food products derived from clones, clone offspring and clone descendants, could generate significant employment losses if third countries do not comply with EU traceability requirements. Employment in the EU and third countries would be at risk if trade is curtailed or stops. Some positive employment effects may occur from Strategy 2 but these effects may be offset by employment losses due to

operators going out of business where already tight profit margins are further eroded or net profit losses occur due to additional administrative burdens incurred.

8.6.2 Impacts of Strategy 1 - adapt existing traceability systems

Direct employment impacts of the traceability approach for domestic operators and in third countries are expected to be limited or negligible for live animals and reproductive materials from clones under Strategy 1. Few EU jobs are sustained by commercial cloning for the species of interest. Few live animals are imported into the EU each year and both EU importers and third country exporters of these animals are unlikely to sustain their business from this trade alone. Reproductive materials are already traceable and in many cases the status of the materials when derived from a clone is also already known or easy to obtain.

The traceability approach may have negative employment impacts for domestic and third country operators where traceability is required for the reproductive materials from offspring and descendants of clones. No third country has systems in place to identify these animals in the supply chain and therefore would not easily be able to do so for their reproductive materials. Such a requirement could trigger a reduction or cut-off in trade of these materials with third countries resulting in impacts similar to those described for the suspension approach in chapter 7.

Packages related to food products, could produce significant employment impacts. Thousands of EU jobs are sustained by the €3 billion - €4 billion worth of meat, dairy and meat-derived food products that are imported to the EU each year (see Chapter 7). If traceability requirements are difficult to meet or third countries decide not to comply with EU requirements, this employment would be at risk if this results in a cut-off in trade of these products. Losses would be offset to some degree by growth in employment in domestic suppliers as domestic output rises to offset the loss of imports. Jobs would also be at risk in exporting countries until such time as replacement markets were found.

8.6.3 Impacts of Strategy 2 – fully comprehensive traceability

Direct employment impacts of the traceability approach under Strategy 2 are expected to be the same as under Strategy 1 for live bovine animals, reproductive materials and food products of all species.

EU jobs would be created under Strategy 2 for live porcine, ovine, caprine and equine animals in order to produce the tags and related tagging equipment needed to identify a large number of animals. Jobs would also be created to develop new computer systems or modify existing ones to record the identity and movements of these animals. Operators may need to hire new employees in order to tag or assist in tagging and recording information about the individual animals.

It would be expected that these employment gains would be more than offset by employment losses caused by the additional administrative burdens placed on the livestock sectors and supply chain. These costs are potentially substantial. There is no offsetting benefit for these businesses, for example, in the form of price premiums. It may be very difficult for livestock producers and other FBOs to pass the costs on down the food chain to consumers, such that costs have to be met out of existing margins.

8.7 Impacts on consumers

This section considers potential impacts on consumers arising from traceability packages. It considers:

- Price effects – that is, where the package may change the prices in consumer markets; and
- Choice effects – that is, where the package may change the variety of goods and services available to consumers.

8.7.1 Summary

There is a risk of negative impacts on consumers under the packages that include food products. This is primarily due to the risk of loss of meat, dairy and other related food imports, and the associated effects on both price and choice where third countries are unwilling or unable to comply with traceability requirements. Consumers may also face higher food costs as a result of the increased administrative burdens imposed on producers in the EU and third countries. This is a particular issue for food products obtained from porcine, ovine and caprine animals under Strategy 2 because of the significant additional costs involved in implementing full individual animal traceability.

Table 8.21 Potential impacts on consumers arising from traceability packages under Strategy 1

Package	Price effects	Choice effects
T-A	Bovine, porcine, ovine and caprine animals: none expected if only clones identified; potential negative price effects if all animals must be identified (clone yes/no)	None expected
T-B	None expected, all species	None expected, all species
T-C & T-D	Bovine, porcine, ovine and caprine animals: none expected if only offspring or descendants identified; Potential negative price effects if all animals must be identified (offspring/descendant yes/no)	Limited, except as a consequence of product scarcity
T-E	None expected, all species	None expected, all species
T-F & T-G	Price effects in dairy markets if imports of dairy products are restricted or cease Potentially significant price effects in meat and meat products sector if imported meat products cease	Product-specific and seasonal loss of access to specific product types or brands Potentially some increased costs for domestic bovine, porcine, ovine and caprine products if all products must be identified Significant for bovine meat and meat products due to significant imports of these products Significant for ovine and caprine meat and meat products due to significant imports of these products

Table 8.22 Potential impacts on consumers arising from traceability packages under Strategy 2

Package	Price effects	Choice effects
T-A	Price effects in porcine, ovine and caprine meat sectors due to increased costs to implement new traceability requirements	Bovine: none expected Porcine, ovine and caprine: potentially significant if increased costs are prohibitive and consumers switch to alternative meats/fish or other products
T-B	None expected, all species	None expected, all species
T-C & T-D	Bovine, porcine, ovine and caprine animals: none expected if only offspring or descendants identified; Potential negative price effects if all animals must be identified (offspring/descendant yes/no)	Bovine: limited, except as a consequence of product scarcity Porcine, ovine and caprine: potentially significant if increased costs are prohibitive and consumers switch to alternative meats/fish or other products
T-E	None expected, all species	None expected, all species

Package	Price effects	Choice effects
T-F & T-G	Price effects in dairy markets if imports of dairy products are restricted or cease Potentially significant price effects in meat and meat products sector if imported meat products cease	Product-specific and seasonal loss of access to specific product types or brands Significant for bovine meat and meat products due to significant imports of these products Significant for porcine meat and meat products due to increased costs for domestic products Significant for ovine and caprine meat and meat products due to significant imports of these products and increased costs for domestic products

8.8 Impacts on SMEs

This section considers impacts of the traceability approach on SMEs. The traceability approach does not include an exclusion for SME businesses. The food chain contains large numbers of SMEs, from the farming sector through to manufacturing and retail, and the approach therefore has the potential to impact on SME profit margins and growth.

The impacts on SMEs will vary depending on the strategy chosen (Strategy 1 or 2) and the information requirements under Strategy 1 (sub-strategy (a) or (b)). If all operators are subject to the traceability requirements such that they must identify the clone status of all animals, reproductive materials and food products then SMEs will be affected similarly to all other EU operators. The requirements are more likely to affect the profits of small producers because they do not benefit from efficient production systems and/or economies of scale enjoyed by larger firms.

There is also likely to be variance in these impacts among Member States. Some MS have a large number of small producers. For example, in Poland (one of the EU countries with the largest pig populations) more than 60 per cent of the pigs are kept on farms with fewer than 50 animals. In Germany, higher production costs are already expected to cause the exclusion from the market of a large proportion of farms with fewer than 200 sows in 2013.[33] Additional costs for traceability could aggravate this impact.

Table 8.23 sets out the expected scale, distribution and type of impact on SMEs arising from the traceability requirements themselves.

Trade-mediated impacts are expected where third countries are unable or unwilling to comply with traceability requirements are set out in Chapter 7, Table 7.14. Expected impacts on the farming sector, which has a high concentration of SMEs, are mixed. The potential (in packages T-E to T-G) for higher prices as the market seeks to compensate for the loss of meat and dairy imports would be offset by the risk of loss of access to imported reproductive materials. Lack of access to such materials would have short run impacts on breeding plans for some businesses and longer run impacts on productivity growth for the sector as a whole.

[33] http://www.thepigsite.com/reports/?category=903&id=903

Table 8.23 Expected scale, distribution and type of impact on SMEs – traceability approach

Package	Sectors where impacts will be concentrated	Principal impact expected	Significance
T-A	Live animal importers	Aggregate value of the trade is small Few businesses likely to rely on trade in live animals to the EU Animals are high-value and therefore likely to be traceable with modest effort	Low
T-B	Importers of reproductive materials (RMs)	Materials are already traceable and identifiable in the major exporting countries as derived from a clone	Low
T-C	Importers of RM Live animal importers Breeders Dairy/beef farmers	Risk of loss of access to imported reproductive materials leads to loss of business for importers where exporters cannot or will not identify reproductive materials from offspring of clones Few businesses likely to rely on trade in live animals to the EU Loss of access to high quality Holstein/other genetics would negatively affects breeding programmes if RM importers halted Farmers need to find alternative RM suppliers to maintain output	High Low High in Member States with high dependency on AI & imported RM
T-D	Importers of RM Live animal importers Breeders Dairy/beef farmers	Risk of loss of access to imported reproductive materials leads to loss of business for importers where exporters cannot or will not identify reproductive materials from descendants of clones Few businesses likely to rely on trade in live animals to the EU Loss of access to high quality Holstein/other genetics would negatively affects breeding programmes if RM importers halted Farmers need to find alternative RM suppliers to maintain output	High Low High in Member States with high dependency on AI & imported RM
T-E	Food importers, processors, food manufacturers, retailers and food service companies	Risk that import trades would be affected because exporters are unwilling or unable to meet the requirements on food products, but a supply chain solution to exclude clones from food suppliers seems more likely than a solution for clone offspring and descendants, which are more numerous and not traced	Low
T-F	Food importers, processors, food manufacturers, retailers and food service companies	Risk of loss of access to imported meat and dairy suppliers Import substitution from domestic supply should raise prices / profitability for EU suppliers	High/critical for specific businesses that have import dependency General negative effect arising from higher input prices Uncertain (ref JRC modelling)
T-G	See analysis for package T-F	See analysis for package T-F	See analysis for package T-F

8.9 Impacts on competitiveness

This section considers the expected impacts of the traceability approach on competitiveness.

8.9.1 Cost competitiveness

8.9.1.1 Competitiveness impacts of Strategy 1 - adapt existing traceability systems

Traceability requirements related only to animal cloning in the EU are expected to have minimal direct effects on companies' cost competitiveness for bovine animals and no direct effects for the other species. This is because there are likely to be only a small number of bovine offspring and descendants and no clones, offspring or descendants for the other species for food production in the business as usual baseline to 2020. Impacts on cost competitiveness may arise through trade losses where third countries cannot or will not meet import traceability requirements. This could raise input costs in the EU market.

If under Strategy 1 all live animals or batches of live animals (where applicable) require identification as a clone, offspring or descendant (yes/no), the effects on cost competitiveness could be more significant, particularly for operators working with animal species for which profit margins are already low (e.g. ovine and caprine animals).

The impacts on cost competitiveness are expected to be neutral for packages T-A and T-B. Negative impacts on cost competitiveness will be concentrated in the breeding/farming sector and for importers of reproductive material under packages T-C and T-D. These will be even higher for breeders/farmers where all live animals (individuals or batches) require identification as to their status. Impacts will be more widely felt across the food chain in sectors related to food production under packages T-E to T-G.

Some of these negative impacts may be offset if imports are restricted from third countries due to lack of compliance with traceability requirements and EU producers benefit from this loss of competition.

8.9.1.2 Competitiveness impacts of Strategy 2 – fully comprehensive traceability

Competitiveness impacts related to traceability for bovine animals and derived products are expected to be the same under Strategy 2 as under Strategy 1. Impacts will also be the same for measures relation to tracing reproductive materials and food products from all species.

Negative competitiveness impacts will be seen where individual traceability requirements are put in place for all porcine, ovine, caprine and equine animals as these would result in significantly higher costs to operators (particularly breeders/farmers) in industries that already have low profit margins

8.9.2 Capacity to innovate

The evidence collected for this study suggests that commercial cloning is unlikely to occur in the EU to 2020. The introduction of traceability requirements is not expected to alter this. Trade-mediated effects resulting from third country unwillingness or inability to comply with the requirements may negatively impact innovation, particularly for the bovine breeding industry which relies on imported reproductive materials and breeding animals to improve the quality of the breeding stock.

8.9.3 International competitiveness

The potential impacts of the traceability approach on international competitiveness are mixed and complex. Impacts may include:

- Strongly negative impacts under Strategy 2 for porcine, ovine, caprine and equine animal industries, due to significantly higher costs to operators (particularly breeders/farmers) in industries that already have low profit margins. This is particularly likely for pork products, for which the EU is a net exporter. No third country has such traceability requirements in place resulting in an advantage over EU operators in trade with other third countries. For domestic consumption, if the requirement is put in place for all third

countries as well, then the overall competitiveness effect will be determined by the ease with which EU operators can comply with the requirements versus their competitors in third countries.

- Traceability could have positive impacts on demand for EU products where it allowed operators to identify their products as 'clone free' and where this is perceived as a premium attribute by consumers. The extent to which this characteristic may be desired by consumers in third country markets is unknown.

9 Approach appraisal: labelling

9.1 Introduction

This chapter examines the feasibility and impacts of applying a labelling requirement or providing for voluntary labelling in addition to traceability for food products derived from clones, clone offspring and their descendants. It is assumed that if a labelling requirement or voluntary labelling option were put in place, it would require new legislation.

The analysis considers the labelling measures as requirements that would be applied in *addition* to traceability (the traceability appraisal is detailed in Chapter 8). And as with the other approaches considered in this study, the measures set out in the labelling approach are also additive—covering food derived from clones first, and then also food products derived from clone offspring and finally, food products derived from clone descendants. The assessment has therefore considered different combinations of measures that provide coherent 'packages' of intervention.

9.2 Definition of the labelling packages and implementation strategies

The labelling measures considered in this appraisal are listed in

Table 9.1 Labelling measures

	Measure description
L1	Labelling + traceability of food products derived from clones
L2	Labelling + traceability of food products derived from the offspring of clones
L3	Labelling + traceability of food products derived from the descendants of clones

Measure L1 (Labelling + traceability of food products derived from clones) is viable on its own, but L2 and L3 are additive to L1 and have been combined into a set of internally coherent packages, labelled L-A to L-C, as described by Figure 9.1. The text here considers only the impacts that are additional to those identified in the traceability approach.

The packages are described in more detail in Annex 6. They vary in scope from covering only the premarket approval of food products derived from clones through to premarket approval of food products derived from clones, their offspring and their descendants.

Labelling measures would cover meat, meat products, milk and milk products and food derived from animal by-products (such as gelatine and casein) intended for human consumption. The labelling approach will create some new obligations on FBOs and CAs.

9.2.2 Definition of the implementation strategies

9.2.2.1 Labelling requirements depend on the objectives of the policy-maker

In the study brief the labelling requirements are stated at a high level--that is, labelling for the food products derived from clones, their offspring and descendants. The interpretation of these requirements determines the labelling approach needed to implement the labelling approach, and what investments may be required to enable labelling for these products in the supply chain. Two potential labelling scenarios were considered before potential implementation strategies were defined.

9.2.2.2 Positive labelling rules

Under a positive labelling regime products are labelled with wording that indicates the presence of clone-derived ingredients (or of offspring or descendants). A positive label could be mandatory or voluntary. Consultations with industry groups indicate that operators are likely to decide that the reputational risk from a positive label is high and therefore a voluntary approach is unlikely to ever be used. There are currently no perceived benefits for industry to such a label and it would therefore only be utilised where (i) it was mandatory to do so and (ii) operators were unable to exclude these products from the supply chain.

Figure 9.1 Representation of the scope of the labelling packages L-A to L-C

		Marketing of live clones (imported)	Marketing of live clones (from EU)	Marketing of reproductive material from clones (imported)	Marketing of reproductive material from clones (EU)	Marketing of live offspring from clones (first generation) [imported]	Marketing of live offspring from clones (first generation) [EU bred]	Marketing of live descendants from clones (all generations) [imported]	Marketing of live descendants from clones (all generations) [EU bred]	Marketing of food from clones [EU material]	Marketing of food from clones [imported material]	Marketing of food derived from offspring from clones (first generation) (i) imported	Food derived from offspring from clones (first generation) (ii) EU bred	Marketing of food derived from descendants from clones (all generations) (i) imported	Marketing of food derived from descendants from clones (all generations) (ii) EU bred
L-A	1														
L-B	1 + 2														
L-C	1 + 2 + 3														

Indicates where 'upstream' traceability required
Indicates where labelling applies
Indicates where no control applies

Such a label could be verified for clones using DNA testing if a registry of clones is maintained (each additional generation of descendants would require registration as well if they were also to be verified). It would not be possible to verify the presence of clone derived material if the animals with clone heritage are not on the registry. A process-based certification of food products, relying on documentary evidence, could be used. The nature of the claim could therefore vary, from a definitive claim such as 'produced from clones (or offspring, or descendants)' to a conditional claim such as 'may contain ingredients derived from clones (or offspring, or descendants).

9.2.2.3 Negative labelling rules

Under a negative labelling regime, products are labelled with wording that indicates the absence of clone-derived ingredients (or of offspring or descendants) for those animal species for which commercial cloning is undertaken.[34] The claim made by such a label cannot be verified since testing could not exclude the possibility that either the clone or the original animal (and the offspring and descendants of these animals) entered the food chain.

Negative labelling could not be employed in the way that it is, for example, under 'GM-free' labelling schemes operating in some Member States, since these rely on verifiable testing of GM presence in a food product. A negative label for clone-derived food products is unlikely to meet EU food labelling rules regulating the use of terms that indicate the absence of a characteristic in a product due to the fact that it is unverifiable and would therefore be misleading.

A certification approach similar to that taken for organic products might be considered, with documentary evidence being used to confirm that sufficient effort had been made by the supply chain to exclude these animals from the *process*, even if the *product* is not verifiable.

[34] EU food laws do not allow labelling that attributes characteristics to a foodstuff that it cannot possess—therefore, for example, it is in theory possible to label beef as 'clone-free' but not chicken, since chickens cannot currently be cloned (and there is no 'cloned chicken' equivalent that could be placed on the EU market). The same principle is already applied for 'GM-free' products in the EU—by the same logic, 'GM-free' labels may be applied to soybean-derived products, since there are GM soybeans authorised on the EU market; the same could not be done for, say, rice-derived products, for which there is no GM rice authorised on the EU market.

A labelling claim such as 'produced without cloning technology' could be considered in this situation.

9.2.3 Specification of the labelling strategies

Two strategies have been identified to illustrate how the labelling approach might be implemented. They examine use of a positive (mandatory) label (Strategy 1) and a negative (voluntary) label (Strategy 2), as explained below. In either case, labelling is only viable where traceability is feasible and enforceable.

9.2.4 Strategy 1 – mandatory labelling + traceability

Labelling Strategy 1 adds a labelling requirement to the traceability approach (Traceability Strategy T1 and T2) as set out in Chapter 8. Food products that contain clone-derived ingredients would be required to carry a label indicating this to the consumer. This system would use batch-based trace back for food products to the holding of origin and could provide an indication of a product that 'may contain clone material', rather than one that is verifiably 'clone-derived'. If a DNA registry and tests were put in place, whole cuts of meat and a selection of mixed meat products could be verified as 'clone derived'. Segregated supply chains could also be used to positively identify these products as 'clone derived', and could be employed to positively identify most mixed meat, dairy and products where DNA has been destroyed.

Strategy 1 is robust within its own terms but the potential for fraud is high because negative consumer views of cloning are likely to drive operators to conceal the presence of any ingredients derived from clones, their offspring or descendants so that these products do not have carry a 'positive' label. The reliability of the system is likely to be greater for domestic products than for imports because oversight of the system will be easier.

Issues of robustness arise if labelled products are placed on the market. The expected response to prominent mandatory labelling from industry, however, is to discontinue sale of food products derived from clones, their offspring and descendants, such that no labels would appear on the EU market. An analogy could be drawn to genetically modified food products – consumer opposition to the technology has driven these products off the market in most Member States. Compared to GM production, cloning technology is not widely used anywhere in the world at present and is not expected to be widely used before 2020.

9.2.5 Strategy 2 – voluntary labelling + traceability

Strategy 2 adds voluntary labelling to traceability Strategy S3 using a supply chain certification approach. Food products produced in a supply chain in which every effort has been made to exclude cloned animals could carry a label indicating that the product has been 'produced without cloning technology'. As with mandatory labelling, voluntary labelling is likely to be more reliable for domestic products than for imports.

There is also a potential for fraud and misleading claims under this strategy, but the incentives are reversed compared to Strategy 1: consumer opposition to cloning means operators may be interested in promoting a 'clone-free' label. A rigorous and robust certification process would be required to reduce the likelihood of fraud.

An analogy could be drawn to organic food products; prior to formalised rules in Member States, and later at EU level, there was considerable scope for operators to claim organic status without having taken sufficient measures in the production process to justify the claim. Formalised certification systems and agreed standards helped to reduce fraudulent claims.

9.3 Feasibility assessment

This section provides a classification of, and commentary on, the technical feasibility of the labelling approach, including the likelihood that the labelling approach will be utilised by operators.

A label indicating whether a food product contains products derived from clones, clone offspring or clone descendants is a mechanism for passing information provided by the

traceability system to consumers to help facilitate informed choice. A labelling system is feasible only to the extent to which the underlying traceability system is feasible. The limitations of traceability for food products are therefore also present for labelling.

Rules would be required on when labelling would be required and the form it would take (as discussed in chapter 8 on the suspension approach). For example rules would need to indicate whether:

- A label would be required if any ingredient, whatever its significance, was derived from clones, clone offspring or clone descendants, or only the principal ingredient.
- An indication of the product's status would be noted on the front of the pack or noted in the ingredients, and whether that rule would apply to any/all ingredients or only the principal ingredient(s);
- The wording that could be used and the size of the wording in relation to other information on the label; and
- Whether the label would be 'positive' (i.e. indicating that the product contains ingredients derived from clones, their offspring or descendants) or 'negative' (i.e. indicating the absence of ingredients derived from clones, their offspring and descendants in a food product).

The analysis finds that:

- All packages are technically feasible for EU production of clones if traceability systems are in place, but for imported food products there are issues as to how compliance would be confirmed. There is a risk that the two packages covering food products from offspring and descendants of clones would not achieve their objectives as identification and traceability of these animals through the supply chain is difficult and subject to more errors in identification than for clones themselves (as discussed in section 8.3).
- The risk is influenced by the EU's evidential requirements. These are problems inherent to the traceability systems themselves rather than the labelling rules but - as labelling relies on effective traceability systems - any difficulties in applying effective traceability systems will reduce the credibility of the labelling.
- Where it is difficult or impossible to confirm that a food product contains clones, offspring or descendants (such as mixed meat and milk products) then it will be difficult to make defensible claims on labels about the status of the product.
- 'Positive' labelling is likely to prompt the industry to exclude labelled products that would be required to carry positive labels from the supply chain, given the negative perception of the cloning technique by consumers and supply chain operators' concern of negative responses by consumers to any labels referring to cloning. There are unlikely to be many such products in the supply chain despite any EU requirements put in place under this approach, unless consumer and supply chain attitudes change.
- A labelling approach that is voluntary (and 'negative') is likely to be appealing to some operators; a certification approach could be used in which sufficient documentary evidence would confirm that the *process* used involved sufficient effort by the supply chain to exclude these animals, even if the *product* is not verifiable.
- The feasibility of the approach would be influenced by the conditions under which food products would require mandatory labelling or could be subject to voluntary labelling and the evidential and administrative requirements specified for using the label.

Table 9.2 Feasibility summary

Package	Commentary on feasibility
Package L-A Labelling for food products derived from clones *[Feasibility of measure L1]*	Determined by sophistication / reliability of public / private traceability systems in place. Analysis suggests segregated supply chain would develop for supply of products derived from animal clones which would simplify source traceability. Clones are typically used for breeding and not for food production therefore the likelihood of use of labels for clones themselves is very low. There is also an issue of whether the labelling requirement applies to food products that are exclusively derived from clones (e.g. a cut of meat) or would also apply to ingredients and, if also applying to ingredients, whether there are any limits to the legislation's application. For example, would the labelling requirement apply to food products where the clone-derived ingredient is less than 1% of the total product?
Package L-B Labelling for food products derived from clones and clone offspring *[Feasibility of measure L2 when applied in addition to Package L-A]*	The analysis for L-A applies also to L-B, but labelling for offspring is less feasible than for clones because the traceability systems on which labelling would rely are less reliable. Clone offspring are much more likely than clones to be produced for food so the likelihood of use of labelling for products derived from clone offspring is higher than under L-A. The observations on thresholds (for ingredients) made above apply equally to L-B.
Package L-C Labelling for food products derived from clones, clone offspring and clone descendants *[Feasibility of measure L3 when applied in addition to Package L-B]*	The analysis for L-B applies also to L-C, but traceability systems are even less likely to be reliable than for clone descendants. Clone descendants are much more likely to be produced for food than clones or clone offspring, therefore the likelihood of use of labelling for clone descendants is higher than under package L-B. The observations on thresholds (for ingredients) made above apply equally to L-C.

9.4 Economic impacts of the labelling approach

This section assesses the impacts arising from a labelling approach to food products derived from clones, their offspring and descendants.

9.4.1 Compliance costs

Operators that need to adapt or redesign product labels in order to accommodate the new labelling requirements will incur additional costs.

The direct regulatory costs of a positive or negative labelling approach would be determined by the specific requirements of the approach. If the costs are limited to labelling redesign only, then these could be modest:

- The average cost at company level for a small label change has been estimated at €2,000-4,000.
- A full label redesign has been estimated at €7,000-9,000 (or €9,000-13,000 in total).

Most companies (~80 per cent) redesign their label every three years as a normal part of their business operation (EC 2008). Potential impacts of labelling changes on businesses can be reduced if the changes are incorporated into the 'label lifecycle'. For dynamic

products, the packaging / label lifecycle may be as little as 12 months; for other products, especially those that are well-established, it may be two to five years (and possibly longer).

A period of 18 months to two years for implementation of statutory changes has broadly been regarded as sufficient to reduce the directly-attributable cost burden, whilst also permitting any indirect consequences arising from the complexity of the product and its label design to be accommodated (Defra 2010).

Table 9.3 summarises the results of three studies assessing the costs of labelling redesign. They suggest a range of €100 to €13,000 per operator and product or product range, depending on the product and the extent of the modifications required (adjustments versus full redesign).

Table 9.3 Costs of labelling change/redesign

Source	Country	Costs
European Commission (2008) *Impact Assessment Report on General Food Labelling Issues*	EU	Average cost at company level for a small label change: €2,000-4,000 per stock keeping unit (SKU) Additional cost for full label redesign: €7000-9000.
Private Label Buyer[35] (2011) *Special Report — Labelling*	US	Cost of redesigning a small private label line of approximately 100 SKUs: $100-$3000 (€77 to €2320) in design fees. Photography and illustration costs could more than double total cost
Defra (2010) *Developing a Framework for Assessing the Costs of Labelling Changes in the UK*	UK	Average costs[36] of changing a label for a food manufacturer: ■ Voluntary redesign 4857 £/SKU (€6050) ■ Implementing of new legislation 2945 £/SKU (€3670) Average costs for country of origin labelling for meat – large company: £600 - £1,150 (€748 to €1433).

The impact of the labelling requirement would be determined in large part by the precise specification of the rules, for example, whether it covered all or only principal ingredients, and whether a prominent front-of-pack label was required or whether a discrete note in the ingredients would be adequate. If labelling requirements focused on the principal ingredient(s) and/or allowed discrete reference to the origin of the clone heritage of the product then the 'exclusion effect' might be less powerful.

A voluntary labelling scheme would involve some additional cost for both traceability and labelling. The scale of those costs would depend on how far 'official' traceability schemes reached down the supply chain and thus the size of the 'gap' that would need to be covered by private traceability measures, and whether requirements were built into the existing private standards applied by retailers or manufacturers to their own suppliers, or developed as an independent, third party scheme. The latter is likely to involve certification and inspection fees.

In a voluntary labelling system, these costs would be expected to be lower than the price premium gained from using the label in order for operators to choose a voluntary approach. Under a mandatory approach, these costs would not be expected to result in any premium for the operator, and are likely to be irretrievable.

[35] leading media brand for US private label retailers

[36] Including: proofs, printing plates, inks, printing technician time, management time, cost of stock write-offs.

Table 9.4 provides an indication of the certification costs to operators under the EU organic certification system. Since this is a well-developed system, the costs are likely to be lower for organic certification than for a 'clone-free' label (organic operators benefit from some economies of scale).

Table 9.4 Certification costs under organic labelling

Source	Country	Costs	Comments
Research Institute of Organic Agriculture (FiBL) (2012) *Report on total costs of three organic certification systems in six European countries with particular focus on organic supply chains*	CH,CZ, DE, DK, IT, UK	Annual business costs borne by food operators: ■ At farm level: – Inspection fee: €500 per farm – Opportunity costs (time required for information search, documentation and preparation for the control visit): €300 per farm ■ At processing level: – Inspection fee: from €477 to €1400 – Opportunity costs: from €484 to €2022	In some regions, farmers receive public subsidies that almost entirely cover the certification fees Total business costs for food processors represent from 0.06 per cent to 0.91 per cent of organic turnover Administrative costs[37] are borne by the standard owners (for example, European Commission), public bodies and control authorities and amount to €12 to €585 per organic operator.
Organic Research Centre (ORC) (2012) *Two exploratory case studies of alternative certification in the UK*	UK	Average organic certification fees for control bodies: €526	
The Soil Association (2012)	UK	Organic certification for food: ■ Application fee (cover the first year): £690 (€862) ■ Certification fee (including costs for inspection and all other services): from £690 to more than £6000 (€7497) depending on the volume of organic sales Fee for additional service of British Retail Consortium (BRC) audit and certification: £1,908 (€2383)	

9.4.2 Direct revenue impacts

The research evidence suggests that label indicating that a product is derived from, for instance, clone offspring is likely to prompt a negative reaction from at least some consumers. This may mean the supplier is pressured into reducing product prices and/or withdrawing the product, or reformulating it.

[37] Those include: labour costs (EU Commission staff as well as expert reimbursement) required for standard development, the EU expert and advisory groups as well as the Standing Committee of Organic Farming (SCOF) meetings of representatives of all Member States

9.4.3 Supply chain effects

A mandatory label is expected to be an additional factor reducing demand for livestock animals produced using the cloning technology and their introduction to the supply chain. It is likely result in retailers and manufacturers putting pressure on suppliers to exclude clones, their offspring and descendants from the supply chain. This will create additional costs on operators throughout the supply chain to take measures that ensure these animals are excluded.

A voluntary label may result in retailers and manufacturers passing the additional costs of certification to upstream operators, rather than to consumers through a higher sales price, especially in times of financial crisis where consumers are looking for ways to cut costs.

9.4.4 Trade-mediated effects

Mandatory or voluntary labels would also create an issue for importers of food products into the EU. If importers could not be sure of the clone status of imported products (due to lack of traceability systems, or fully segregated supply chains), they may lose access to key markets because their products would be rejected.

The traceability approach poses the risk of triggering significant trade-mediated impacts on the EU supply chain. These effects are considered in Chapter 8 and are not discussed further here because labelling is additional to traceability, and any effects triggered by the traceability approach would also appear where labelling is added.

In a scenario where businesses exporting to the EU from a third country are able to identify food products as being derived from the offspring or descendants of clones and satisfy the EU's import conditions for traceability, a compulsory product labelling scheme might drive EU buyers to seek alternative supplies. This would result in changes in the distribution of demand across the supply chain.

9.5 Social (employment) impacts

The employment impacts of labelling need to be considered independently of the employment impacts of traceability system on which the labelling scheme is based. These are discussed in Chapter 8. The research suggests few products would be brought to the market with labels indicating that the product contains clones, clone offspring or clone descendants. Additional employment impacts are likely to be very small.

In the (unlikely) scenario where businesses exporting to the EU from a third country were able to identify food products as being derived from the offspring or descendants of clones and satisfy the EU's import conditions for traceability, a compulsory product labelling scheme might drive EU buyers to seek alternative supplies. This could result in changes in the distribution of employment in the supply chain. Strong global demand for meat and other food products mitigates the risk that suppliers in third countries could not find alternative outlets for their production.

9.6 Other impacts

No significant consumer, SME or competitiveness impacts are anticipated over and above those seen under the traceability approach.

10 Approach appraisal: premarket approval

10.1 Introduction

This chapter examines the feasibility and impacts of applying a premarket approval (PMA) requirement in addition to traceability for: food products derived from clones, clone offspring and their descendants. It is assumed that the requirement for premarket approval would be introduced through new EU legislation or revision of the Novel Food Regulation (Regulation (EC) 258/97).

The analysis considers the premarket approval measures as requirements that would be applied in *addition* to traceability (the traceability appraisal is detailed in Chapter 8). And as with the other approaches considered in this study, the measures set out in the premarket approval approach are also additive—covering food derived from clones first, and then also food products derived from clone offspring and finally, food products derived from clone descendants. The assessment has therefore considered different combinations of measures that provide coherent 'packages' of intervention.

10.2 Definition of the premarket approval packages

The premarket approval measures considered in this appraisal are listed in Table 10.1.

Table 10.1 Premarket approval measures

	Measure description
P1	Premarket approval + traceability of food products derived from clones
P2	Premarket approval + traceability of food products derived from the offspring of clones
P3	Premarket approval + traceability of food products derived from the descendants of clones

Measure P1 (PMA + traceability of food products derived from clones) is viable on its own, but P2 and P3 are additive to P1 and have been combined into a set of internally coherent packages, labelled P-A to P-C, as described by Figure 10.1. The text here considers only the impacts that are additional to those identified in the traceability approach.

The packages are described in more detail in Annex 7. They vary in scope from covering only the premarket approval of food products derived from clones through to premarket approval of food products derived from clones, their offspring and their descendants.

10.3 Feasibility assessment

This section provides a classification of, and commentary on, the technical feasibility of the premarket approval approach, including the likelihood that the PMA procedure will be utilised by operators. It covers PMA on foods derived from clones, clone offspring and clone descendants. Premarket approval applications could be submitted by operators in the EU or in third countries (with regard to food being exported to the EU).

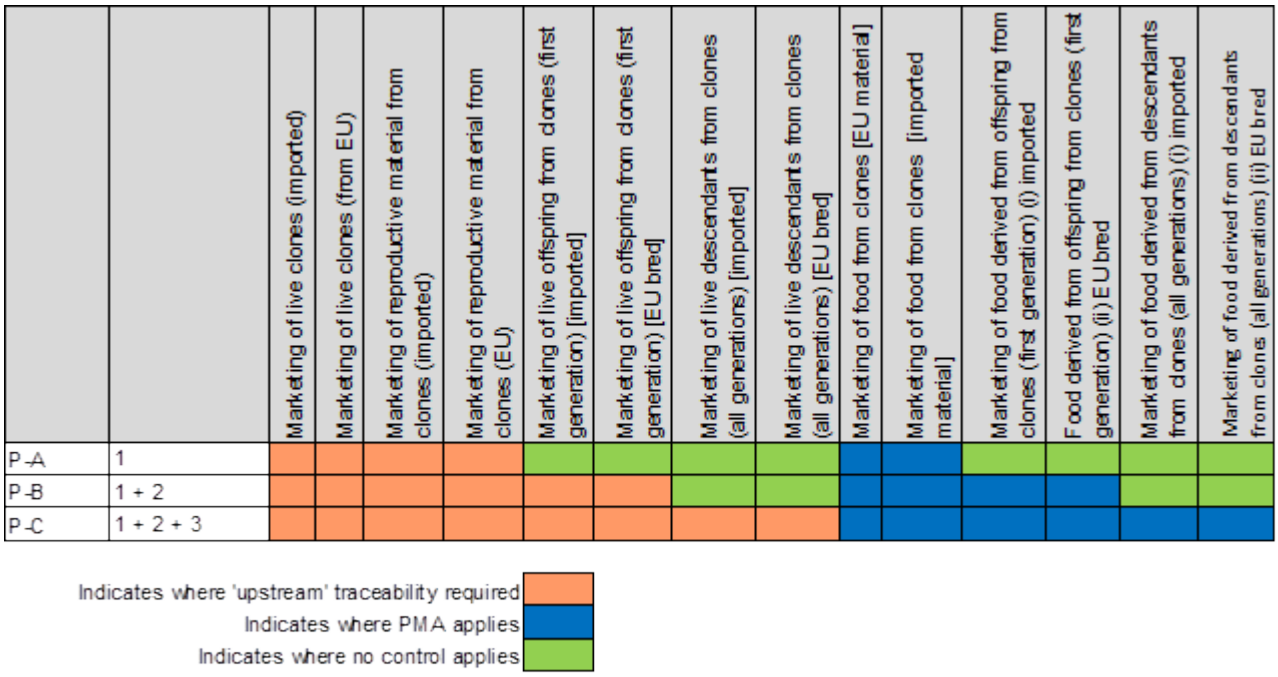
All of the PMA measures are feasible where underpinning traceability systems can be provided. As noted in the chapter on traceability, there are certain challenges in extending traceability into food products. The traceability system underlying PMA for products derived from descendants of clones will be more demanding than products derived from clones and offspring of clones due to the difficulty in recording animal heritage over multiple generations. PMA for products derived from descendants is less feasible than for clones, or for offspring of clones, because the underpinning traceability systems for descendants are less feasible.

It would be difficult for food importers and manufacturers to determine with confidence whether imported products were derived from animal clones, their offspring or descendants (and thus would trigger a PMA requirement) if matching traceability systems or segregated supply chains were not present in third countries. The risk is influenced by the EU's evidential requirements. Feasibility increases if the EU is prepared to recognise private

traceability systems in third countries and other systems and measures in place that record the movements of clones, their offspring and descendants.

These are problems inherent to the traceability systems, themselves, rather than PMA, but as PMA relies on effective traceability systems, any difficulties in applying effective traceability systems will equally reduce the effectiveness of the PMA process as well.

Figure 10.1 Representation of the scope of the premarket approval packages P-A to P-C



The PMA requirement has further implications for trade. If exporters were not able to demonstrate to the satisfaction of the EU that their products were not derived from clone offspring or clone descendants then they would need to apply for PMA. This would result in a disruption to existing trade patterns as applications were processed. The disruption would be more significant if the PMA was assigned on a specific product basis (e.g. specific cut, specific country or producer) rather than on a generic basis (e.g. bovine meat, ovine milk). The more demanding (and expensive) the EU's evidence requirements for PMA the less likely it is that exporters will invest in approval.

Consultation with industry suggests that applications are unlikely to be submitted in the period from 2012-2020 even where identification and traceability systems are possible given:

- The low to non-existent levels of cloning in the EU;
- Lack of interest in use of the technique by operators due to lack of consumer acceptance of the technique; and
- The fact that clones are currently too expensive to be produced for food purposes (they are used for breeding).

Table 10.2 Feasibility summary

Package	Commentary on feasibility
Package P-A Premarket approval for food products derived from clones *[Feasibility of measure P1]*	Determined by sophistication / reliability of public / private traceability systems in place. Analysis suggests segregated supply chain would develop for supply of products derived from animal clones which would simplify source traceability. Clones are typically used for breeding and not for food production, both in the EU and third countries, and therefore the likelihood of use of PMA for clones themselves (domestic production and imports) is very low.
Package P-B Premarket approval for food products derived from clones and clone offspring *[Feasibility of measure P2 when applied in addition to Package P-A]*	The analysis for P-A applies also to P-B, but PMA for descendants is less feasible than for clones or for offspring of clones because the traceability systems on which PMA would rely are less reliable. Clone offspring are much more likely to be produced for food than clones themselves, both in the EU and third countries, and therefore the likelihood of use of PMA for clone offspring (domestic production and imports) is higher than under package P-A.
Package P-C Premarket approval for food products derived from clones, clone offspring and clone descendants *[Feasibility of measure P3 when applied in addition to Package P-B]*	The analysis for P-B applies also to P-C, but traceability systems are even less likely to be reliable than for clone offspring, which means that the enabling conditions required for a market containing products devoid of clone descendants and PMA-approved products with such content are not in place. Clone descendants are much more likely to be produced for food than clones or clone offspring, both in the EU and third countries, and therefore the likelihood of use of PMA for clone descendants (domestic production and imports) is higher than under package P-B.

10.3.2 Specification of the premarket approval system

The first challenge is to determine what is to be approved. It is assumed that the legislation would specify that premarket approval is required for specific food products (e.g. a cheese made wholly or partially from milk produced by clone offspring) and for ingredients destined for use in food products. Applications would be made by whoever is placing the product on the market or selling it with that objective – for example, the manufacturer, the importer, the third country producer or the exporter.. There are two main types of PMA procedure that may be applied:

- A product-specific PMA, which requires each operator that wishes to place on the market a product derived from clones, clone offspring and/or clone descendants to obtain an approval.
- A 'generic' PMA which requires an initial application by a specific operator that wishes to place on the market a product derived from clones, clone offspring and/or clone descendants, but once the generic authorisation has been granted, all other operators may place the same product on the market without an additional approval. Once granted, the regulator decides whether products that meet the generic authorisation requirements also require a label.

  The implication of a generic approval model is that all derived ingredients would be covered by the PMA awarded to the generic product. Thus, for instance, approval for bovine milk would provide approval for cheese, yoghurt, caseins, dried milk powder and other derived products.

It is assumed that the generic PMA would be defined on a species by species basis. A decision would be needed on whether the PMAs were restricted to species covered by EFSA Opinions.

The approval process would operate in the context of EFSA Opinions on the safety of products derived from clones and their offspring and descendants. Looking at evidence on cattle and pigs, EFSA has found no indication that differences exist in terms of food safety for meat and milk of clones and their progeny compared with those from conventionally bred animals. This conclusion is based on the assumption that meat and milk are derived from healthy animals which are subject to relevant food safety regulations and controls. The EFSA Opinions cover all products derived from the given species, and are not specific to individual clones or to specific food products derived from clones.

Current evidence suggests that there is nothing genetically or chemically distinctive about clones, clone offspring or descendants, or the derived products. Given the EFSA Opinions, the 'added value', from a risk management perspective, of premarket approval for these food products would need to be explained. Potential justifications for premarket approval could include:

Provision of administrative data on products containing products derived from animal clones, their offspring or descendants for use if the scientific advice on safety changed; or

Provision of a mechanism for the collection and assessment of additional data on the safety of food products derived from clones, clone offspring and clone descendants.

The evidential and administrative requirements for product approval would need to be specified in the legislation. For the purposes of this study (and without prejudice to future choices) the following hypothetical options have been considered:

- Administrative information only, for example, information that specifies the product, the ingredient(s) that are derived from animal clones, their offspring or descendants, the source of those ingredients and the traceability arrangements in place;
- Administrative information (as above) plus results of toxicological tests; and
- Administrative information, toxicological tests, plus more comprehensive safety tests.

The 2008 EFSA Opinion noted that as food animals other than cattle and pigs have also been produced *via* SCNT, risk assessments should be performed on these species when relevant data become available. The legislation could specify that results from more comprehensive tests would be required for products derived from species not already covered by EFSA Opinions.

The approval process would need to be defined. Aspects to be determined include:

- The identity of the applicant;
- The institution receiving the application;
- The institution assessing safety evidence (where applicable); and
- The final decision-making entity and the associated decision criteria.

There are various pre-existing models for such processes already in use in the EU. It is assumed that the approval is for placing the product on the EU market as a whole. A purely administrative process could be handled most simply by a designated EU institution.

For specific and generic product approvals, the scope would need to be defined. It might be relatively broad (e.g. covering all meat products, all dairy products) or narrower.

10.4 Economic impacts of the premarket approval approach

This section assesses the impacts arising from a requirement for premarket approval.

10.4.1 Summary

No applications have yet been submitted for cloned animals for food production under the Novel Food Regulation. Consultation with industry suggests that none are likely before 2020 given the low to non-existent levels of cloning in the EU at present and lack of interest in use of the technique by operators due to lack of consumer acceptance of the technique. Moreover, the challenges for operators to identify food products containing clone offspring and descendants greatly reduces the feasibility of a PMA procedure for food products derived from these animals. Therefore, there are unlikely to be any direct (or indirect) impacts from the premarket approval requirement. This section examines the issues arising and the potential scale of costs if approvals were requested.

The expected costs to industry of approvals are less than €30,000 per product for a purely administrative approval mechanism. Toxicological tests are unlikely to be required, but if these were required the costs could be more than €300,000 for testing and detailed risk assessment.

The designated authority would incur costs to establish the prescribed approval system, even if it was not used.

The PMA requirement would be expected to drive the establishment of segregated supply chains for animals that fell within scope of the package adopted (though little or no such domestic supply is expected before 2020). Meat and other products from such animals could not be sold except as products or product ingredients that had PMA approval.

There are risks of trade-mediated impacts on the food supply chain arising from suppliers in third countries being unable or unwilling to meet the terms of the EU's traceability requirements. These are assessed in chapter 8 on traceability (which would be applied in addition to the PMA requirement).

10.4.2 Compliance costs

The direct regulatory costs of a requirement for premarket approval would be determined by the application requirements. If the application requirements are limited to administrative information only the costs would be modest. Costs per product rise rapidly if the requirements extend into toxicological and other testing.

Consultations suggest that direct regulatory costs to operators for a premarket approval of current Tier 1 applications under the Novel Food Regulation are on the order of:

- Up to €50,000 for submission (elaboration of the application dossier and following the administrative procedures); and
- €250,000 for toxicology testing (if this were required).

The €50,000 submission figure comprises €30,000 in administrative costs to prepare an application dossier and to follow the administrative procedure, which takes from two to five years, and €20,000 in costs to answer questions from the authority about the application. Administrative costs for premarket approval of a product derived from animal clones, their offspring or descendants should be much lower than €50,000 if the application and approval process is purely administrative. Under the generic authorisation approach to PMA, costs would be incurred only for the first product approved Products with a generic authorisation may then be placed on the market by any business following the first approval without additional approval.

Applicants might also be required to pay a processing fee. Under similar existing systems the costs per application are estimated to range from €5,000 – €25,000, depending on the Member State. EFSA does not currently charge fees, but this is expected to change in the future.

It is thus assumed that costs would be:

- Less than €30,000 for the first product to seek approval only, where generic authorisations are possible and for a purely administrative process (including documentation of supply chain traceability arrangements), plus agency processing fees.

All subsequent products that fall under the generic authorisation would not require any approval.

- Less than €30,000 per product where individual approval is required for a purely administrative process (including documentation of supply chain traceability arrangements), plus agency processing fees;
- Up to €300,000 per product for a process requiring toxicological testing, plus agency processing fees (although toxicological testing is unlikely to be required by EFSA); and
- Above €300,000 per product for a process requiring more than toxicological testing (also unlikely to be required by EFSA).

Demand for premarket approvals is expected to be negligible in the period to 2020 on the basis that the EU supply chain is expected to avoid bringing cloning-related products to market. The expected direct regulatory costs are therefore low, though some businesses may incur 'learning costs' as they seek to understand the new legislative requirements.

The designated authority or authorities would incur costs defining and establishing the premarket approval application and decision-making system, preparing industry guidance, training staff and communicating the requirements. This expenditure would need to happen to provide the EU with the capacity to implement the legislation, even if it was then found that there was no market demand for the service.

10.4.3 Supply chain effects

If the content thresholds for premarket approval set by the legislation are low, the requirement would mean that the meat and other products derived from clones, clone offspring and clone descendants could only be marketed in products that have received premarket approval. The meat and other products could not be sold on the general market. Any business producing and marketing meat and other products from animal clones, their offspring or descendants would, in effect, need to set up a segregated supply chain that resulted in 'approved' products. This issue would be eliminated where generic authorisations were possible. Traceability systems underlying the PMA approach would need to allow food products to be identified as derived from clones, offspring or descendants, but this would not be a specific requirement subsequent to a generic premarket approval. The labelling approach (chapter 9) is also available if the regulator required these food products to be identifiable to consumers.

Given the information available on consumer demand and market attitudes to cloning in the EU, the requirement for premarket approval is considered to be an additional factor reducing demand for animal clones, their offspring or descendants.

10.4.4 Trade-mediated effects

The PMA requirement would create issues for FBOs importing meat and other products into the EU. If importers could not be sure (due to lack of traceability systems, or fully segregated supply chains) that imported meat and other products were not free of animal clones, their offspring or descendants then they would not be able to use them in products placed on the EU market. As with the other approaches, the PMA requirement would therefore pose the risk of triggering disruptions to imports of meat and other animal products from third countries. Trade disruptions may be as significant as those detailed under the suspension approach (chapter 7, section 7.6.3.2). This problem could be reduced where generic authorisations are possible but, even under a generic system, the issue would remain until such time as the first authorisation was granted. The system could provide for a transitional period for PMA that allowed food products that may be derived from clone offspring and descendants to continue to enter the market (if they are already) without approval. A two-year period is likely to be the transitional period required, as the first approval may take as long as two years to be granted.

The traceability approach, as discussed in chapter 8, poses the risk of triggering significant trade-mediated impacts on the EU food supply chain. These effects are not considered further here because the PMA requirement is assumed to apply in addition to the traceability

approach and to attribute trade impacts to the PMA requirement other than those described above would constitute double-counting.

10.5 Social (employment) impacts

The PMA requirement is not expected to have measurable employment impacts if applied in addition to a traceability approach with the same scope. The expected trade-mediated impacts would be attributable to the traceability approach rather than the PMA requirement. Research suggests that demand for approvals would be low to zero. The PMA requirement would be an additional driver for the exclusion of animal clones, their offspring or descendants from the supply chain by operators.

10.6 Other impacts

No significant consumer, SME or competitiveness impacts are anticipated over and above those seen under the traceability approach.

11 Environmental impacts

11.1 Impacts on genetic diversity

11.1.1 The genetic diversity of livestock used for food production has been declining

The genetic diversity of domesticated animal food species has been declining over time. For example more than 7,600 breeds were listed in the FAO's Global Databank for Animal Farm Genetic Resources 15 years ago but 190 have now disappeared. Since 2002, at least 60 breeds of cattle, goats, horses, pigs and poultry have become extinct (FAO 2007).

Loss of genetic diversity is often irreversible. When a breed disappears, the unique adaptive attributes held in its genetic resources are lost forever (FAO 2007). Moreover, breeding programmes that rely on only a few species increases the susceptibility of an animal population to risk factors such as infection by diseases, climate change, and other factors (EFSA 2008).

Commercial breeders tend to focus on a few specialised breeds in order to maximise their output and increase their profitability in the short term. For example, more than one third of the global pig supply is produced from a few commercial breeds. In the dairy industry high-output dairy cattle breeds like the Holstein account for 75 per cent of the world's milk supply (FAO 2007).

The development of assisted reproductive technologies has facilitated further productivity improvements but at the expense of a narrower genetic base (Bulfield 2000). Artificial insemination is thought to contribute to the loss of livestock genetic resources by enabling herds to be maintained from a smaller number of 'high quality' breeding stock (Basrur & King 2005).

11.1.2 Cloning's net impact on genetic diversity depends on how it is deployed

Cloning is a technique that can be used to replicate animals. Its impact on genetic resources depends on how it is used. It could contribute to the loss in animal genetic diversity and be used to maintain genetic resources.

Commercial use of cloning to duplicate elite breeding animals would be expected to further narrow the top of the breeding pyramid of animals - reducing the number of animals used in breeding programmes and contributing to the further loss of genetic diversity (EFSA 2008). Conversely, cloning can be used to replicate rare indigenous breeds of livestock (Wells et al. 1998) or individual animals within a breed which possess unique characteristics (Westhusin et al. 2007) and therefore help to maintain distinct genetic attributes without the mixing effects associated with convention reproduction.

11.1.3 The evidence on uptake of cloning suggests that there will be no measurable impacts on genetic resources in the EU in the period up to 2020

The evidence gathered for this study suggests that the food chain expect little or no uptake of cloning on a commercial basis before 2020. Use of the technique is restricted to a very small number of animals and is concentrated in a single species (bovine animals). Use of the technique is not expected to be widespread enough to 2020 to have a measurable impact on genetic diversity. The EU's 'exposure' to the impacts of cloning over that period are likely to be indirect, mediated though use by operators in the EU of genetic materials brought in from North America.

11.1.4 The policy packages could change genetic diversity in the EU livestock population by reducing access to genetics from elsewhere in the world

The policy packages tested in this study have the potential to change genetic diversity in the EU through changing the EU breeding sector's access to genetics from elsewhere in the world. If, in extremis, trade in reproductive materials ceased then EU breeders in the dairy sector and elsewhere would need to develop alternative strategies for the same breeds or

turn to other breeds. The EU would, in functional terms, be cut off from access to the global 'pool' of genetic resources.

11.2 Animal welfare

The evidence gathered on the animal welfare issues associated with cloning suggests that the negative welfare impacts are highest for the cloning process and decline rapidly thereafter – with no evidence that clone descendants suffer additional welfare problems. The incremental animal welfare benefits are thus highest for the measures and packages that focus only on cloning (measure S1, package S-A; measure T1, package T-A).

As the scope of the packages increases to cover offspring, descendants and food, the additional animal welfare benefits decline while the additional economic impacts, and risks, increase.

11.3 Food safety

Food safety regulators have judged foods derived from clones of particular species to be safe. On this basis the packages would not have direct food safety impacts.

12 Synthesis

In this summary chapter, the feasibility and impacts of the four approaches are considered comparatively and progressively through the supply chain, from packages that focus on live animals and their reproductive materials through to food products.

12.1 Feasibility

The feasibility assessment considers the issues involved in the construction and operation of systems that could be developed to deliver on each of the four approaches. It focuses on technical feasibility, that is, whether a compliant system can be constructed, as well as the strengths and weaknesses of each package of measures.

12.1.1 Feasibility of packages focused on live clones

The suspension of the cloning technique in the EU and marketing of clones (S-A) and traceability of live clones by adapting existing traceability systems (T-A, Strategy 1) are feasible without significant adjustment to existing EU (or third country) systems.

Domestic cloning would therefore be relatively easy for competent authorities to regulate. Few companies are capable of carrying out cloning and clones are high-cost animals that would be used for breeding purposes. They are highly identifiable since operators breeding from high-value animals tend to keep detailed records for future breeding purposes.

Imports are more problematic, but there are a small number of animals to control. Imported live animals can be controlled relatively easily through risk-based surveillance of trade focusing on the main sources of food production animals with the highest levels of cloning activity.

12.1.2 Feasibility of packages focused on reproductive materials from clones

The production of reproductive materials is already a highly regulated industry in the EU and in the third countries from which the EU sources imported materials. Individual identification and traceability is already enabled in the EU for all semen and embryos.

There is no known EU domestic production of clone reproductive materials for bovine, porcine, ovine or caprine animals. Private sector agreements also already identify cloned reproductive materials from bovine and equine animals originating in the US and Canada. There is no known trade in reproductive materials from clones of the other species. Reproductive materials produced from clones are high-value and their traceability as being clone-derived is important to maintaining that value.

The following packages are therefore feasible without significant adjustment to existing EU (or third country) systems:

- Suspension of the marketing of reproductive materials from clones (S-B); and
- Traceability of reproductive materials from clones under all traceability strategies (T-B).

12.1.3 Feasibility of packages focused on live animals – offspring and descendants

Domestically produced offspring are identifiable due to agreements with North American operators to identify reproductive materials from clones. The offspring produced from these reproductive materials are most likely to be high-value breeding animals and therefore records will be kept of the animals' parentage.

Identifying domestically produced descendants will be complicated by the record keeping required. Particularly as descendants become part of multiplication herds (rather than being kept for selective breeding), parentage information may not be fully reliable due to mixing of animals on farm. Incentives may not encourage compliance, especially if operating the system entails additional cost and identification of animals as clone descendants has an impact on market values.

Few live animals are imported into the EU and those that are imported are generally 'high value' animals whose heritage would be documented. Offspring of clones will be relatively easy to identify since parentage records are kept for these high-value animals for at least the previous generation. Identifying clone descendants is much more complicated than for clone offspring because current systems in third countries do not require traceability of clone offspring or descendants and third countries are unlikely to make this a new requirement. Assuming that the EU requires documentary evidence at the point of import, this package would therefore require countries exporting to the EU to establish new systems that identify each clone offspring and descendant. These systems would need to incorporate trade in animals and reproductive materials amongst third countries to be comprehensive.

Pedigree status of reproductive materials would be needed but this kind of documentation is not currently required. Systems in place in North America to identify clone reproductive materials do not extend to reproductive materials from clone offspring or descendants. Additional steps would need to be taken by operators to identify these reproductive materials.

'Legacy' presence of clone offspring and descendants in the EU is a potential problem and source of additional regulatory costs for suspension and traceability packages covering descendants because identifying all such animals could be difficult and expensive. A decision would be needed on how to treat these animals, for example, through accepting a low level legacy presence of clone offspring and descendants in the food chain and focusing efforts on excluding new sources.

The following packages are thus feasible, but would require considerably more adjustment to existing systems than for clones themselves:

- Suspension of the marketing of clone offspring (S-C) and descendants (S-D);
- Traceability of clone offspring (T-C, Strategy 1) and descendants (T-D, Strategy 1).

These packages are more vulnerable to fraud than those covering clones themselves and clone reproductive materials; third countries are unlikely to change their traceability systems to ensure that imports of live animals into the EU conform to EU requirements. Together, these issues put packages related to clone offspring and descendants at risk of not meeting their objectives.

12.1.4 Feasibility of packages that require identification of the status of all animals or batches of animals/reproductive materials

Traceability approaches that require identification of the status of all animals or batches of animals will require adjustment to all existing traceability systems to enable an indication to be provided as to whether or not the animal is a clone, clone offspring or descendant, or batch of animals contains animals that are clones, clone offspring or descendants. At present, this should be straightforward for porcine, ovine and caprine animals, since cloning activity for these species is very limited. Bovine animals are more complicated because offspring and descendants may be produced in the EU. There is also an issue of 'legacy' bovine offspring and descendants in the EU at present.

Traceability approaches that require individual animal identification and traceability will require significant adjustments to existing traceability systems and may require new systems where existing systems cannot cope with identifying the number of new animals that require traceability. Third countries are unlikely to implement new traceability systems for these species without recognised human health or safety risks

Packages covering traceability of clone offspring (T-C, Strategy 1 – ID all animals or batches and Strategy 2) and descendants (T-D, Strategy 1 - ID all animals or batches and Strategy 2) are technically feasible, but would require major changes to the systems for some species and where there is likely to be little, if any, cloning activity.

12.1.5 Feasibility of packages focused on food products

The greatest challenge to feasibility of approaches related to food products arises from imports; confirmation of the status of these food products would depend on traditional documentary methods used in supply chain traceability systems. This kind of documentation is not currently required for imported food products. International trade in reproductive materials will make it difficult to be certain that the animals, and thus food products, from a country that does not use the cloning technique were not actually derived from reproductive materials from clones, their offspring or descendants obtained in another country.

Suspending the marketing of food products derived from clones (S-E) is the most feasible of the packages evaluated. The number of potential EU suppliers is small. Proportionate systems for suspension of clone imports are also technically feasible through working with trading partners. The risk of clones being used systematically for food in the next few years is low as clones are uncommon and very valuable and so are more likely to enter the food chain at the end of their working lives as breeding animals.

Nonetheless, demonstrating and documenting that foods are free of clones would require systems that do not currently exist. Third countries that export to the EU would require appropriate traceability systems or segregated supply chains. Verification of claims would not be possible. Moreover, enforcing the suspension of use of clones in imported food products is a significant challenge due to the high volume of EU meat product imports, especially from bovine animals.

Constructing a system that can exclude clone offspring (S-F) and descendants (S-G) is less feasible than for clones themselves. Trading partners would need to either identify and trace all clone offspring as live animals and then trace them through the food chain to demonstrate that exports to the EU did not contain products derived from clone offspring, or to establish fully segregated 'clone-free' supply chains. The feasibility of the system for all animals would depend on the specification of the evidential requirements applied to imports under the EU legislation.

Traceability packages (T-E, T-F, T-G) face the same challenges as suspension packages for food products derived from clones, their offspring and descendants – identification and traceability beyond clones themselves is difficult, if not impossible, without completely segregated supply chains. Trading partners will need to adapt their traceability systems, and are unlikely to do so.

12.1.6 Feasibility of labelling and premarket approvals for food products derived from clones, their offspring and descendants.

Labelling and premarket approval approaches for food products derived from clones (L-A, P-A), their offspring (L-B, P-B) and descendants (L-C, P-C) are feasible only to the extent to which the underlying traceability systems are feasible. The limitations of traceability described above are thus also present for labelling and premarket approvals. Where it is difficult or impossible to confirm that a food product contains clones, their offspring or descendants (e.g. mixed meat products), then it will be difficult to label these products, for example, and there are likely to be more errors in identification.

A labelling approach that requires 'positive' labelling is likely to prompt the industry to exclude from the supply chain the products that would be required to carry the label. This is due to the negative perception of the cloning technique by consumers and supply chain operators' concern about negative responses of consumers to any label referring to cloning.

A labelling approach that is voluntary (and 'negative') is likely to be appealing to some operators. A certification approach could be used in which sufficient documentary evidence would confirm that the process used involved sufficient effort by the supply chain to exclude these animals, even if the product is not verifiable.

Even so, there is a risk that the two labelling packages covering food products from clone offspring (L-B) and descendants (L-C) would not achieve their objectives because of difficulties in confirming the claims made for imported food products derived from offspring and descendants.

There is also an issue of whether the labelling or premarket approval requirement applies to food products that are exclusively derived from clones (e.g. a cut of meat) or would also apply to ingredients, and if also applying to ingredients, whether there are any limits to the legislation's application. For example, the requirement could apply to food products where the clone-derived ingredient represents only a small percentage of the total product.

12.2 Impacts

Due to the low to non-existent levels of cloning activity in the EU at present and expectation that this activity will remain low to non-existent to 2020, virtually all of the impacts arising from the proposed approaches assessed in this study will arise from the development of systems to control activities and products that are not present in the supply chain, or in the case of bovine animals, present at extremely low levels.

Labelling requirements are likely to be an additional factor reducing demand for livestock animals produced from the use of cloning technology and their introduction into the supply chain. Mandatory 'positive' labelling is likely to result in downward pressure on upstream operators by retailers and manufacturers to exclude clones, their offspring and descendants from the supply chain. Operators will face additional costs to take measure to exclude these animals.

12.2.1 Direct administrative burdens

The direct administrative burdens on EU operators are expected to vary significantly depending on the approach taken, the information requirements of the approach and the compliance, reporting and enforcement strategy of competent authorities. An indication of the types and scale of expected costs is provided below.

12.2.1.1 'Learning costs' and 'compliance reporting, inspection and enforcement costs'

The suspension and traceability (and thus under the labelling and premarket approval) approaches will trigger:

- One-time 'learning costs' as directly affected operators familiarise themselves with the new legal requirements; and
- On-going 'compliance reporting, inspection and enforcement costs' which involve, for example, operator responses to requests for information (i.e. reporting) and/or inspections from CAs.

Estimates of these provide only an general indication of the scale of the costs that might be involved since the CA's approach to regulation will determine the precise burdens on operators. For example, if CAs take a risk-based approach that focuses on EU organisations capable of conducting cloning and targeted checks on imports, then regulatory costs can be contained. If CAs attempt to implement a comprehensive monitoring and reporting framework, then the costs will be far higher. In all cases, the costs increase as the packages involve more of the supply chain, and particularly for those that cover food products. Nonetheless, some general conclusions can be drawn from the impact assessment regarding the 'learning' and 'reporting' costs that are likely to be imposed on operators. Learning costs may vary as follows:

- Learning costs under the suspension and traceability (Strategy 1) approaches are likely to be modest where packages focus on upstream operators—estimated at less than a €100,000 for packages S-A and T-A due to the small number of directly affected operators, and approximately one million euro for packages S-B to S-D and T-B to T-D, with most of the costs under these packages borne by the AI industry where there are the largest number of upstream operators.
- Learning costs increase significantly where packages include regulation of food products: under the suspension packages (S-E to S-G), meat food importers will also be directly affected, increasing costs by more than five million euro. Under traceability packages (T-E to T-G) costs could increase by approximately 200 million euro in administrative burdens under each package where other downstream operators in the

EU (slaughterhouses, markets, food importers, processors, manufacturers, wholesalers, and retailers) must also learn about the new requirements.

- Learning costs for breeders/holdings can vary from relatively modest (a couple of million euro) where packages focus only on identification and traceability of clones themselves to hundreds of millions of euro where all holdings must learn about new requirements related to traceability under Strategy 1 if all animals/batches of animals must be identified as a clone (or not) and under Strategy 2 if all individual animals must be identified and traced. This is because the scope of the regulation changes from focusing only on those operators handling animals that may be clones, offspring or descendants to all operators raising livestock animals in the EU. Even if each of these operators only needs a minimal amount of time to learn about the new requirements, there are nearly eight million operators that may be directly affected under these scenarios.

Reporting costs are more difficult to estimate because they can vary significantly based on the CA's approach. Nevertheless, the scope and scale of these costs will follow a similar pattern to those estimated for 'learning':

- Annual reporting burdens under the suspension and traceability (Strategy 1) approaches will be modest where packages focus on upstream operators—estimated at approximately €15,000 per year for packages focusing upstream in the supply chain (S-A to S-D and T-A to T-D).
- Annual reporting burdens will grow to approximately 35 million euro under traceability packages T-E to T-G that encompass operators downstream in the supply chain to cover food products.
- Annual reporting burdens could be zero to negligible for breeders/holdings under traceability Strategy 1 where positive ID is required only for clones, their offspring and descendants to more than 100 million euro per year where all animals require identification.

12.2.1.2 'Operating costs' arising from additional traceability requirements

The traceability approach will impose additional operating costs on competent authorities, both on-going and one-off costs for changing paper-based documentary and IT based traceability systems that will be required to comply with the new rules. For Strategy 1 these changes could be made through minor adjustments to existing traceability systems. Strategy 2 would involve much more significant investments in databases and associated communication systems. Countries with large populations of porcine, ovine and caprine animals would need to have systems that could accommodate individual ID of all of these animals (potentially millions of additional animals). New systems may need to be built to record this information. The costs of adjusting or creating new systems under Strategy 2 would likely cost millions of euros in total across the EU.

There would also be additional operating expenses for the livestock sector to work to the new system in which individual animal ID and traceability is required (without derogation). This includes the costs of acquiring and maintaining equipment and increased administrative burdens.

12.2.1.3 Other compliance costs

The labelling and premarket approval approaches will impose costs on operators and competent authorities that are additional to the costs of the traceability systems underlying any labelling or PMA approaches adopted. These additional costs include:

- Regulatory costs for labelling: operators that need to adapt or redesign product labels in order to accommodate new labelling requirements will incur additional costs that are expected to range from as little as €100 to as much as €13,000 per stock keeping unit depending on the requirements. The incremental costs will be lower where changes can be integrated into the labelling 'lifecycle' and included during the regular 'refresh' of a product label.

- Regulatory costs for premarket approval: the expected costs to industry of approvals are less than €30,000 per product for a purely administrative approval mechanism. Toxicological tests are unlikely to be required, but if they were, the costs could be more than €300,000 for testing and detailed risk assessment. The designated authority will also incur costs to establish the approval system.

12.2.2 Trade-mediated effects

Trade-mediated effects may occur where exporters to the EU are unable or unwilling to comply with the terms of the suspension or traceability requirements. The scale of these impacts will vary depending on the scope of the legislation. The precise impacts will also depend on the behavioural responses by the EU supply chain and by actors in third countries. The analysis has considered trade and jobs 'at risk' rather than specifying definitive losses. The value of trades and the number of businesses at risk are set out in Table 12.1

Table 12.1 Summary of potential trade-mediated impacts arising from suspension and traceability approaches

Issue	Package	Number of businesses at risk	Value of trade at risk (€m/yr)	Significance of impacts if full cessation of trade
Cloning technique is unavailable in EU	All suspension packages (S-A to S-G)	LOW – no known food-related companies conducting cloning in the EU	**N/A**	LOW – potential limited impact to 2020 in the dairy sector
Imports of live animals cease	All suspension and traceability packages (S-A to S-G and T-A to T-G)	LOW - small numbers of live animals imported	LOW - 2.3	MEDIUM – small numbers of animals, but important to EU breeding sector
Imports of RM cease	S-B to S-G and T-B to T-G	MEDIUM – 120 companies may go out of business; 294 AI companies may be affected	MEDIUM - 14	MEDIUM - HIGH The EU breeding industry is heavily reliant on imported RM, esp. for bovine animals
Imports of food products cease	S-E to S-G and T-E to T-G	MEDIUM – 715 companies may go out of business; effects greatest for bovine, ovine and equine meat importers	HIGH - 3,667	LOW – caprine food imports MEDIUM – porcine, ovine and equine food imports HIGH – bovine food imports

Traceability arrangements required to implement a suspension approach or to ensure traceability in the EU pose risks of triggering significant trade-mediated effects on the EU food supply chain. These requirements add cost and complexity for operators exporting to the EU and for EU importers to check that requirements have been met. Under traceability Strategy 1, these include additional costs where third country operators cannot ensure traceability for supply chains where commercial cloning may have been involved. It will also add costs under Strategy 1 if all animals or batches of products require an indication as to their clone status. Under Strategy 2, requirements extending to individual identification and traceability of all animals will add significant costs to operators where they wish to and can comply. Evidential requirements under all scenarios are expected to be harder to meet, and therefore entail additional costs, related to offspring and descendants of clones because no third country traces these animals in the supply chain at present.

Premarket approvals could also create issues for importers of meat and other products into the EU if importers cannot be sure that imported products are free of animal clones, offspring and descendants because they will not be able to place them on the EU market. PMA requirements risk triggering trade disruptions to meat and other animal product imports. Generic authorisations could reduce the problem.

Even under a generic system issues remain until the first authorisation is granted Authorities could provide for a transitional period for PMA to allow food products that may be derived from clone offspring and descendants to continue to enter the market without approval until end of the transition period.

12.2.3 Impacts on competitiveness

In addition to direct economic impacts and indirect trade-related effects on EU and third country operators and competent authorities, there may be impacts arising from the proposed approaches related to competitiveness, including cost competitiveness, capacity to innovate and international competitiveness. These are each considered in turn below.

12.2.3.1 Cost competitiveness

Packages that extend beyond control of cloning are expected to have negative impacts on the cost competitiveness of EU businesses. It is not clear that EU controls on use of cloning would confer an advantage in export markets that would help to offset the additional costs. In the EU domestic market the negative impacts of the additional administrative burdens would be mitigated by an increase in demand for domestically production if access to imports was reduced.

The largest direct cost impact domestic producers is triggered by a requirement for individual animal traceability in the porcine and ovine/caprine sectors; many producers in those sectors already exist on low margins and it is unlikely that the incremental costs could be passed in full down the supply chain. Indirect effects may be greater than the direct effects, particularly where trade losses occur due to third countries not being able or willing to meet traceability requirements. If trades are halted, input costs could rise in the EU, for example, in the breeding sector.

Table 12.2 Cost competitiveness

Packages	Direct effects	Indirect effects
S-A, S-B, S-E & T-A, T-B, T-E	None as no commercial cloning expected in the EU in the baseline (business as usual) scenario	Some additional administrative costs to meet requirements Risk of loss of access to imports of live animals and RM which could raise input costs, if existing private schemes are not recognised and extended
S-C, S-D & T-C, T-D	Negative impacts on farmers and importers of animal genetics for bovine species Where all animals require ID, significant additional administration and equipment costs in porcine and ovine/caprine sector would cost competitiveness	Potential trade losses where third countries do not meet traceability requirements to allow importers to meet requirements of suspension or traceability approach in the EU –could raise input costs in the EU
S-F, S-G & T-F, T-G	increased compliance and reporting costs	Risk of widely distributed negative impacts due to loss of imports Some negative impacts may be offset if imports are restricted from third countries due to lack of compliance with traceability requirements and EU producers benefit from loss of competition

12.2.3.2 *Capacity to innovate*

The evidence collected for this study suggests that commercial cloning is unlikely to occur in the EU to 2020:

- The introduction of traceability requirements are not expected to alter this trajectory in the EU.
- Suspension measures, which prohibit access to and use of new technologies risk inhibiting the EU's capacity to innovate, though the short-term impacts of the approach on cloning research and innovation are expected to be small. Suspension could have longer and indirect effects on the allocation of innovation investments in industry and upstream research funding by signalling explicitly that market prospects for the technology are not positive in Europe. Businesses seeking to invest in developing this technology may decide to place their investments elsewhere.

The indirect (and uncertain) trade-mediated effects have the potential to immediately impact on innovation and thus productivity growth in the livestock sector in the EU, particularly for bovines. If trading partners cut off trade with the EU in live animals and reproductive materials, it would also affect Europe's access to high quality genetics in key breeds and thus the sector's ability to improve the quality of the EU breeding stock.

12.2.3.3 *International competitiveness*

The scale and direction of the net effect on the EU's international competitiveness from traceability and suspension approaches is uncertain. Impacts may include:

- Packages that interrupt imports could reduce domestic producers' exposure to competition in the EU market, which could improve their competiveness.
- Packages that result in lack of access to high quality genetic materials from third countries could negatively impact on competitiveness in price-sensitive export markets.
- Suspension, traceability, and labelling approaches that enable 'clone free' status for EU products, could have a positive impact on demand in third countries if this is seen as a premium attribute by consumers.
- Traceability packages under Strategy 2 could have negative impacts for porcine, ovine, caprine and equine animal industries due to significantly higher costs imposed on operators in industries that already have low profit margins.

Competitiveness impacts arising from the labelling and premarket approval approaches are expected to flow predominantly from the traceability systems underlying them.

12.2.4 Impacts on SMEs

The four approaches as specified do not provide an exclusion from the requirements for SME businesses. The food chain contains large numbers of SMEs, from the farming sector through to manufacturing and retail. All four approaches therefore have the potential to impact on SME growth. The impacts on SMEs are likely to vary depending on the approach and strategy chosen, as well as information requirements. Indicative likely impacts are described in Table 12.3.

Table 12.3 Expected scale, distribution and type of impacts on SMEs

Package	Sectors	Principal impacts expected	Comments	Significance
S-A & T-A	Live animal importers	Risk of loss of market in live animal imports	Aggregate value of trade is small Few businesses rely on trade in live animals to the EU, but important to those few businesses Animals are high-value and therefore likely to be traceable with modest effort	High for affected businesses Low overall
S-B	Importers of RM	Materials will need to be identified as derived from clones and excluded (S-B) from EU market	Existing system can and does already screen out clone RM where required	Low
T-B	Importers of RM	Materials will need to be identified as derived from clones and traced in EU market	Materials are already traceable and identifiable in major exporting countries as derived from a clone	Low
S-C, S-D & T-C, T-D	Importers of RM	Risk of loss of access to imported RM leads to loss of business for importers where exporters cannot or will not identify RM from clone offspring/ descendants	Existing 'screening' system does not extend to offspring and descendants of clones	High
	Breeders	Loss of access to high quality Holstein/other genetics would negatively affect breeding programmes	Some Member States are heavily dependent on AI and imported RM for breeding programmes	High in select MS Low in other MS
S-E, S-F, S-G & T-E, T-F, T-G	Food importers, processors, manufacturers, retailers etc.	Risk of loss of access to imported meat and dairy suppliers Import substitution from domestic supply should raise prices/profitability for EU suppliers	Higher input prices likely Some businesses rely entirely on imports	High/critical for businesses dependent on imports General negative impact from higher input prices

12.2.5 Social (employment) impacts

The expected 'direct' employment impacts arising from the suspension approach are expected to be negligible for all packages because few, if any, EU jobs are sustained by commercial livestock cloning. The principal employment impacts of the traceability approach are:

- Employment losses created by the additional administrative burdens place on livestock producers and other FBOs; and
- The risk to jobs in food import and associated EU supply chains created by requiring third countries to comply with traceability conditions that they may be unable or unwilling to meet.

Potential employment impacts arising from both approaches are expected to be greatest where they arise through induced and indirect legislative effects. Direct and indirect (trade-mediated) employment impacts of the suspension and traceability approaches, as well as labelling and premarket approvals are summarised in Table 12.4.

Table 12.4 Social (employment) impacts

	Direct impacts	Indirect (trade-mediated impacts)
Suspension	Negligible for all packages – few if any EU jobs sustained by commercial cloning in the food chain	Potential high negative impacts; suspension puts jobs at risk in businesses importing products and in downstream supply chains – impacts expected in the EU and third countries, especially for packages related to food products (S-E, S-F, S-G)
Traceability – Strategy 1	Negligible for live clones (T-A) and their reproductive materials (T-B) – few EU jobs sustained by commercial cloning; reproductive materials are already traceable and the status of the RM is easy to determine	May have negative impacts for domestic and third country operators for reproductive materials from clone offspring (T-C) and descendants (T-D) – third countries unlikely to implement required systems to enable traceability. Packages related to food products (T-E to T-G) could produce significant employment impacts in sectors currently sustaining thousands of jobs in the EU and third countries if traceability requirements results in a cut-off in trade of these products
Traceability – Strategy 2	Direct impacts for live bovine animals, and RM of all species (T-A, T-B) expected to be the same as under Strategy 1 EU jobs would be created for live porcine, ovine, caprine and equine animals to produce tags, equipment, computer systems for individual ID and to implement the systems (T-A, T-C, T-D)	Impacts for food products of all species (T-E to T-G) expected to be the same as under Strategy 1. Employment gains through expanded traceability for porcine, ovine, caprine and equine animals likely to be offset by employment losses caused by additional administrative burdens place on livestock sectors and supply chain.
Labelling	Few products likely to be brought to market under 'positive' labelling Voluntary labelling may result in creation of a small number of jobs in administration of requirements, inspections, etc.	[Impacts expected to be related to traceability, rather than labelling itself]
Premarket approval	No measurable employment impacts expected – demand for approvals likely to be zero	[Impacts expected to be related to traceability, rather than PMA itself]

12.2.6 Impacts on consumers

The suspension and traceability approaches could create impacts on consumers. These impacts include both price effects (i.e. price changes in consumer markets) and choice effects (i.e. changes in the availability of goods and services available to consumers). Short run impacts are likely to be highest for packages that include food products. This is primarily

due to potential for disruption to food imports which may limit the availability of certain products and may increase their price where they must be sourced from other trading partners or supplemented by domestic production. Traceability Strategy 2 may also increase the production costs for operators, and these costs may be passed to consumers, increasing costs to purchase these products.

Table 12.5 Potential consumer impacts

Package	Price effects	Choice effects
S-A, S-B & T-A, T-B (Strategy 1, positive ID only)	None expected	None expected
S-C, S-D & T-C, T-D (Strategy 1, positive ID only)	Price effects in dairy markets if dairy sector loses access to imported reproductive materials Marked short run effects may occur in MS with high dependence on imported RM and heavy use of AI Price effects in meat and meat products sector if meat production sector loses access to imported RM	Limited, except as a consequence of product scarcity
T-A, T-C, T-D (Strategy 1 and 2, ID all animals/batches)	Negative price effects if all animals must be identified	None expected
S-E to S-G and T-E to T-G (Strategy 1 and 2)	Price effects in dairy markets if imports of dairy products cease Potentially significant price effects in meat and meat products sector if imported meat products cease (primarily bovine, as well as ovine meats)	Product-specific and seasonal due to loss of access to specific brands/types of dairy product. Significant for bovine meat and meat products Significant for ovine and caprine meat products Limited for porcine and equine meat products

12.2.7 Environmental impacts

The evidence suggests that the negative welfare impacts are concentrated in the cloning process itself, with no evidence that clone descendants suffer additional welfare problems. The incremental animal welfare benefits are thus highest for the measures and packages that focus only on cloning (measure S1, package S-A; measure T1, package T-A). As the scope of the packages increases to cover offspring, descendants and food, the additional animal welfare benefits decline while the additional economic impacts, and risks, increase.