



Directorate-General for Agriculture
and Rural Development

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report

On

Plant Protection Products

The EGTOP adopted this technical advice at the 4th plenary meeting
of 14 and 15 December 2011

About the setting up of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and technologies in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission established the Expert Group for Technical Advice on Organic Production (EGTOP).

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and technologies which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

EGTOP Permanent Group

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The report of the Expert Group presents the views of the independent experts who are members of the Group. They do not necessarily reflect the views of the European Commission. The reports are published by the European Commission in their original language only, at the following webpage:

www.organic-farming.europa.eu

ACKNOWLEDGMENTS

Members of the Sub-group are acknowledged for their valuable contribution to this technical advice. The members are:

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With regard to their declared interests, the following members did not participate in the adoption of conclusions on the substances mentioned below:

Monique Jonis (kaolin, laminarin and sodium hypochlorite)
Bernhard Speiser (kaolin).

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All declarations of interest of Permanent Group and Sub-group members are available at the following webpage:

www.organic-farming.europa.eu

TABLE OF CONTENTS

| | |
|---|-----------|
| ACKNOWLEDGMENTS ----- | 3 |
| EXECUTIVE SUMMARY ----- | 5 |
| 1. BACKGROUND ----- | 6 |
| 2. TERMS OF REFERENCE ----- | 6 |
| 3. CONSIDERATIONS AND CONCLUSIONS ----- | 7 |
| 3.1 LAMINARIN----- | 7 |
| 3.2 KAOLIN / ALUMINIUM SILICATE ----- | 9 |
| 3.3 SHEEP FAT ----- | 11 |
| 3.4 SODIUM HYPOCHLORITE----- | 14 |
| 3.5 UV ----- | 17 |
| 3.6 OTHER ISSUES: HARMONIZATION WITH TRANSVERSAL LEGISLATION ----- | 20 |
| 3.7 OTHER ISSUES: PHASING OUT OF THE PYRETHROIDS DELTAMETHRIN AND LAMBDA-CYHALOTHRIN ----- | 23 |
| 3.8 TEMPLATE FOR DOSSIERS CONCERNING PESTICIDES ----- | 23 |
| 4. LIST OF ABBREVIATIONS / GLOSSARY ----- | 24 |
| 5. REFERENCES ----- | 24 |
| ANNEX 1: TEMPLATE FOR DOSSIERS CONCERNING PESTICIDES ----- | 27 |

EXECUTIVE SUMMARY

The expert group for technical advice on organic production (EGTOP; thereafter called ‘the Group’) has discussed whether the use of the substances/products/techniques mentioned below is in line with objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and whether they can therefore be authorised in organic production under the EU legislation. The Group concluded the following:

- Provided that the kelp is harvested in a sustainable way, the use of laminarin is in line with the objectives, criteria, and principles of organic farming. It should therefore be included in Annex II to Commission Regulation (EC) No 889/2008 (Annex II).
- The use of aluminium silicate (kaolin) is in line with the objectives, criteria, and principles of organic farming. It should therefore be included in Annex II.
- The use of sheep fat is in line with the objectives, criteria, and principles of organic farming. It should therefore be included in Annex II with the following conditions for use: (i) not to be applied to the edible parts of the crop; (ii) not to be applied in situations where the treated plant material may be ingested by sheep or goats.
- On the basis of the evidence received, the Group does not consider that the exceptional and essential need consistent with Regulation (EC) No 834/2007 has been sufficiently demonstrated and does not at this stage recommend the inclusion of sodium hypochlorite in Annex II. The Group acknowledges that in the future there might be situations where seed disinfection with sodium hypochlorite could be necessary. If such a need were demonstrated, the Group would re-consider recommending the inclusion of this use in Annex II.
- The use of UV light is not prohibited under the current organic regulation. However, the Group recommends that UVC should not be used in the field or greenhouse until the absence of sub-lethal mutagenic effects on micro-organisms (both target and non-target) is clearly demonstrated.

In addition to the mandate, the Commission asked the Group whether some terms for substances, and the uses of copper and sulphur, mentioned in Commission Regulation (EC) No 889/2008 should be harmonized with those used in Commission Implementing Regulation (EU) No 540/2011. The Commission further asked whether beeswax should be eliminated from the list of authorized pesticides in Annex II. The Group concluded the following:

- In the case of copper compounds, ‘(tribasic) copper sulphate’ should be renamed into ‘tribasic copper sulphate’, ‘cuprous oxide’ should be renamed into ‘copper oxide’, and ‘Bordeaux mixture’ should be added to the list.
- In the case of sheep fat, however, the Group recommends to use the term ‘sheep fat’ rather than ‘repellents by smell of animal or plant origin / sheep fat’ which is used in Commission Implementing Regulation (EU) No 540/2011. The latter might cause confusion about whether other repellents are implicitly also allowed.
- For copper compounds, the use as bactericide should be added in Annex II.
- For sulphur, the use as repellent could be eliminated from Annex II.
- Beeswax could be eliminated from Annex II, when the regulatory status in all member states is clarified. At the same time, it should be communicated to organic farmers that beeswax can still be used for pruning and grafting in organic farming.

Furthermore, the Commission asked the Group whether the use of pyrethroids could be limited to a certain period (phasing out, for example within 2 - 3 years time).

- The Group concluded that a full dossier on the synthetic pyrethroids deltamethrin and lambda-cyhalothrin, covering various crops and regions, should be prepared, before definitive decisions on phasing out are taken.

The Group also drafted the template for the dossier mentioned in Art. 16(3)(b) of Council Regulation (EC) No 834/2007 in relation to pesticides.

1. BACKGROUND

In recent years, several Member States have submitted dossiers under Article 16(3)(b) of Council Regulation (EC) No 834/2007 concerning the possible inclusion of a number of substances in Annex II to Commission Regulation (EC) No 889/2008 (hereafter called 'Annex II') or, more in general, on their compliance with the above mentioned legislation. In 2010, France introduced a request on Sodium hypochlorite, Laminarin and Kaolin. Austria submitted a dossier on Sheep fat on 2007 and in 2008 Denmark presented a dossier on the possible use of ultraviolet light (UV) as plant protection method.

A need has been identified to provide Member States with a template with a view to facilitate the elaboration of complete technical dossiers.

2. TERMS OF REFERENCE

a) In the light of the most recent technical and scientific information available to the experts, the Group is requested to answer the following question:

Is the use of the following substances/techniques:

Laminarin
Kaolin
Sheep fat
Sodium hypochlorite
UV

in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and can they therefore be authorised in organic production under the EU legislation?

In preparing its final report, the Group may also suggest amendments to the current list in Annex II, as well as take into account possible alternatives to the substances in question. In such cases, the proposal(s) should be accompanied by a brief explanation of the reasons.

b) The Group is also requested to draft the template of the dossier mentioned in Art. 16(3)(b) of Council Regulation (EC) No 834/2007 in relation to plant protection products.

3. CONSIDERATIONS AND CONCLUSIONS

3.1 Laminarin

Introduction, scope of this report

Laminarin is a polysaccharide from the group of the glucanes. The request is for inclusion in Annex II, for use in the protection of a wide range of plants against fungi and bacteria.

Authorization in general agriculture or food processing

Laminarin is approved as an active substance for use in plant protection products (PPP) according to Commission Implementing Regulation (EU) No 540/2011 (EC, 2011). It was approved in the year 2005 (EC, 2005). Currently, PPP containing laminarin are registered in Belgium, Greece, France, the Netherlands, the UK and Germany (plant strengtheners); registration is pending in Spain and Portugal.

PPP are authorized in conventional production against various fungal (mainly Powdery Mildews) and bacterial diseases of wheat, barley, apple, pear, strawberry and vegetables (zucchini, pumpkin and tomato).

Agronomic use, technological or physiological functionality for the intended use

Laminarin acts as an elicitor of the plants's self-defence mechanisms (Trouvelot *et al.*, 2008). Laminarin has a partial efficacy ranging from 40 to 80 %. The use of laminarin allows for reducing the number of fungicide or bactericide treatments on a crop, but it cannot replace all of them. The dose is always very low, for example 37g/ha on cereals (SANCO, 2004).

Known alternatives

Depending on the crop and pest to be controlled, there are several alternatives (e.g. copper, sulphur and some PPP based on micro-organisms), besides the preventative agronomic measures.

Origin of raw materials, methods of manufacture

Laminarin is extracted from *Laminaria digitata*. *L. digitata* belongs to the brown algae, which are also referred to as 'kelp'. All laminarin used in plant protection products in Europe is currently supplied by the same manufacturer, who employs the following manufacturing process: seaweeds are harvested specifically for the purpose of laminarin production from September to November, when laminarin content is highest (10 – 15 % of dry matter). Harvesting takes place in Northern Europe. The kelp blades are harvested by cutting manually or mechanically. Laminarin is extracted from the kelp by dipping in acid, aqueous solution at 60 °C. The solution is then purified by filtration with specific membranes.

Environmental issues, use of resources, recycling

'Kelp forests' are renowned for their species richness and biodiversity (Birkett *et al.*, 1998). The harvesting process for laminarin production described above is less damaging than the harvesting methods used by the alginate industry, where entire plants are ripped from the substratum. Kelp forests can be harvested in a way that allows them to recover fully. Seaweeds are mainly harvested to provide emulsifiers (alginate); the use of laminarin for plant protection is quantitatively of minor importance.

In the assessment of laminarin for inclusion in Council Directive 91/414/EEC (EC, 1991) (now replaced by Regulation (EC) No 1107/2009 of the European Parliament and of the Council; (EC, 2009c)) no unacceptable effects of the use of laminarin on the environment were found (SANCO, 2004).

Animal welfare issues

No issues identified.

Human health issues

In the assessment of laminarin for inclusion in Council Directive 91/414/EEC (EC, 1991), no harmful effects on human health were identified (SANCO, 2004). Commercial products are not classified with risk phrases. Kelp can be used as food.

Food quality and authenticity

In the assessment of laminarin for inclusion in Council Directive 91/414/EEC, no relevant residues were expected (SANCO, 2004).

Traditional use and precedents in organic production

Seaweeds and seaweed products are already authorized as fertilizers in Annex I to Commission Regulation (EC) No 889/2008 (EC, 2008b). This category can also contain products made from kelp and laminarin. Seaweed meal is authorized as non-organic feed material in Annex V. Sodium and potassium alginate (E 401, E 402) are authorized as food additives in Annex VIII section A to the above mentioned Regulation.

Aspects of international harmonization of organic farming standards

The Codex Alimentarius guidelines for the production, processing, labelling and marketing of organic foods (Codex Alimentarius Commission, 1999) authorises seaweed, seaweed meal and seaweed extracts for plant protection and for fertilization. Laminarin is currently not authorized for organic farming in the USA.

Necessity for intended use

Laminarin can be useful as part of a broader strategy including agronomic measures and the use of other plant protection products. It could be particularly useful in regions where fire blight (*Erwinia amylovora*) is a threat.

Reflections of the Group

In some cases, laminarin could be a tool to reduce (but not to replace) the use of products which have more negative effects on the environment, such as copper or sulphur.

Any potential negative impact on the environment caused by the harvesting of kelp can be minimised by appropriate harvesting consistent with Commission Regulation (EC) No 710/2009 (EC, 2009a).

Conclusions

The Group concluded that provided that the kelp is harvested in a sustainable way the use of laminarin is in line with the objectives, criteria, and principles of organic farming as laid down in Regulation (EC) No 834/2007. It should therefore be included in Annex II.

3.2 Kaolin / Aluminium silicate

Introduction, scope of this report

Kaolin is a naturally occurring aluminium silicate. In Commission Implementing Regulation (EU) No 540/2011 (EC, 2011), it is referred to as ‘aluminium silicate’, while in the organic sector, it is generally known as ‘kaolin’. In this report, the term ‘aluminium silicate (kaolin)’ is used to describe calcinated kaolin as defined in the above mentioned legislation. If the substance is to be included in Annex II, the Group recommends using the term ‘aluminium silicate (kaolin)’.

The request is for inclusion of kaolin in Annex II as an insect repellent.

Authorization in general agriculture or food processing

Aluminium silicate (kaolin) is approved for use in PPP according to Commission Implementing Regulation (EU) No 540/2011 (EC, 2011). It was approved in the year 2008 (EC, 2008a). PPP are currently registered in Belgium, Greece and France.

Agronomic use, technological or physiological functionality for the intended use

Aluminium silicate (kaolin) is applied to crops at a rate up to 50 kg/ha. It forms a layer on plant surfaces which is repellent for insect pests. It perturbs pests by altering the appearance or surface structure on the crops. It is registered for use against the ‘pear Psylla’ (*Psylla pyricola*) and several species of fruit tree aphids. Aluminium silicate (kaolin) has also an effect against other pests such as the olive fruit fly (*Bactrocera oleae*), and against the grape leafhopper (*Empoasca vitis*) and grapevine moth (*Lobesia botrana*) on grapevine, but these uses are not registered yet.

Aluminium silicate (kaolin) can also be used to protect crops from UV radiation (Glenn *et al.*, 2002) and from russeting (pome fruits).

Known alternatives

Depending on the crop, several other products and methods allowed in organic farming can be alternatives to aluminium silicate (kaolin) such as soft soap, oils, azadirachtin, pheromones or beneficial insects. In organic farming, aluminium silicate (kaolin) would be the most effective product against the pear Psylla.

Origin of raw materials, methods of manufacture

Aluminium silicate (kaolin) originates from mines in North America and Europe. It is physically purified, heated to remove water of constitution (‘calcination’) and finally micronized to form a wettable powder. The purity of the raw aluminium silicate (kaolin) is monitored by the manufacturer. This prevents the formation of unwanted residues during calcination.

Environmental issues, use of resources, recycling

In the assessment of aluminium silicate (kaolin) for inclusion in Council Directive 91/414/ECC (EC, 1991), no unacceptable effects on the environment were found (SANCO, 2008a). The minimum purity must be 99.98 % of mineral aluminium silicate (kaolin). Even though side effects on predatory mites may occur (Wright *et al.*, 2000), the Group did not consider this to be a significant issue.

Animal welfare issues

No issues identified.

Human health issues

In the assessment of aluminium silicate (kaolin) for inclusion in Council Directive 91/414/EEC, no harmful effects on human health were identified (SANCO, 2008a). Kaolin is used as an ingredient in anti-diarrhoeal medication and as an anti-caking agent in food (E 559).

Food quality and authenticity

The quality (appearance and taste) of fruits as well as of processed products such as jams and juices can be affected by aluminium silicate (kaolin). When there is little rain, this product remains on the fruits until harvest, and it is difficult to clean them properly. On fresh fruits aluminium silicate (kaolin) produces spray spots. In processed products it may induce unwanted clarification effects. To reduce these problems, the last treatment should not be applied close to the harvest.

Traditional use and precedents in organic production

Aluminium silicate (kaolin) is contained in some plant strengtheners, and therefore traditionally used on organic crops. Stone meal and clays are included in Annex I, and are therefore authorised to be used on organic crops.

Other uses include painting of tree trunks as protective coating against sudden changes of temperatures. E 559 'kaolinitic clays' are authorized as binders and anti-caking agents for organic feed and kaolin is authorized as processing aid for organic food (Annexes VI and VIII B of Commission Regulation (EC) No 889/2008, respectively).

Aspects of international harmonization of organic farming standards

The Codex Alimentarius guidelines for the production, processing, labelling and marketing of organic foods (Codex Alimentarius Commission, 1999) authorises 'silicates / clay' for plant protection. Aluminium silicate (kaolin) is authorised as a repellent in the USA and in Switzerland. In Australia, it is authorised as crop production input. In Japan, kaolin is authorised as processing aid for organic food (Japanese Agricultural Standards).

Necessity for intended use

In regions where the pear Psylla is a key pest, there is a great need for a control method against this pest, for example the use of aluminium silicate (kaolin). Against some aphids, aluminium silicate (kaolin) is very useful, particularly at the end of winter / beginning of spring, when the beneficials are not settled yet.

Reflections of the Group

The Group's conclusion on environmental impacts is based on the assumption that purity levels of the commercial product are guaranteed by the registration process. The potential, negative impacts on quality will be reduced by good practices implemented by farmers in their own interest.

Conclusions

The Group concluded that the use of aluminium silicate (kaolin) is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex II.

3.3 Sheep fat

Introduction, scope of this report

Sheep fat is a triglyceride consisting predominantly of glycerine esters of palmitic acid, stearic acid and oleic acid. Its use as a repellent against game animals was requested for fruit trees, vines, forest trees and arable crops. In Commission Implementing Regulation (EU) No 540/2011 (EC, 2011), sheep fat is referred to as 'repellents by smell of animal or plant origin / sheep fat'. For this report, the Group decided to use the shorter term 'sheep fat'.

Authorization in general agriculture or food processing

Sheep fat is approved as an active substance for use in PPP according to Commission Implementing Regulation (EU) No 540/2011 (EC, 2011). It was approved in the year 2008 (EC, 2008a). Sheep fat based PPP are currently registered in Austria, Hungary, Sweden and Slovenia; registration is pending in Italy.

Agronomic use, technological or physiological functionality for the intended use

Sheep fat acts as a repellent by smell. It is used to protect young deciduous and coniferous trees, newly emerging shoots and leaves of grapevines, apple trees, elder, hop and some arable crops (e.g. sunflower, soybeans, rape seed) from damage by deer. It is sprayed onto the plants at doses of 10 – 20 l/ha. It is only applied in periods when no edible crop parts are available (until flowering or after harvest). Product documentations report reductions of damage over 80 %.

Known alternatives

Fences are alternatives to sheep fat, but they are expensive and not always practicable. Quartz sand is also authorized as repellent, but current national authorizations do not cover the same crops in the same countries. Quartz sand is therefore only a partial alternative.

Origin of raw materials, methods of manufacture

Sheep fat is extracted from fatty sheep tissues by heat extraction, and mixed with water to obtain an oily water emulsion. Sheep fat must be in compliance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council (as mentioned in Commission Implementing Regulation (EU) No 540/2011 (EC, 2011)).

Environmental issues, use of resources, recycling

In the assessment of sheep fat for inclusion in Council Directive 91/414/EEC no unacceptable effects on the environment were found (SANCO, 2008b).

Animal welfare and health issues

In the assessment of sheep fat for inclusion in Council Directive 91/414/EEC (EC, 1991), no harmful effects on animal health were identified (SANCO, 2008b). However, it was recently demonstrated that scrapie prions are present also in fat tissues (Race *et al.*, 2008), and prion sorption to soil is thought to play an important role in the transmission of scrapie via the environment (Saunders *et al.*, 2011). The Group cannot make a final judgement of these potential risks. In case that the evidence for such risks is substantiated, these risks should be managed by transversal legislation, and not by the organic regulation. As a precautionary measure, the Group suggests that sheep fat should not be used in situations where the treated plant material may be ingested by sheep or goats. Scrapie is an infection of sheep and goats exclusively, and therefore poses no risks for human health.

Human health issues

In the assessment of sheep fat for inclusion in Council Directive 91/414/EEC (EC, 1991), no harmful effects on human health were identified (SANCO, 2008b). Glycerin esters of palmitic, stearic and oleic acids, which are components of sheep fat, are food additives (E570). Sheep fat is applied before flowering of the crops or after harvest, and therefore no direct contact of sheep fat with the edible part of the crop should occur. In order to avoid any bovine spongiform encephalopathy (BSE) risks, sheep fat must be in compliance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council (EC, 2009b), as specified in Commission Implementing Regulation (EU) No 540/2011 (EC, 2011).

Food quality and authenticity

When sheep fat is used on hop or elder, adverse effects on the quality of the harvested products cannot be excluded according to the registration for Austria. There are no requirements concerning the rearing of animals. The Group does not exclude that sheep fat may contain residues of synthetic veterinary drugs.

The Group's opinion is that applications to edible parts of crops should not be allowed for sanitary and ethical reasons (vegetarians). The Vegetarian Society defines vegetarians as persons who do not eat any meat, poultry, game, fish, shellfish or by-products of slaughter¹. The use of sheep fat on non-edible crop parts is compatible with this definition of vegetarianism. By contrast, vegans also exclude 'any other products which are derived from animals', which might conflict with the use of sheep fat. In this respect, the use of sheep fat is similar to the foliar application of other by-products of animal origin such as hydrolyzed proteins.

Traditional use and precedents in organic production

Unwashed wool in dispensers is traditionally used as repellent in organic and conventional farming.

Aspects of international harmonization of organic farming standards

Sheep fat is currently not authorized in the USA. It is authorized in Switzerland (under the category 'repellents of plant and animal origin').

Necessity for intended use

In certain areas, game animal represent a serious threat to crops (and young trees) and fencing is not always practicable.

Reflections of the Group

In the Group's opinion, the potential risks of TSE (transmissible spongiform encephalopathy) for sheep due to the use of sheep fat have a very low probability, but cannot be ruled out completely. The Group's conclusion on animal welfare and health issues is based on the assumption that potential risks due to TSE could be managed by the relevant transversal legislation, which provides measures for the prevention, control and eradication of transmissible spongiform encephalopathy (EC, 2001). The Group identified no risks of BSE for humans, because according to Commission Implementing Regulation (EU) No 540/2011 (EC, 2011), sheep fat must be in compliance with Regulation (EC) No 1069/2009 of the European Parliament and of the Council.

¹ www.vegsoc.org >What is a vegetarian?

Although the Group does not exclude the possible presence of chemical residues in sheep fat, this is not a major concern to the Group due to the application mode, timing and dose used. The possible impact on quality of hop/elder will be avoided by good practices, implemented by farmers in their own interest.

Conclusions

The group concluded that the use of sheep fat is in line with the objectives, criteria, and principles of organic farming as laid down in Council Regulation (EC) No 834/2007. It should therefore be included in Annex II with the following conditions for use:

- not to be applied to the edible parts of the crop
- not to be applied in situations where the treated plant material may be ingested by sheep or goats

3.4 Sodium hypochlorite

Introduction, scope of this report

Sodium hypochlorite is also known as bleach or as javel water. The request is for inclusion in Annex II as seed treatment (viricide, bactericide). The purpose of the request mainly seems to be a harmonization of the requirements for control of Pepino Mosaic virus (PepMV) with the requirements for organic seeds (treatment only with substances listed in Annex II), but the dossier was apparently not updated since Commission Decision 2004/200/EC (EC, 2004) is in force.

Authorization in general agriculture or food processing

Sodium hypochlorite is approved as an active substance for use in PPP according to Commission Implementing Regulation (EU) No 540/2011 (EC, 2011). It was approved in the year 2008 (EC, 2008a). PPP based on sodium hypochlorite are currently registered in Belgium, France, Ireland and the UK. They are used on mushroom substrates against bacterial blotch (*Pseudomonas tolaasii*), and as seed treatment against various pathogens including viruses.

Agronomic use, technological or physiological functionality for the intended use

Sodium hypochlorite is a disinfectant with numerous uses. Its effect is due to the chlorine. The dossier highlights the case of the PepMV of tomato, which is subject to compulsory phytosanitary measures in the EU (EC, 2004). For tomato seeds, an appropriate acid extraction is always legally required (EC, 2004). It is unclear to the Group to what extent acid extraction eliminates the need for subsequent disinfection, for example with sodium hypochlorite. Such subsequent disinfections are routinely applied by some seed houses, but their efficacy would apparently need to be verified in controlled experiments (Werkman and Sansford, 2010). However, the Group does not question the efficacy of sodium hypochlorite as a disinfectant for seeds.

Known alternatives

Agronomic preventive measures (rotation, green manure, proper soil management, proper choice of crop, variety and site etc.) are not always sufficient to prevent seed contaminations by seed pathogens. Heat treatment controls some seed-borne diseases, but it is ineffective against PepMV (Cordoba-Selles *et al.*, 2007). No disinfectant is currently authorized for treatment of organic seeds. The information in the dossier is insufficient to evaluate the need for seed disinfectants in crops other than tomatoes, and for diseases other than the PepMV. Also, the dossier contains no information on possible alternative methods and substances.

Origin of raw materials, methods of manufacture

Sodium hypochlorite is synthetically manufactured. It is obtained by reacting chlorine (Cl₂) and caustic soda (NaOH).

Environmental issues, use of resources, recycling

Sodium hypochlorite is highly toxic for all aquatic organisms. However, no environmental risk is foreseen if it is used according to label instructions (SANCO, 2008c). The quantities used are very small (0.02 l of sodium hypochlorite per kg of seeds) and after the treatment, the seeds have to be rinsed three times in drinking water before drying. Furthermore, hypochlorites break down rapidly in soil and water (see Draft Assessment Report (EC, 2008c)). The quantities remaining on seeds after treatment are thus very small and cannot represent a threat for soil organisms.

Animal welfare issues

No issues identified.

Human health issues

Concentrated hypochlorite is dangerous for the skin and the eyes, while chlorine gas is toxic and irritates the respiratory system. However, if used according to the label instructions, it should not pose any risk to operators (SANCO, 2008c). Sodium hypochlorite is widely used as a disinfectant in households, industry and conventional/organic agriculture (e.g. livestock houses, units for milk and meat processing), where much larger quantities are used than in seed treatment. The disinfection of seeds prior to the production of sprouts could improve food safety.

Food quality and authenticity

The potential application of sodium hypochlorite as a seed treatment before sowing would not imply any contact with the edible part of the crop. The Group has not verified whether authorizations for seed treatment would also cover the disinfection of seeds prior to the production of sprouts. However, even for this latter use, there would be no contact of sodium hypochlorite with the sprouts, because hypochlorites break down rapidly in soil and water.

Traditional use and precedents in organic production

Until 2003 (i.e. before Commission Regulation No 1452/2003 (EC, 2003) was in force), it was legally possible to use conventional seeds, and there were no restrictions regarding possible treatments of these seeds. The Group is not aware that conventional seeds treated with sodium hypochlorite were used in organic farming, but cannot exclude the possibility that it might have happened.

Sodium hypochlorite is authorized for cleaning and disinfection of buildings and installations for animal production (Annex VII of Commission Regulation (EC) No 889/2008 (EC, 2008b)).

Aspects of international harmonization of organic farming standards

In the USA, the use of sodium hypochlorite is authorized for a number of purposes including crop management, but not for plant protection (seed treatment).

Necessity for intended use

No disinfectant with fungicidal, bactericidal or viricidal action is currently authorized for treatment of organic seeds. On the basis of the evidence received, the Group does not consider that the exceptional and essential need required by Council Regulation (EC) No 834/2007 (Art 4(c) and Art 16(2)(c)) has been sufficiently demonstrated. The Group acknowledges that in the future there might be situations where seed disinfection could be necessary, and the availability of a proven disinfectant for organic seeds could be useful for various crops.

With respect to PepMV, the Group cannot make a final statement on the necessity of sodium hypochlorite, because it is unclear to what extent the legally prescribed acid extraction eliminates the need for subsequent disinfection (see section on agronomic use).

Reflections of the Group

Sodium hypochlorite is of synthetic origin, which is not fully in line with the principles of organic farming. Despite its synthetic origin, it could theoretically be eligible for inclusion in Annex II because its use would not imply a direct contact with the edible parts of the crop (Art. 16 point 2(c)(ii) of Council Regulation (EC) No 834/2007), (EC, 2007).

The availability of healthy seeds is very important. This should be achieved primarily with preventive agronomic measures, and secondly with physical methods such as heat treatment, while the use of disinfectants should be the last option only if there is an unavoidable need. In this case, the option of sodium hypochlorite should be considered together with other authorised

substances. Among the theoretically available substances, sodium hypochlorite is registered for seed treatment against fungi, bacteria and viruses, and it is already authorised for other uses in organic farming (such as disinfection of livestock buildings), where larger quantities are used in comparison to seed treatment.

The Group is concerned that seed disinfection will kill all beneficial microflora on the surface of the seed.

Conclusions

On the basis of the evidence received, the Group does not consider that the exceptional and essential need consistent with Council Regulation (EC) No 834/2007 (Art 4(c) and Art 16(2)(c)) has been sufficiently demonstrated and does not at this stage recommend the inclusion of sodium hypochlorite in Annex II.

The Group acknowledges that in the future there might be situations where seed disinfection with sodium hypochlorite could be necessary. If such a need were demonstrated, the Group would re-consider recommending the inclusion of this use in Annex II.

3.5 UV

Introduction, scope of this report

Ultraviolet (UV) light is electromagnetic radiation with a wavelength shorter than that of visible light, but longer than X-rays. The International Commission on Illumination (CIE) recognizes three major categories: UVA (wavelength 315 - 400 nm), UVB (280 - 315 nm) and UVC (100 - 280 nm)².

The original request is based on a device emitting UVC for use on crops in the field or glasshouse. The Group decided to evaluate UVC in a more general way, and not the specific device. In particular, the Commission asked EGTOP whether UV light could be considered as a thermal or mechanical treatment.

Authorization in general agriculture or food processing

UV generated by electric equipment is not covered by the legislation concerning the placing of plant protection products on the market (EC, 2009c). However, devices emitting UV are subject to the so-called 'Low Voltage Directive' (EC, 2006b) and to the 'Machinery Directive' (EC, 2006a). The Low Voltage Directive requires that equipment will be used safely (Annex I, Article 1.(a)), that persons are adequately protected against the danger of physical injury (Article 2.(a)), that radiation which could cause danger is not produced (Article 2.(b)) and that persons are adequately protected against non-electrical dangers (Article 2.(c)). The Machinery Directive requires that any functional, non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons (Annex I, Article 1.5.10).

Agronomic use, technological or physiological functionality for the intended use

UVC acts by damaging DNA. Activity of UVC is highest at 185 and at 265 nm, i.e. the absorption peaks of DNA molecules. UVC can be used for sterilization, including recycling water in glasshouses. UVC might potentially be applied on all kinds of equipment used in plant or animal production, or in food processing/handling. Under laboratory conditions, UVC is effective against some viruses, bacteria and fungi. Because microorganisms may be shielded from UVC in small cracks or other shaded areas, UVC could be used mainly to complement other sterilization techniques.

At the moment, the Group sees the main application of UVC in greenhouses for sterilization (water, equipment). Some practitioners claim that UVC strengthens greenhouse-grown plants and induces resistance against diseases, but the Group could not verify these effects.

The publicly available information concerns mainly the sterilization of water and equipment, while some information is also available on post-harvest treatments of fruits (mainly small fruits) for sanitation purposes (against *Escherichia coli*, *Salmonella* etc.). There is very little information available on the pre-harvest use of UVC. The available information indicates that treatments of crops are at the moment not sufficiently effective (Lamers and Bus, 2009; Lamers and Topper, 2010). The Group noted that it is almost impossible to achieve a constant intensity of UVC radiation within the vegetation, due to different distances from the radiation source, and particularly due to shading.

Known alternatives

Preventive sanitary measures and currently authorised plant protection products.

² The CIE nomenclature is not always followed rigorously and in some sources, UVC is defined as radiation with a wavelength of 200 - 280 nm.

Origin of raw materials, methods of manufacture

UVC may be artificially produced by special lamps or LEDs. In nature, the ozone layer of the earth's atmosphere blocks almost all of the UVC emitted by the sun.

Environmental issues, use of resources, recycling

It has been shown that communities of micro-organisms regularly occur on crops (Granado *et al.*, 2008) and the use of UVC for plant protection might destroy these communities, as well as the micro-organisms on the soil surface. Sub-lethal doses of UVC might induce mutations in micro-organisms (Watanabe *et al.*, 2011), which might lead to unpredictable side-effects.

Animal welfare issues

If farm animals are exposed to UVC, the hazard is similar as for humans (see below).

Human health issues

The effects of UV vary with the wavelength; UVC has the highest energy and is the most dangerous type of UV. However, little attention has been given to UVC in the past, since natural UVC is filtered out in the atmosphere. UVC is reasonably anticipated to be a human carcinogen (NTP, 2000). When applied for plant protection, the equipment should ensure that humans are not exposed to UVC. If the low voltage and machinery directive are followed, no risk is implied. It is unclear to the Group if mutation of microflora induced by UVC exposure may cause the emergence of new and potentially dangerous strains.

Food quality and authenticity

UVC treatment leaves no residues in food. The Group is not aware about physiological effects on the treated crops which could affect the quality of the edible products.

Traditional use and precedents in organic production

UVC is occasionally used in organic food processing/handling, and there is limited use for disinfection of equipment in greenhouses. It is used for water treatment. UVC treatment of crops was recently introduced in a few organic farms in the Netherlands, but this use is not common.

Aspects of international harmonization of organic farming standards

The use of UV is not regulated under the 'National Organic Program' in the USA, nor in the Swiss organic farming ordinance.

Necessity for intended use

There is a great need for alternative means in plant protection for organic farming, for example in the case of late blight (*Phytophthora infestans*) and Downy Mildew. UVC could, in principle, play a role in this regard. However, the currently available techniques for field and glasshouse treatments are not yet sufficiently effective.

Reflections of the Group

The use of UV light is not covered by the current organic regulation. UVC cannot be considered as ionizing radiation (which is prohibited under Council Regulation (EC) No 834/2007, Art. 10). UVC is different from thermal radiation with respect to the wavelength (the wavelength of infrared is 750 - 1 million nm), and it has a different mode of action (UVC acts by damaging DNA, which is not the case for infrared). UVC is not a mechanical treatment either.

Although the Group recognises a certain potential for the use of UVC, the actual state of art in its implementation does not allow sufficient effectiveness. The main concern of the Group relates to the above mentioned potential mutagenic effect of UVC on micro-organisms.

Conclusions

The group concluded that the use of this technique is not prohibited under the current organic regulation. However, the Group recommends that UVC should not be used in the field or greenhouse until the absence of sub-lethal mutagenic effects on micro-organisms (both target and non-target) is clearly demonstrated.

3.6 Other issues: harmonization with transversal legislation

3.6.1 Harmonization of the terminology for substances

Introduction

In addition to the mandate, the Commission asked the Group whether some terms for substances used in Commission Regulation (EC) No 889/2008 (EC, 2008b) should be harmonized with those used in Commission Implementing Regulation (EU) No 540/2011 (EC, 2011).

Reflections of the Group

In the opinion of the Group, it is desirable to harmonize the terms used in Commission Regulation (EC) No 889/2008 with those used in Commission Implementing Regulation (EU) No 540/2011.

As regards Bordeaux mixture, this is a mixture of copper sulphate and calcium hydroxide, which are both authorized, and it is traditionally used in organic farming.

Conclusions

The Group concluded that in the case of copper compounds, '(tribasic) copper sulphate' should be renamed into 'tribasic copper sulphate', 'cuprous oxide' should be renamed into 'copper oxide', and 'Bordeaux mixture' should be added to the list.

In the case of sheep fat, however, the Group recommends to use the term 'sheep fat' rather than 'repellents by smell of animal or plant origin / sheep fat' which is used in Commission Implementing Regulation (EU) no 540/2011 (EC, 2011). The latter might cause confusion about whether other repellents are implicitly also allowed.

3.6.2 Harmonization of listed uses for copper compounds

Introduction

In addition to the mandate, the Commission asked the Group whether the uses of copper compounds mentioned in Commission Regulation (EC) No 889/2008 (EC, 2008b) should be harmonized with those registered in Commission Implementing Regulation (EU) No 540/2011 (EC, 2011).

Reflections of the Group

In the first version of Regulation 2092/91, the uses of copper compounds were not specified. Later, the use as fungicide was added, while the use as bactericide was not added. In the organic sector, the addition of the fungicide use was perceived as a purely formal act, and it was never discussed as a change of practice. Therefore, the Group assumes that the use as bactericide was omitted by mistake, and not on purpose. Wide parts of the organic sector assume that copper compounds can be used against all plant diseases for which they are registered, and this is also the normal practice in countries where copper fungicides are registered. The following pathogens are examples of bacterial diseases controlled by copper: *Pseudomonas syringae* (cherry, vegetables), *Erwinia amylovora* (pome fruit), *Clavibacter michiganensis* (tomato), *Xanthomonas campestris* (cabbage), *X. hortorum* (ornamentals).

A few years ago, it was concluded that, at that moment, there was still a need for copper compounds (EC, 2002). The Group does not want to open this discussion again in this context. In the Group's opinion, the arguments given at that time apply also to the bactericide use. Formally, inclusion of the use as bactericide may appear to be an extension of the uses of copper compounds. In practice, however, it only legalizes a traditional practice. Although the Group

recommends the formal inclusion of bactericide use of copper, it fully agrees with the explicit goal of reduction of copper use.

Conclusions

The Group concluded that for copper compounds, the use as bactericide should be added in Annex II.

3.6.3 Harmonization of listed uses for sulphur

Introduction

In addition to the mandate, the Commission asked the Group whether the uses of sulphur mentioned in Commission Regulation (EC) No 889/2008 (EC, 2008b) should be harmonized with those registered in Commission Implementing Regulation (EU) No 540/2011 (EC, 2011).

Reflections of the Group

Commission Regulation (EC) No 889/2008 authorizes the use of sulphur as fungicide, acaricide and repellent. However, the Group is not aware of registered uses of sulphur as repellent. In the opinion of the Group, it is desirable, but not strictly necessary, to harmonize the uses for sulphur mentioned in Commission Regulation (EC) No 889/2008 with those registered in the legislation concerning the placing of plant protection products on the market (EC, 2009c). In some cases, other uses (e.g. as repellent) may be authorized outside the EU.

Conclusions

The Group concluded that for sulphur, the use as repellent could be eliminated from Annex II.

3.6.4 Listing of beeswax

Introduction

In addition to the mandate, the Commission asked the Group whether beeswax should be eliminated from the list of authorized pesticides in Annex II. The argument was that beeswax is a food additive (E901), and therefore cannot be a pesticide.

Reflections of the Group

The argument that supports the request is not correct. For example, lecithine, gelatine and some plant oils are also food additives, and are at the same time listed in Annex II.

Beeswax is currently used for wound protection in the context of pruning or grafting. According to the EU pesticides database these uses are outside the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (EC, 2009c), and waxes are not considered as plant protection products. Thus, it is not strictly necessary to list waxes in Annex II. However, plant protection products containing beeswax and authorized for organic farming are registered in some member states (e.g. France).

In the Group's opinion, beeswax should remain authorized for pruning and grafting. If it should be deleted from Annex II for formal reasons, the Group is concerned that (i) this might cause problems in countries where products containing beeswax are registered plant protection products, and (ii) organic farmers might not know whether beeswax is authorized for pruning and grafting or not. The Group recommends that for products/technologies which are neither fertilizers nor plant protection products, there should be a transparent tool of communicating whether they are allowed in organic production or not.

Conclusions

The Group concluded that beeswax could be eliminated from Annex II, when the regulatory status in all member states is clarified. At the same time, it should be communicated to organic farmers that beeswax can still be used for pruning and grafting in organic farming.

3.7 Other issues: phasing out of the pyrethroids deltamethrin and lambda-cyhalothrin

Introduction

The Commission asked the Group whether the use of pyrethroids could be limited to a certain period (phasing out, for example within 2 - 3 years time).

Reflections of the Group

In the opinion of the Group, the synthetic pyrethroids deltamethrin and lambda-cyhalothrin are not fully in line with the pesticides normally used in organic farming. Indeed, it seems that they were only authorized out of necessity, as at that time no alternatives were available. In organic farming, these pyrethroids are only authorized for use only in traps, and only against the olive fruit fly (*Bactrocera oleae*) and the Mediterranean fruit fly (*Ceratitis capitata*). These two pests can cause severe damage to olives, other fruit trees including tropical fruits, and some vegetables. Possible alternatives are spinosad, as well as prevention strategies to control the damage caused by the Mediterranean fruit fly in citrus involving degreening with ethylene (both authorised for organic farming in 2008). Another possible alternative, if authorized, may be kaolin (see this report).

In the Group's opinion, there are good indications that the synthetic pyrethroids deltamethrin and lambda-cyhalothrin are not essential any longer in the organic production of olives and citrus in Mediterranean countries. Concerning tropical crops, it is not clear to the Group whether deltamethrin and lambda-cyhalothrin are still essential or not.

In view of the economic importance of the above mentioned crops, the Group recommends that a full dossier is prepared, with specific emphasis on the necessity for/alternatives to the synthetic pyrethroids deltamethrin and lambda-cyhalothrin. The dossier should cover various Mediterranean countries and different crops, but also tropical countries and crops. If the dossier should demonstrate that there are sufficient alternatives to synthetic pyrethroids, a process of phasing out within 2 - 3 years may be initiated.

Conclusions

The Group concluded that a full dossier on the synthetic pyrethroids deltamethrin and lambda-cyhalothrin, covering various crops and regions, should be prepared, before definitive decisions on phasing out are taken.

3.8 Template for dossiers concerning pesticides

The Group considered that it would be helpful to develop some interpretative guidelines to support the dossier template. The document presented in Annex 1 to this report includes in part A a questionnaire and in part B a section incorporating the criteria for assessment of consistency with the EU organic regulation.

4. LIST OF ABBREVIATIONS / GLOSSARY

| | |
|------------------|--|
| <u>Annex II</u> | Annex II to Commission Regulation (EC) No 889/2008 |
| <u>BSE</u> | Bovine Spongiform Encephalopathy (commonly known as ‘mad-cow disease’) |
| <u>CIE</u> | <i>Commission internationale de l’éclairage</i> (International Commission on Illumination) |
| <u>PepMV</u> | Pepino Mosaic Virus |
| <u>PPP</u> | Plant Protection Product |
| <u>Scrapie</u> | Scrapie is a TSE in small ruminants (sheep and goats) |
| <u>The Group</u> | The Expert Group for Technical Advice on Organic Production (EGTOP) |
| <u>TSE</u> | Transmissible Spongiform Encephalopathy |
| <u>UV</u> | Ultra Violet light |
| <u>UVC</u> | Ultra Violet C |

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Annex 1: Template for dossiers concerning pesticides

Part A

DOSSIER CONCERNING THE REQUEST TO AMEND ANNEX II Pesticides — plant protection products referred to in Article 5(1) of Commission Regulation (EC) No 889/2008

Articles 16(3)(b) of Council Regulation (EC) No 834/2007.

"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraph 1, or that the specifications of use mentioned in subparagraph (a) should be amended, the Member State shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States."

General information on the request

| | |
|-----------------------|--|
| Nature of the request | <input type="radio"/> Inclusion <input type="radio"/> Deletion <input type="radio"/> Change of disposition |
| Request introduced by | [Member State]: Contact e-mail: |
| Date | |

Please indicate if the material provided is confidential.

Requested inclusion / change in Annex II

| Name | Description, compositional requirement, conditions for use |
|------|--|
| | |

1. Identification

Identification of substance, terminology, synonyms

| |
|--|
| Chemical name(s) |
| Other names |
| Trade names |
| CAS code (Chemical Abstracts Systematic Names) |
| Other code(s) |

2. Characterisation

Raw materials, methods of manufacture

| |
|---|
| Composition |
| Active ingredients (as far as known) |
| Relevant physical/chemical properties including solubility |
| Origin of raw materials (including aspects of mining/harvesting them), production methods |

3. Specification of use

Agronomic use

| |
|--|
| Type of use (fungicide, insecticide, repellent, etc.) |
| Crops treated and pests/diseases controlled |
| Formulation |
| Application method |
| Dosage and number of applications |
| Stage of plant development when the substance is applied |
| Physiological effect, mode of action |
| Side-effects on crops |

4. Status

Authorization in general agriculture

| |
|--|
| Historic use |
| Regulatory status (EU, national, others) |

5. Reasons for the inclusion, withdrawal or amendments

| |
|---|
| Explain the need for the proposed pesticide |
| What alternative solutions are currently authorised or possible? |
| Is there any traditional use or precedents in organic production? |

6. Consistency with objectives and principles of organic production

Please use the checklist in part B of this Annex to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 Title II and Title III as applicable.

7. Other aspects

| |
|---|
| Environmental issues relating to production and use |
| Animal health and welfare issues relating to production and use |
| Human health issues relating to production and use |
| Food quality and authenticity, residues |
| Ethical issues relating to production and use |
| Socio-economic issues relating to production and use |
| Various aspects, further remarks |

8. References**9. Annexes**

CHECKLIST FOR CONSISTENCY

with objectives and principles of organic production with reference to specific articles in the organic regulation

Part B

| Criteria | Specific articles in Reg. 834/2007 | Fulfilled? Yes / no / not applicable | Brief qualification |
|--|---|---|----------------------------|
| Exclude the use of GMOs and products produced from or by GMOs | Art. 4(a)(iii); Art. 9(1) | | |
| Enhances the health of soil, water, plants and animals | Art. 3(a)(i) | | |
| High level of biodiversity | Art. 3(a)(ii) | | |
| Makes responsible use of energy and the natural resources, such as water, soil, organic matter and air | Art. 3(a)(iii) | | |
| Aim at producing products of high quality | Art. 3(b) | | |
| Use living organisms and mechanical production methods | Art. 4(a)(i) | | |
| Limited to natural or naturally-derived substances | Art. 4(b)(ii) | | |
| For chemically synthesized inputs: appropriate management practices do not exist | Art. 4(c)(i) | | |
| For chemically synthesized inputs: organic, natural or naturally-derived alternative substances are not available on the market | Art. 4(c)(ii) | | |
| For chemically synthesized inputs: use of organic, natural or naturally-derived alternative substances contributes to unacceptable environmental impacts | Art. 4(c)(iii) | | |
| Maintenance of plant health primarily by preventative measures, such as resistant species/varieties, appropriate crop rotations, cultivation techniques, mechanical and physical methods, thermal processes and the protection of natural enemies of pests | Art. 5(f); Art. 12 (1)(g) | | |

Report on Plant Protection Products

| Criteria | Specific articles in Reg. 834/2007 | Fulfilled? Yes / no / not applicable | Brief qualification |
|---|---|---|----------------------------|
| All plant production techniques used shall prevent or minimise any contribution to the contamination of the environment | Art. 12 (1)(f) | | |
| The corresponding use is authorised in general agriculture [...] | Art. 16 (1) | | |
| Their use is necessary for sustained production and essential for its intended use | Art. 16(2)(a) | | |
| All products and substances shall be of plant, animal, microbial or mineral origin ... | Art. 16 (2)(b) | | |
| ... except where products or substances from such sources are not available in sufficient quantities or qualities or if alternatives are not available | Art. 16 (2)(b) | | |
| Their use is essential for the control of a harmful organism or a particular disease for which other biological, physical or breeding alternatives or cultivation practices or other effective management practices are not available | Art. 16 (2)(c)(i) | | |
| If products are not of plant, animal, microbial or mineral origin and are not identical to their natural form, they may be authorised only if their conditions for use preclude any direct contact with the edible parts of the crop | Art. 16(2)(c)(ii) | | |
| Products and substances to be withdrawn or their use amended/ limited | Art. 16(3)(b) | | |
| Others: please specify | | | |