

Upstream meeting RSB – DG SANTE
Impact Assessment on legislation for plants obtained by certain new genomic techniques (NGTs)

The purpose of RSB upstream meetings is for report authors and Board members to discuss informally questions concerning how to prepare the best possible report on the issue at hand. Board members give their advice in a personal capacity and advice is not binding for the subsequent Board meeting.

20 May 2022

List of participants:

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DG SANTE introduced the initiative which aims to address the identified issues with the current applicable legislation regulating NGTs, in particular that the legislation is no longer fit for purpose and needs to be adapted to scientific and technical progress for certain NGTs. The main objectives of the initiative are to ensure that the legislation is proportionate to the risk involved, maintains high level of safety, provides legal certainty and contributes to a sustainable food system. The policy options cover the full range of measures supported by stakeholders and build on the authorisation system, including: i) authorisation with adapted risk assessment; ii) authorisation with sustainability incentives; iii) authorisation with sustainability requirements; and iv) pre-notification for certain products.

Points raised in the discussion

- Board members noted the importance of clearly demonstrating the **problem** and getting the evidence to show the magnitude of the problem, in particular in view of the political sensitivity of the initiative and the apparent lack of recent evaluation of the legislation. Board members suggested that specific examples on why the current legislation is not fit-for-purpose could help better present the problem and the baseline. The report should be clear if the different aspects of the identified problem are interlinked or

independent. The competitiveness aspect vis-à-vis developments in third countries should be clarified upfront.

- **Coherence** with ongoing SANTE initiatives (Plant Reproductive material, Framework for sustainable food systems) should be clearly demonstrated and consistency with initiatives in other policy areas (environment, agriculture, fishery etc.) should be ensured. In this context, the coherence in terms of the concept of **sustainability** (as emerging in the context of the upcoming (food) sustainability framework) is very important and the focus will stay on the sustainability aspect.
- The **objectives** need to be developed more specifically on what needs to be achieved, so that progress and ultimately success can be measured and a clear data collection strategy designed. The report should also define a simplification objective. The challenging task of the initiative to promote innovation and apply the precautionary principle at the same time should be explained.
- The **options** need to be further elaborated and specified, explaining how each option tackles the different aspects of the problem. The criteria used for the risk assessment needs to be explained. The design of options may consider providing certain flexibility to address future challenges. The available key policy choices and the trade-offs involved need to be clearly brought out. The description of the options should be detailed enough to understand how the proposed measures will work, who will be affected and how.
- Board members underlined the importance of the **evidence** base relevant for the assessment and the need to be explicit about the availability, limitations and robustness of data. The report needs to clearly demonstrate the scientific evidence base, in particular the robustness of the evidence on the link between the initiative and the human health and environmental adverse impacts.
- Regarding **impacts**, it is essential to present a balanced analysis in terms of costs and benefits. Considering the political sensitivity and importance of the initiative, the identified impacts need to be well substantiated. The report needs to include an assessment on competitiveness, in particular vis-à-vis third countries, as well as an assessment of how the 'do no significant harm' will be respected. In context of the one in, one out approach, the report should identify and quantify (to the extent possible) administrative costs and savings to citizens and businesses.
- Considering the political sensitivity and wide divergence of views, **stakeholders' views** need to be well explained and the report needs to clearly identify who is in favour or against.
- Board members emphasised the importance of clarity and reader-friendliness. It should provide a clear and concise narrative, understandable to non-expert readers that can assist policy-makers to take an informed choice and to explain that choice in plain language.

JRC comments on RSB upstream meeting with DG SANTE on IA for a revision of the legislation for plants produced by certain New Genomic Techniques (NGTs), 20 May 2022

JRC.I1.CC-ME stated that other parts of the JRC are already supporting this file, and made the following comments in view of future monitoring and evaluation.

1. How to measure success. The Inception Impact Assessment (IIA) states the following objectives of the initiative:

(a) “Maintain high level of protection of human and animal health and of the environment”;

(b) “Enable safe plants to provide benefits and contribute to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies”;

(c) “Enhance the competitiveness of the EU agri-food sector and ensure a level-playing field for its operators and ensure the effective functioning of the internal market”.

It would be important to define indicators or measures of success overall and for each of these objectives. This is relevant both to compare merits of options in the impact assessment (IA), as well as for the planning of future monitoring and evaluation.

2. Measuring success on protection of human and animal health and of the environment, see point (a).

i. Plant diseases and pests influence the availability and safety of plants for human and animal consumption, and reduce food availability. Hence, possible indicators associated with success for the initiatives (outcomes of interest for monitoring and evaluation) include:

- number and spread of cases of plant diseases and pests;
- amount of natural resources and fertilisers employed in agriculture;
- amount of pesticides used in agriculture;
- amount of antibiotics or other pharmaceutical treatments for plant diseases and pests;
- amount of food production destroyed by pests and pathogens across Member States, and the associated income loss;
- number of cases of food-borne illness and hospitalizations related to plant consumption.

All these outcomes are expected to be reduced by the legal initiative. Is this how “success” will be measured in monitoring and evaluation?

ii. In order to attribute change to the revised legislation, it would be important to have data on these outcomes at a granular level, together with data on type of seeds used (with NGT or otherwise). What granular data sources are going to be used for these outcomes? Will the use of NGT be monitored on a fine geographical scale as well, so as to allow this analysis?

iii. If granular data at field level is available, one can envisage a difference in difference identification strategy to see if NGT agricultural productions and non-NGT agricultural productions can be compared before and after the change in regulation. Is this foreseen?

3. Measuring success on innovation and sustainability objectives, see point (b).

i. Possible measures of success (and costs) that can be considered include:

- (private and public) agri-food sector R&D investments on new genomic techniques related to increases in crop resistance and adaptation to pathogens;
- (reduction in) amount of chemicals in soil (thanks to lower use of chemical fertilizers and pesticides in agriculture);
- the acreage of cultivated land; here one may have an increase of cultivated land in order to keep production levels constant with respect to the use of standard chemical products.

Is this foreseen?

ii. What sources of data are foreseen to measure specific investment in R&D, on the use of chemicals and acreage of cultivated land? Are balance sheet data in ORBIS going to be used to trace R&D investments in agri-food firms?

4. Measuring success on enhance the competitiveness of the EU agri-food sector and ensure a level-playing field (internal market).

i. Possible outcomes to measure success include:

- growth of the agri-food exports from EU Member States to third countries;
- trade balance of the agri-food sector in EU Member States;
- market shares and turnover of firms in the agri-food industry in Member States, see e.g. Wijnands, J., S. van Berkum and D. Verhoog (2015).
- mark-up in the agri-food industry benchmarked against third countries.

ii. What sources of data will be used to measure these indicators? Is ORBIS going to be used for this?

5. Joint monitoring and evaluation plan. The monitoring and evaluation of this initiative could have synergies with other initiatives, such as the Sustainability aspects in Framework for a Union sustainable food system (FSFS) and the revision of the legislation on plant (and forest) reproductive material (PRM & FRM). The administrative cost for a joint monitoring and evaluation plan with some of these other initiatives may imply synergies and cost-savings. Enough information should however be collected to distinguish the specific contribution of the present initiative. A side effect of a joint monitoring and evaluation plan would be to see how different related initiatives are working, reinforcing each other or otherwise

JRC.I1.CC-ME would be happy to discuss and give further input if useful.

It also shared the following piece of information, in case modelling is used in this IA:

Models used in support to Commission Impact Assessments (IA) should be made available in MIDAS, the Modelling Inventory of the Commission, at the time of publication of the IA report. If there is a plan to use simulation models, please contact the Competence Centre on Modelling at EU-MIDAS@ec.europa.eu to insert in MIDAS the description of the model as well as of its contribution to the IA. Models already used on behalf of the Commission are already included in the system; in this case, the information can be easily retrieved and updated if needed. Please note that the model descriptions included in MIDAS allow to easily generate the information required for Annex 4 of the IA report.

References

Wijnands, J., S. van Berkum and D. Verhoog (2015), "Measuring Competitiveness of Agro-Food Industries: The Swiss Case", OECD Food, Agriculture and Fisheries Papers, No. 88, OECD Publishing, Paris. <http://dx.doi.org/10.1787/5jrvvkrhtmwg-en>