

**Minutes of the 9th meeting of the Interservice Steering Group
for a proposal for a Regulation of the
European Parliament and of the Council on the deliberate release,
including placing of the market, of plants obtained by targeted
mutagenesis or cisgenesis, and their food and feed products**

1 February 2023

SANTE made a short introduction, indicating that this was the last meeting of the Interservice Steering Group (ISSG) before submission of the draft Staff Working Document (SWD) to the Regulatory Scrutiny Board (RSB), but ISSG meetings on the legal proposal will follow later. SANTE also noted that minutes from this meeting will be submitted to RSB together with the draft SWD and that the deadline for written comments on the draft SWD was 2 February close of business.

SANTE thanked all DGs who had provided comments to the earlier draft of the SWD and its Annexes, recalled the main comments from DGs expressed during the last three ISSGs and how they are now reflected in the SWD. Comments on scientific issues were addressed in the Annexes and the main body of the text, references to the bio-based industry were included and concerns related to impacts on organic production had been further addressed.

SANTE underlined the time pressure to deliver this initiative, recalling that it is listed in the 2023 Commission President's 'State of the Union Letter of Intent' and is also a legislative priority for the Commission, the Council and the European Parliament¹.

SANTE invited participants to raise any outstanding key issues for their DG, that in their view should still be addressed in the SWD.

SG thanked everyone for the work and confirmed that early June is the most likely adoption date for the legislative proposal, underlining that no delay is possible. SG suggested that, in collaboration with DG GROW, it would be useful to summarise in the SWD the comments regarding challenges raised in relation to Intellectual Property (IP) issues, in particular as regards SMEs. SG noted that even though there are a lot of references in relation to sustainability, a description of the coherence with the future Framework for Sustainable Food System (FSFS) was missing.

SANTE agreed to add text on both issues. SANTE also recalled that regulation of patent issues is not part of the NGT proposal but that discussions with GROW are taking place to identify whether any steps should be taken in the relevant legal framework regarding IP issues related to NGTs.

AGRI explained that they had prepared written comments. The following comments were provided at the meeting and in writing:

"DG AGRI remains by and large positive about NGTs and thanks DG SANTE for having taken into account of some of our comments. The revised text has improved."

¹ Joint Declaration of the European Parliament, the Council of the European Union and the European Commission, <https://commission.europa.eu/system/files/2022-12/221213-Joint%20Declaration%202023-2024.pdf>

The IA has significantly improved the description of the potential contribution of NGTs to the sustainability agenda.

*Concerning **intellectual property**, DG AGRI insists on better presentation of the issues and of stakeholders' views even though the issues are intended to be addressed outside the scope of the legislative proposal. In addition, it is important also to refer to the finding of the underpinning study that licenses to use NGTs for R&D purpose are affordable but much more expensive for commercial development. DG AGRI will propose drafting suggestions that it would like to see reflected in the final text of the IA.*

[REDACTED]

In the impact assessment, DG SANTE is not proposing to exclude certain technologies but to deregulate products on a case-by-case basis.

From DG AGRI perspective, it is essential to preserve the farmers' right to choose the type of seeds (and propagating material) they want and to protect the integrity of the organic production chain. Therefore, plant varieties obtained with NGTs and their progeny and products must be clearly identified, preferably through a proper labelling or at least a QR identification code linking with the public register that is proposed to be created. It is also necessary to provide for a business-to-business obligation for NGT operators to inform along the production chain. Unless coexistence measures at level of field cultivation are foreseen, it will not be possible to ensure the integrity of organic crops. Member States' right to establish GMO-free areas should be considered also for NGTs.

Concerning the public register, the impact assessment does not clarify which information will be available in the public register: organic livestock farmers and food and feed processors should also be able to choose the type of feed or food ingredients they use, therefore the public register will need to provide full transparency across the entire food chain.

[REDACTED]

[REDACTED]

As more secondary points, DG AGRI notes that the Impact Assessment is very negative vis a vis the EU GMO framework. A more balanced approach would have been desirable as the GMO framework has had positive effects for European agriculture beyond ensuring environmental and health safety.

In addition, as explained in the SWD on food security drivers, NGTs enable the introduction of multiple resistance genes into market ready varieties. This implies that conventional breeding will remain the backbone of plant variety innovation, NGTs will only be an add-on. This should be made clear to avoid giving the impression that NGTs are stand-alone techniques that will replace conventional breeding."

SANTE clarified that, regarding the protection of the organic sector, for products subject to authorisation, all safeguards in the current GMO legislation would remain (traceability and labelling, basis for coexistence measures). SANTE explained that products meeting the notification criteria would be subject to the rules applicable to conventional products, while ensuring transparency about NGT products to allow choice in the supply chain. Impacts on the organic sector would depend on whether such NGT products would be banned from the organic agriculture. The negative impacts resulting from the impact assessment referred to by AGRI relate to the scenario where the relevant NGT products would remain prohibited: the need to ensure that this prohibition is respected, for products that in many cases could not be differentiated by analytical methods and which would be treated as conventional plants in many trading partners, would result in challenges for the organic sector. SANTE recalled different stakeholders' views on the matter of whether NGTs that could have been obtained conventionally should be available to the organic sector, as expressed in the consultations. SANTE welcomed the availability of AGRI to work together in the context of the legal proposal to address these issues.

As regards the comment from AGRI seeking clarification about the registry foreseen for notified products, SANTE clarified that, while the details would be developed in the proposal, the intention is indeed to ensure that operators can make an informed choice whether or not to use NGT plants. In reply to the comment that the SWD appears as very negative vis à vis the EU GMO framework, SANTE indicated that the SWD is only looking at the current framework from the perspective of its suitability for NGT plants, not attempting to draw general conclusions, and that it would consider any necessary changes to make this clear.

JRC expressed the view that the draft SWD is good, the policy options are clearly presented and evidence has been used wherever it exists; work from the JRC and the external contractor has been correctly incorporated in the document. JRC declared to be ready for further collaboration in support of the initiative. JRC further informed that the updated version of the European Network of GMO Laboratories' (ENGL) report on the detection of plants obtained by NGTs, to which a reference is made in the draft SWD, will not be ready before March.

SANTE informed the ISSG that ENGL had been asked to update the 2019 report on detection methods for NGT plants² and noted that the final impact assessment will reflect the findings in the updated ENGL.

RTD thanked SANTE for the very good collaboration and agreed with JRC on the good SWD. RTD welcomed the references to Horizon Europe projects, but would appreciate more emphasis on bio-economy, and especially on EU bio-economy strategy supporting the innovation principles and Green Deal objectives. SANTE took note and indicated that it will incorporate references to the bio-economy strategy.

TRADE congratulated SANTE for the clear document and balanced approach of options 2 and 4 that will facilitate innovation and trade, and contribute to other objectives of the Commission. TRADE enquired how the notification procedure will be implemented, especially in comparison to trading partners. TRADE proposed appropriate wording for some parts of the SWD related to trade matters.

² European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289). <https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-reportENGL.pdf>

SANTE thanked for the comments and noted that discussions on the details of the notification procedure will continue in the context of the preparation of the legislative proposal. SANTE pointed out that the criteria on whether a plant produced by NGTs will fall under notification or authorisation are a key issue and are reflected in the SWD (and work will continue on them in the context of the preparation of the legislative proposal). The criteria were developed on the basis of scientific evidence and in discussion with JRC. The criteria used by other countries have also been considered. SANTE also pointed out that the procedural dimension of the notification procedure is also currently under consideration and will be shared at the start of the discussions on the legislative proposal. SANTE underlined that the notification procedure should be simple as time is an important factor, and that procedures need to be accessible to SMEs.

AGRI inquired which authorities will play a role in the assessment of the products. SANTE replied that the procedure for the authorised products will remain as it is today, but for the notified products, this has not yet been decided.

SANTE informed that ENV, which could not be present in the meeting, had sent comments in writing prior the meeting. The comments are reproduced below:

“DG Environment would like to make the following points at the ISSG on new genomic techniques in relation to the final version of the SWD:

The guiding principle should remain the need to achieve the highest level of protection of human health and the environment. The options chosen should strive to achieve this within the framework of the existing policy framework.

The use of the precautionary principle is also paramount for DG ENV

[REDACTED]

[REDACTED]

The IA also states that there are: “Limitations and robustness of findings: The data collection and analysis carried out have some intrinsic limitations, key among those the lack of historical data on the cultivation and commercial use of plants produced by targeted mutagenesis and cisgenesis, as the first of these products have only recently reached the markets of non-EU countries, and there is no experience at all within the EU.”

[REDACTED]

More specifically, in relation to selected options, (being a combination of option 4 for products that could also occur naturally or be produced by conventional breeding and of an adapted option 2 for all other products) DG ENV remains concerned about the level to which this choice of a combined options as been fully impact assessed. Specifically, we would like more details and

[REDACTED]

The IA also discusses also the impact of a possible new NGTs regime on Organic Farming. DG ENV would like to remind the ISSG that Organic Farming is a key target of the Farm to Fork strategy, whereby 25% of agricultural surface should be under organic farming by 2030. Significant EU funds and policy action have been, and will continue to be invested, to ensure that by 2030 25% of EU agricultural area is under organic farming.

[REDACTED]

[REDACTED]

DG ENV supports, in this regard, the comments from DG AGRI from the previous ISSG meeting, where they noted that NGT seeds should be identified so that GM-free production systems can continue to operate and have access to seeds, and that a solution can be found for coexistence.

DG ENV is also concerned about the different labelling options proposed under option 4,

[REDACTED]

[REDACTED]

[REDACTED]

Regarding the next steps, SANTE informed the ISSG that the submission date to the RSB is 15 February, and the hearing date is 15 March. A tentative date for the next ISSG is 20 March.

SANTE concluded the meeting by thanking all the participants for their comments and the constructive discussions.

Annex:

- List of participants

ANNEX

Participants 1 February 2023

DG	Name	Unit
SG		D2
AGRI		B3
		B3
JRC		F5
		D4
		D4
		D4
LEGAL SERVICE		
RTD		B2
		B2
TRADE		D3
		D3
SANTE		R1
		R1
		O1
		A2
		G1
		E3
		E3
		E3
		E3
		E3
		E3
		E3
		E3
		E3
		E3
Excused		ENV/D2
		GROW/C4
		GROW/C4
		MARE/C3
		CLIMA/A3
		COMP/ E-TF
		Task-Force Food