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From: [redacted] (SANTE)
Sent: lundi 13 février 2023 13:29
To: [redacted] (ENV)
Cc: [redacted] (ENV); [redacted] (SANTE); [redacted] (SANTE)
Subject: 9th ISSG meeting on new genomic techniques and ENV comments

Dear [redacted]

Thank you for sharing the ENV comments with us and the ISSG.

You have now seen the minutes of the 9th ISSG meeting, which were circulated on 8 February to the ISSG participants. Your comments are fully incorporated to the minutes. However, as you were not present at the meeting, we did not explicitly react to some issues raised by ENV during the meeting.

Therefore, we would like to detail further how we address the issues you have raised, a few of which we already discussed in our bilateral meeting on 18 January.

[redacted]

We would like to note that although few products have reached the market so far, there are numerous and comprehensive studies and opinions addressing potential risks associated to these techniques.

The policy action is based on the scientific opinions of EFSA, whose conclusions are shared by major scientific bodies. EFSA concluded that, as regards risks for human and animal health and the environment, there are no new hazards specifically linked to targeted mutagenesis or cisgenesis compared to conventional breeding and transgenesis. On a case-by-case basis, a lesser amount of data might be needed for the risk assessment of the relevant products compared to transgenesis. EFSA also concluded that in targeted mutagenesis, the potential for unintended effects, such as off-target effects, may be significantly reduced compared to insertions of exogenous DNA in random manner or conventional breeding. Furthermore, these techniques can produce alterations of the genetic material that can also occur naturally or that can be obtained by conventional breeding. Therefore, SANTE considers that there is sufficient scientific information to propose that those NGT products, which could have occurred in nature or obtained by conventional breeding, are treated in a similar manner as conventionally bred plants. We have included an annex in the draft SWD with scientific considerations (Annex INTR2 on Opinions of EU scientific advisory bodies and scientific organisations on NGTs).

The preferred policy option does not provide for a blanket exemption for these techniques but will maintain a regulatory oversight on a case-by-case basis. A key aim of the criteria for determining the equivalence of NGT plants to conventional plants that are being developed is to ensure that NGT plants will not pose more hazards than conventional plants. You will have seen that the draft criteria are now specified in the SWD (section 5.2.4).

ENV also questions in relation to the preferred option (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), to which level this choice has been fully impact assessed. Both options have

[redacted]. Option 4 was from the outset designed to only cover conventional-like NGT products and was assessed for such products only. The analysis of option 2 assesses the impact of adapted risk assessment/regulatory incentives for certain priority traits/labelling. This option is chosen to cater for other NGT products (not conventional-like).

Concerning your specific questions, while option 4 is assessed to be the one with the highest potential to bring products on the market, we have provided explanations in the draft SWD section 6.6, why it is difficult to anticipate the share of NGT plants/products that would fall under the notification regime compared to the authorisation regime. The relevant authority, who would make the decision of the status of the notified products, has not yet been decided. The draft criteria are being proposed based on the analysis of scientific literature on conventionally bred plants in cooperation with JRC. They have been well received by Member States experts in the specific meeting we had last week.

In the ENV written comments it is stated that "**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]

DG ENV is also concerned about the different labelling options proposed under option 4 [redacted] In response, we would first want to clarify that under option 4, there would be no specific labelling on the notified products as, being conventional-like, these would be treated in a similar way also as regards labelling obligations (although transparency about the fact that the products concerned have been obtained by NGTs would be ensured in a public register).

Secondly, under the adapted option 2, the labelling for authorised products would be similar to what is required today for GMOs. The new element would be to also give factual information on the type of trait the genetic modification has resulted in (e.g., genetically modified for the purpose of improving resistance to pests). As you know, the impact assessment looked at an option featuring the possibility of claims, and the adaptation to a factual statement is the response to the findings of the impact assessment and the potential issues that a claim would raise. There are already examples of requirements for such factual statements in the GMO legislation today (e.g. '*genetically modified soybean with stearidonic acid*' (Decision (EU) 2022/798).

I hope these clarifications are useful and we look forward continuing the work on the proposal with you

Best wishes

[redacted] for the NGT Team

European Commission
DG Health and Food Safety
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