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# REGULATORY SCRUTINY BOARD OPINION

Legislation for plants produced by certain new genomic techniques

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EUROPEAN COMMISSION
REGULATORY SCRUTINY BOARD

Brussels,
RSB

# Opinion

## Title: Impact assessment / Legislation for plants produced by certain new genomic techniques

## Overall 2nd opinion: POSITIVE WITH RESERVATIONS

**(A) Policy context**

New genomic techniques (NGT) can be used in various ways to change the genetic material of an organism. The term NGT refers specifically to genomic techniques developed after the adoption of the current EU legislation on genetically modified organisms (GMOs) in 2001. NGTs are intended to offer more precise and efficient breeding techniques in comparison with existing genetic modification and conventional breeding.

This initiative explores to what extent the current legislative framework can be adapted to allow for the development and placing on the market of NGT plants and plant products contributing to the innovation, sustainability and a well-functioning internal market. Any legislative change should be combined with maintaining a high level of protection of human and animal health and of the environment.

**(B) Summary of findings**

**The Board notes the revision of the report in response to the Board's previous opinion.**

**However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DGs to rectify the following aspects:**

**(1) The report does not describe in sufficient detail the notification procedure and criteria to verify whether a product could also occur naturally or be produced by conventional breeding.**

**(2) The report is not sufficiently clear on the preferred option concerning the use in organic production of NGT plants/products fulfilling the notification criteria.**

**(3) The report does not present a comprehensive overview of benefits and costs.**

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**(C) What to improve**

(1) The report should provide further information on the risk assessment via the notification procedure retained in the preferred option. It should better explain how the procedure will ensure that the NGTs covered are plants that could also occur naturally or be produced by conventional breeding. It should describe in more detail the key elements of the pre-determined notification criteria, their scientific basis and their implementation in practice.

(2) As regards the use in organic production of NGT plants/products fulfilling the notification criteria, the report should be clear that the two scenarios presented are in fact policy sub-options. It should indicate the preferred sub-option as regards use in organic production and if no preferred sub-option is chosen, it should clearly state this, together with an explanation why. The policy choices, implications and impacts of each sub-option should be explained, including under what circumstances notified NGT plants/products could be used or not.

(3) As regard the option "authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability", the report should be clear on the retained sub-options for labelling. It should also clarify how the label would identify those NGT as "product of biotecthnology".

(4) The report should clearly present the reasons behind wide ranges such as 'up to 85%' cost savings on the risk assessment, and provide further explanations of circumstances under which breeders might receive no savings.

(5) The report should clarify the efficiency analysis. While the report includes elements of costs quantification, in particular on coexistence, based on relevant projects and studies, including the support study, it should clarify how these available cost quantifications should be taken into account in the efficiency analysis of options and in the overview of benefits and costs, referring, if appropriate, to uncertainties and data limitations. It should explain why the aggregate cost for option on "authorisation with incentives for products containing modified traits that have the potential to contribute to sustainability" and option on "authorisation with the requirement that products do not contain modified traits that can be detrimental to sustainability" are identical when the latter introduces an additional 'trait-specific' requirement described as the most demanding for operators. The report should explain why the savings on incentives are excluded from the efficiency analysis.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

| **(D) Conclusion**<br>**The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.**<br>**If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.** | |
|---|---|
| Full title | Legislation for plants produced by certain new genomic techniques<br>Proposal for a Regulation of the European Parliament and of the Council on the deliberate release, including placing of the market, of plants, and food and feed plant products, obtained by targeted mutagenesis or cisgenesis |
| Reference number | PLAN/2021/11456 |
| Submitted to RSB on | 25 April 2023 |
| Date of RSB meeting | Written procedure |

## ANNEX: Quantification tables extracted from the draft impact assessment report

*The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.*

*If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.*

| **I. Overview of Benefits (total for all provisions) – Preferred Option** | | |
|---|---|---|
| ***Description*** | ***Amount*** | ***Comments*** |
| | ***Direct benefits*** | |
| **Cost savings for breeders** | **Notification:** Compared to the baseline breeders are expected to have a reduction in compliance costs, due to the removal of the detection method requirement, the removal of the post-market environmental monitoring and to the change in data requirements for the notification (data to show compliance with the notification criteria instead of data for a risk assessment).<br>The savings for the breeders per notification are estimated to range from EUR 9 952 000 to EUR 11 171 000.<br>**Authorisation:** Compared to the baseline, breeders are expected to have a reduction in compliance costs linked to the data requirement for the adapted risk assessment. These savings will be variable as the adapted risk assessment will not treat all products in the same way.<br>The savings for the breeders per authorisation are estimated to range from EUR 0 to EUR 10 365 000.<br>**Incentives**: The waiving of fees for the validation of the detection methods is considered as a potential incentive would add an extra saving for breeders in the authorisation procedure which would be of EUR 105 000 except for SME for which the savings would be of EUR 52 500[1].<br>**Total savings for breeders under the preferred option:**<br>Total savings for notification are estimated to range from EUR 99 520 000 to 111 710 000 per year.<br>Total savings for authorisation are estimated to range from EUR 0 to 51 825 000 per year. | For the notification, the estimated savings are dependent on the future data requirements for the notification.<br><br>For the authorisation, the estimated savings Are dependent on the future data requirements for the risk assessment and by the type of NGT<br><br>**Total savings for breeders under the preferred option:** A hypothetical scenario was used in which the breeders would submit 10 notifications and 5 authorisations per year. These are recurrent savings per year. |
| **Cost savings for administrations[2]** | **Notification:** Compared to the baseline scenario, Member States administrations are expected to have cost reductions due to the change in data requirements for the notification and to the removal of the traceability and labelling obligation.<br>The savings for administrations are estimated to be up to EUR 140 000 for the analysis of the data for notification. In addition, it is estimated that Member States would have significant savings in the enforcement, due to the removal of the traceability and labelling requirement, but these were not quantifiable.<br>**Authorisation:** Compared to the baseline scenario, Member States administrations are expected to have costs reductions due to the adapted data requirement for the risk assessment.<br>The savings for administrations are estimated to range from EUR 0 to EUR 140 000.<br>**Total savings for administrations under the preferred option:**<br>Total savings for notification are estimated to be up to EUR 1 400 000 per year.<br>Total savings for authorisation are estimated to range from EUR 0 to 700 000 per year. | For the notification, no data were available for the savings as the notification is linked to new data requirements. The monetisation of this saving corresponds to a hypothetical scenario in which the only requirement would be the current requirements for molecular characterisation of a GMO.<br><br>**Total savings for administrations under the preferred option:** A hypothetical scenario was used in which the breeders would submit 10 notifications and 5 authorisations per year. These are recurrent savings per year. |

[1] Fees for the validation of the detection methods for GMO by the EURL are described in Regulation (EC) 1981/2006. Article 4 of this Regulation currently sets up a 50% reduction of the fees for SMEs.
[2] Cost savings for the EU institutions were not considered for this table.

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| **Net economic impact/market value for farmers** | Range of 9% per hectare yield improvement (for oil and fibre crops) to 16% (for cereals) by 2030-2035. This represents, when including cost savings from reduced input use, a total annual economic market value of EUR244 m (for oil and fibre crops) to EUR2.7 bn (for cereals).<br>Expected economic benefits to further grow afterwards as more NGT plants are authorised / accepted under the notification procedure and more crops are introduced. | |
| **Time to market** | **Breeders:** Reduction of the current 4.5-year risk assessment period for imports (6 years for cultivation). Reduction depends on case-specific data requirements.<br>Application of NGTs leads to significant shorter development times and lower development costs. For example, the introduction into the market of a NGT potato variety is estimated to take five years, at a cost of EUR0.5 m instead of 13-15 years for a conventionally bred variety, at a cost of EUR2-3 m per variety. | |
| **Regulatory certainty** (likelihood that a product is able to be admitted to the market after the R&D-process) | Work on the criteria for risk assessment is intended to ensure adaptability (requirements proportionate to hazards on a case-by-case basis depending on the plant's risk profile), and predictability (ability of potential applicants to anticipate regulatory requirements). Work on the equivalence criteria for notification is intended to ensure predictability (ability of potential applicants to anticipate whether the requirement for notification would be met) and based on the product's molecular characterisation | |
| **Trade** | The preferred option minimises (compared to the other options) regulatory divergence with EU trade partners. For example, the detection of non-authorised GMO Triffid flax in EU food products and the subsequent import ban on Canadian flax led to a EUR40 m loss for the EU flax processing industry and 600 jobs lost | Differences in the regulation of NGTs increase the likelihood of regulatory asynchronicity. |
| **Environmental benefits – pesticide reduction** | According to the JRC study of Schneider et al. (2023; see Annex 7):<br>For cisgenic potatoes: 50-80% reduction of fungicide usage, or 9 kg per hectare, without impacts on yield or quality.<br>For cisgenic apples bred with monogenic resistance against scab disease: reductions between 14% in the Netherlands and 58% in France could be achieved, the latter equivalent to 15 kg per hectare less fungicide use. | |
| **Environmental benefits: fertiliser reduction** | Projections 2030-2035 based on the contractor's study:<br>A decrease of 0.1% and 4%, depending on crop species and rate of adoption of NGT plants | |
| **Environmental benefits: GHG reduction** | Multipurpose use of gene-edited root chicory (production of inulin and health-beneficial terpenes): reduction of GHG emissions of around 10% compared to the current inulin production process when considering the entire value chain.<br>Use of gene-edited pennycress (*Thlaspi arvense*) as a cash cover crop for biofuel production without displacing food crops<br>Projections 2030-2035 based on the contractor's study:<br>A decrease of up to 3.1% depending on crop species and rate of adoption of NGT plants. | |
| **Social benefits – Health: nutritional impacts-food security** | Health benefits for consumers would result from increased beneficial bioactive compounds in food and feed, such as increased levels of vitamin A, antioxidants, production of monounsaturated fatty acids and GABA. Moreover, harmful bioactive compounds such as cyanide, glycoalkaloids, allergens could be removed.<br>NGTs may affect overall health benefits (in terms of QALYs) in different ways, including improving the accessibility to products that might lead to healthier diets.<br>Such direct and indirect benefits are presented by the JRC study of Sanchez *et al*. (2023), described in Annex 7 on low-gluten wheat.<br>Food security benefits are especially relevant for developing countries, as Annex 7 demonstrates with the example of Maize Lethal Necrosis (MLN) resistance (JRC 2023), a severe threat to food security in Eastern Africa. | |
| **Social benefits: consumer variety** | Consumers will experience improved product choice. | |

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| **and choice** | | |
| ***Administrative cost savings related to the 'one in, one out' approach**** | | |
| **Administrative cost savings for breeders** | **Notification:**<br>Reduction in administrative costs related to regulatory support is expected. The savings for breeders are estimated to range from EUR 83 300 to EUR 833 000.<br>Reduction in administrative costs related to scientific support. The savings for breeders are estimated to range from EUR 35 700 to EUR 357 000.<br>Reduction of the administrative costs as the data requirements for notification may not require studies to be performed under GLP/ISO guidelines. The savings for breeders are estimated to range from EUR 56 000 to EUR 1 120 000.<br>Reduction of administrative costs as the notified NGT plant will not require the submission of post-market monitoring. The savings for breeders are estimated to be EUR 1 200 000.<br>Reduction in administrative costs as the notified NGT plants will not be subject to a renewal procedure. The savings for breeders are estimated to be EUR 240 000.<br>The total savings per notification is estimated to range from EUR 1 615 000 to EUR 3 750 000<br>**Authorisation:**<br>Reduction in administrative costs related to regulatory support is expected. The savings for breeders are estimated to range from EUR 0 to EUR 833 000.<br>Reduction in administrative costs related to scientific support. The savings for breeders are estimated to range from EUR 0 to EUR 357 000<br>Reduction of administrative costs as the data requirement in the adapted risk assessment for authorisation may not require or may require less studies to be performed under GLP/ISO guidelines. The savings for breeders are estimated to range from EUR 0 to EUR 560 000.<br>The total savings per authorisation is estimated to range from EUR 0 to EUR 1 750 000<br>**Total administrative cost savings for breeders under the preferred option:**<br>Total administrative cost savings for notification are estimated to range from EUR 16 150 000 to 37 500 000 per year.<br>Total administrative cost savings for authorisation are estimated to range from EUR 0 to 8 750 000 per year. | For the notification, the estimated savings are dependent on the future data requirement for the notification.<br><br>For the authorisation, the estimated savings are dependent on the future data requirements for the risk assessment and by the type of NGT<br><br>**Total savings for breeders under the preferred option:** A hypothetical scenario was used in which the breeders would submit 10 notifications and 5 authorisations per year. These are recurrent savings per year. |
| **Administrative costs saving for food businesses** | **Notification:** Unquantifiable recurrent savings are in administrative costs for food businesses is expected due to the removal of the traceability and labelling obligation. | |

| **II. Overview of costs – Preferred option** | | | |
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| | **Breeders** | **Administrations** | **Farmers and food businesses** |
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| **Notification of a NGT product** | Indirect costs | n/a | n/a | **Recurrent costs for organic farmers**. Potential unquantifiable increases costs risk management practices and market monitoring (for accidental presence of GM/NGT product) due to the uncertainties of potential presence of notified NGT plants in conventional seeds.<br><br>**Recurrent costs for farmers**. potential unquantifiable costs for segregation/coexistence systems. |
| **Authorisation of a NGT product** | Administrative costs | n/a | n/a | **Recurrent costs for food businesses.** Limited unquantifiable cost increases due to additional information in the label (identification on the label of the purpose of the genetic modification to the label) and related segregation costs. |
| **Incentive for NGT products with traits that can contribute to sustainability** | Direct adjustment costs | n/a | **One-off costs:** Support given to the applicant during authorisation process due to sustainability incentive. Potential unquantifiable significant increase in cost for the administrations | n/a |
| ***Costs related to the 'one in, one out' approach*** | | | | |
| **Total** | Direct adjustment costs | n/a | n/a | n/a |
| | Indirect adjustment costs | n/a | n/a | Unquantifiable increase for farmers. |
| | Administrative costs (for offsetting) | None | None | **Recurrent costs for food businesses.** Limited unquantifiable cost increases due to additional information in the label (identification on the label of the purpose of the genetic modification to the label) and related segregation costs. |

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# Opinion

## Title: Impact assessment / Legislation for plants produced by certain new genomic techniques

## Overall opinion: NEGATIVE

**(A) Policy context**

New genomic techniques (NGT) can be used in various ways to change the genetic material of an organism. The term NGT refers specifically to genomic techniques developed after the adoption of the current EU legislation on genetically modified organisms (GMOs) in 2001. NGTs are intended to offer more precise and efficient breeding techniques in comparison with existing genetic modification and conventional breeding.

This initiative explores to what extent the current legislative framework can be adapted to allow for the development and placing on the market of NGT plants and plant products contributing to the innovation, sustainability and a well-functioning internal market. Any legislative change should be combined with maintaining a high level of protection of human and animal health and of the environment.

**(B) Summary of findings**

**The Board notes the additional information provided and commitments to make changes to the report.**

**However, the Board gives a negative opinion because the report contains the following significant shortcomings:**

**(1) The report does not present a clear, consistent, and hierarchical set of general and specific objectives.**

**(2) The report does not describe in sufficient detail what the main elements of the options and the key policy choices are.**

**(3) The report does not sufficiently assess the impact on consumer trust, the organic sector, the environment and health. It does not present a comprehensive overview of the costs and benefits.**

**(4) The report does not provide a comprehensive assessment of all relevant (combinations of) options in terms of effectiveness, efficiency and coherence.**

**(C) What to improve**

(1) The report should present a more comprehensive overview of the current context including how NGTs are being developed at global level, the and the implications for sustainability and for EU strategic autonomy and competitiveness. It should better explain the magnitude of the problems and consequences identified.

(2) The report should present a clear, consistent, non overlapping and hierarchical set of general and specific objectives. It should more clearly outline what the substantive key objectives of this initiative are. In particular, it should explain in more detail the significance of the sustainability objective, and whether this is a new objective requiring the revision of the Directive. The report should clarify to what extent EU strategic autonomy, including food security, is a key objective of this initiative based on the problems identified. The report should further improve the link between the problems and objectives. It should, clarify what objectives remain the same (e.g. human and animal health and environment in accordance with precautionary principle) and which ones emerge from the identified problems.

(3) The report should more fully describe the main elements of the options and explain who are the actors determining, implementing, and enforcing them. It should clearly outline how the notification regime and adapted risk assessment would work, what parameters would apply, who would decide, and what follow-up would be ensured. The report should set out how the sustainability objective is addressed in each option, and on whether there are further alternative elements or combinations of options. It should provide more detail on what the regulatory incentives and the different criteria presented would look like in their final form. It should provide a comprehensive explanation of why the choice of labelling requirement differs across the identified options. The report should be clear on the policy choices and trade-offs, and to how they are addressed in the policy options. In addition, the report should clarify the approach retained in the preferred option as regards the organic sector.

(4) The report should further develop the assessment of the impact on health, environment, consumer trust and the organic sector. Concerning health and environment, the report should provide a more balanced analysis accounting for likely environmental and social benefits as well as possible risks for the environment and for human and animal health and how they will be monitored and mitigated. It should also explain how the impacts on sustainability are assessed. The report should provide further evidence - coming from recent social science research and surveys - on consumer attitudes towards NGT products and assess how consumer trust may impact uptake of future NGT products. It should discuss the risk that benefits might not materialise as a result of lack of consumer trust. The report should further develop the analysis of the impacts on the organic sector including quantification of the costs for this sector.

(5) The report should present a clear and comprehensive overview of the costs and benefits for each option. It should better describe the uncertainties and limitations of the analysis based on hypothetical scenarios. It should further explain the credibility and reliability of the wide ranges of estimates presented.

(6) The report should provide a better comparison of options, with a consideration of different combinations of options. It should identify all relevant combinations upfront and assess and compare them along the individual options. The effectiveness analysis should be based on the revised set of specific objectives, avoiding any double counting. The comparison summary table should be critically reviewed to remove overlaps and inconsistencies. The efficiency analysis should include quantified and monetised cost and

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| benefit estimates. The used scoring methodology should be better explained, and the individual scores better justified. The report should provide a clear assessment of coherence, in particular in light of concerns expressed by stakeholders as regards Farm to Fork and the role of organic farming.<br>*Some more technical comments have been sent directly to the author DG.* |

| **(D) Conclusion**<br>**The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.** | |
|---|---|
| Full title | Legislation for plants produced by certain new genomic techniques<br>Proposal for a Regulation of the European Parliament and of the Council on the deliberate release, including placing of the market, of plants, and food and feed plant products, obtained by targeted mutagenesis or cisgenesis |
| Reference number | PLAN/2021/11456 |
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| Date of RSB meeting | 15/03/2023 |



Electronically signed on 26/05/2023 13:22 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121