Proposal for a Regulation on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

General exclusion of HTVs from category 1 NGT plants

5 January 2024

Executive summary

- In its draft general approach of 7 December 2023, the Council has introduced a general exclusion of herbicide-tolerant varieties ("HTVs") from category 1 NGT plants. Such a general exclusion is not scientifically based and contrary to the very rationale of the proposed regulation.

- From a scientific perspective, there is evidence proving that HTVs allow targeted field-by-field weed control, thus enabling a rational use of herbicides. Scientific reports even show higher pesticide uses in non-HTVs plots compared to HTVs ones. In any case, the risks identified by the Council are only linked to proven cases of increased use of herbicides, not to the general use of HTVs. In this regard, risks posed by the use of herbicides are already assessed as part of Regulation (EC) 1107/2009.

- Further, by providing for a general exclusion from category 1 NGT plants of HTVs that address current challenges in the agri-food system and contribute to the innovation and sustainability objectives, the draft general approach of the Council runs counter the very rationale of the proposed Regulation to facilitate the development and placing on the market of innovative NGT plants. This is further not consistent with recital (36) of the Commission's proposal which clarifies that the regulation is not intended to take specific measures on herbicide tolerant NGT plants.

- For all these reasons, in line with the European Parliament AGRI Committee Opinion, it is proposed to stick to the Commission's proposal by removing the general exclusion of HTVs from category 1 NGT plants.

On 5 July 2023, the European Commission presented a proposal for a Regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed. The proposed regulations distinguishes varieties considered equivalent to conventional plants (category 1 NGT plants) from all other plants obtained through NGTs (category 2 NGT plants) namely, targeted mutagenesis and cisgenesis. Category 1 NGT plants are exempted from the requirements of the GMO legislation and are subject to the provisions applicable to conventional plants. Category 2 NGT plants are subject to the procedures of the GMO legislation with some adaptations.

Under the Commission's proposal, category 1 NGT plants are NGT plants that fulfill the criteria of equivalence to conventional plants set out in Annex I. In its draft general approach of 7 December 2023, the Council has however introduced a general exclusion of HTVs from category 1 NGT plants, considering that "NGT plants that include tolerance to herbicides among the intended traits conveyed by the genetic modification should be subject to the provisions for category 2 NGT plants".

Such a general exclusion of HTVs from category 1 NTG plants is not scientifically based and contrary to the very rationale of the proposed regulation.

First, a general exclusion of HTVs from category 1 NTG plants is not justified from a scientific perspective. The Council justify such an exclusion by the fact that "if [the cultivation of HTVs] is not done under appropriate conditions, it may lead to development of weeds resistant to those herbicides or to the need
to increase of quantities of herbicides applied, regardless of the breeding technique, with the risk of a negative impact on human and animal health and the environment”.

However, there is scientific evidence proving that HTVs allow a targeted field-by-field weed control, thus enabling a rational use of chemical herbicides. Scientific reports even show higher pesticide uses in non-HTVs plots compared to HTVs ones.

For instance, a 2021 report from the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) concluded that (i) non-HTVs plots consume more pre-emergence herbicide active substances than HTVs plots and that (ii) the number of different active substances used is greater in non-HTVs plots, reflecting the fact that farmers combine a greater number of herbicide solutions. As explained on ANSES’ website:

"ANSES notably tested an indicator that compares the health risks associated with farmers’ exposure depending on whether a sunflower crop is an HTV or non-HTV, based on use data from the Ministry of Agriculture’s 2017 “plant protection products-arable crops” survey. The results of these tests suggest that the value of the risk indicator for the non-HTV group is higher than that of the HTV group. These findings can be explained by the use of more active substances with more unfavourable toxicological profiles to control weeds in non-HTV plots" (emphasis added).

ANSES further stresses on the same website that "a preliminary analysis, based on an environmental risk indicator and pesticide use data, suggested that the impacts of weed control practices on aquatic organisms such as fish or aquatic plants may be greater for non-HTV crops" (emphasis added).

In the same vein, during a meeting of the SCoPAFF Committee of 12 May 2023, at the occasion of an exchange of views on a request from France to be authorised to prescribe appropriate cultivation conditions for HTVs, "One Member State pointed out that there are studies showing that the use of herbicide tolerant varieties has resulted in overall lower use of herbicides" (emphasis added).

In any case, even if justified (quod non), the risks identified by the Council are only linked to proven cases of increased use of herbicides, not to the general use of HTVs. In this regard, risks posed by the use of herbicides are already assessed as part of Regulation (EC) 1107/2009 which lays down rules for authorising the sale, use and control of plant protection products in the EU.

Second, a general exclusion of HTVs from category 1 NTG plants is contrary to the very rationale of the proposed regulation, which is to facilitate the development and placing on the market of innovative NGT plants. NGTs indeed allow precise and efficient development of improved plant varieties that can be climate resilient, pest resistant, require less fertilisers and pesticides, or ensure higher yields.

Although specific criteria of equivalence have been set in Annex I to determine which plants fall into category 1, the draft general approach of the Council will result in excluding from such category 1 NGT plants, HTVs that would nonetheless meet such criteria. Such a general exclusion would thus render the development and placing on the market of such NGT plants more difficult, although HTVs enable a rational use of

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2. Standing Committee on Plants, Animals, Food and Feed - Section Seeds and Propagating Material for Agriculture and Horticulture.
chemical herbicides by providing a technical solution for targeted field-by-field weed control (see above).

By setting a general exclusion from category 1 NGT plants of HTVs that address current challenges in the agri-food system and contribute to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies, the draft general approach of the Council runs counter the very rationale of the proposed Regulation.

The draft general approach of the Council is in any case not consistent with recital (36) of the Commission’s proposal which clarifies that the proposed regulation is not intended to take specific measures on herbicide tolerant NGT plants.

For all these reasons, in line with the European Parliament AGRI Committee Opinion, it is proposed to stick to the Commission’s proposal by removing the general exclusion of HTVs from category 1 NGT plants.

Finally, it is worth reminding that the proposed regulation should stick to a positive list of traits justifying the regulatory incentives for category 2 NTG plants and not exclude herbicide tolerant traits. As explained above, the proposed regulation is indeed not intended to take specific measures on herbicide tolerant NGT plants.