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## The latest EU agriculture, environment & trade news

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- **COMMISSION TO PROPOSE ALLOWING FOOD & FEED FROM NGTs WITHOUT LABELS**
- **IMPACT STUDY SHOWS SAVINGS, ADVANTAGES IN TACKLING CLIMATE CHALLENGES**

### COMMISSION TO PROPOSE ALLOWING FOOD & FEED FROM NGTs WITHOUT LABELS

The European Commission is planning to propose that food & feed produced from plants obtained by certain New Genomic Techniques (NGTs) should be allowed on to the EU market without labels, if they could also occur naturally, or as a result of conventional breeding. According to a draft obtained by *Agra Facts*\*, an exception would be made for plants with herbicide resistance, which would still have to be labelled as GM, while seeds would be labelled to help organic farmers to avoid them.

The 23-page draft proposal for a Regulation on plants obtained by certain NGTs and their food and feed is due to be unveiled by the Commission on July 5 as part of a 'Food & Biodiversity' package (*as per the latest College agenda dated June 13*) including the Soil Health law, Revision on Seeds & other plants & forest reproductive material & Revision of food waste & textiles aspects of the EU Waste Framework Directive. *On the latter, an expert group of Member States is meeting on June 29, with sources indicating that the Commission may present a revised proposal on 'date marking' on food, but there is no confirmation about that yet.* In the draft text circulating this week, Commission (DG SANTE) officials say the move will reduce the administrative burden on plant breeders, while encouraging the development of traits that help fulfil UN Sustainable Development Goals, including those related to tackling hunger & climate change.

*\*This article is based on a draft version circulating at the time of going to print; Still subject to change before the 'big reveal' in early July; Usual caveats apply; AGRA FACTS understands that the draft proposal entered into the interservice consultation (ISC) last week, with the document under strict restrictions; The ISC on the controversial & long-awaited file was reportedly quite short;*

**DG SANTE prepares five policy options:** The draft explanatory memorandum outlines **five policy options**, including the **baseline** under which "plants obtained by targeted mutagenesis & cisgenesis would continue to be subject to the current regulations of the GMO legislation (risk assessment, authorization, traceability & labelling) with no change." **Option one** would mean plants obtained by those techniques would require an authorization, as they do today. "The risk assessment will be adapted to cater for their diverse risk profiles & to address detection challenges," the Commission says. "Traceability & labelling would be maintained as in the baseline." **Option two** would also involve a requirement for an authorization, & a similar risk assessment. "Measures would be introduced to incentivise plant products that could contribute to a sustainable agri-food system," it says. "Traceability would be maintained as in the baseline." The EU's executive explained that it had considered several labelling alternatives including a GM label accompanied by a sustainability label, a factual statement on the trait introduced, or no GMO label if the NGT trait has the potential to contribute to sustainability. Under **Option three** there would still be a requirement for an authorization under the same type of risk assessment, & requirements on traceability & labelling. "Applicants for authorisation would be required to show that the introduced trait is not detrimental to sustainability," the Commission says.

The **final option** would require a "notification procedure for plants obtained by targeted mutagenesis or cisgenesis that could also occur naturally or be produced by conventional breeding." "Such plants would be treated similarly to conventional plants & would not require authorisation, risk assessment, traceability & labelling as GMOs; a transparency register would be established for these plants," it says "This option is intended to apply in combination with the baseline or options 1, 2 or 3 (for plants not fulfilling the criteria for notification.)" Officials say that "the preferred option is a combination of **Option 4** for products that could also occur naturally or be produced by conventional breeding & of **Option 2** for all other products," an arrangement which they feel "ensures to the largest possible extent that NGT plants & their food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden." It would also mean that such plants, "featuring a wide range of plant species & traits by various developers are placed on the market," so that they can "contribute to a sustainable agri-food system."

**Beneficial traits:** This choice, "creates an enabling framework to meeting the demands of farmers for the development of new varieties," DG SANTE officials outline in the draft text, noting that it also allows the "commercialisation (of) plant reproductive material with beneficial traits to respond to the constraints of the agroecological context." Notification "achieves safety while ensuring that requirements are proportionate to risk," they stress. "It has by far the strongest impact on the development & placing on the market of NGT products, as it results in a higher degree of simplification & reduction of administrative burden for applications & authorities."

The Commission also claims that it has “the highest potential to facilitate the contribution of NGTs to the sustainability of the agri-food system,” & is “the most advantageous for SMEs, as administrative & compliance costs will substantially decrease,” while it would have “the strongest impact on competitiveness & would be least disruptive of trade.”

**Incentives for sustainable varieties:** The Commission is also thinking in terms of “regulatory incentives” that would “help steering the development of NGTs towards traits with sustainability potential & would support the competitiveness of SMEs.”

For plants subject to authorisation, the “existing GM label will be complemented with the possibility to inform of the purpose of the genetic modification to allow operators & consumers to make informed choices.” “This is expected to drive market demand for products with beneficial traits,” it asserts. The content of the statement on purpose “will be determined in the authorisation, but its use will be voluntary for operators, to address concerns identified during the impact assessment linked to its burden if made mandatory,” particularly if it makes further segregation necessary.

Even if they fulfil the notification criteria, herbicide tolerant NGT plants, “will remain subject to authorisation... in order to be able to assess their impacts on human, animal health & the environment in the medium & long-term.” “There is evidence showing that herbicide resistant weeds may arise from the combined use of herbicide tolerant varieties & overuse of the associated herbicide,” it adds, noting “potential health & agroecosystem impacts.”

The Commission had decided that NGT products that “meet the criteria to be considered equivalent to conventional breeding, should be treated as GMOs for the purposes of organic production based on the majority position of the organic sector.” That means that “these NGT plants will remain prohibited in organic production,” it says, adding that “to allow choice at the beginning of the supply chain to support maintaining organic production free from NGTs & preserve consumer trust..., an additional measure is proposed: the indication of the use of NGTs in the labelling of seeds.” Officials insist that “by enabling the development & marketing of NGTs, the current proposal responds to the objective of climate neutrality.” They claim it has “the potential to contribute towards the implementation of several SDGs,” notably those on ending hunger & taking urgent action to combat climate change & its impacts.

### **IMPACT STUDY SHOWS SAVINGS, ADVANTAGES IN TACKLING CLIMATE CHALLENGES**

The Commission’s preferred plan for the marketing of foods produced using crops from NGTs shows a major saving in costs for plant breeders, & an advantage for the EU in securing supplies of food & feed, with new varieties better adapted to stand up to the challenges created by climate change.

The EU market for plant reproductive material (PRM) (agriculture & forestry) has an estimated annual value of €15 billion, it says. “The EU seed market is the third largest after the USA & China & accounts for around 20% of the global market.” It puts the value of the EU seed market at €7-10 billion, with around 7 000 companies, most of them small & medium sized, involved employing some 52 000 people.

**China leads:** The largest share of world research into NGTs is conducted in China, with 43%, the Commission says, while the US is responsible for 18% & the EU 14%. EU research into the crops is mainly taking place in FR, DE, IT, BE & NL. “The EU breeding sector is highly innovative & spends around 15% of its annual turnover on R&D,” it says. It goes on to explain that NGTs have been developed over the last two decades as understanding of the functioning of genes has advanced, pointing out that the range of techniques involved is diverse. Looking at targeted mutagenesis & cisgenesis, which are included among new genomic techniques, it points to their “higher precision & speed,” & “introduction of genetic material from a crossable species,” as novel features. They do not introduce genetic material from a non crossable species, the transgenesis technique, used in established genomic techniques.

The Commission quotes scientific bodies finding that certain new genomic techniques increase precision compared to conventional breeding. “Changes introduced with conventional breeding techniques occur randomly,” it says, “while certain NGTs can produce precisely located alterations to DNA sequences.” The new techniques avoid the need to screen large plant populations for the organism with the desired characteristics. “When changes are small & known in other organisms, the resulting products are expected to display more predictable characteristics,” the Commission says. “For these reasons & for their increased precision, many NGTs shorten the development time to obtain organisms with desired traits.”

**NGTs more controllable:** It explains that EFSA has evaluated the scientific literature provided by scientific bodies & “has confirmed that NGT’s are more precise, controllable & predictable down conventional methods & their precision is continually increasing with technological progress,” it said.

It notes that “GMOs have been a controversial topic in the EU since the introduction of the EU GMO legislation,” adding that “since the entry into force of Regulation (EC) No 1829/2003, no draft Commission decision proposing the authorisation of GM food & feed has obtained a favourable opinion by qualified majority of the Member State(s) in the relevant Regulatory Committee, notwithstanding favourable EFSA opinions.” The only GMO authorised for cultivation in the EU is maize MON810, grown in Spain & Portugal, but 18 of 27 Member States have restricted or prohibited its cultivation in all or part of their territories. A further point made is that while the market for GM food in the EU is small, the Union makes use of a

substantial amount of GM feed, as it is a major importer of high protein agricultural commodities from countries where production is dominated by GMOs.

**Securing food production:** The Commission also claims that “gene-editing technologies will have far reaching implications for agri-food & social systems in terms of their potential for improving & securing production of food.” It notes that “the Covid 19 pandemic & Russia’s war of aggression against Ukraine have also revealed the EU’s external dependencies,” highlighting a “global spike in prices of inputs needed for agri-food production, in particular energy, animal feed & feed additives, & fertilisers,” showing the EU’s “vulnerability to price shocks.”

“There is currently a strong demand by a range of stakeholders including breeders, farmers & academia, to adapt the regulatory framework to enable the development, marketing & use of NGTs as tools contributing to address current challenges,” it points out. “Other stakeholders, however, consider that the benefits of NGTs are hypothetical & achievable by means other than biotechnology.” Environmental organisations are concerned about safety, while organic & GM-free producers have worries about the possible impact on their businesses.

On citizens’ perceptions of the NGTs, it says that studies show that most (60-64%) of Europeans have not heard of the techniques & that knowledge of NGT organisms & GMOs is limited. “Research conducted globally suggests that the majority of the respondents are receptive to the use of NGT products, particularly in the agricultural sector, as long as they bring societal benefits & promote sustainability, for example, through traits adapted to climate change, reduced pesticide use & improved nutritional content,” it says. “The majority of respondents in research studies believe that labelling of NGT products is necessary.”

Looking at the Commission’s preferred option, **Option four**, with a notification procedure, but no labelling on food, the EU’s executive says in its impact assessment, that it is “the best performing option to deliver on the objectives of this initiative & shows positive impacts in terms of innovation & interest of developers in marketing these products in the EU, enabling products to contribute to sustainability & food security.” “This option scores best as regards coherence & proportionality,” while entering the products into a public register, “would increase public transparency compared to the treatment today, of GMOs exempted from the requirements of the GMO legislation (e.g. the products of random mutagenesis) for operators... & consumers.” “The current GMO label is perceived as a warning on possible risks,” it notes, but points out that “only plants as safe as comparable conventional plants can be placed on the market.” That means that labelling “would impact consumer acceptance especially of food,” & is “a key driver of negative consequences on the attractiveness to develop NGT plants in the EU.” “Consumer acceptance of NGTs is necessary for the benefits of NGTs to materialise,” it stresses. “Initiatives to inform & engage consumers about NGTs need to be considered to accompany & explain the transparency measures – label in option two, registry in option four – provided in the legislation.”

**Savings for breeders:** For plant breeders, the Commission puts the savings in adjustment costs under its preferred option, based on the assumption that they submit ten notifications & five applications for authorisation each year, at between €99.5 million & €163.5m a year. For farmers using NGT crops, the recurrent savings in adjustment costs would be between €22m for vegetable crops & €2.7 billion for cereals. Breeders would also save €16.15m to €46.25m in administrative costs, but no administrative costs are identified for farmers, while food business are expected to see a “limited unquantifiable increase in administrative cost, due to additional information in the GMO label... & related segregation costs.”

*The next edition of AGRA FACTS will follow on Friday evening (June 16);*

*ENDS*