EuropaBio comments on the public consultation on Proposal P1055 – Definitions for gene technology and new breeding techniques

EuropaBio, the European Association for Bioindustries (www.europabio.org), promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions.

As the leading industry association for biotechnology in Europe, we appreciate the opportunity to respond to Proposal P1055 and have outlined our comments below.

General comments
We appreciate FSANZ's consideration of the available scientific evidence in preparing the proposal. We agree with FSANZ that a product-based, risk-proportionate regulatory oversight framework is a prerequisite for the development of an efficient and competitive food industry. Regarding FSANZ's proposed approach, we have some reservations, as outlined below.

Chapter 3 'Assessment'
Under section 3.3 (*implications for risk management)*, we agree with the assessment that "for determining risk, the assessment shows the focus should be on the food itself and its characteristics, not the types of genetic change occurring in a food organism or whether the changes were intended or unintended." However, we find that the proposal includes inconsistent argumentation and uses a hybrid approach with both process- and product-based definitional criteria focusing mainly on the food safety risk. For instance, "foods produced using gene technology" is a process-focused term even though it is intended to be a product-focused term.

Chapter 4 'Risk Management'
Regarding section 4.3.2 of the proposal (*Exclusion Criteria for certain foods*), we would like to comment on certain exclusion criteria raised under the headings on NBT food and refined ingredients:

NBT food that is the same as conventional food (pp. 25-26)

"(ii) the trait introduced using gene technology does not modify the levels of key nutrients, endogenous toxicants or anti-nutrients so they are outside the documented range for an equivalent conventional food; (…)
(v) the endogenous allergen content of the food has not been modified as a result of gene technology."

Loss of a trait is something that can happen spontaneously in nature. Therefore, if the synthesis of endogenous toxicants, allergens, or anti-nutrients is suppressed, this should be in the best interest of all, and should not prevent exemption simply because complete deletion might be "outside the documented range for an equivalent conventional food".

Refined ingredients

In the EU, absence of rDNA is not formally a regulatory requirement for fermentation products. However, the acceptable level of DNA has been discussed for years and the discussion is still ongoing.

The fermentation industry has provided multiple lines of argumentation why "absence of rDNA" should continue *not* to be a regulatory criterion, due to:

- rDNA typically not being a safety issue
- Complexity of setting up and validating analytical methods (many fermentation products, many matrices [straights, different formulations, different premixes, etc.]) and the associated complexity of enforcement

For more detailed information, please refer to the recently published open-access full Legal Expert Opinion on rDNA Traces in Fermentation Products Using Genetically Modified Microorganisms (GMMs)[1]. This Legal Expert Opinion was commissioned by EuropaBio, FEFANA and AMFEP[2] and undertaken by Prof. Hans-Georg Dederer, Chair of Constitutional and Administrative Law, Public International Law, European and International Economic Law at the University of Passau, Germany.

In line with this, we do not see a justification for using rDNA as a regulatory decision criterion (or as an exclusion criterion for pre-market review), neither in the EU nor in Australia or New Zealand. If, however, FSANZ decides to introduce absence of rDNA or novel proteins as a decision criterion, then the details of its implementation would be very critical.

For fermentation products, our recommendation would be to focus on the absence of viable genetically modified microorganisms, rather than focusing on rDNA and/or novel proteins. It is currently far more demanding to set up analytics for novel proteins over rDNA. We would also like to point out that in a refined oil, rDNA levels will naturally be very low, because DNA is poorly soluble in oil. It is however more difficult to remove rDNA from, e.g. a food or feed enzyme.

[1] Dederer, H. rDNA Traces in Fermentation Products Using Genetically Modified Microorganisms (GMMs) Zeitschrift für Stoffrecht. Volume 18, Issue 3 (2021) pp. 135 - 147
DOI: https://doi.org/10.21552/stoffr/2021/3/6

[2] Legal expert opinion commissioned by AMFEP: Association of the Manufacturers and Formulators of Enzyme Products; FEFANA: EU Association of Specialty Feed Ingredients and their Mixtures; and EuropaBio: European Association for Bioindustries

Comments on the supporting documents

Definition of cisgenesis (SD1, p.5): This definition of cisgenesis seems rather narrow and it also raises questions such as:

- Would this definition disqualify combining a strong promoter with an open-reading frame that naturally has a weak promoter by considering this a 'change in arrangement'?
- How would codon optimization be handled? Codon optimization is an efficient means of modulating the expression of a gene of interest without any changes in the encoded amino acid sequence. Codon optimization is widely used and is generally seen to be compatible with "self-cloning"/"cisgenesis".
- Can the difference in assessment for cisgenesis and intragenesis be clarified? It is argued that intragenesis cannot be assessed the same way as cisgenesis as "foreign" DNA may be inserted by intragenesis. However according to the definition on page 5 only DNA from the same species or cross-compatible species can be inserted so we do not consider this as "foreign". Further, we consider that safety concerns are not defined by the degree of foreign-ness but rather by the trait encoded.

Inconsistent use of the term 'genetic modification': (p. 4, 6, 20, 21): We find inconsistency in the use of the term genetic modification. On page 20 and 21, it is clear that 'genetic modification' covers all genetic changes, whether from conventional breeding, traditional GM approaches, or from NGTs. On page 4, on the other hand, a "genetically modified organism" is only "An organism whose genome has been modified using gene technology" (so, excluding conventional breeding).

We also find that the definition of 'null segregant' on page 6 is unclear: "*Progeny that have not inherited a genetic modification*". In the vast majority of cases, the null segregant will have a genetic modification as a result of the entire process. However, the null segregant should not inherit the 'gene technology' modification introduced temporarily.

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