

Response to Consultation paper:

Food derived using new breeding techniques

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Mutations and genomic rearrangements are the cornerstones of evolution and provide the novel traits that underlie the continuing improvement of our food crops. From variants of Australian native foods (i.e. <http://www.agrifutures.com.au/farm-diversity/finger-lime/>) to the introduction of novel varieties of tomatoes and other common fruits and vegetables (<https://www.syngenta.com.au/news/vegetables/tomato-trials-prove-fruitful-growers>), novel DNA and the trait advantages it brings is regularly introduced to the marketplace to the appreciation and benefit of consumers.

Modern breeding programs use accelerated mutagenesis and artificial combinations of existing germplasm¹. These techniques are considered conventional and the food products derived from them safe for consumption because of their long history of safe use^{2,3}. These conventional approaches take advantage of DNA mutations, both ancient and recent and both spontaneous and induced. Spontaneous and accelerated mutagenesis can induce a variety of DNA modifications, ranging from single nucleotide changes to large, multiple chromosomal rearrangements. All of these changes have the potential to elicit advantageous characteristics in the affected organism.

In accelerated mutagenesis, the application of mutagens such as ethyl methanesulfonate (EMS) or MNU (N-methyle-N-nitrosourea) generally causes multiple, random, generally point mutations (single nucleotide polymorphisms, SNPs) (Kurowska et al., 2012)⁴. By contrast, X-ray or gamma radiation has been shown to cause multiple, often large-scale changes to DNA. A study by Morita et al (2009)⁵, for example, found that gamma radiation of barley induced multiple small mutations (1-16bp), several large deletions (9.4-129.7kbp), several substitution mutations and two chromosomal inversion mutations. Although these approaches induce large-scale DNA mutagenesis, these techniques are considered as mimicking processes that occur in nature. Foods containing novel characteristics because of the DNA mutations introduced by these techniques are considered safe because of a long history of the safe use of the techniques in breeding programs^{1, 2, 3}.

NBTs such as genome editing typically introduce novel characteristics through directed deletion or insertion (indel) mutations at precise locations in a genome, through NHEJ⁶, or targeted substitutions through base editing. It is difficult to argue that precisely targeted mutations are less safe than random mutagenesis. Both approaches are designed to elicit genetic modifications that result in advantageous phenotypes. Given the global challenges we are facing, it makes sense to embrace discoveries like NBTs that can improve our capacity to respond to changes. The NBTs should be treated the same as other conventional breeding techniques.

3.1.1 Questions

Do you agree, as a general principle, that food derived from organisms containing new pieces of DNA should be captured for pre-market safety assessment and approval?

Should there be any exceptions to this general principle?

As a general principle, I agree that it is reasonable to capture foods derived from organisms that contain recombinant DNA from species that would not normally be able to share DNA in nature for pre-market safety assessment and approval.

Strictly defined cisgenesis (EMBO 2006; 7(8): 750–753 doi:10.1038/sj.embor.7400769) by contrast can be argued to simply greatly improve upon the basic tenets of conventional breeding and should be exempted from regulations governing foods produced using gene technology.

3.1.2 Questions

Should food from null segregant organisms be excluded from pre-assessment and approval?

If yes, should that exclusion be conditional on specific criteria and what should those criteria be?

If no, what are your specific safety concerns for food derived from null segregants?

By definition, the chromosomes in null segregants are derived from the wild-type versions of the chromosomes from the parents that did not contain the novel DNA. Although it is likely that the recombinant DNA that has been selected against to obtain the null segregant was originally inserted to fulfil a function, such as introducing gene editing machinery, it is not reasonable to consider the food safety implications of a DNA element that is not present in the organism in question. If the organisms in question are true null segregants then it should not be conditional.

3.1.3 Questions

Are foods from genome edited organisms likely to be the same in terms of risk to foods derived using chemical or radiation mutagenesis? If no, how are they different?

If yes, would this apply to all derived food products or are there likely to be some foods that carry a greater risk and therefore warrant pre-market safety assessment and approval?

No, they will not be the same. Foods from genome edited organisms are likely to be less problematic in terms of risk to foods than foods derived from chemical or radiation mutagenesis. As argued above, this is because the alterations to the DNA introduced through genome editing are in general likely to be less disruptive and more precisely defined than those produced using chemical and radiation mutagenesis.

Whereas arguments have been forwarded that foods carrying a known food safety risk (i.e. peanuts) should be considered separately because of a danger of inadvertently increasing the level of the safety risks associated with the food, it is unreasonable to consider that genome editing techniques would increase this risk to the same level as the chemical and radiation mutagenesis techniques that are considered as safe within the same category of foods.

3.2 Questions

Are you aware of other techniques not currently addressed by this paper which have the potential to be used in the future for the development of food products?

Should food derived from other techniques, such as DNA methylation, be subject to pre-market safety assessment and approval?

Techniques for agricultural pest and disease control using RNAi-based gene silencing sprays is being actively developed. It has been proposed that these RNAi sprays will be used on food crops (Pest Management Science 2018, <https://doi.org/10.1002/ps.4813>).

3.3 Questions

Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs? If no, what other approaches could be used?

If yes, how could a process-based approach be applied to NBTs?

Are there any aspects of the current definitions that should be retained or remain applicable?

Yes. I consider a process-based definition as being appropriate for triggering a requirement for a pre-market approval process in the case of NBTs where the NBT technique used

includes the insertion of recombinant DNA directly in the food product under consideration. All other uses of NBTs should not be considered for pre-market approval.

References:

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Regards

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