Food derived using new breeding techniques

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Submitted by

MOD

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CONTACT INFORMATION

Organisation

Mod NZ was formed in 2017 as a science research, advisory and communications organisation, but is not yet registered by the New Zealand Companies Office. Some of Mod NZ's initiatives include legal authorisations, partnerships and sponsorships by the University of Auckland. This document was drafted by Mod NZ and is authorised by its Managing Director, Hadleigh Waldegrave.

First Contact

Hadleigh Waldegrave
Managing Director
25 Middleton Rd, Remuera, Auckland 1050
+6421 151 4907
hrwaldegrave@gmail.com

Second Contact

Ethan Daugherty
Science Communications Lead
1/34 Pukeora Ave, Remuera, Auckland 1050
+6421 024 67024
themowzoon@hotmail.com

Introducing our perspective

SUMMARY

Through primary and secondary research, including interviews with NZ industry experts and survey statistics provided by NZ Government organisations, we have gained a multifaceted perspective. Our academic background has made us acutely aware of the most common arguments against GMOs. Given the infamous monopolisation by Monsanto it's no surprise that people's arguments often built upon both a distrust for 'greedy corporates', and a justified resistance to ecologically damaging agricultural intensification. Having studied in the University of Auckland's Faculties of Science and Business, we have also been exposed to the cultural views of an upcoming workforce which largely advocates corporate social responsibility, solutions for environmental pollution, and climate change. This does not fall short of countless young geneticists who yearn for policy updates which allow for the safe, efficient, and competitive implementation of GM technologies. This notion introduces two key terms which we would like to make explicit:

Green Genetic Engineering — The engineering of plants with the explicit purpose of reducing environmental harm, increasing the nutritional properties of foods, creating novel medicines and vaccines, and reducing world hunger through increased environmental resilience.

Freer Markets — The implementation of new GMO policy which does not undermine safety, yet lowers barriers to entry for entrepreneurial research groups. As we will cover, this can include selectively removing a case-by-case approach for some categories of GMOs. Encouraging competition in industries whose productivity and impact can be improved by gene technology is one key way of preventing a primary public concern: The potential monopolisation by a gene technology based corporation whose performance pressures may incur unethical actions.

As FSANZ is a governmental agency, we think it is best to cite government publications, such as one publication compiling ten years of GMO research funded by the European Union[1] and the American Association for the Advancement of Science[2], for evidence surrounding the safety of GMOs. We are also aware that there may be many studies cited as evidence against GMOs submitted, and we have chosen to submit a review article that looks at a variety of high profile anti-GMO papers and finds statistical malpractice in them[3].

Genomes Containing New DNA

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?

Assuming the current process based approach is maintained, yes, they should be captured for pre-market safety assessment, however it is important to reduce barriers of entry into the market for many reasons including maintaining a freer market (e.g. avoiding monopolies and encouraging commercial competition).

In a process based approach, having new DNA inserted as one of the criteria for pre-market safety assessment capture is reasonably viable and efficient. However it is still an inadequate approach when thinking long term. For example, the current system will capture a food with a nonsense sequence inserted in its heterochromatin (i.e. identical to unchanged foods), just as it would capture the same food if it had been changed beyond recognition, and this is cumbersome. A product based approach, which uses phenotype (i.e. specific protein expression profile) as a definition for capture would be preferable.

If we use a product based approach to define the criteria for pre-market assessment, foods with novel phenotypes produced by non-novel gene technologies could effectively be captured as a 'novel food' under Code Standard 1.5.1. This clarifies how pre-market assessment for GM foods would only apply if a food is developed using a 'novel gene technology'. By this we mean, when there are no approved foods on the market that were developed using the same gene technology.

Genomes Unchanged by Gene Technology

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?

Yes, the term ‘genome’ in this case should capture all forms of potential genetic engineering, including future epigenetic technologies, not just the genome. Again, this assumes a process based approach is kept. If we are just using a process to improve production/development of a food product, as long as the product is genetically indistinguishable (e.g. speeding up how traditional plant breeding works), it should be excluded from pre-market assessment because there is no difference in the food being consumed. The only caveat is with environmental/ moral arguments (Indoor vs outdoor farming has already partially addressed this).

As long as you can prove that there is no genetic material remaining from the process/engineering, your product should be excluded from pre-market assessment. Proving that there is no residual genetic material should be the only pre-market assessment needed. Companies should not have to label these foods as a GMO product (which is currently the case in most countries, e.g. radiation mutagenesis derived corn in the US).

Other Techniques

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?

An example of a GMO technology that is not captured by current policy is the use GM rootstock for nutrient increase. We personally feel that food produced by this technique should not be subject of pre-market safety assessment.

We feel it is not useful to mention the rest of the known techniques as the question is overly focused on a process-based approach. There are many techniques not explicitly covered in this questionnaire that are known and have already been used and documented to date. Our aim is to make sure that any new definition, code or regulation should capture all novel techniques that will inevitably arise in our future. This gives merit to a product-based approach. For example, if a GMO food is created with a novel technique, then the food should be subject to pre-market safety assessment until the technique is deemed safe. If this GMO food product makes it to market then following GM food submissions using this technique should not be subjected to pre-market safety assessment. This is justified by the assertion that a GM food that has been released into the market means the regulators were confident in the safety of the novel technique.

Regulatory Trigger

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?

No. Considering the specificity of NBTs, and the rapid pace of new technologies emerging, we feel a product-based approach to pre-marketing approval is better. By this we mean to simply ask: Is this food/product safe to consume? We believe there should be additional tests for foods that have a new protein sequence introduced in them (i.e. Allergen testing). We feel that by turning the focus away from processes to the product, the regulation has the ability to catch possibly harmful products while not penalising those who wish to be innovative and efficient. It should be noted that this view for a product based approach is also shared by the German National Academy of Sciences[4] which also "argue against a general ban on GMO cultivation… The Academies consider such prohibitions in Germany an acute threat to freedom of research and professional freedom, to property protection and general freedom of action, and thus to opportunities for studying, developing and commercially utilising genetically engineered crop plants".

The general idea is that businesses could apply to operate under a genetic processes license, whereby they can submit NBTs for assessment. This assessment would stay away from traditional GMO concerns (as preempted by a new law) and focus explicitly on criteria such as environmental and human hazards. This could work efficiently by explicitly excluding preempted considerations like general moral arguments.

The default safety testing needs to be defined with the intention to capture the masses of new food products within a freer market. This would likely result in a change in how chemical/radiation mutagenesis derived foods are tested, as well as other traditional GM derived foods, not just 'genome edited' foods.

Other Relevant Issues

Are there other issues not mentioned in this paper, that FSANZ should also consider, either as part of this Review or any subsequent Proposal to amend the Code?

As we have stated, one goal of our submission is to encourage a 'freer market' approach to GM industries. This is to prevent a monopoly (e.g. 'another Monsanto') and to prevent larger GM companies from outcompeting smaller players using their greater access to legal advice (i.e. using finding to find loopholes and 'playing the system' that small competitors could not otherwise do). Furthermore, NZ and Australia have relatively little power when it comes to influencing global biotech/genetics patenting laws. This could likely result in competitors (especially smaller ones) relying on keeping their research held, in secret from their competitors, on private or third party databases. As the GM industry will scale, this then begs new GM law to take into consideration the effects encryption and hacking, given that encryption-cracking technology is advancing more rapidly. We must take into account cases whereby a GM company is unknowingly hacked by a competitor for their IP. This obviously is not directly applicable to a new definition for 'gene technology' in the Food Standards Code, but is nevertheless a vital consideration.

For FSANZ's future questionnaires, we would recommend the following:

- Having less focus on process based approaches for redefining 'gene technology', and more on product based policy.

- Including additional questions that can segregate respondents based on their views or biases for or against GMOs. An example question could ask: "If a product was shown to be safe to consume, to what extent does the method the product was derived from matter, and why?". This line of questioning makes people reason with their own potential biases and shows FSANZ what biases each respondent has. Considering the polarised and vitriolic nature of the dialog surrounding GMOs, knowing the respondents' position provides vital context for their submission.

Some concise research

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