SPS International, Inc.
1099 West Front Street
Boise, ID 83702
United States of America

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Food Standards Australia New Zealand
Submission sent to: NBTConsultSubmissions@foodstandards.gov.au

Re: Consulting Paper: Food derived using new breeding techniques

- This submission is made by Tracy Rood, Director Regulatory Affairs, Simplot Plant Sciences, 5369 W. Irving Street. Boise, Idaho 83706, U.S.A. (T: +1-208 708 6066; E: tracy.rood@simplot.com).
- This response was authorized by Susan Collinge, Vice President, Simplot Plant Sciences, at the J.R. Simplot Company.

SPS International Inc. (SPSII) appreciates the opportunity to provide this submission in response to the FSANZ's Consulting Paper: Food derived using new breeding techniques. This consultation is important to the plant-based food industry, especially for biotechnology companies generating new varieties of crops that are required to improve the sustainability of food production. Review of the Australia New Zealand Food Standards Code (the Code) in consideration of its application to the food products of new breeding techniques (NBTs) can provide certainty for consumers as well as for food companies and supply chains that generate and deliver food for domestic and global markets.

SPS International Inc. (SPSII) is a wholly owned subsidiary of the J.R. Simplot Company (Simplot), which developed its biotechnology business through Simplot Plant Sciences (SPS), one of the groups within Simplot. SPSII files applications for approval of Simplot's biotech products in international markets, including submissions to FSANZ.

About Simplot

The J.R. Simplot Company is a privately held food and agribusiness company headquartered in Boise, Idaho, United States. Simplot produces primarily phosphate fertilizer and frozen potato and vegetable products. Simplot pioneered the frozen French fry and was the first supplier of frozen fries to major foodservice businesses and restaurants. Simplot continues to pioneer innovations in plant nutrition and food processing and researches new ways to feed animals and sustain ecosystems, striving to feed a growing global population.

While Simplot's roots remain in Idaho, it does business around the globe. There are major operations in Australia, New Zealand, Canada, China, and Mexico, with products marketed in more than 40 countries. As one of Australia's top ten food and beverage companies, Simplot Australia manufactures and sells frozen, canned and fresh products through an extensive network of supermarkets, convenience stores, and food service outlets.

Simplot Plant Sciences has pioneered a new advance in variety development. Innate® technologies transform potato plants with potato DNA, without the incorporation of selectable markers or vector backbone sequences. This technology was developed to address the needs of the potato industry and consumers for potatoes with late blight protection, reduced black spot, lower free asparagine, and lower reducing sugars.

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Response to Questions

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?

No. SPSII is of the view that regulatory oversight should be scientifically based on the risks inherent in the end-product, not the process used to develop that product (e.g., breeding, mutagenesis, genetic modification, genome editing, GM rootstock grafting, cisgenesis, intragenesis, null segregants, etc.). Regardless of the source of DNA, when the end-product poses little to no risk, regulation should not be required.

If this policy change were accepted, guidelines should be expanded to help applicants determine whether potential risk in new products would require premarket regulatory assessment and approval.

- Should there be any exceptions to this general principle?

Yes, the product and not the process should trigger whether a review is necessary. Standard triggers for products that need review could be delineated, e.g.:

- Composition changes outside the range of existing food products with a history of safe use
- Lower nutrition of the crop compared to varieties on the market
- Increase toxicity of a food product
- Increase allergenicity of a food product
- Changes to the intended use of a food product that could increase food safety risk.

Regulatory familiarity with new products and their safety should be applied to subsequent reviews of products that are similar. For example, multiple trait additions in potato are difficult to achieve through traditional breeding because potato is tetraploid, highly heterozygous, and sensitive to inbreeding depression. This means that for a given set of desirable traits, multiple potato varieties may need to be transformed since different varieties are used for different purposes.

- Regulatory learning from the first reviews should reduce data requirements for subsequent events with the same traits in the same crop.

Many disease resistance traits are present in cultivated and wild-potato varieties. Since back-crossing and breeding traits into commercial varieties is not feasible, cisgenesis and intragenesis offer effective solutions.

- The lower inherent risk of cisgenic or intragenic traits should be reflected in the data requirements for these products.

In all cases data requirements for new food products should take into account the history of safety use of traits, and be commensurate with the level of potential risk.

3.1.2 Questions

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

Yes

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

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The developers should retain scientific evidence confirming that the products are null segregants. This should be made available to national food regulatory agencies if requested.

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

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?

Yes

- 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?

All food is subject to food safety regulation once on the market. SPSII would recommend that FSANZ establishes guidelines for premarket assessment of potential risk in new food products. These would be the same for any new food product and would be based on the new traits, not the process. Traits that increase toxicity or allergenicity, or change the use or processing of food in a way that could increase safety risk are examples of new foods that should trigger premarket safety reviews.

Traits that are comparable to foods already on the market or that could be introduced by traditional breeding methods, including mutagensis, and traits/products that provide no reason for increased risk over foods on the market should not require premarket regulation.

Where potential risk is identified, a tiered approach to data requirements should be applied where the data requirements reflect the level of risk, rather than the amount of data that can be collected on a product.

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?

We would recommend that FSANZ maintains science-based reviews that assess the safety of new food products developed through technologies. This will capture all new technologies as they develop.

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

DNA methylation is an epigenetic change that can happen in any breeding process. Unless a new food product specifically raises food safety concerns, the process should not trigger regulation.

3.3 Questions

- Do you think a process-based definition is appropriate as a trigger for pre-market approval in the case of NBTs?

No. The process-based definition assumes there is something in the process that increases safety risk. In fact, the risk of safety issues arising with GM and NBTs is not higher than with other unregulated breeding tools. For GMOs, this has been demonstrated in the last twenty years of GMO regulation. Event selection is effective at identifying and weeding out plants that do not perform well or have off-types. New breeding technologies will also apply event evaluation to select the best commercial events.

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- If no, what other approaches could be used?

We recommend premarket regulation and assessment based on the safety of the product, focusing on the safety of the new traits.

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

FSANZ Code 1.5.2 defines gene technology as 'recombinant DNA techniques that alter the heritable genetic material of living cells or organisms'. If FSANZ continues to implement process-based review of biotechnology food products, it will be important to provide exceptions. These should exclude products from new breeding technology that have the same outcome as other breeding technology. For example, small nucleotide changes that could be introduced by mutagenesis, and the insertion of cisgenic or intragenic DNA sequences from sexually compatible plants.

3.4 Question

- 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?

SPSII recommends that FSANZ assesses opportunities to reduce the regulatory data requirements associated with the review of vegetatively propagated crops (e.g. potato) where the same construct is used to transform different varieties of the same crop.

Regulators in some countries have developed mechanisms to streamline the review of additional events produced with the same construct. A streamlined review process reduces the regulatory burden for crops developed using biotechnology.

- USDA uses an extension process that allows companies to provide abbreviated dossiers for review when new events are similar to previously deregulated events, with faster approval timeframes.
- The Canadian Food Inspection Agency (CFIA) uses a retransformation review process that is faster for new events that are similar to those already approved.

FSANZ has started streamlining review processes. Some of the Simplot events are the result of two successive transformations with two different constructs. FSANZ approved the events transformed with the first construct as part of the approval of the events transformed with both constructs. FSANZ required some additional data for the first event to enable its approval. This has streamlined the application process and regulatory review of multiple similar events without compromising on the safety of the new food crops.

Thank you for this opportunity to provide input for the consultation on food derived using new breeding techniques.

Yours sincerely,

Tracy A. Rood

Tracy Rood
Director, Regulatory Affairs