gene ethics
working for a GM-free future
[redacted]

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Re: A1198 – glufosinate tolerant GM maize

Thanks for the opportunity to comment on this application.

Recommendations

We recommend that FSANZ reject this application, for the reasons that follow.

Credibility Gap

Corteva's application and the FSANZ SD1 summary document both cite (Anderson et. al., 2019) in support of their claims that DP202216 maize is safe to eat, without acknowledging that all the authors of this paper are Corteva employees.

The paper discounts findings of statistically significant differences between experimental and control group results with a qualified statement:

> "Only three amino acids (glycine, methionine, and serine) and two vitamins (vitamin B1 and vitamin B3) were statistically different (raw *p*-value < 0.05) between DP202216 maize grain and control grain … However, when controlling for false positives using the FDR method, … these differences **were likely false positives and may not be biologically relevant."**

But Corteva's application misrepresents these findings with the more assertive and unequivocal claim that:

> "A statistically significant difference (P-value < 0.05) was observed between DP202216 maize and control maize mean values for glycine, methionine, and serine; however, … the statistical differences **are not biologically meaningful."**

This unqualified assertion misrepresents the uncertainties of Anderson's evidence. Moreover, the application does not even mention the significant differences in Vitamin B1 and B3 levels that Anderson et. al. report, between GM and control maize. Instead, Corteva's Table 10 blandly claims that "All Data Values" for these substances were "Within Tolerance Interval".

The FSANZ SD1 document uncritically reproduces all but the last column of the applicant's Table 10 (as its Table 9) and, without making direct reference, merely rephrases Anderson's claim as:

> "Using the raw P-value, a statistically significant difference was observed in DP202216 compared to the control for vitamin B1 and B3 (Table 9). **With the FDR adjustment, the P values were no longer significant."**

This is an example of the common practice of applicants massaging the narrative in their applications and also, inexcusably, in FSANZ assessment documents.

For instance, also in support of Corteva's safety claims, the application repeatedly cites a paper (Hérouet C. et. al., 2005) without disclosing that the authors were all Bayer Cropscience employees.

And the SD1 assessment bases several of its reassurances about safety upon references to secret, unpublished, anonymously authored, Corteva documents. This means the public and independent experts have no opportunity to evaluate the veracity or relevance of any data that the company may or may not have presented in confidence to FSANZ. We do not accept that on trust.

The application also makes numerous claims that the proteins and amino acids in DP202216 maize are "identical" – not substantially equivalent or even just a little different. These absolute claims appear to be based on an unspecified "in silico translation" - a computer simulation. Yet FSANZ's SD1 assessment document does not discuss or dispute or discredit the applicant's claims that the Genetic Manipulation event DP202216 and non-modified conventional maize are "identical". This is an unhelpful lapse.

Glufosinate is not approved for spraying on crops in the European Union[i] so our concerns are raised. Used in the USA on glufosinate tolerant crops, the presence of glufosinate residues and metabolites in food supplies appears inevistable.

The assessment should have discussed this discrepancy in standards between two major trading partners and also have more fully explored novel herbicide metabolites in GM herbicide-tolerant plants. Only baldly asserting "It is expected that no new glufosinate metabolites would be generated in corn event DP202216," is very unsatisfactory and unreassuring.

The SD1 assessment paper says "The most likely products to be imported from DP202216 would be wet-milled starch for sweetening products, maize oil and high fructose corn syrup (HFCS). In Australia and New Zealand, maize starch is used in dessert mixes and canned foods and HFCS is used in breakfast cereals, baking products, corn chips and extruded confectionary."

But SD1 does not discuss the potential for these products to contain residues of glufosinate or its metablolites and what effects they may have in the short and long term on food safety. SD1 does not reference FSANZ's own document, which contains the following table,[ii] nor assess the likely levels of glufosinate or its metabolites in corn products, to comply with the ADI.

Chemical	ADI *(mg/kgbw/d)*	NOAEL		
Glufosinate	0.007 / 0.67	0.67	11 August 1988	
Glufosinate ammonium	0.02 / 2.1	2.1	28 August 2001	130-week dietary rat study; a NOAEL of 2.1 mg/kg bw/d was based on decreased glutathione levels in the liver and blood at the next higher dose.

Public Health

The Consumer and Public Health Dialogue (CPHD) that FSANZ hosted, was supportive of including a definition of public health in the FSANZ Act, believing that:

- "It is imperative that improving nutrition and total dietary patterns to reduce all diet-related disease AND promote health is the mainstream objective of the food regulation system with emphasis on inhibiting chronic disease in the current context.
- There should be a strong focus on creating food regulatory systems that support healthy lifestyle behaviours and do not undermine healthy food choices.
- As well as being a vehicle to help the public make healthier food choices, food regulation can also encourage the food industry to innovate and develop healthier food products, and thereby assist public health goals.
- The interpretation of 'protecting public health' needs to be inclusive of the social and environmental implications of food regulatory policies and practices. Social implications extend to consideration of equity in health outcomes associated with food regulation policy and practice."[iii]

FSANZ should be much more pro-active in supporting and promoting community health and well-being and no longer shirk its responsibilities to Australians and New Zealanders.

So blatantly serving the interests of the global food, chemical and seed industries by approving the worthless products of crops like DP202216 maize is no longer an acceptable option.

We know that ultra-processed food ingredients and the foods made from them, like those based on DP202216 maize will be very high in sugar, and likely also salt and fat.

Many papers and a recent literature review confirm that ultra-processed foods in the human food supply are associated with higher risks of obesity[iv], heart disease, stroke, type-2 diabetes[v], cancer, general ill health[vi], depression and death.[vii]

We expect much better and more from FSANZ and the Food Forum.

Conclusion

We recommend that FSANZ reject A1198 in the interests of promoting community health and safety, and because of the deficiencies in the application and its assessment.

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[i] EU Pesticides database. https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1436

[ii] FSANZ, Acceptable daily intakes for agricultural and veterinary chemicals, Edition 2/2020, current as of 30 June 2020, https://apvma.gov.au/node/26596

[iii] CPHD Discussion Paper1: Definition of Public Health https://www.foodstandards.gov.au/about/committees/Documents/DP1%20Definition%20of%20Public%20Health[1].pdf

[iv] Consumption of high-fructose corn syrup in beverages may play a role in the epidemic of obesity https://academic.oup.com/ajcn/article/79/4/537/4690128

[v] Bray, G A, Potential Health Risks From Beverages Containing Fructose Found in Sugar or High-Fructose Corn Syrup https://doi.org/10.2337/dc12-1631

[vi] High fructose corn syrup induces metabolic dysregulation and altered dopamine signaling in the absence of obesity https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5747444/

[vii] Elizabeth, L.; Machado, P.; Zinöcker, M.; Baker, P.; Lawrence, M. Ultra-Processed Foods and Health Outcomes: A Narrative Review. *Nutrients* 2020, *12*, 1955.