

Joint Submission to Food Standards Australia New Zealand

Re: Application A1192 MON87429 corn line.

MON87429 corn line is genetically engineered to tolerate being sprayed with glufosinate, dicamba, 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase inhibitors (known as FOPs herbicides). It is also genetically modified to provide tissue-specific tolerance to glyphosate, to facilitate hybrid seed production. A1192 seeks to change the Food Code so that the products of MON87429 corn line and the herbicide residues they may also contain are approved for inclusion in the human food supply.



GE Free NZ in Food and Environment
Auckland GE Free Coalition.
GE Free Northland



Gene Ethics



Physicians & Scientists for Global Responsibility

Physicians and Scientists for Global Responsibility



Safe Food Campaign



South Australian Genetic Food Information Network (SAGFIN)

PUREHARVEST



Pure Harvest Organic Foods



Manna Hill Estate Olive Oil



Tuckers Natural



Jonny's Popcorn.

21 May 2020

Dear FSANZ,

Thank you for the opportunity to make a submission regarding Bayer/Monsanto's proposal to enter MON87429 corn line in our food chain.

We ask you to reject application A1192 as the applicant Bayer/Monsanto has failed to submit exhaustive and compelling evidence that the combined effects of the resultant recombinant proteins expressing traits for herbicide tolerance and the multiple synthetic chemical herbicide residues that will be sprayed on the MON87429 corn crop, are safe for short and long term human ingestion and therefore should not enter the food chain.

We are making this joint submission on behalf of a range of Organisations involved in food production and our many members in Australia and New Zealand who share our concerns over the lack of independence and serious gaps and deficiencies in the evidence the applicant submitted in support of its application, A1192.

If it were to approve A1192, FSANZ would fail to conform to the primary object of its Act to ensure:

Object of the FSANZ Act

The object of this Act is to ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

- (a) A high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
- (b) An effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
- (c) The provision of adequate information relating to food to enable consumers to make informed choices;
- (d) The establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

Due to gaps in the evidence and a lack of relevant documentation submitted, the potential health and safety risks of this genetically manipulated corn that can be sprayed with up to twelve different herbicides cannot be properly assessed. Neither can those individuals and organisations wanting to comment on the proposal make detailed, fully informed and well-considered submissions

MON87429, has been genetically manipulated to tolerate the following herbicides: glufosinate, dicamba, 2,4-dichlorophenoxyacetic acid (2,4-D) and the whole category of aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase inhibitors (known as FOPs herbicides) which include: clodinafop (Topik®), cyhalofop (Barnstorm®), diclofop (Cheetah® Gold*, Decision®, Hoegrass®), fenoxaprop (Cheetah® Gold* , Wildcat®),

fluazifop (Fusilade®), haloxyfop (Verdict®), propaquizafop (Shogun®), quizalofop (Targa®)¹

MON87429 has also been genetically modified to provide tissue-specific tolerance to glyphosate to facilitate hybrid seed production.

This means that this corn is genetically manipulated, to express traits for tolerance to up to 12 different herbicides, with the following genetic constructs added:

- *pat* gene encoding phosphinothricin-N-acetyltransferase (PAT) protein providing tolerance to the herbicide, glufosinate
- *dmo* gene encodes a dicamba mono-oxygenase (DMO) protein providing tolerance to the herbicide, dicamba
- *ft_t* gene a modified version of the *Rdpa* gene a 2,4-D and FOPs dioxygenase protein (FT_T) providing tolerance to 2,4-D and FOPs herbicides
- *cp4 epsps* gene which encodes a 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) providing tolerance to the herbicide, glyphosate.

These genetic constructs have never previously been combined in nature nor in the products of any GM organism entering the human food chain. Yet the applicant has not provided any data from studies *in vitro* and/or *in vivo* on the cumulative or interactional effects of the chemical pesticides, nor on the recombinant genes in the MON87429 corn or the food products derived from it.

Problems FSANZ' assessment of MON87429 include:

1. The 26 March 2020 [119-20] Supporting Document 1, Safety Assessment of Application A1192 does not fulfill the policy objectives outlined in FSANZ's Regulatory Science Strategy 2019-2023 or meet the regulator's responsibilities to provide public information and food safety protection. It is merely a basic cut and paste of assessments of previous applications. The questionable concept of 'substantial equivalence' is invoked when FSANZ concludes:

"No potential public health and safety concerns have been identified in the assessment of herbicide-tolerant corn line MON87429. On the basis of the data provided in the present application, and other available information, food derived from MON87429 is considered to be as safe for human consumption as food derived from conventional corn varieties."

Recommendation: specify and provide substantial supporting evidence on a lack of allergenicity, and the animal feeding studies that were assessed, to justify the finding of "as safe for human consumption as food *derived from conventional corn varieties*."

2. No data from animal feeding studies conducted on the whole MON87429 corn was submitted or is elsewhere available. Though FSANZ notes that the applicant did not provide any data from feeding studies, the regulator did not request or require it either. This contradicts the FSANZ Regulatory Science Strategy² which assures the public and the Ministerial Forum that the regulator evaluates peer-reviewed

¹ CropLife Australia, Herbicide Mode of Action Table.

<https://www.croplife.org.au/resources/programs/resistance-management/herbicide-moa-table-4/herbicide-moa-table-4-draft-2/>

² <https://www.foodstandards.gov.au/publications/RegulatoryScienceStrategy201923/Pages/default.aspx>

science, as the basis for robust hazard identification and risk analysis, incorporating the best available scientific evidence. We question the relevance and conclusiveness of the scientific data submitted, which fails to meet any reasonable criteria for the rigour and independence.

Monsanto provided an *in vitro* pepsin digestive fluid assay test on the EPSPS protein gene (Appendix 18), which claims to have found that the protein was degraded after 15 minutes.

This conclusion is contradicted by the findings of an ingestion study that Netherwood et al (2004)³ conducted. Following one meal, consisting of a GM soy-burger and soymilk containing the CP4 EPSPS gene, the scientists found that a small amount of the transgene survived passage through small bowel of ileostomy subjects, with a maximum of 3.7% recovered at the stoma of one individual.

Though Netherwood concluded that it was unlikely one meal would alter the gastrointestinal function or pose a risk to human health, "*Nevertheless, the observed survival of transgenic DNA from a GM plant during passage through the small intestine should be considered in future safety assessments of GM foods.*" (p.208)

The Applicant provided documentation on mice which underwent a single dose gastric lavage and were observed for 14 days. Each test was on individual CP4EPSPS, DMO, *pat* and FT_T proteins, but all were derived from recombinant E-coli (Appendix 23, 24, 25, 26) not from MON87429 corn itself.

Monsanto's CP4 EPSPS unpublished findings (Appendix 26) showed significant on female reproductive systems (hydrometra) but the results were dismissed as biologically unimportant.

No further evidence was submitted to demonstrate whether or not there were any unexpected effects caused by the recombinant gene insertions from the MON87429 whole corn event

Recommendation: FSANZ must fulfill its responsibility to require evidence and data from long term feeding studies to demonstrate beyond reasonable doubt that MON 87429 corn line products, containing novel DNA coding for multiple traits and chemical herbicide residues are safe to eat. Long term human and animal studies must test for the cumulative and synergistic effects of these new additions to the food supply.

3. Appendices 19, 20, 21, and 22 detail heat tests on the e-coli-derived proteins, which found that some, survived at up to 75°C. Though degraded, all survived at 37°C, except the CP4EPSPS protein, which had 88% activity, for 15 minutes.

FSANZ has not met its responsibility to fully assess the effects of the proteins when the food is eaten raw or steamed at times less than 15 minutes, and the consequences of them surviving digestion. The regulator must also resolve what health effects the proteins may have if they enter the blood stream from the gut.

³ Netherwood, T., Martín-Orúe, S., O'Donnell, A. *et al.* Assessing the survival of transgenic plant DNA in the human gastrointestinal tract. *Nat Biotechnol* 22, 204–209 (2004). <https://doi.org/10.1038/nbt934>

Schubbert et al (1994)⁴ published the peer-reviewed results of a feeding study in which mice were fed foreign DNA, which survived digestion and entered the blood stream. Yet the ultimate fate of foreign DNA from MON87429 corn remains unknown and has not been assessed.

The selective assessment of unpublished data provided by the applicants, and the absence of critical reviews of peer-reviewed and published data, brings FSANZ's regulatory science into legitimate question. The scientific method, with its tried and true methods and standards, must be used.

Recommendation: FSANZ require independent studies to be conducted, to show whether or not the food products of MON87429 corn that are not degraded in cooking times less than 15 minutes, survive digestion and also enter the blood stream. The studies should also be designed to determine the long term impacts on the health and well-being of those who consume such products. Separate studies should also produce data on the cumulative and synergistic impacts on health of the herbicide residues in MON87429 corn products.

4. Much of the information that the applicant submitted came from prior applications and has little relevance to MON87429.

FSANZ ignores:

- the cumulative and synergistic effects of the pesticide residues that would remain in the corn and products made from it;
- the fact that many of the FOP herbicides are not registered with New Zealand Ministry of Primary Industries (MPI) for use in the human food chain;
- The 5 different transgenes and their effect on the corn's phenotype that may have health impacts.

Chiu Y et al (2018) study on females undergoing infertility treatment using assisted reproductive technology (ART) found that

"Higher consumption of high-pesticide residue of fruit and vegetables (FV) was associated with lower probabilities of pregnancy and live birth following infertility treatment with ART. These data suggest that dietary pesticide exposure within the range of typical human exposure may be associated with adverse reproductive consequences".⁵

MON87429 corn also contains a dsRNA gene edit that has not been evaluated. FSANZ failure to consider the pesticide residues on human health is a serious omission in protecting public health.

⁴ Schubbert, R., Lettmann, C. & Doerfler, W. Ingested foreign (phage M13) DNA survives transiently in the gastrointestinal tract and enters the bloodstream of mice. *Molec. Gen. Genet.* 242, 495–504 (1994). <https://doi.org/10.1007/BF00285273>

⁵ Chiu Y, Williams PL, Gillman MW, et al. Association Between Pesticide Residue Intake From Consumption of Fruits and Vegetables and Pregnancy Outcomes Among Women Undergoing Infertility Treatment With Assisted Reproductive Technology. *JAMA Intern Med.* 2018;178(1):17–26. doi:10.1001/jamainternmed.2017.5038

5. The FSANZ assessment disregards significant changes to key components of the corn and fails to meet its own requirement for additional nutritional studies.

“If the compositional analysis indicates biologically significant changes, either intended or unintended, to the levels of certain nutrients in the GM food, additional nutritional studies should be undertaken to assess the potential impact of the changes on the whole diet⁶.” (FSANZ Supporting document SD1, p.46)

Total fatty acids and minerals were significantly changed in MON87429 corn line but, contrary to public assurances, FSANZ has not required nutritional studies to assess the potential dietary impacts of such changes. Changes in essential minerals should be a compelling reason to look further into how such change may affect the corn's overall composition, nutritional value and safety.

The significant changes in the fatty acid profiles in MON87429 were not evaluated for the production of the metabolites tetrahydrofurandiols (THC-diols) that may have serious health implications.

The Markaverich (2002) study on mice with corn cob bedding and whole corn kernels detected a high level of the metabolite THC-diols which led to endocrine disruption, causing female and male reproductive disorders⁷. Markaverich's follow up in vitro research on human cells also found significant endocrine disruption effects with mitogenic activity⁸. The study's authors also mentioned significant differences between non-GM and GM corn.

6. Random insertion events, mutations or up/down regulation silencing were not assessed, to rule out the possible unforeseen and unpredictable allergic or immune reactions. Targeted serum screen tests were not completed.

FSANZ provides no scientific data to justify this claim of substantial equivalence:

“MON87429 is considered to be as safe for human consumption as food derived from conventional corn varieties”.

7. Pesticide residues in A1192—

All the pesticides that will be sprayed during the growing of MON87429 have links to endocrine disruption and cancer. But the APVMA sets Maximum Residue Limits (MRLs) based on agronomic rather than health and safety grounds. Nor does the pesticide regulator or FSANZ consider the cumulative and synergistic impacts of synthetic chemical herbicide residues. Though state chemical and food regulators are charged with testing and monitoring of residues, they rarely fulfill this responsibility to protect public health and safety.

⁶ <https://www.foodstandards.gov.au/code/applications/Documents/A1192%20SD1.pdf>

⁷ Markaverich, B., Alejandro, M., Markaverich, D., Zitzow, L., Casajuna, N., & Camarao, N. et al. (2002). Identification of an Endocrine Disrupting Agent from Corn with Mitogenic Activity. *Biochemical And Biophysical Research Communications*, 291(3), 692-700. doi: 10.1006/bbrc.2002.6499

⁸ Markaverich, B., Mani, S., Alejandro, M., Mitchell, A., Markaverich, D., & Brown, T. et al. (2002). A novel endocrine-disrupting agent in corn with mitogenic activity in human breast and prostatic cancer cells. *Environmental Health Perspectives*, 110(2), 169-177. doi: 10.1289/ehp.02110169

Summary:

- The MON87429 kernels in the whole grain have not been tested for the combined and cumulative safety over the long term, when ingested in GM food.
- There has never been a food on the market containing the five recombinant bacterial genes found in MON87429 - or the proteins they produce.
- The pesticides sprayed over the MON87429 corn crop are endocrine disruptors and can induce cancer. The medium to long-term impacts of their presence in food products and ingredients are little researched and not understood.
- As FSANZ bases most assessments on unpublished and non-peer-reviewed corporate-generated assertions, and its assessments on irrelevant and unrelated data and information, Australian and New Zealand citizens cannot have confidence in the safety of MON87429 corn line and its products.
- The food industry cannot effectively fulfil its responsibility to provide public information to customers when the labelling of MON87429 corn line and its products, as GM containing the residues of up to 12 herbicides, is not mandatory.
- Without adequate information and labelling of MON87429 corn line and its products shoppers are denied the right to know the origin of these ingredients and to make informed choices in defence of their health.
- FSANZ's failures to exercise scientific independence and its selective references to the literature severely reduce the safeguards for public health and consumer protection in the short and long term.

FSANZ fails to uphold and take into account the legislated consumer protections and responsibilities to which it is bound. FSANZ should stop the clock on this application and require further scientific evidence from independently generated raw data, to be submitted for assessment prior to further consideration of this application. The data should be from long term, independent, multi-generational feeding trials in mammals and allergen tests using targeted IgE antibody serum assays, to search for any cross-reaction with the expressed proteins.

The MON 87429 corn line application A1192 should not be approved.