PSGR

Physicians & Scientists for Global Responsibility

To: Food Standards Australia New Zealand

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PSGR SUBMISSION ON

BAYER/MONSANTO APPLICATION A1192 TO FSANZ FOR APPROVAL OF IT'S PRODUCT MON 87429 CORN

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BAYER/MONSANTO APPLICATION A1192 TO FSANZ FOR APPROVAL OF IT'S PRODUCT MON 87429 CORN

1. THE APPLICATION

1.1 This application seeks FSANZ approval for a product designated as MON87429.

1.2 This product may be described in general terms as a seed that has been genetically engineered to tolerate being sprayed with glufosinate, dicamba, 2,4-dichlorophenoxyacetic acid (2,4-D), aryloxyphenoxypropionate (AOPP), and acetyl coenzyme A carboxylase inhibitors (known as FOPs herbicides).

1.3 The product is also genetically modified to provide tissue-specific tolerance to glyphosate, to facilitate hybrid seed production.

1.4 The Application (A1192) seeks to change the Food Code so that food products derived from MON87429 corn and any herbicide residues that might be contained in these food products are approved for inclusion in the human food supply of both Australia and New Zealand.

1.5 PSGR recommends to FSANZ that this application must be rejected on the grounds set out in this Submission.

2. GROUNDS TO REJECT THE APPLICATION

2.1 The reasonable probability that food products will contain the residues from multiple applications of toxic herbicides that the herbicide tolerant GE plant, that gave rise to the food products, is designed to resist is sufficient to reject the Application on the grounds of public safety.

2.2 It is understood that there have been no independent and long-term longitudinal studies to prove that probable toxins in food derived from MON87429 will be safe for human consumption.

2.3 In addition to explicit statutory functions of FSANZ that apply to its consideration of this Application, there are other legal obligations that arise.

2.4 FSANZ has a fiduciary obligation to consider all relevant considerations that have a reasonable probability of applying to issues of public and environmental safety when considering this Application.

2.5 Like all administrators of statutory functions and powers, FSANZ has a duty of trust to give meaningful and due weight to the precautionary principle when considering public and environmental risks.

2.6 FSANZ is not free to consider Applications solely within the confines of its statutory functions and obligations: it must also consider a raft of other relevant statutory provisions that have a reasonable probability of being impacted by any decision that FSANZ makes. Not to consider these other statutory obligations would create absurdities that would likely destroy public confidence in the machinery-of-government.

2.7 In that regard the principles of administrative law apply: the provisions of statutes are never 'at large' ; they are confined by constitutional and administrative law principles so that their administration might better focus upon the public interest and the broader intentions of Parliament.

2.8 It is plain that the intended use of this seed will have a high probability of adverse toxic impacts on life-forms in the areas in which it is grown. For example, it is understood that MON87429 seed will be coated with neonicotinoids (known to be toxic to insects and vertebrates). Consideration of additive toxicity from neonicotinoid applications is never included in registration, nor are material adverse effects on soil microbiomes and freshwater ecosystems.[1] [2] It is submitted that these are most serious matters that parallel and add to the high probability of toxic residues in food products derived from MON87429.

2.9 FSANZ has an obligation to act where there is new knowledge. A recent paper has built on other studies[3] [4] [5] [6] [7] that suggest inadequate risk assessment for herbicide tolerant GE crops. This study concerned soybeans, however the authors considered that the outcomes would apply in principle to other crops including MON 87429. It is apparent that field trials do not match real conditions. The timing of spraying of herbicides impact gene expression, agronomic performance and plant composition and applied dosage often exceeds applications in field trials. Thus material prepared for feeding studies is different from material entering the food chain. The indirect, cumulative and combinatorial effects of the multiple formulations[8] applied on the crops, including synergists are excluded from assessment with the consequence that the accumulative toxicity of residues arising from the recommended spray regime is not fully determined. Considerations of toxicity necessarily includes herbicide-plant interactions.[9] Potential for the herbicide residues to promote antibiotic resistance remains outside standard risk assessment practices.[10] [11]

2.10 Therefore both the precautionary principle and the broader public and environmental interests must be given due weight in FSANZ deliberations about this Application.

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[1] Sánchez-Bayo et al 2016. Contamination of the Aquatic Environment with Neonicotinoids and its Implication for Ecosystems. Front. Env. Sci. https://doi.org/10.3389/fenvs.2016.00071

[2] Pisa et al 2017. An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 2: impacts on organisms and ecosystems. Environmental Science and Pollution Research. DOI 10.1007/s11356-017-0341-3

[3] Tsatsakis et al 2017. Impact on environment, ecosystem, diversity and health from culturing and using GMOs as feed and food. Food and Chemical Toxicology. 107A:108-121

[4] Bøhn T and Millstone E. The introduction of thousands of tonnes of glyphosate in the food chain - An evaluation of glyphosate tolerant soybeans. Foods. 2019 Dec 11;8(12). pii: E669. doi: 10.3390/foods8120669.

[5] Lurquin PF (2016) Production of a toxic metabolite in 2,4- d -resistant GM crop plants. 3 Biotech 6:82. https ://doi.org/10.1007/s1320 5-016-0387-9

[6] Reuter W (2015) Toxicology of glyphosate, isoxaflutole, dicamba and possible combination effects. Testbiotech.

[7] Benbrook C. Why Regulators Lost Track and Control of Pesticide Risks: Lessons From the Case of Glyphosate-Based Herbicides and Genetically Engineered-Crop Technology. Current Environmental Health Reports 5:387–395(2018)

[8] Mesnage, R., Defarge, N., de Vendômois, J., & Séralini, G. (2014). Major Pesticides Are More Toxic to Human Cells Than Their Declared Active Principles. Biomed Res Int, Article ID 179691.

[9] Miyazaki J. et al 2019. Insufficient risk assessment of herbicide-tolerant genetically engineered soybeans intended for import into the EU. Environmental Sciences Europe.(2019) 31:92

[10] Kurenbach, B., Gibson, P., Hill, A., Bitzer, A., Silby, M., Godsoe, W., & Heinemann, J. (2017). Herbicide ingredients change Salmonella enterica sv. Typhimurium and Escherichia coli antibiotic responses.. Microbiology, 1-11. doi:10.1099/mic.0.000573

[11] Kurenbach, B., Hill, A., Godsoe, W., van Hamelsveld, S., & Heinemann, J. (2018). Agrichemicals and antibiotics in combination increase antibiotic resistance evolution. 2018. PeerJ, 6, e5801.

2.11 FSANZ needs to be both transparent, lawful and independently well-informed about the scientific issues raised by this Application.

2.12 PSGR is most concerned that FSANZ appears to be reliant upon an applicant's version of 'relevant science' while lacking determined independent science evaluation of risks and probabilities of harm to people and their environment.

2.13 Without independent science evaluation, rigour and associated transparency of reported findings, the public and the environment are left to wear the risks – and that public left to conclude that there is blatant 'regulatory capture' by industry of the statutory powers assigned for administration by Parliament.

2.14 FSANZ cannot reasonably rely upon 'a submissions process' to provide the rigour necessary to consider properly very complex scientific matters like those raised by this Application: rather this Application requires highly-competent and independent scientific evaluation plus in-depth competencies in public law and statutory interpretation.

2.15 Such independent science competencies are not presently evident in FSANZ consideration of this Application.

2.16 Nor does FSANZ appear to consider its broader obligations to provide decisions that are compatible with Parliament's intentions expressed in associated (and therefore relevant) Acts.

2.17 These broader statutory considerations are arguably foundation matters in public law to which FSANZ has a duty to comply – to keep the trust of the public and to be an effective administrator of its particular statutory functions and powers.

3. RECOMMENDATIONS

3.1 That FSANZ should refer this Application for independent scientific evaluation that includes due weight to the precautionary principle and to broad public safety and environmental safety considerations as set out in related statutes.

3.2 That FSANZ should reject (or suspend) this Application until such time as an independent science assessment of the public and environmental risks of the MON87429 product can be assessed properly and transparently.

4. PSGR ASSISTANCE

4.1 PSGR offers to assist FSANZ to identify independent science sources that could undertake a proper assessment of this Application in the public and environmental interests