GM Freeze response to Food Standards Agency (FSA) and Food Standards Scotland (FSS) consultation on applications for nine genetically modified organisms for food and feed uses

Submitted by email to RPconsultations@food.gov.uk

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1. Introduction

This response is submitted by Liz O'Neill on behalf of GM Freeze, a non-governmental organisation based in England but operating across the UK. The response is not confidential and will be published at www.gmfreeze.org.

GM Freeze is the UK umbrella campaign for a responsible, fair and sustainable food system, focused on concerns around the use of genetic engineering in food and farming. Our member organisations include large NGOs, scientists, farmers, retailers and grassroots campaign groups.

We are concerned to see that neither civil society organisations nor citizens themselves are identified as interested parties for this consultation - in category descriptions at the start of the FSA Consultation pack; in the very limited *List of interested parties* included in the FSA pack as Annex A; or in the more extensive *List of Interested Parties* published by FSS as Annex C. Public concern about the presence of genetically modified organisms in the food chain is high (see 1.3.1, below) and this first set of food and feed approvals following the UK's exit from the European Union represents a key opportunity to demonstrate that it is UK citizens rather than the biotechnology lobby that have "taken back control" of the food chain.

In addition to the general concern above, we are aware of many misconceptions around the role of single-issue campaigns and would like to stress that we exist because we are needed. GM Freeze member organisations and the thousands of individuals who support and follow our work, tell us that they find it difficult to follow issues around the use of genetic engineering in food and farming in detail. They ask us to keep up with the technical and political developments on their behalf and share what we learn in language that they can understand. We experience significant hostility from politicians, journalists and those working in various fields of genetic engineering, with our single-issue focus presented as a reason to discount and diminish our contribution to healthy debate. We trust that this attitude will not prevail in the analysis of responses to this consultation and look forward to ongoing respectful dialogue as a key stakeholder on this issue.

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1. Our response to the consultation questions, in respect of all nine applications

We submit the following points in response to all nine applications: RP476, RP526, RP535, RP606, RP607, RP620, RP714, RP715, RP716

1.1. Concerns on the safety of the products/events which have not been considered [in the FSA/FSS advice] with respect to the intended consumers, stakeholders or impacts

1.1.1. The risk assessments carried out by the European Food Safety Authority (EFSA), that form the basis of the positive FSA/FSS opinions on each of the nine applications are inadequate. The German non-profit organisation Testbiotech provides independent information and scientific expertise on the risks and consequences of genetic engineering for humans and the environment. We draw the agencies' attention to the detailed critiques that Testbiotch has published for most of the risk assessments relevant to these applications (see 2, below). Common themes in these analyses include:

- No "omics" analysis has been carried out on material from the GM plants to investigate the potential for unexpected gene products or changes to metabolic pathways. Without this sort of analysis, it is impossible to know whether or not the genetic engineering process has had unintended effects.

- There is inadequate data on gene expression in a range of environmental conditions.

- The assessments do not reflect agricultural practices or the varied conditions under which the crops will be grown.

1.1.2. Several of the GMOs under consideration feature multiple stacked traits. FSA/FSS advice on each stacked-trait application notes that some combinations have been analysed but that others are "expected to be as safe as and nutritionally equivalent to the single events, the previously assessed sub-combinations and the [full] stack". This is a wholly inadequate approach as both the inserted genes and the phenotypic traits their insertion may induce can interact in unexpected ways[1]. The combinatorial effects of all possible sub-combinations should be examined and made available for independent scrutiny before approval is considered.

1.1.3. The toxicity of the GM plants engineered to kill insects has not been properly analysed. Only two of the Bt toxins produced by the crops that FSA/FSS has judged safe for human consumption (Cry1Ac and Cry1Ab) have been tested in detail for their possible effects on the immune system. Cry1F Cry3A, mCry3A and eCry3.1Ab have not been tested in this way and no crops that produce these insecticides should be allowed into the UK food chain until such tests have been completed, submitted to peer review and shared publicly.

1.1.4. The potential health impacts of consuming the weed-killer-friendly crops have not been properly assessed. The quantities of linked herbicides sprayed on the field trial test samples used in EFSA risk assessments do not reflect the quantities likely to be used in the commercial cultivation of these crops.

These GMOs will be grown in territories where public protections against toxic chemicals are less robust than here in the UK. We must, therefore, protect UK food standards by testing the potential impacts of herbicide residues when the linked chemicals are sprayed on the GM plants at the maximum levels which the GMOs can withstand. Such assessments should fully investigate the risks and potential health impacts of different commercially available formulations, rather than focusing only on the main active ingredient. As has been shown for glyphosate[2] the inclusion of adjuvants and other ingredients in commercially traded formulations can significantly increase toxicity.

Similarly, the safety of the GMOs cannot be properly assessed until there has been a detailed examination of effects of mixed herbicide residues. The toxicity of chemical cocktails is not simplicity the sum of its parts[3] and the long-term effects of consuming GMOs grown under herbicide-dependant cultivation regimes has not been adequately considered. The applications should be refused until evidence can be provided that the long-term consumption of these crops, combined with the various herbicides with which they will be sprayed, will not affect the immune system, endocrine system or gut microbiome of humans or animals.

1.1.5. Several of the GMOs combine both insect-killing and weed-killer-friendly traits but the EFSA analysis considers each trait separately. GMO traits are not simple "building blocks" and a stacked trait GMO is more than the sum of its parts – plant composition and gene expression can be influenced by the stacking process itself. As noted above, the health and environmental safety of the GMOs cannot be properly assessed until studies have been completed on the combined effects of the different toxins produced and the herbicide spraying regimes that they will be subject to. In addition, the interaction between these two types of traits must be properly examined, considering the way that the various Bt toxins and linked herbicides may interact under a range of conditions. Such an examination should consider, for example, whether the application of linked herbicides, in the presence of insect toxins, could influence the expression of the transgenes or any other genetic activity in the plants.

1.1.6. With the renewal applications (RP476, RP620, RP715, RP716), recent field trial data should be required and considered, rather than relying on the original field trials carried out many years ago.

1.2. Comments or concerns on the impacts in consideration of authorising or not authorising the individual GMOs, and if in favour of authorisation, the terms on which the GMOs are authorised

We are opposed to the authorisation of each of the nine GMOs. However, if they are authorised it is vital that post release monitoring proposals are improved. We strongly dispute the assertion, in each FSA/FSS opinion, that no post-market monitoring is required for the use of the food for human consumption. Without systematic monitoring it will be impossible to ascertain whether or not there are any adverse effects on the health of the people or animals that consume these genetically engineered crops. In addition to food and feed safety, monitoring should encompass nutrition and health impacts across the whole food chain as well as the environmental consequences of the release of each GMO, including via spillage of viable seed, distribution of waste products and the presence of GM material in sewage.

1.3. Factors that should be considered by Ministers that have not been highlighted

1.3.1. Consumers do not want GMOs in the food chain. FSS's own survey in October 2020[4] found that genetically engineered food was a top issue of concern (second only to chlorinated chicken which had been in the news for months ahead of the survey) and that only one in ten was likely to buy GM food, even if it was significantly cheaper. Another 2020 study conducted by the National Centre for Social Research[5] found that 59% of people wish to maintain restrictions on genetically engineered crops. A 2021 survey by the UK's National Economic and Social Research Council[6] found that 64% of those who took part were opposed to the cultivation of genetically engineered food. If authorised for food and feed use, the vast majority of the GMOs imported into Great Britain will be used as commercial animal feed. The GM-fed meat, eggs, dairy products and fish that they are used to produce will not be labelled, denying consumers the right to exercise freedom of choice about an issue on which many have deep and enduring concerns.

1.3.2. As noted above, the GMOs under consideration have all been engineered to produce toxins, withstand repeated spraying with weed killers, or both. They support unsustainable farming practices and, as pests evolve, are driving an agrochemical arms race. None of the crops is authorised for cultivation in the UK and the regimes under which they will be grown do not meet our standards for environmental protection. Authorising the import of these crops amounts to exporting environmental harm, a practice that is both irresponsible and unethical.

1.3.3. The GM crops being considered for release into the UK food chain are all patented. GM Freeze holds, as a core value[7] that "genetic resources are a public good and should not be controlled by any individual, group or company". The patenting of GM crops gives large multinational corporations disproportionate control over the food chain and prevents the kind of seed saving and sharing that supports the development of a resilient, genetically diverse and locally adapted seed supply.

1.4. Other feedback

1.4.1. FSA and FSS are tasked, in this instance, with serving society by assessing the safety of the nine GMOs. In order to discharge this responsibility, the agencies should conduct their own thorough and systematic review of relevant literature. We have seen no evidence that such an exercise has been conducted. Rather, it appears that the agencies are relying entirely on evidence presented by the applicants who have an obvious conflict of interests.

1.4.2. The UK's exit from the European Union is an opportunity to realise the Government's environmental ambitions and to back British farming. Opening the UK's door to GM crops grown to lower standards is a step in the wrong direction.

2. Our additional response to individual applications

In addition to the points above, which apply to all nine applications, we submit the following points for consideration regarding individual applications.

2.1. Additional concerns regarding RP476

We highlight Testbiotech's response to EFSA's assessment of genetically engineered maize MIR604 for renewal authorisation,[8] particularly regarding weaknesses in toxicological analysis. The Bt proteins used in the original risk assessment exhibited a different structure and biological activity compared to those produced in the plants. In addition, a sub-chronic feeding study performed with MIR604 for the original risk assessment identified significant concerns.

2.2. Additional concerns regarding RP526

We highlight Testbiotech's response to EFSA's assessment of genetically engineered maize MZIR098 for food and feed uses[9] particularly regarding weaknesses in data provided by the applicant. No experimental data was provided on the allergenic or immunogenic potential of mCry3A and eCry3.1Ab.

2.3. Additional concerns regarding RP535

We highlight Testbiotech's response to EFSA's assessment of genetically engineered maize MON 87427 x MON 89034 x MIR162 x NK603 and sub-combinations, for food and feed uses[10].

2.4. Additional concerns regarding RP606

We highlight Testbiotech's response to EFSA's assessment of genetically engineered maize MON87427 x MON89034 x MIR162 x MON87411 and sub-combinations, for food and feed uses, particularly noting the apparent absence of chronic or sub-chronic feeding studies[11].

2.5. Additional concerns regarding RP607

We highlight Testbiotech's response to EFSA's assessment of genetically engineered soybean MON87751 x MON87701 x MON87708 x MON89788 and sub-combinations, for food and feed uses[12]. In particular we note with concern that no feeding study was conducted on the fully stacked soya plants and that no data has been considered on the combined toxicity of glyphosate and dicamba when used together.

2.6. Additional concerns regarding RP620

As far as we are aware, a comprehensive critique of the EFSA risk assessment for Bt11 has not been published, but many of the points made for the other GM crops considered in this consultation remain relevant.

2.7. Additional concerns regarding RP714

We highlight Testbiotech's response to EFSA's assessment of genetically engineered maize MON 87427 x MON87460 x MON 89034 x MIR162 x NK603 and sub-combinations for food and feed uses[13]. In particular, we are concerned that no feeding study was conducted for the fully stacked GM maize and that field trials only featured one transgenic variety. In addition, this GM maize includes genes for resistance to the clinically important antibiotics neomycin and kanamycin.

The devastating health, social and economic impacts of the COVID 19 pandemic have highlighted the vulnerability of both human beings and the communities we have created to the spread of infectious disease. The rise of antibiotic resistant infections is recognised as a key concern by the general public and learned organisations such as the European Medicines Agency (EMA)[14]. In 2019, the UK government published a 20-year vision and 5-year national action plan[15] to prevent further antimicrobial resistance (AMR). The vision calls tackling antimicrobial resistance a "global priority", so we have a responsibility to prevent the cultivation of antibiotic resistant GM crops by denying their entry to the UK food chain.

2.8. Additional concerns regarding RP715

We highlight Testbiotech's response to EFSA's assessment of genetically engineered maize MON88017 for renewal authorisation for food and feed use,[16] noting in particular that compositional analysis assessed by EFSA in 2009 revealed a range of statistically significant differences in the composition of maize MON88017 and its non-GM comparator.

2.9. Additional concerns regarding RP716

We note that TestBiotech has warned[17] that in maize 89034 a new, synthetic Bt toxin is produced. Combining Cry1Ac, Cry1F and Cry1Ab, the novel toxin has no native form, yet its safety has not been adequately assessed for human health or impacts on the farmed animals most likely to consume the GM crop if authorised for continued import into the UK food chain.

3. Concluding remarks

We are disappointed and concerned that FSA and FSS have chosen to accept EFSA's assessments of the nine GMO applications rather than pursuing further the many weaknesses outlined above. There is a particular gap in the risk assessment of the stacked-trait crops, where all sub-combinations should be examined individually to check for unexpected impacts and combinatorial effects. All the GM plants under consideration have been engineered to kill insects, support the blanket spraying of particular weed killers, or to do both at the same time. These crops have no place in a responsible, fair and sustainable food system. We respectfully request that the agencies to reconsider their advice and urge Ministers to truly "take back control" by refusing to allow GMOs that don't meet UK farming standards into our food.

References

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