Consultation on applications for nine genetically modified organisms for food and feed uses: summary of stakeholder responses

This consultation was launched on 30 November 2021 and closed on 25 January 2022. This report is a summary of the consultation survey results and the main themes identified from written feedback.

Stakeholders' views were sought in relation to the authorisation of nine genetically modified organisms (GMOs), which were submitted for authorisation to be placed on the GB market, in accordance with Retained EU Regulation 1829/2003. Four of these applications were for renewal of authorisation, and five were new applications. The GMOs included in this consultation are currently authorised for use in Northern Ireland, in line with legislation that applies there, under the Northern Ireland Protocol.

The applications on which the consultation sought views were:

Renewal of the authorisation of the following four GMOs:

- RP476 – MIR604 maize;
- RP620 – Bt11 maize;
- RP715 – MON 88017 maize;
- RP716 – MON 89034 maize

Authorisation of the following five new GMOs:

- RP526 – MZIR098 maize;
- RP535 – MON 87427 × MON 89034 × MIR162 × NK603 maize and its sub-combinations;
- RP606 – MON 87427 × MON 89034 × MIR162 × MON 87411 maize and its sub-combinations ;
- RP607 – MON 87751 × MON 87701 × MON 87708 × MON 89788 soybean ;
- RP714 – MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations.

Stakeholders were requested to consider any relevant provisions of retained EU law and factors (e.g. consumer interests, technical feasibility and environmental factors) that the Food Standards Agency (FSA) and Food Standards Scotland (FSS) identified as relevant to these applications.

Consultation reach was comprehensive, with automatic notifications sent to 18,165 UK-wide subscribers of FSA alerts at the time of launch. Automatic notifications were also issued to FSA subscribers registered to receive updates in relation to national content - 20,580 subscribers to England, 11,317 subscribers to Northern Ireland and 12,003 subscribers to Wales. Key stakeholders whose businesses/organisations are affected by, or have an interest in, UK GM

policy were contacted directly for their feedback. To ensure representation of a broad spectrum of opinion, stakeholders known to be opposed to the introduction of GM products in the UK, as well as those previously supportive of it, were included. The FSA consultation was also shared with the FSA's 58,300 Twitter and 87,200 LinkedIn followers. The FSA consultation page received 1,600 views.

The FSA is grateful to all those who responded. The responses, grouped by theme, are set out in Table 1.

Characteristics of respondents

A total of 76 consultation responses were received from trade bodies, non-governmental organisations (NGOs), and members of the public.

Across the 76 respondents, the majority (51) gave their location as the UK, without specifying the country. Twenty-two reported living in England and two living in Wales. There was one response from the USA.

A list of those who responded can be found at the end of this document.

Summary of responses

Of the 76 responses received, all those representing industry (8) and one individual were supportive. Of those responding in an individual capacity or representing NGOs, the majority (6 NGOs, 61 individuals) had concerns with the proposed authorisations. The number of responses was low in comparison with actual numbers of stakeholders reached.

The main concerns raised related to the methods used for risk assessments and the possible impact of GMOs on the environment (primarily the increased use of herbicides and pesticides and the impact of this on biodiversity). Some respondents believed that the GMOs should not be authorised since they are not approved for cultivation in the UK. The FSA has considered carefully the comments provided and the views expressed, and these have been assessed by our experts. Many of the comments concern the cultivation of genetically modified crops in general. However, they do not fall within the scope of this specific consultation, which concerns the placing on the market of genetically modified food and feed.

Our responses to stakeholders' comments are set out below.

Summary of substantive comments

The responses to the consultation have been analysed and the main themes identified. The FSA's responses to the comments made are included in the following table.

1. Support for authorisations

Summary of Stakeholders' comments

Respondents commenting on behalf of industry were in support of the authorisations. The main reasons cited were a lack of safety concerns, the potential for disruption to trade and resulting increased costs if the GMOs are not authorised, and the importance to trade of avoiding divergence from the EU, due to logistics. One individual respondent was in favour of the authorisations.

Whilst being supportive of the authorisations being consulted on, several trade associations had concerns over the speed of authorisations and mentioned their desire for the UK to deliver authorisations at pace now that we have left the EU.

FSA's Response

Comments noted.

We note these suggestions and will consider them in shaping the process in future. We are mindful of impact on industry and the importance of not disadvantaging UK industry.

2. Running of consultation

Summary of Stakeholders' comments

Three respondents raised concerns with the running of the consultation (for example, reach, targeting). They felt that the consultation had not been open to the general public, and that it was targeted at the GMO industry.

FSA's Response

Eighty-two percent of respondents to the FSA consultation were members of the public.
The FSA has a subscription service, where interested parties can sign up to receive news and alerts, including consultation launches, by email.

The consultation alert was received by over 62,000 stakeholders subscribed to the FSA alerts mailing lists (UK wide, England, Northern Ireland or Wales) and promoted on the FSA's Twitter and LinkedIn channels. Key trade associations with a strong interest in GMOs and local authorities were contacted directly for their feedback. The consultation page was viewed 1600 times, resulting in 294 downloads.

Further details on how the FSA consults on the Engagement and consultations page.

3. Consumer choice

Summary of Stakeholders' comments

Seven responses raised concerns about the lack of labelling and traceability of GM-fed meat and dairy products, which would allow consumers to choose whether to consume them.

FSA's Response

We support giving consumers choice and recognise that some people will not want to buy or consume GM foods.

In the UK, foods must say on their label if they contain or consist of GMOs or contain ingredients produced from GMOs.

GM animal feed is not regarded as an ingredient to the meat, milk and eggs of the animals that were fed on GM animal feed and do not need to be labelled as containing or consisting of GM material. Food from animals which are fed with authorised GM crops is considered to be equivalent to food from animals fed on non-GM crops.

4. Safety for human consumption

Summary of Stakeholders' comments

Those responding on behalf of industry commented that they had no concerns over the GMOs being safe to consume.

Potential concerns with the consumption of these GMOs were raised by 17 people responding as individuals and 4 NGOs.

FSA's response

The FSA’s overarching mission is food we can trust, and we use a scientific, evidence-based approach to ensure food is safe and what it says it is.

Risk assessments on these GMOs were reviewed by the European Food Safety Authority (EFSA). In-house experts at the FSA subsequently reviewed the EFSA opinions and are satisfied in the conclusion that the use of these GMOs in food and feed would not pose a risk to human health when consumed.

5. Risk assessments

Summary of Stakeholders' comments

The methods used for risk assessment and a perceived lack of lack of post-marketing monitoring requirements were raised as a concern by 22 respondents, who felt that the risk assessment carried out by the European Food Safety Authority (EFSA) were not adequate.

FSA's response

The FSA’s overarching mission is food we can trust, and we use a scientific, evidence-based approach to ensure food is safe and what it says it is.

The authorisation procedure that these GMOs have gone through are some of the most comprehensive and stringent procedures taken for a regulated product authorisation. It is essential for every GMO to have been assessed and receive favourable scientific assessment given by an independent committee of experts. An authorisation grants validity for a period of 10 years, after which the supporting safety data package submitted with the original application is reviewed and re-assessed before a renewal can be granted.

Any product produced from these GMOs will be subject to the strict labelling and traceability rules, and post-marketing monitoring reports will continue to be supplied on an annual basis.

6. Stacked GM traits

Summary of Stakeholders' comments

Eight respondents were concerned that ‘stacked traits’ (where more than one genetically modified trait is introduced to the plant) have not been appropriately risk assessed, as not all the combinations have been studied.

FSA's response

The FSA's overarching mission is food we can trust, and we use a scientific, evidence-based approach to ensure food is safe and what it says it is.

All individual events in stacked applications have been assessed by the European Food Safety Agency (EFSA). The risk assessment of stacked events, in line with the EFSA guidelines on risk assessment of stacked events, incorporates assessment of the stability and expression of the events and potential interactions between the events to ensure the integrity of the modifications.

Compositional analysis, animal trials and assessment of the potential for increased toxicological, allergenic and nutritional concerns are performed, comparing the stack-containing GM plant to parental GM plants and the non-GM comparator. Interactions between the stacked events and target and non-target organisms are also assessed. Additional assessment is required whenever the potential for safety concerns is identified, including additional field trials, appropriate animal feeding studies and environmental studies.

A specific objection was raised to assessing MIR604 maize (renewal) as a single event, stating that it should be treated as a stack application. As described in the original EFSA opinion, a single transformation was carried out on a hybrid maize line (NP2500/NP2499). This hybrid maize variety was produced by conventional inbreeding and not genetic modification. This is therefore not a stacked event as only a single Agrobacterium tumefaciens transformation was performed.

7. Scope of consultation

Summary of Stakeholders' comments

Twenty respondents expressed concern that these GMOs are not considered safe for cultivation in the UK, therefore should not be authorised.

FSA's Response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

It is not the case that these GMOs are not safe for cultivation in the UK; the applications for these GMOs have not included a request to approve for cultivation by any of the applicants.

8. Transparency of approval process

Summary of Stakeholders' comments

Concerns that GM interested parties and lobbyists have undue influence on decision making around GMO authorisations were raised by 4 respondents. They raised concerns around conflicts of interest.

FSA's Response

The FSA is committed to being open and transparent in how we conduct, respond to, and publish these consultations, which are vital in providing stakeholders and the wider public with an opportunity to input on the advice given to Ministers relating to applications for approval.

However, consultations only form one aspect of the total evidence base and it is vital, in our role as a responsible regulator with consumer interests at heart, we also take into account the very best science when making recommendations on product authorisations.

9. GB legislation post-Brexit

Summary of Stakeholders' comments

The position of Great Britain post-Brexit in terms of developing legislation was mentioned by two individual respondents. One asserted that there is now the opportunity to implement different standards to the EU, and not to authorise these GMOs. Conversely, another respondent said that Brexit should not be used as an excuse to remove the high food standards that the EU has developed over the years.

FSA's Response

The FSA is open to maintaining a review of our regulatory frameworks to ensure they remain proportionate and fit-for-purpose. Our Innovation and Regulation Plan aims to bring together the work we do and sets out how our regulatory framework can work by working effectively to support innovation and keep pace with modernising business models. We value meaningful engagement with all stakeholders to inform and develop our policy decisions and will assess the impacts of these. The FSA has a statutory objective to protect public health and consumers' other interests in relation to food. We strive to be a fair and effective regulator, proportionate and forward-looking in our regulatory approach and focused on achieving the outcomes we seek. Our pledge is to put consumers first in everything we do, so that food is safe and what it says it is, that we have access to an affordable healthy diet, and can make informed choices about what we eat, now and in the future.

10. Need for GM production

Summary of Stakeholders' comments

A lack of need for GM production was stated by eight respondents (one NGO and seven individuals). Theses respondents said that they saw no role for GMOs in a sustainable and responsible food system and cited the amount of food wasted in the UK each year.

FSA's Response

The UK’s animal feed sector is highly dependent on the import of agricultural commodities. Imports of soybean and maize are essential to supplement the demand needed to meet the livestock sector, with a significant proportion of these commodities being derived from a GMO source. The only GMO varieties permitted to enter onto the market will have been subjected to pre-market authorisation after being assessed on the grounds of any potential risk to health and the environment.

11. Assessment of environmental impact

Summary of Stakeholders' comments

Nineteen respondents expressed their concern that there had been a lack of assessment of environmental impact.

FSA's Response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

An Environment Risk Assessment on these GMOs has been undertaken by the appropriate expert committee for the UK. The Advisory Committee on Releases to the Environment (ACRE) concluded that the use of these GMOs in food and feed would not pose a greater risk to the domestic environment than a traditionally bred or naturally occurring version of that organism.

12. Increased herbicide and pesticide usage

Summary of Stakeholders' comments

The potential for increased use of herbicides and pesticides was an issue raised by 44 respondents.

The safety of glufosinate, glyphosate and dicamba was raised by a number of people and organisations.

FSA's Response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

The Health and Safety Executive (HSE) is responsible for regulating the use of plant protection products.

As with all approved active substances in plant protection products, any that have received approval will have passed a thorough evaluation process which includes the safety of their use in terms of application and consumption of any residues. No food products, whether imported or grown domestically, can be placed on the market if they contain levels of residues that exceed the Maximum Residue Levels (MRLs). Food products that contain compliant levels of residual pesticides or herbicides are considered to be safe for consumption.

Glufosinate, glyphosate and dicamba are active substances authorised for use in accordance to retained EU legislation 1107/2009 and are available on the HSE’s database for Plant Protection Products.

13. Safety of Bt toxins

Summary of Stakeholders' comments

The effect of pesticidal properties of the GM crops themselves and the safety of Bt toxins was raised by 3 NGOs and 6 individuals.

Concerns raised mainly related to Cry proteins, as well as Vip3A, insecticidal delta-endotoxins from B. thuringiensis introduced to confer resistance to lepidopteran pests.

Concerns were also raised regarding protease inhibitors and enzymes produced by host organisms that could delay the degradation of Bt toxins.

FSA's Response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

There is an extensive history of safe use of GMOs in which Bt toxin genes have been introduced both as single events and as stacks containing multiple Bt toxin-encoding genes. A wide range of Bt toxins have been assessed by the European Food Safety Agency (EFSA) GMO panel in the

context of previous applications, during which no toxicological or allergenic concerns have been identified for humans or animals as part of this process. Updated bioinformatics analyses and additional toxicity studies performed as part of the applications considered here were consistent with previous studies and identified no concerns.

Numerous peer reviewed studies have been published on individual Bt toxins and Bt toxins in general, assessing their function, mode of action, and potential for toxicity and allergenicity.

Protease inhibitors and enzymes produced by host organisms that could delay the degradation of Bt toxins are not exclusive to the GMOs assessed as part of these applications and are common throughout plants and other organisms. Rapid degradation of Bt toxins in gastric fluid has been demonstrated, in addition to denaturation of Bt toxins due to cooking and food preparation techniques. There is, therefore, no concern for human and animal health in relation to delayed degradation of Bt toxins.

14. Impact on insect and biodiversity

Summary of Stakeholders' comments

A concern raised by 45 respondents was the indiscriminate impact that increased pesticide usage has on insects and the effect on biodiversity and the wider food chain.

FSA's Response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

For crops that have been genetically modified to confer pest resistance, the risk assessment process specifically considers the potential impact on ‘non-target’ organisms. This use of GM technology can contribute to reducing the reliance on the use of spraying plant protection products (such as herbicides and pesticides) onto crops. Excessive and indiscriminate use of plant protection products is not specific to the genetically modified crops. It is the responsibility of the grower to ensure their uses are appropriate and in accordance to permitted standards. The maximum residue levels of plant protection products permitted on crops are rigorously enforced and regulated by the Health and Safety Executive.

15. Development of increased resistance by insects and weeds

Summary of Stakeholders' comments

Thirty-one respondents expressed concerns that GMOs result in increased herbicide and pesticide usage, which in turn results in the development of increased resistance by insects and weeds.

FSA's response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

An overreliance on having too few control strategies in agriculture production is likely to encounter increases with resistance by crop pests and weeds over time as a result of their evolutionary adaption. Continued innovation in the farming sector in terms of crop production strategies can ensure continued food security can be supplied to the population at large.

GM technology provides for one aspect in the tools and strategies that can be made available to growers. It is the statutory duty of the Advisory Committee on Releases to the Environment (ACRE) to assess the impact to the domestic environment before a GMO crop can be approved for import and use in food or animal feed.

16. Issues with cross pollination

Summary of Stakeholders' comments

The contamination of wild and non-GM plants through cross-pollination was raised as a concern by 2 individuals.

FSA's response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

No GM crops are currently grown commercially in the UK. For approved GM crops the consequences of cross-pollination is assessed by regulators, and not considered to be at risk. In countries that do commercially cultivate GM plants, cross-pollination can be minimised with measures such as distance barriers between GM and non-GM crops to support consumer choice and seed purity standards.

17. Contamination of soil and water

Summary of Stakeholders' comments

The potential contamination of soil and waterways from increased herbicide and pesticide usage was a concern raised by 8 respondents.

FSA's response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

Issues relating to herbicide and pesticides contaminating soil and waterways can arise from improper use in the cultivation of both GM and non-GM crops.

18. Impact of GM cultivation on climate change

Summary of Stakeholders' comments

Three respondents (1 NGO and 2 individuals) raised concerns over the contributory impact that monoculture farming is having on climate change.

FSA's response

This consultation concerned the placing on the market of genetically modified food and feed, in accordance with Retained EU Regulation 1829/2003.

The FSA is committed to our Environmental Sustainability Strategy that sets out our support to the UK government in meeting its target of reducing emissions by 2035, helping the UK to be net

zero by 2050. As part of this commitment, the FSA aims to positively influence the sustainability performance of suppliers and evaluate the sustainability credentials of the goods and services that we purchase. Biotechnology can help to produce crops which are more resilient to climate change.

19. Impact in countries of cultivation

Summary of Stakeholders' comments

There were general concerns raised over the impact of GMOs in countries in which they are cultivated.

FSA's response

The FSA is committed to our Environmental Sustainability Strategy. As part of this commitment, the FSA aims to positively influence the sustainability performance of suppliers and evaluate the sustainability credentials of the goods and services that we purchase.

20. Impact on traditional farming

Summary of Stakeholders' comments

The potential impact on farmers practising traditional methods of farming was an issue raised by 25 respondents.

FSA's response

The FSA is encouraging of continued innovation in the farming sector with the development of new crop production strategies to ensure continued food security can be supplied to the population at large. Diversifying farming practices can offer consumers greater choice in what they choose to eat and will help to reduce an overreliance on having too few control strategies in agriculture production.

Next steps

- The next step of the authorisation process is for relevant Ministers in England, Wales and Scotland to make decisions on authorisation.
- The FSA/FSS risk assessment opinions on these applications concluded that the GMO products are safe to be authorised based on the proposed terms of authorisation. No reasons to change the advice that these GMOs should be authorised have been identified during the consultation process. On that basis, the final advice to respective Ministers recommends authorisation of these GMOs on the proposed terms of authorisation.
- If Ministers move to authorise new regulated products, the next step is for Statutory Instruments to be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland).
- Regulations in Northern Ireland will not be amended as the GMOs are already authorised for use in Northern Ireland, in line with EU legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

List of respondents

This list does not include those respondents who asked for their response to be kept confidential or responses from individuals.

1. National Farmers' Union
2. Grain and Feed Trade Association (GAFTA)
3. Agricultural Industries Confederation (AIC)
4. GeneWatch UK
5. GM Freeze
6. Organic Farmers & Growers CIC (OF&G)
7. MAIZALL
8. GM Watch
9. EcoNexus
10. Agricultural Biotechnology Council (ABC)
11. National Farmers' Union Wales