Consultation on applications for eight genetically modified organisms (GMOs) for food and feed uses and for the change of authorisation holder for fifty-one authorised GMOs: Summary of stakeholder responses

This report is a summary of the consultation responses in relation to the authorisation of eight genetically modified organisms (GMOs).

This consultation was issued on 12 October 2022 and closed on 6 December 2022.

This report is a summary of the consultation results and the main themes identified from written feedback.

Stakeholders' views were sought in relation to the authorisation of eight genetically modified organisms (GMOs), which were submitted for authorisation to be placed on the GB market and the modification of authorisation holders' details for fifty-one authorised GMOs in accordance with Retained EU Regulation 1829/2003.
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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 two GMOs:

- RP1179 – MON 88017 x MON 810 maize
- RP1263 – GT73 oilseed rape

Authorisation of the following six new GMOs:

- RP1133 – DAS-81419-2 x DAS-44406-6 soybean ?
- RP1134 – DAS-81419-2 soybean
- RP1138 – SYHT0H2 soybean
- RP1180 – MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 maize and its sub-combinations ?
- RP1184 – 1507 x MIR 162 x MON 810 x NK 603 maize and its sub-combinations
- RP1205 - GHB614 x T304-40 x GHB119 cotton

Change of authorisation holder for the following authorised GMOs:

- RP1093 - Application from Syngenta for the transfer of authorisation for FG72 soybean from BASF Agricultural Solutions Seed US LLC (represented in Great Britain by BASF SE) to Syngenta Crop Protection AG, Switzerland, represented in Great Britain by Syngenta Limited UK
- RP1100 - Application from BASF for the transfer of authorisation for FG72 soybean from BASF Agricultural Solutions Seed US LLC (represented in Great Britain by BASF SE) to Syngenta Crop Protection AG, Switzerland, represented in Great Britain by Syngenta

Limited UK.
- RP1329 - Change in representative and authorisation holder for 50 GMO applications held under heritage companies Dow AgroSciences and Pioneer Hi-Bred International to Corteva Agriscience.

Stakeholders were requested to consider any relevant provisions of retained EU law and other legitimate factors (for example, 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 22,900 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 and a further 30,991 country specific subscribers (England, Wales and Northern Ireland). 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 60,000 Twitter followers and 98,300 LinkedIn followers. The FSA consultation page received 193 visitors, resulting in 305 page views.

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

Characteristics of respondents

A total of 38 consultation responses were received from trade bodies, non-governmental organisations (NGOs), and members of the public. Across the 38 respondents, the majority gave their location as the UK.

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

Summary of responses

Of the 38 responses received, all those representing industry (4) were supportive. Of those responding in an individual capacity or representing NGOs, (2 NGOs, 32 individuals), all 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 possible impact of GMOs on the environment primarily the increased use of herbicides and pesticides and the impact of this on insects and 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, responses relating to cultivation 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 in the next section.

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 table below.

1. Support for authorisations

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 and Northern Ireland, due to logistics.

Whilst being supportive of the authorisations being consulted on, concerns were raised over the speed of authorisations and the need to avoid a situation where GMO approvals lag behind those of other key exporting and importing nations.

FSA Response

Comments noted. We note these suggestions and will consider them in shaping the process in the future.

2. Running of consultation

Some respondents raised concerns with the running of the consultation, including timescales, deadlines for responses, and conflict with similar consultations over same timeframe.

FSA Response

Details on how the FSA consults can be found here: Engagement and consultations.

The FSA has a subscription service, where interested parties can sign up to receive news and alerts, including consultation launches, by email.

The consultation ran for 8 weeks which the FSA considered to be a proportionate time frame to allow for a meaningful consultation which has resulted in 38 responses.

The consultation alert was received by over 53,000 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 FSA consultation page received 193 visitors, resulting in 305 page views.

3. Consumer choice

Four 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 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 which 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

Eight respondents cited concerns with the consumption of GMOs and long-term effect on health including concerns over antibiotic resistance.

FSA 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 conducted by the European Food Safety Authority (EFSA). Scientific experts in the FSA's science evidence and research division 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

Respondents raised concerns regarding the methods and thoroughness of risk assessments.

FSA 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 procedures 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 to 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

Concern was raised that 'stacked traits' (where more than one genetically modified trait is introduced to the plant) have not been appropriately assessed, as not all the combinations have been studied and no data has been considered on the various combinations that approval would cover.

FSA 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 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.

7. Scope of consultations

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

FSA Response

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

These GMOs have not been proven to be unsafe for cultivation in the UK.

The applications for these GMOs are only for food and feed and do not include approval for cultivation by any of the applicants.

8. Transparency of approval process

Three respondents raised concerns that GM interested parties and lobbyists have undue influence and conflicts of interest on decision making around GMO authorisations.

FSA 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 consider the very best science when making recommendations on product authorisations. We ensure that our Scientific Advisory Committees properly declare any interests by requiring them to complete a Declaration of Interests form, declare any new interests as they arise and adhere to the Code of Practice for Scientific Advisory Committees.

9. Need for GM production

A lack of need for GM production was stated by four respondents. These respondents said that they saw no good reason to authorise GM crops.

FSA Response

The UK's animal feed sector is highly dependent on the import of agricultural commodities. Imports of soybean and maize are essential to meet the demand for 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.

10. Assessment of environmental impact

Ten respondents expressed their concern that there had been a lack of assessment of environmental impact of growing GM crops.
A lack of research which adequately assesses the potential dangers of GM plants to consumers, to ecology and to the environment.

FSA 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 Great Britain. 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 environment in Great Britain than a traditionally bred or naturally occurring version of that organism. These GM crops are not for cultivation in Great Britain.

11. Increased herbicide and pesticide usage

The potential for increased use of herbicides and pesticides was an issue raised by 14 respondents.
The safety of glufosinate and glyphosate,and mesotrione and other p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides was raised.

FSA 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 and glyphosate 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.

12. Safety of Bt toxins

The effect of pesticidal properties of the GM crops themselves and the safety of Bt toxins was raised.

FSA 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 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.

13. Impact on insects and biodiversity

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

FSA Response

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

Excessive and indiscriminate use of plant protection products is not specific to genetically modified crops. It is the responsibility of the grower to ensure their uses are appropriate and in accordance to permitted standards. MRLs of plant protection products permitted on crops are rigorously regulated and enforced by the Health and Safety Executive. 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.

14. Development of increased resistance by insects and weeds

Ten respondents expressed concerns that evolution of insects and weeds results in increased herbicide and pesticide usage, to combat increased resistance.

FSA 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 too few control strategies in agriculture production is likely to lead to increased resistance of 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 for the population at large.

GM technology provides one aspect of the tools and strategies that can be made available to growers. It is the statutory duty of the 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.

15. Issues with cross-pollination

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

FSA Response

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

For approved GM crops the consequences of cross-pollination is assessed by regulators. No GM crops are currently grown commercially in GB. In countries that do commercially cultivate GM plants, it is the responsibility of regulators in those countries to implement measures to manage risks related to the release into the environment of GMOs.

16. Contamination of soil and water

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

FSA Response

These GMO authorisations are not for UK cultivation. 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.

17. Impact of GM cultivation on climate change

Concern was raised that UK Farming practices should promote sustainability and diversity to slow climate change and introducing GMO products will put the balance of our nation's ecosystem at great risk.

FSA Response

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

These issues are covered within the assessment of impacts as part of the consultation process.

The FSA aims to positively influence the sustainability performance of suppliers and evaluate the sustainability credentials of products prior to authorisation.

18. Impact in countries of cultivation

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

FSA Response

Countries are responsible for conducting their own safety assessment before a GM organism is authorised for cultivation in their territory.

19. Impact on traditional farming

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

FSA Response

Innovation in the farming sector with the development of new crop production strategies helps to ensure continued food security. 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.

20. Comments or concerns on the impacts of the change of authorisation holder

Nine respondents expressed concern, including:

Too few companies have control over the food chain, and the companies that do are agricultural giants who need to consider their profits may well clash with what is in the best interests of the public.

Governance, and process should be paramount to avoid conflicts of interest and selective approval.

FSA Response

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in Great Britain (GB), applications RP1093, RP1100 and RP1329 have been submitted for administrative amendments to be made, to change the authorisation holder.

All administrative amendments requested relate to current authorisations that remain as applicable to GB, under their retained EU law status.

Authorisations are subject to post market monitoring which is enforceable. It is in the interest of the authorisation holders to comply with regulation as lack of compliance could lead to the revocation of the authorisation meaning that the product could not be legitimately placed on the market in GB.

Next Steps

- the next step of the authorisation process is for relevant Ministers in England, Wales and Scotland to make decisions on authorisation. In the absence of Ministers in Northern Ireland, the Northern Ireland Department of Health Permanent Secretary will be informed of the recommendation to authorise. 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 FSA/FSS advice to Ministers will be to authorise these GMOs on the proposed terms of authorisation outlined in the FSA/FSS opinions.
- should Ministers move to authorise, Statutory Instruments will be prepared in England and Wales (and a Scottish Statutory Instrument in Scotland) in line with the terms of authorisation previously outlined in the FSA/FSS opinion.
- 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

1. National Farmers' Union
2. Grain and Feed Trade Association (GAFTA)
3. Agricultural Industries Confederation (AIC)
4. GeneWatch UK
5. GM Freeze
6. National Farmers' Union Cymru
7. Individual Respondents