Consultation on applications for nine genetically modified organisms for food and feed uses

Launch date: 30 November 2021

Respond by: 25 January 2022

This consultation will be of most interest to

- Animal feed manufacturers, importers/exporters and retailers
- All feed purchasers, including for food and non-food producing animals
- Trade bodies representing stakeholders on animal feed, agriculture and the environment
- Trade unions representing stakeholders in the farming industry
- Organisations representing consumer interests in the feed and food-chains
- Enforcement Authorities

A list of interested parties is included in Annex A.

Consultation subject and purpose

This consultation is to seek stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation. We ask stakeholders to consider any relevant provisions of retained EU law and other legitimate factors (other evidence further supporting clear, rational and justifiable risk analysis, such as consumer interests, technical feasibility and environmental factors) that the Food Standards Agency (FSA) and Food Standards

Scotland (FSS) have identified as relevant to these applications. This is stakeholders' opportunity for input on the advice given to Ministers to inform decision making.

The finalised FSA/FSS opinions, and the views gathered through this consultation, will be considered and included alongside those of Officials of the Devolved Governments in Northern Ireland, Scotland and Wales and UK Government Departments other than the FSA to inform Ministers' decision making on whether to authorise the individual genetically modified organisms (GMOs) for use in England, Scotland and Wales.

A parallel consultation is being published by FSS.

How to respond

Responses to this consultation should be sent to:
Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Chemical Safety Policy Unit

Details of consultation

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, the applications included in this consultation have been submitted for authorisation.

Nine GMOs have been submitted for authorisation in each nation of Great Britain (GB), where the decision on authorisation is made by the respective Ministers in England, Scotland and Wales. This is a function that was previously carried out at a European Union (EU) level. Since the end of the transition period, assessing food and animal feed safety in the UK is the responsibility of FSA/FSS and the authorisation of regulated products is the responsibility of the relevant appropriate authority of each of the nations of GB.

In respect to Northern Ireland, EU Food Law on GMOs continues to apply under the current terms of the Protocol on Ireland/Northern Ireland (NIP). This means GMOs require authorisation under the EU's authorisation procedures before being placed on the market in Northern Ireland.

Each application is considered within a separate annex, including the regulated product ID number and title of the application (Ctrl+Click to follow link):

Introduction

The FSA and FSS have been working together to ensure that the high standard of food safety and consumer protection in the UK continues following the UK's exit from the EU. Regulated product applications for the GB market, including GMOs, are now subject to the UK's own risk analysis process, with FSA/FSS continuing to provide advice to Ministers on matters of food safety.

GMOs are plants and animals with a genetic make-up that has been modified using techniques of biotechnology. Genetic modification allows scientists to produce plants, animals and micro-organisms with specific qualities. Genetically modified food and feed contain or consist of GMOs or are produced from GMOs.

For new authorisations and renewals of authorisations for GMOs to be placed on the GB market, an application shall be submitted in accordance with Retained EU Regulation 1829/2003.

Following consultation, the next step of the authorisation process is for relevant Ministers in England, Scotland and Wales to make decisions on authorisation (with Ministers in Northern Ireland kept informed), taking into account the FSA/FSS opinion, any relevant provisions of retained EU law and any other legitimate factors. Details of the individual GMOs are given in the annexes. FSA/FSS advice to Ministers, subject to views gathered in the consultation, will be to authorise these GMOs on the proposed terms as outlined in the FSA/FSS opinions.

In line with FSA/FSS' responsibility to provide advice to Ministers in respect of matters connected with food safety or other interests of consumers in relation to food (section 6, Food Standards Act 1999), we have identified factors which may inform Ministerial decision making. The outlines of these factors also take into account the impact of any decision ultimately made by Ministers, whether this is to authorise or not. Stakeholders are invited to use this opportunity to comment on these factors or highlight any additional factors that should be brought to the attention of Ministers before a final decision is made.

Ministers in all four nations have provisionally agreed to a provisional common framework for Food and Feed Safety and Hygiene. This consultation has been developed under the commitments to collaborative four-nation working set out in this framework. As such, this consultation has been developed through cross-government forums with the Department

of Health and Social Care (DHSC), Welsh Government and Scottish Government. The content of this consultation represents the views of FSA/FSS and the factors that FSA/FSS has identified as relevant to these applications. Final advice will be agreed on a four-nation basis before being presented to Ministers.

Impacts

As part of the risk analysis process, FSA/FSS has assessed the impacts that would result from authorisation of these GMOs, should Ministers decide to authorise. Our collective assessment of the proposals did not identify any significant impacts. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e., Local Authority Delivery, Health, Environment, Growth, Innovation, Trade, Competition, Consumer Interests or Small and Micro Businesses). The authorisation of these products should generally result in greater market competition supporting growth and innovation in the sector.

Under the provisional common framework for Food and Feed Safety and Hygiene, Northern Ireland continues to have full participation in the risk analysis processes concerning food and feed safety. This reflects Northern Ireland's integral role within the UK and ensures that any decision made fully considers the potential impacts on the whole of the UK. The GMOs included within this consultation are authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol. Therefore, authorising in all GB nations will protect against divergence within the UK.

Consumer interests:

FSA/FSS has a unique role as the non-Ministerial Government department that looks after consumer interests when it comes to food. We invest in consumer research so that we have evidence on consumer behaviours, understanding and preferences to inform policy decisions.

Our flagship social research survey and Official Statistic, Food and You 2, gives us the ability to analyse a large sample database of consumer behaviour, attitudes and concerns bi-annually.

In the FSA's Public Attitudes Tracker we ask consumers about issues that concern them, and publish the results, and genetically modified foods is one of the issues listed. This is also conducted by the FSS with the Food in Scotland Consumer Tracker.

We have carried out specific research on Consumer Attitudes towards Emerging Technologies which included genetically modified foods.

We also follow other consumer surveys such as The British Social Attitudes Survey which has also asked about attitudes towards genetically modified food production. The genetically modified responses to these questions can be found in the 'Science' chapter included in the 36th annual report.

Engagement and Consultation Process

Details of all validated applications for regulated products are published on the Register of Regulated Product Applications on the Food Standards Agency Website.

Stakeholders are invited to consider the questions posed below in relation to any relevant provisions of retained EU law and other legitimate factors.

Following the consultation process responses will be published and made available to stakeholders and Ministers.

Questions asked in this consultation:

1. Do you have any concerns on the safety of the products/events which have not been considered below with respect to the intended consumers, stakeholders or impacts?
2. Do you have any 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 (as outlined in the FSA/FSS opinions)?
3. Are there any other factors that should be considered by Ministers that have not been highlighted?
4. Do you have any other feedback?

Responses

This consultation will run for 8 weeks. Responses are required by close 25 January 2022. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents) and in which nation you are based.

All responses to this consultation will be published by the Food Standards Agency within 12 weeks of the consultation closing.

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response:

Response to [insert RP number(s)] consultation

Please send response to RPconsultations@food.gov.uk

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice at https://www.food.gov.uk/about-us/privacy-notice-consultations.

Responses will be shared with FSS.

Further information

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

This consultation has been prepared in accordance with HM Government consultation principles.

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Sabrina Roberts
GM Policy Advisor
Chemical Safety Policy Unit

Annex A: List of interested parties

Key stakeholder trade associations which are represented across all four nations of the UK who have a strong interest in GMOs across the wider sector will be contacted directly for feedback on this consultation:

- The National Farmers' Union
- The Agricultural Biotechnology Council
- The Grain and Feed Trade Association
- The Agricultural Industries Confederation
- The Pet Food Manufacturers Association
- The British Equestrian Trade Association
- The British Association of Feed Supplement and Additive Manufacturers

This is not an exhaustive list.

Annex B: RP476 – MIR604 maize (renewal)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP476 has been submitted for the assessment of genetically modified MIR604 maize, as a renewal of authorisation for food and feed uses.

Event MIR604 is a genetically modified maize developed to confer field protection against the Western Corn rootworm, and the Northern Corn rootworm, and other related coleopteran species. It also expresses a marker protein, phosphomannose isomerase (PMI), that allows the plants to utilise mannose as a carbon source.

MIR604 (Unique Identifier: *SYN-IR6Ø4-5*) is a genetically modified maize developed to confer field protection against corn root worms.

The cry3A gene from *Bacillus thuringiensis* codes for a Bt-toxin (Cry3A), which confers resistance to western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*D. longicornis barberi*) and other related coleopteran species.

Expression of the PMI gene from the bacterium *Escherichia coli* allows the plant to use mannose as a carbon source through production of the PMI protein and is used as a selectable marker.

In the December 2009 publication of Official Journal of the European Union, Commission Decision 2009/866/EC had authorised the placing on the market of genetically modified maize MIR604 (SYN-IR6Ø4-5) for a validity period of 10 years. The renewal of genetically modified maize MIR604 (SYN-IR6Ø4-5) was applied by the authorisation holder to uphold the authorisation for a further 10 year period.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the Joint Research Centre (JRC) as used for the detection and control of MIR604 maize. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice. The renewal of authorising genetically modified MIR604 maize has not changed its current status with regards to mandatory genetically modified labelling requirements.
- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.
- In the case of pre-packaged genetically modified food/feed products, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified maize’ must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.
- Operators shall ensure the Unique Identifier SYN-IR6Ø4-5 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

This GMO is authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex C: RP526 – MZIR098 maize (new application)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP526 has been submitted for the assessment of genetically modified MZIR098 maize, as a new authorisation for food and feed uses.

Event MZIR098 maize is a genetically modified maize developed to provide field protection against feeding damage incurred by certain coleopteran pests of maize and confer tolerance to herbicides containing glufosinate-ammonium.

The maize MZIR098 (Unique Identifier: *SYN-ØØØ98-3*) has been modified to be tolerant to the herbicide glufosinate ammonium (glufosinate) and to be protected against coleopteran pests, particularly western corn rootworm (*Diabrotica virgifera virgifera*), northern corn rootworm (*D. berberi*), and Mexican corn rootworm (*D. vigifera zeae*).

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of MZIR098 maize. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice.

- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier: SYN-ØØØ98-3 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political,

economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

This GMO is authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex D: RP535 – MON 87427 × MON 89034 × MIR162 × NK603 maize and its sub-combinations (new application)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP 535 has been submitted to the FSA for the assessment of genetically modified maize and its sub-combinations MON 87427 × MON 89034 × MIR162 × NK603, as a new authorisation for food and feed uses.

MON 87427 × MON 89034 × MIR162 × NK603 is produced by crossing maize plants containing MON 87427, MON 89034, MIR162 and NK603 using traditional breeding methods. Therefore, this product inherited the traits as present in the parental lines, glyphosate-tolerance (from MON 87427 and NK603) and insect-protection (from MON 89034 and MIR162). The stacked maize line was obtained through the traditional cross breeding of the parental organisms MON 87427 × MON 89034 × MIR162 × NK603 (Unique Identifier: *MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ6Ø3-6*). The line inherited genes that express cry1A.105, cry2Ab2, vip3Aa19 and cp4epsps. The expression of these genes confer glyphosate herbicide tolerance and resistance to Lepidoptera and Coleoptera.

The sub-combinations in this context refers to any two or three combinations of the four genetic modification insertions: MON 87427, MON 89034, MIR162, NK603; to the genetically modified crop.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of MON 87427 × MON 89034 × MIR162 × NK603. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice.

- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ6Ø3-6 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there

are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

This GMO is authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex E: RP606 – MON 87427 × MON 89034 × MIR162 × MON 87411 maize and its sub-combinations (new application)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP 606 has been submitted to the FSA for the assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 its sub-combinations, as a new authorisation for food and feed uses.

MON 87427 × MON 89034 × MIR162 × MON 87411 is produced by crossing maize plants containing MON 87427, MON 89034, MIR162 and MON 87411 using traditional breeding methods. Therefore, this product inherited the traits as present in the parental lines, glyphosate-tolerance (from MON 87427 and MON 87411) and insect-protection (from MON 89034, MIR162 and MON 87411).

The stacked maize line MON 87427 × MON 89034 × MIR162 × MON 87411 (Unique Identifier: *MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9*) was obtained through the traditional cross breeding each of the parental organisms. The line inherited genes that express cry1A.105, cry2Ab2, vip3Aa19 and cp4epsps. The expression of these genes confer glyphosate herbicide tolerance and resistance to Lepidoptera and Coleoptera. The line also contains a suppression cassette that expresses an inverted repeat sequence that results in the formation of a double-stranded RNA (dsRNA) transcript containing a 240 bp fragment of the WCR Snf7 gene (DvSnf7) and is designed to match the sequence of western corn rootworm (WCR).

The sub-combinations in this context refers to any two or three combinations of the four genetic modification insertions line MON 87427, MON 89034, MIR162, MON 87411 to the genetically modified crop.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and its sub-combinations. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice.

- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there

are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

This GMO is authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex F: RP607 – MON 87751 × MON 87701 × MON 87708 × MON 89788 soybean (new application)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP607 has been submitted to the FSA for the assessment of genetically modified soybean MON 87751 x MON 87701 x MON 87708 x MON 89788, as a new authorisation for food and feed uses.

Glycine max- soybean is a four-event stack produced via conventional crossing, consisting of cry lepidopteran resistance (MON 87551, MON 87701), dicamba and glyphosate tolerance (MON 87708) and glyphosate tolerance (MON 89788).

The stacked soybean line MON 87751 × MON 87701 × MON 87708 × MON 89788 (Unique Identifier: *MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1*) was obtained through the traditional cross breading of each of the parental organisms to produce a soybean that expresses each of dicamba monooxygenase, Cry1Ac, Cry2Ab2, Cry1A.105 and EPSPS genes. The expression of these genes is expected to confer resistance to Lepidoptera and tolerance to dicamba and glyphosate herbicide.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control MON 87751 x MON 87701 x MON 87708 x MON 89788. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice.

- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified soybean' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in

making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

This GMO is authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland, under the Northern Ireland Protocol.

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Annex G: RP620 – Bt11 maize (renewal)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP 620 has been submitted to the FSA for the assessment of genetically modified Bt11 maize, as a renewal of authorisation for food and feed uses.

Event Bt11 is a genetically modified maize developed to provide protection against certain lepidopteran pests of maize and tolerance to herbicides containing glufosinate-ammonium. Bt11 maize plants contain the transgene cry1Ab, which encodes the insecticidal protein Cry1Ab, and the transgene pat, which encodes the enzyme phosphinothricin acetyltransferase (PAT).

Bt11 maize (Unique Identifier: *SYN-BT Ø11-1*) is an insect-resistant and herbicide tolerant maize produced by inserting the cry1Ab gene from *Bacillus thuringiensis subsp. kurstaki* to confer resistance to the European corn borer (*Ostrinia nubilalis*), and the phosphinothricin N-acetyltransferase (PAT) encoding gene from *Streptomyces viridochromogenes* to confer tolerance to phosphinothricin (PPT) herbicide, specifically glufosinate ammonium.

In the August 2010 publication of Official Journal of the European Union, Commission Decision 2010/419/EU had renewed authorising the placing on the market of genetically modified maize Bt11 (SYN-BT Ø11-1) for a validity period of 10 years. The renewal of genetically modified maize Bt11 (SYN-BT Ø11-1) was as previously, again been applied by the authorisation holder to uphold the authorisation for a further 10 year period.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of Bt11 maize. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice. The renewal of authorising genetically modified Bt11 maize has not changed its current status with regards to mandatory genetically modified labelling requirements.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier SYN-BT Ø11-1 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

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Annex H: RP714 – MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations (new application)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP 714 has been submitted to the FSA for the assessment of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations as a new authorisation for food and feed uses.

MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 is produced by crossing maize plants containing MON 87427, MON 87460, MON 89034, MIR162 and NK603 using traditional breeding methods. Therefore, this product inherited the traits as present in the parental lines.

The five-event stack maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 (Unique Identifier: *MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6*) was produced by conventional crossing to combine five single maize events: MON 87427 (expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein); MON 87460 (expressing the cold shock protein B (CSPB) and neomycin phosphotransferase II protein (NPTII)); MON 89034 (expressing the Cry1A.105 and Cry2Ab2 proteins); MIR162 (expressing the Vip3Aa20 and phosphomannose isomerase (PMI) proteins)); and NK603 (expressing the CP4 EPSPS protein and the variant CP4 EPSPS L214P) to confer resistance to certain lepidopteran pests and tolerance to drought and glyphosate-containing herbicides.

The sub-combinations in this context refers to any two, three or four combinations of the five genetic modification insertions: MON 87427, MON 87460, MON 89034, MIR162, NK603; to the genetically modified crop.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and its sub-combinations. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice.

- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there

are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

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Annex I: RP715 – MON 88017 maize (renewal)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP 715 has been submitted to the FSA for the assessment of genetically modified MON 88017 maize and its sub-combinations, as a renewal of authorisation for food and feed uses.

MON 88017 provides protection against certain coleopteran pests and tolerance to glyphosate based herbicides by the expression of Cry3Bb1 and CP4 EPSPS proteins, respectively.

Corn rootworm-resistant maize line MON88017 (Unique Identifier: *MON-88Ø17-3*) was produced using recombinant-DNA techniques to express the cry3Bb1 gene encoding a Coleopteran-specific insecticidal protein from *Bacillus thuringiensis (subsp. kumamotoensis)* in order to control infestation with corn root worm, and the cp4 epsps gene from the soil bacterium *Agrobacterium ssp.* strain CP4.

In the November 2009 publication of Official Journal of the European Union, Commission Decision 2009/814/EC had authorised the placing on the market of genetically modified maize MON88017 (MON-88Ø17-3) for a validity period of 10 years. The renewal of genetically modified maize MON88017 (MON-88Ø17-3) was applied by the authorisation holder to uphold the authorisation for a further 10 year period.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of MON 88017 maize. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice. The renewal of authorising genetically modified MON 88017 maize has not changed its current status with regards to mandatory genetically modified labelling requirements.
- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.
- Operators shall ensure the Unique Identifier MON-88Ø17-3 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and

consumer behaviours. We have highlighted consumer interests in the main text of this document.

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Annex J: RP716 – MON 89034 maize (renewal)

Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed, application RP 716 has been submitted to the FSA for the assessment of genetically modified MON 89034 maize and its sub-combinations, as a renewal of authorisation for food and feed uses.

MON 89034 provides protection against certain lepidopteran pests by the expression of Cry1A.105 and Cry2Ab2 proteins.

Maize line MON 89034 (Unique Identifier: *MON-89Ø34-3*) expresses two Bt-toxins encoded by the genes cry1A.105 and cry2Ab2 from *Bacillus thuringiensis* that confer resistance against certain lepidopteran pests such as fall armyworm (*Spodoptera sp.*), black cutworm (*Agrotis ipsilon*), European corn borer (*Ostrinia nubilalis*) and the corn earworm (*Helicoverpa zea*).

In the November 2009 publication of Official Journal of the European Union, Commission Decision 2009/813/EC had authorised the placing on the market of genetically modified maize MON 89034 (MON-89Ø34-3) for a validity period of 10 years. The renewal of genetically modified maize MON 89034 (MON-89Ø34-3) was applied by the authorisation holder to uphold the authorisation for a further 10 year period.

Proposed terms of authorisation

The opinion states that FSA/FSS is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined in the FSA/FSS opinion, and the opinion has concluded that this product is safe to be authorised on those terms.

Any relevant provisions of retained EU law

Analytical methods

- This has been verified by the JRC as used for the detection and control of MON 89034 maize. Valid analytical methods have been published.

Labelling

- Labelling provides information for consumers and allows them to make an informed choice. The renewal of authorising genetically modified MON 89034 maize has not changed its current status with regards to mandatory genetically modified labelling requirements.

- In accordance with Retained EU Regulation 1830/2003, concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, there is a traceability and labelling requirement for food and feed products derived from genetically modified sources regardless of the presence of detectable novel genetic material in the final product, or of the quantity of intentionally used genetically modified ingredient present.

- In the case of pre-packaged genetically modified food/feed products, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified maize' must appear on a label. In the case of products without packaging these words must still be clearly displayed immediately next to the product.

- Operators shall ensure the Unique Identifier MON-89Ø34-3 is accompanied with a written declaration of GMO presence for traceability functions, starting at the initial stages of placing on the market including in bulk quantities.

Other legitimate factors identified that Ministers may consider in making decisions

The next step of the authorisation process is for Ministers to make decisions on authorisation. Taking into account the FSA/FSS opinion, Ministers could decide to authorise the product. As the opinion has concluded that the product is safe to be authorised based on the proposed terms of authorisation, FSA/FSS views are that there are no reasons for Ministers to refuse authorisation unless there are other legitimate factors that might indicate otherwise. In presenting advice and assisting Ministers the FSA and FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. FSA/FSS has not identified any other legitimate factors that would prevent authorisation taking place, so unless the responses to this consultation identify any other legitimate factors Ministers must take into account in

making decisions on authorisation, the FSA/FSS advice to Ministers will be to authorise on the proposed terms of authorisation outlined in the opinion.

Our collective assessment of the other legitimate factors Ministers may consider in making decisions did not identify anything of significance, except for the recent EU authorisation of this GMO. The other legitimate factors considered included political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. We have highlighted consumer interests in the main text of this document.

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