# Consultation pack for applications for eight genetically modified organisms (GMOs) for food and feed uses and for the change of authorisation holder for fifty-one authorised GMOs

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation, renewal of authorisation, or modification of existing authorisation (change of authorisation holder details).

**Launch date:** 12 October 2022

**Respond by:** 6 December 2022

## This consultation will be of most interest to:

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

A list of interested parties is included in Annex A.

## Consultation subject and purpose

This consultation seeks stakeholders' views, comments and feedback in relation to the regulated product applications considered in this document, which have been submitted for authorisation, renewal of authorisation, or modification of existing authorisation (change of authorisation holder details). 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), including those that the Food Standards Agency (FSA) and Food Standards Scotland (FSS) have identified as relevant to these applications. This provides the opportunity for stakeholders to input on the advice given to Ministers to inform decision making.

The FSA/FSS opinion comprised in this document (including the proposed terms of authorisation) takes into account the FSA/FSS scientific opinion documents. The views gathered through this

consultation will be considered and included alongside those of officials across the FSA and FSS and UK Government Departments other than the FSA to inform Ministers' decision-making on whether to authorise / renew the individual GMOs for use in GB.

A parallel consultation is being published by the FSS.

# How to respond

Please respond to the consultation via the?online survey.  If this is not possible, you can email a response to:

Email: RPconsultations@food.gov.uk
Name: Regulated Products Approvals Team
Division/Branch: Regulatory Services

# Details of consultation

## Introduction

In order to be placed on the market, applications for the authorisation of regulated products must be  submitted in 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.

Regulated product applications for the GB market, including genetically modified organisms (GMOs), are now subject to the UK's own risk analysis process.

The FSA/FSS have been working together to ensure that the high standard of food and feed safety and consumer protection in the UK continues. This is 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 and section 3, Food (Scotland) Act 2015).

In 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.

Our risk assessors deliver the science behind our advice. They are responsible for identifying and characterising hazards and risks to health, and assessing levels of exposure. Where the European Food Safety Authority (EFSA) had commenced an assessment of an application prior to the end of the transition period for the UK exiting the European Union (EU), the FSA/FSS' risk assessors will take the EFSA opinion into account as part of its risk assessment, where it has been published by EFSA. For the applications in this consultation, the FSA/FSS have had access to all supporting documentation that was provided to EFSA for the purposes of forming its opinion as this information was provided to the FSA/FSS by the applicant.  After evaluation, the FSA/FSS have agreed with EFSA's conclusions in its opinions.  The change of authorisation holder applications are administrative in nature, so are not subject to a risk assessment.

Following risk assessment, this consultation seeks to gather stakeholders' views on the proposed regulated product authorisations.

Ministers in all four nations have 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 relevant cross-government forums with the Department of Health and Social

Care (DHSC), Welsh Government and Scottish Government. Final advice will be agreed on a four-nation basis before being presented to Ministers.

The content of this consultation presents the views of the FSA/FSS and the factors that the FSA/FSS have identified as relevant to these applications, including the potential impact of any decision made by Ministers. 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.

Following feedback on the opinions and responses to the 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 scientific opinions, any relevant provisions of retained EU law and any other legitimate factors, including those raised during the consultation process.

### Subject of this consultation

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

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

This consultation concerns eight applications for GMOs. Details of each GMO application are given in the annexes. Unless the views gathered in the consultation provide additional evidence, the FSA/FSS will recommend that these regulated products are authorised on the proposed terms.

This consultation also includes three applications for the modification of authorisation holders' details for fifty-one authorised GMO’s for food and feed use.
Each application is considered within a separate annex, including the regulated product ID number and title of the application.

## Impacts

As part of the risk analysis process, the FSA/FSS have assessed the potential impacts that would result from authorisation of these GMOs for food and feed use, 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 fully participate 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 already authorised for use in Northern Ireland, in line with legislation that applies in Northern Ireland under the NIP. Therefore, authorising in England, Scotland and Wales would

not result in divergence within the UK.

# Other legitimate factors

We have considered a range of other legitimate factors that Ministers may consider in making decisions about these GMOs, including political, economic, environmental, technical feasibility, societal, consumer interests and consumer behaviours. For the eight applications for authorisation or renewal of authorisation, our collective assessment of these identified the following:

## Environmental

These authorisations are for uses in food and feed only and any controls on plant propagating material are regulated and controlled in England under the Genetically Modified Organisms (Deliberate Release) Regulations 2002, in Wales under the Genetically Modified Organisms (Deliberate Release) (Wales) Regulations 2002 and in Scotland under the Genetically Modified Organisms (Deliberate Release) (Scotland) Regulations 2002. EU authorisations applicable in Northern Ireland relate to uses in food and feed only. Any controls on plant propagating material are regulated and controlled in Northern Ireland under the Genetically Modified Organisms (Deliberate Release) Regulations (Northern Ireland) 2003.

## Consumer Interests

The FSA/FSS invests 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; genetically modified foods is one of the issues listed. This is also conducted by the FSS with the Food in Scotland Consumer Tracker.

The FSA 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 responses to questions on genetic modification can be found in the 'Science' chapter included in the 36th Annual Report.

## Political

We welcome responses to this consultation. However, these applications are not for cultivation and, therefore, the consideration of this political aspect is not relevant to risk management decision making as part of this consultation.

The Genetic Technologies (Precision Breeding) Bill is currently going through Parliament and, should the passage of the Bill be successful, this will mean that in England, the FSA will introduce a new regulatory framework for precision bred organisms (PBOs) which is separate from the regulatory framework for GMOs. The trajectory of this Bill is not relevant to the regulated products in this consultation.

## Social

There is considerable variation in public opinion on GMOs, with a general tendency towards unfavourable attitudes when considering the use of GM technology in food production. However, GM labelling requirements allow consumers to make an informed choice whether to purchase foods that contain or are produced from GMOs. Food products derived from animals fed with feed containing GMOs do not fall within the scope of the specific GM labelling requirements.

## Options for Authorisation

Having considered the risk assessment, legal requirements and other legitimate factors and impacts, Ministers will have the following options for each of the applications:

a. Option 1: Authorise for use in food and feed in line with the proposed terms of authorisation.
b. Option 2: To make a decision not in accordance with the FSA/FSS recommendation.

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

Stakeholder responses will be considered along with risk assessment and other factors in development of advice provided to Ministers. Unless the views gathered in the consultation provide additional evidence, the FSA/FSS will recommend that these regulated products are authorised on the proposed terms.

## Engagement and Consulation 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? Please provide details or links to the information that has led to your safety concerns of these GMOs for use in food and feed.
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 these 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 comments or concerns on the impacts of the change of authorisation holder details?
5. Do you have any other feedback?

Please note: This consultation concerned the placing on the GB market of genetically modified food and feed; the applications for these GMOs have not included a request to approve for cultivation by any of the applicants. Therefore, comments concerning cultivation do not fall within the scope of this specific consultation.

## Responses

This consultation will run for 8 weeks. Responses are required by close of 6 December 2022.

Please respond to the consultation via the?online survey. If this is not possible, you can email a response to: RPconsultations@food.gov.uk

Please indicate which application(s)/product(s) you are responding about by using the following subject line for your response:
Response to [insert regulated product number(s)] GMO consultation.

If responding by email, 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.

For information on how the FSA handles your personal data, please refer to the Consultation privacy notice.

Responses will be shared with the 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,
Regulated Products Approvals Team,
Regulated Services

## 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
- GM Freeze
- Beyond GM
- Gene Watch
- Farmers' Union Wales
- NFU Cymru

- Ulster Farmers Union
- Northern Ireland Grain Trade Association

This is not an exhaustive list.

# Annex B: RP1133 – DAS-81419-2 x DAS-44406-6 soybean (new authorisation)

## Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1133 has been submitted for the assessment of genetically modified DAS-81419-2 x DAS-44406-6 soybean, as a new authorisation for food and feed uses.

The two-event stack soybean was produced by conventional crossing combining two single soybean events.

Event DAS-81419-2 expresses the proteins Cry1F, Cry1Ac and PAT to confer protection against specific lepidopteran pests and tolerance to glufosinate ammonium-based herbicides. Event DAS–44406–6 expresses the proteins 2mEPSPS, AAD–12 and PAT, to confer tolerance to glyphosate-containing herbicides, 2,4-dichlorophenoxyacetic acid and other related phenoxy herbicides.

This product is authorised for placing on the market in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1387.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined below.

Genetically modified organism and unique identifier:

i. Soybean DAS-81419-2 x DAS-444Ø6-6

1. Designation and specification of the products:

i. foods and food ingredients containing, consisting of or produced from genetically modified soybean DAS-81419-2 x DAS-444Ø6-6;
ii. feed containing, consisting of or produced from genetically modified soybean DAS-81419-2 x DAS-444Ø6-6;
iii. products containing or consisting of genetically modified soybean DAS-81419-2 x DAS-444Ø6-6 for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

The genetically modified soybean DAS-81419-2 x DAS-444Ø6-6 expresses the 2mepsps gene, which confers tolerance to glyphosate-based herbicides, the aad-12 gene, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, the pat gene, which confers tolerance to glufosinate-ammonium based herbicides and the synthetic cry1F and cry1Ac genes, which confer protection against certain lepidopteran pests.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained Regulation (EC) No 1829/2003, and in Article 4(6) of Retained Regulation (EC) No 1830/2003, the ‘name of the organism’ shall be ‘soybean’.
ii. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean DAS-81419-2 x DAS-444Ø6-6, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those individually validated for genetically modified soybean events DAS-81419-2, DAS-44406-6, and further verified on soybean stack DAS-81419-2 x DAS-44406-6
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: ERM®-BF437 (for DAS-81419-2) and ERM®-BF436 (for DAS-444Ø6-6) are accessible via the Joint Research Centre (JRC) of the European Commission.

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1133” submitted to the Food Safety Authority on 1 June 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. Corteva Agrisciences LLC
ii. Represented in the UK by Corteva Agriscience UK Limited European Development Centre 3B Park Square, Milton Park, Abingdon Oxon OX14 4RN

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to of Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of DAS–81419–2 x DAS–44406–6 soybean. 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present
- in accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ must appear on a label. In the case of products without packaging these words must still appear on, or in connection with, the display of the product

- operators shall ensure the Unique Identifier DAS-81419-2 x DAS-444Ø6 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

The next step of the authorisation process is for Ministers, taking into account the FSA/FSS opinion and the stakeholders' responses to the consultation, to decide whether to authorise the product. As the FSA/FSS opinion has concluded that the product is safe to be authorised on the proposed terms, the 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. The FSA/FSS have not identified any other legitimate factors that would prevent authorisation taking place so, unless the responses to this consultation identify any other legitimate factors to be taken in to account, the FSA/FSS advice to Ministers will be to authorise on the proposed terms outlined in the opinion.

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

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

## Annex C: RP1134 – DAS-81419-2 soybean (new authorisation)

### Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1134 has been submitted for the assessment of genetically modified DAS-81419-2 soybean, as a new authorisation for food and feed uses.

Soybean DAS-81419-2 was developed to confer resistance to certain lepidopteran chewing pests. The resistance is achieved by the expression of the Cry1F and Cry1Ac proteins from Bacillus thuringiensis. Soybean DAS-81419-2 also expresses the PAT protein from Streptomyces viridochromogenes, which confers tolerance to glufosinate ammonium-based herbicides and that was used as a selectable marker gene.

This product is authorised for placing on the market in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1386.

### Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined below.

Genetically modified organism and unique identifier:

i. Soybean DAS-81419-2
1. Designation and specification of the products:
i. foods and food ingredients containing, consisting of or produced from genetically modified soybean DAS-81419-2;
ii. feed containing, consisting of or produced from genetically modified soybean DAS-81419-2;
iii. products containing or consisting of genetically modified soybean DAS-81419-2 for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

The genetically modified soybean DAS-81419-2 expresses the synthetic cry1Fv3 gene and the synthetic cry1Ac gene, which confer protection against certain lepidopteran pests. In addition, the pat gene, conferring tolerance to glufosinate-ammonium-based herbicide, was used as a selection marker in the genetic modification process.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained EU Regulation No 1829/2003, and in Article 4(6) of Retained EU Regulation No 1830/2003, the 'name of the organism' shall be 'soybean'.
ii. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean DAS-81419-2, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those validated for genetically modified soybean event DAS-81419-2.
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: ERM®-BF437 is accessible via the Joint Research Centre (JRC) of the European Commission.

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP1134" submitted to the Food Safety Authority on 1 June 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

6. Authorisation holder:

i. Corteva Agrisciences LLC
ii. Represented in the UK by Corteva Agriscience UK Limited European Development Centre, 3B Park Square, Milton Park, Abingdon, Oxon. OX14 4RN

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of DAS–81419–2 soybean. 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' 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 DAS-81419-2 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

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, the 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 the FSS are acting pursuant to their functions under the Food Standards Act 1999 and Food (Scotland) Act 2015. The FSA/FSS have 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 outlined in the opinion.

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

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

## Annex D: RP1138 – SYHT0H2 soy bean (new authorisation)

### Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1138 has been submitted for the assessment of genetically modified SYHT0H2 soybean, as a new authorisation for food and feed uses.

Soybean SYHT0H2 was developed to confer tolerance to the herbicidal active substances mesotrione and other p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides and glufosinate ammonium. Soybean SYHT0H2 contains a single insert consisting one copy of the

avhppd-03 gene and four copies of the pat gene.

This product is authorised for placing on the market in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/64.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined below.

Genetically modified organism and unique identifier:
i. Soybean SYN-ØØØH2-5

1. Designation and specification of the products:

i. foods and food ingredients containing, consisting of or produced from genetically modified soybean SYN-ØØØH2-5;
ii. feed containing, consisting of or produced from genetically modified soybean SYN-ØØØH2-5;
iii. products containing or consisting of genetically modified soybean SYN-ØØØH2-5 for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

The genetically modified soybean SYN-ØØØH2-5 expresses the avhppd-03 gene, which confers tolerance to p-hydroxyphenylpyruvate dioxygenase (HPPD)-inhibiting herbicides, and the pat gene, which confers tolerance to glufosinate-ammonium based herbicides.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained EU Regulation No 1829/2003, and in Article 4(6) of Retained EU Regulation No 1830/2003, the ‘name of the organism’ shall be ‘soybean’.
ii. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified soybean SYN-ØØØH2-5, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those validated for genetically modified soybean event SYN-ØØØH2-5.
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: AOCS 0112-A is accessible via the American Oil Chemists Society (AOCS)

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1138” submitted to the Food Safety Authority on 6 June 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. Syngenta Crop Protection AG
ii. Represented in Great Britain by Syngenta Limited of Jealott's Hill International Research Centre, Bracknell, Berkshire, England, RG42 6EY.

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of SYHT0H2 soybean. 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' 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-ØØØH2-5 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, the 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 have 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 outlined in the opinion.

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

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

# Annex E: RP1179 – MON 88017 x MON 810 maize (renewal of authorisation)

## Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1179 has been submitted for the assessment of genetically modified MON 88017 x MON 810 maize, as a renewal authorisation for food and feed uses.

The genetically modified maize MON 88017 x MON 810 expresses the Cry3Bb1 and Cry1Ab proteins which respectively confer protection against certain coleopteran (MON 88017 trait) and lepidopteran pests (MON 810 trait), and the CP4 EPSPS protein which confers tolerance to glyphosate-based herbicides (MON 88017 trait).

This product's authorisation was renewed in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1393.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation remain as for the current authorisation and are outlined below.

Genetically modified organism and unique identifier:
i. Maize MON88Ø17-3 x MON-ØØ81Ø-6

1. Designation and specification of the products:

i. foods and food ingredients containing, consisting of or produced from genetically modified maize MON88Ø17-3 x MON-ØØ81Ø-6;
ii. feed containing, consisting of or produced from genetically modified maize MON88Ø17-3 x MON-ØØ81Ø-6;
iii. products containing or consisting of genetically modified maize MON88Ø17-3 x MON-ØØ81Ø-6 for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

The genetically modified maize MON88Ø17-3 x MON-ØØ81Ø-6 expresses the Cry3Bb1 and Cry1Ab proteins which respectively confer protection against certain coleopteran and lepidopteran pests and the CP4 EPSPS protein which confers tolerance to glyphosate-based herbicides.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained EU Regulation No 1829/2003, and in Article 4(6) of Retained EU Regulation No 1830/2003, the 'name of the organism' shall be 'maize'.
ii. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize MON88Ø17-3 x MON-ØØ81Ø-6 with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON88Ø17-3, MON-ØØ81Ø-6, and further verified on MON88Ø17-3 x MON-ØØ81Ø-6 maize.
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: AOCS 0406-D2 (for MON-88Ø17-3) accessible via the American Oil Chemists Society and ERM®-BF413 (for MON-ØØ81Ø-6) accessible via the Joint Research Centre JRC) of the European Commission, Institute for reference Materials and Measurements (IRMM).

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1179” submitted to the Food Safety Authority on 25 June 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. Bayer CropScience LP
ii. Represented in Great Britain by Bayer CropScience Ltd of 230 Cambridge Science Park, Milton Road, Cambridge, England, CB4 0WB

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of MON 88017 x MON 810 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 maize MON 88017 x MON 810 will not change 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ 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 MON88Ø17-3 x MON-ØØ81Ø-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, the 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. The FSA/FSS have 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 outlined in the opinion.

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

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

## Annex F: RP1180 – MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 maize and its sub-combinations (new authorisation)

### Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1180 has been submitted for the assessment of genetically modified MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 maize and its sub-combinations, as a new authorisation for food and feed uses.

The six-event stack maize was produced by conventional crossing to combine six single maize events: MON 87427 expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein to confer tolerance to glyphosate-containing herbicides; MON 87460 expressing the cold shock protein B (CspB) to confer drought tolerance and expressing the neomycin phosphotransferase II protein (NPTII) used as selectable marker to facilitate the selection process of transformed plant cells; MON 89034 expressing the Cry1A.105 and Cry2Ab2 proteins to confer protection against certain lepidopteran pests; 1507 expressing the Cry1F protein to confer protection against certain lepidopteran pests and the PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides; MON 87411 expressing the Cry3Bb1 protein and the DvSnf7 dsRNA to confer protection against certain coleopteran pests and the CP4 EPSPS protein for tolerance to glyphosate-containing herbicides; and 59122 expressing the Cry34Ab1 and Cry35Ab1 protein to confer protection against certain coleopteran pests and the PAT protein.

This product is authorised for placing on the market in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1394.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined below.

Genetically modified organism and unique identifier:
Maize MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 and its sub-combinations :

- (a) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122;
- (b) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411;
- (c) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507 × 59122;
- (d) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411 × 59122;
- (e) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411 × 59122;
- (f) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411 × 59122;
- (g) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411 × 59122;
- (h) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 1507;
- (i) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × MON 87411;
- (j) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 89034 × 59122;
- (k) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × 1507 × MON 87411;
- (l) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 1507 × 59122;
- (m) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × MON 87411 × 59122;
- (n) the unique identifier MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87427 × MON 89034 × 1507 × MON 87411;
- (o) the unique identifier MON-87427-7 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 89034 × MON 87411 × 59122;
- (p) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × 1507 × MON 87411 × 59122;
- (q) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × 1507 × MON 87411;
- (r) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 1507 × 59122;
- (s) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × MON 87411 × 59122;

- (t) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × MON 87411 × 59122;
- (u) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × 1507 × MON 87411 × 59122;
- (v) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87427 × MON 87460 × 1507;
- (w) the unique identifier MON-87427-7 × MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87427 × MON 87460 × MON 87411;
- (x) the unique identifier MON-87427-7 × MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87460 × 59122;
- (y) the unique identifier MON-87427-7 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified MON 87427 × 1507 × MON 87411;
- (z) the unique identifier MON-87427-7 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87427 × MON 87411 × 59122;
- (aa) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 for genetically modified MON 87460 × MON 89034 × 1507;
- (bb) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × MON-87411-9 for genetically modified maize MON 87460 × MON 89034 × MON 87411;
- (cc) the unique identifier MON-8746Ø-4 × MON-89Ø34-3 × DAS-59122-7 for genetically modified maize MON 87460 × MON 89034 × 59122;
- (dd) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 87460 × 1507 × MON 87411
- (ee) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 × DAS-59122-7 for genetically modified maize MON 87460 × 1507 × 59122;
- (ff) the unique identifier MON-8746Ø-4 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87460 × MON 87411 × 59122;
- (gg) the unique identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize MON 89034 × 1507 × MON 87411;
- (hh) the unique identifier MON-89Ø34-3 × MON-87411-9 × DAS-59122-7 for genetically modified maize MON 89034 × MON 87411 × 59122;
- (ii) the unique identifier DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 for genetically modified maize 1507 × MON 87411 × 59122;
- (jj) the unique identifier MON-8746Ø-4 × DAS-Ø15Ø7-1 for genetically modified maize MON 87460 × 1507;
- (kk) the unique identifier MON-8746Ø-4 × MON-87411-9 for genetically modified maize MON 87460 × 87411;
- (ll) the unique identifier MON-8746Ø-4 × DAS-59122-7 for genetically modified maize MON 87460 × 59122;
- (mm) the unique identifier DAS-Ø15Ø7-1 × MON-87411-9 for genetically modified maize 1507 × MON 87411;
- (nn) the unique identifier MON-87411-9 × DAS-59122-7 for genetically modified maize MON 87411 × 59122.

1. Designation and specification of the products:

i. foods and food ingredients containing, consisting of or produced from genetically modified maize MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 and its sub-combinations;
ii. feed containing, consisting of or produced from genetically modified maize MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 and its sub-combinations;
iii. products containing or consisting of genetically modified maize MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 and its sub-combinations for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

- the genetically modified maize MON-87427-7 expresses the cp4 epsps gene, which confers tolerance to glyphosate-containing herbicides.
- the genetically modified maize MON-8746Ø-4 expresses a Bacillus subtilis modified cspB gene, which aims to reduce yield loss caused by drought stress. in addition, the nptII gene, conferring kanamycin and neomycin resistance, was used as a selection marker in the genetic modification process.
- the genetically modified maize MON-89Ø34-4 expresses the cry1A.105 and cry2Ab2 genes, which confer protection against certain lepidopteran pests.
- the genetically modified maize DAS-Ø15Ø7-1 expresses the cry1F gene, which confers protection against certain lepidopteran pests and the pat gene, which confers tolerance to glufosinate-ammonium-based herbicides.
- the genetically modified maize MON-87411-9 expresses the cp4 epsps gene, which confers tolerance to glyphosate-containing herbicides, the cry3Bb1 gene and the DvSnf7 dsRNA, which confer protection against corn rootworm (Diabrotica spp.).
- the genetically modified maize DAS-59122-7 expresses the cry34Ab1 and cry35Ab1 genes, which confer protection against certain coleopteran pests and the pat gene, which confers tolerance to glufosinate-ammonium-based herbicides.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained Regulation EU No 1829/2003, and in Article 4(6) of Retained Regulation EU No 1830/2003, the ‘name of the organism’ shall be ‘maize’.
ii. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 and its sub-combinations, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events MON-87427-7, MON-8746Ø-4, MON-89Ø34-3, DAS-Ø15Ø7-1, MON-87411-9, DAS-59122-7, and further verified on maize stack MON-87427-7 × MON-8746Ø-4 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 and its sub-combinations
ii. Validated by the EU reference laboratory established under Regulation (EC) No 1829/2003.
iii. Reference Material: AOCS 0512 (for MON-87427-7), AOCS 0709 (for MON-8746Ø-4), AOCS 0906 (for MON-89Ø34-3) and AOCS 0215 (for MON-87411-9) are accessible via the American Oil Chemists Society and ERM®-BF418 (for DAS-Ø15Ø7-1) and ERM®-BF424 (for DAS-59122-7) are accessible via the Joint Research Center (JRC) of the European Commission.

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1180” submitted to the Food Safety Authority on 25 June 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. Bayer CropScience LP
ii. Represented in Great Britain by Bayer CropScience Ltd of 230 Cambridge Science Park, Milton Road, Cambridge, England, CB4 0WB

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of maize MON 87427 × MON 87460 × MON 89034 × 1507 × MON 87411 × 59122 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' 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 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7 or of a sub-combination combining two, three, four or five of the single events 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

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, the 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. The FSA/FSS have 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 outlined in the opinion.

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

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

# Annex G: RP1184 – 1507 x MIR 162 x MON 810 x NK 603 maize and its sub-combinations (new authorisation)

## Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1184 has been submitted for the assessment of genetically modified maize 1507 x MIR 162 x MON 810 x NK 603 and its sub-combinations, as a new authorisation for food and feed uses.

The four-event stack maize was produced by conventional crossing to combine four single maize events: 1507 (expressing the Cry1F and PAT proteins), MON810 (expressing the Cry1Ab protein), MIR162 (expressing the Vip3Aa20 and PMI proteins) and NK603 (expressing the CP4 EPSPS and CP4 EPSPS L214P proteins) to confer resistance to certain lepidopteran pests and tolerance to glyphosate- and glufosinate ammonium-based herbicides.

This product is authorised for placing on the market in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1388.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined below.

Genetically modified organism and unique identifier:

i. Maize DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 or of a sub-combination combining two or three of the single events:

(a) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × MON810 × NK603;
(b) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize 1507 × MIR162 × MON810;
(c) the unique identifier DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ6Ø3-6 for genetically modified maize 1507 × MIR162 × NK603;
(d) the unique identifier SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 for genetically modified maize MIR162 × MON810 × NK603;
(e) the unique identifier SYN-IR162-4 × MON-ØØ81Ø-6 for genetically modified maize MIR162 × MON810.

1. Designation and specification of the products:

i. foods and food ingredients containing, consisting of or produced from genetically modified maize DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 and its sub-combinations;
ii. feed containing, consisting of or produced from genetically modified maize DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 and its sub-combinations;
iii. products containing or consisting of genetically modified maize DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 and its sub-combinations for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

- The genetically modified maize DAS-Ø15Ø7-1 expresses the pat gene, which confers tolerance to glufosinate-ammonium based herbicides, and the cry1F gene, which confers

protection against certain lepidopteran pests.
- The genetically modified maize SYN-IR162-4 expresses a modified vip3Aa20 gene, which provides protection against certain lepidopteran pests. In addition, the pmi gene, coding for the PMI protein, was used as a selection marker in the genetic modification process.
- The genetically modified maize MON-ØØ81Ø-6 expresses the cry1Ab gene, which confer protection against certain lepidopteran pests.
- The genetically modified maize MON-ØØ6Ø3-6 expresses the CP4 epsps and the CP4 epsps L214P genes, which confers tolerance to glyphosate-based herbicides.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained EU Regulation No 1829/2003, and in Article 4(6) of Retained EU Regulation No 1830/2003, the 'name of the organism' shall be 'maize'.
ii. The words 'not for cultivation' shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified maize DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 and its sub-combinations, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those individually validated for genetically modified maize events DAS-Ø15Ø7-1, SYN-IR162-4, MON-ØØ81Ø-6, MON-ØØ6Ø3-6, and further verified on maize stack DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6.
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: ERM®-BF418 (for AS-Ø15Ø7), ERM®-BF413 (for MON-ØØ81Ø-6) and ERM®-BF415 (for MON-ØØ6Ø3-6) is accessible via the Joint Research Centre (JRC) of the European Commission and AOCS 1208 (for SYN-IR162-4) is accessible via the American Oil Chemists Society

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number "RP1184" submitted to the Food Safety Authority on 28 June 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. Corteva Agriscience LLC (currently Pioneer Hi-Bred International, Inc.).
ii. Represented in Great Britain by Corteva Agriscience UK Limited, Cpc2 Capital Park, Fulbourne, Cambridge CB21 5XE

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of maize 1507 x MON 810 x MIR 162 x NK 603 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' 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 DAS-Ø15Ø7-1 × SYN-IR162-4 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6 or of a sub-combination combining two or three of the single events 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, the 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. The FSA/FSS have 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 outlined in the opinion.

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

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

## Annex H: RP1205 - GHB614 x T304-40 x GHB119 cotton (new authorisation)

### Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1205 has been submitted for the assessment of genetically modified cotton GHB614 x T304-40 x GHB119, as a new authorisation for food and feed uses.

The three-event stack cotton GHB614 × T304-40 × GHB119 was produced by conventional crossing to combine three single events: GHB614 (expressing the modified 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS) protein)), T304-40 (expressing Cry1Ab and phosphinothricin acetyltransferase (PAT)) proteins) and GHB119 (expressing Cry2Ae and PAT proteins) to confer resistance to certain lepidopteran pests and tolerance to glyphosate- and glufosinate ammonium-based herbicides.

This product is authorised for placing on the market in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1389.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation are outlined below.

Genetically modified organism and unique identifier:

i. Cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8

1. Designation and specification of the products:

i. foods and food ingredients containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
ii. feed containing, consisting of or produced from genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8;
iii. products other than food and feed containing or consisting genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 cotton for uses other than those provided for in points (i) and (ii), with the exception of cultivation.

The genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 expresses the 2mepsps gene, which confers tolerance to glyphosate based herbicides, the bar gene, which confers tolerance to glufosinate-ammonium based herbicides, the cry1Ab and the cry2Ae genes, which confer resistance to certain lepidopteran pests.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained EU Regulation No 1829/2003, and in Article 4(6) of Retained EU Regulation No 1830/2003, the ‘name of the organism’ shall be ‘cotton’.
ii. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified cotton BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those individually validated for genetically modified cotton events BCS-GHØØ2-5, BCS-GHØØ4-7, BCS-GHØØ5-8, and further verified on cotton stack BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: AOCS 1108-A5 (for BCS-GHØØ2-5) is accessible via the American Oil Chemists’ Society (AOCS). ERM-BF429 (for BCS-GHØØ4-7) and ERM-BF428 (BCS-GHØØ5-8) are accessible via the Joint Research Centre (JRC) of the European Commission.

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1205” submitted to the Food Safety Authority on 21 July 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. BASF Agricultural Solutions Seed US LLC
ii. Represented in Great Britain by BASF plc, 2 Railway Road, Stockport, SK1 3GG

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of cotton GHB614 × T304-40 × GHB119. 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ 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 BCS-GHØØ2-5 × BCS-GHØØ4-7 × BCS-GHØØ5-8 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, the 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. The FSA/FSS have 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 outlined in the opinion.

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

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

# Annex I: RP1263- GT73 oilseed rape (renewal of authorisation)

## Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, application RP1263 has been submitted for the assessment of genetically modified GT73 oilseed rape, as a renewal authorisation for feed uses.

The GT73 oilseed rape has been genetically modified to provide tolerance to the herbicide glyphosate. The oilseed rape was genetically modified with two genes encoding proteins conferring glyphosate tolerance. One of the proteins is glyphosate tolerant 5-enolpyruvylshikimate-3-phosphate synthase from Agrobacterium sp. strain CP4 (CP4 EPSPS). The EPSPS activity is needed for the biosynthesis of aromatic amino acids in plants and in micro-organisms; the plant enzyme is usually sensitive to glyphosate, thereby causing the plants to be killed by the herbicide. The second protein is glyphosate oxidoreductase (GOX) which acts by breaking down glyphosate.

This product's authorisation was renewed for feed uses in the EU and Northern Ireland, under the NIP, as specified in Commission Implementing Decision (EU) 2021/1385.

## Proposed terms of authorisation

The FSA/FSS opinion, which takes into account the scientific opinion, is in favour of the authorisation of this GMO, based on risk assessment and safety conclusions. The proposed terms of authorisation remain as for the current authorisation and are outlined below.

Genetically modified organism and unique identifier:
i. Oilseed rape MON-ØØØ73-7

1. Designation and specification of the products:

i. feed containing or consisting of genetically modified oilseed rape MON-ØØØ73-7;
ii. products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7 for uses other than those provided in point (1) and other than food, with the exception of cultivation. (b) Designation and specification of the products: the genetically modified oilseed rape MON-ØØØ73-7 expresses the cp4 epsps and goxv247 genes, which confer tolerance to glyphosate-based herbicides.

2. Labelling:

i. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Retained EU Regulation No 1829/2003, and in Article 4(6) of Retained EU Regulation No 1830/2003, the

‘name of the organism’ shall be ‘oilseed rape’.
ii. The words ‘not for cultivation’ shall appear on the label of and in the documents accompanying the products containing or consisting of genetically modified oilseed rape MON-ØØØ73-7, with the exception of food and food ingredients.

3. Method for detection:

i. The quantitative event-specific PCR detection methods are those validated for genetically modified oilseed rape event MON-ØØØ73-7.
ii. Validated by the EU reference laboratory established under EU Regulation No 1829/2003.
iii. Reference Material: AOCS 0304-B accessible via the American Oil Chemists Society.

4. Monitoring plan for environmental effects:

i. The authorisation holder must ensure that the monitoring plan for environmental effects, which accompanied the application for authorisation of the genetically modified maize referred to in paragraph 1, reference number “RP1263” submitted to the Food Safety Authority on 15 September 2021, is implemented.
ii. The authorisation holder must submit to the Food Safety Authority annual reports on the implementation of, and the results of the activities set out in, the monitoring plan in accordance with the format set out in Annex 2 of Decision 2009/770.

5. Authorisation holder:

i. Bayer CropScience LP
ii. Represented in Great Britain by Bayer CropScience Ltd of 230 Cambridge Science Park, Milton Road, Cambridge, England, CB4 0WB

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to Retained EU Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of GT73 oilseed rape. 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 GMOs, and the traceability of food and feed products produced from GMOs, there is a traceability and labelling requirement for food and feed products derived from GM sources regardless of the presence of detectable GMOs in the final product, or of the quantity of intentionally used GM ingredient present.

In accordance with Retained EU Regulation 1830/2003, pre-packaged food/feed products consisting of, or containing GMOs, the words ‘This product contains genetically modified organisms’ or ‘This product contains genetically modified [name of organism(s)]’ 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-ØØØ73-7 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, the 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. The FSA/FSS have 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 outlined in the opinion.

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

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

## Annex J: RP1093, RP1100, RP1329 - change of authorisation holder

### Background

In accordance with Retained EU Regulation 1829/2003 for the placing on the market of genetically modified food and feed in GB, applications RP1093, RP1100 and RP1329 have been submitted for administrative amendments to be made, to change the authorisation holder. All administrative amendments requested are with current authorisations that remain as applicable to Great Britain (GB), under their retained EU law status.

### Proposed terms of authorisation

The FSA/FSS recommend agreement to the administrative amendments to authorisations under RP1093, RP1100 and RP1329 to reflect the changes in authorisation holders and to update the relevant information. These are as follows:

RP1093: Application from Sygenta 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 by Syngenta Crop Protection NV/SA, Belgium.

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 by Syngenta Crop Protection NV/SA, Belgium.

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.

## Any relevant provisions of retained EU law

### Analytical methods

In accordance with Article 32 and Annex I to  Retained (EC) Regulation 1829/2003, analytical methods have been verified by the GMO Reference Laboratory, LGC, as appropriate for use in the detection and official controls of genetically modified food and feed authorisations. Valid analytical methods have been published and will not be altered as a result of implementing this change in the authorisation holder company name.

### Labelling

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.

There is no legislative requirement for information relating to the authorisation holder to appear or be provided on the labelling or as part of the traceability measures at any point during the manufacturing or sale of GM food and feed products.

## 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.

As the proposed changes are administrative in nature, the FSA/FSS views are that there are no reasons for Ministers to refuse the change to authorisation holders' details 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.  We do not foresee any impacts from this legislative change in updating the authorisation holder details. By ensuring that the contact information held on the authorisation holder is kept up-to-date and aligned with the company's international operations will prevent any handling confusion with authorities based in other countries.

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 change the authorisation holder details.

Similar amendment requests to those in RP1093 and RP1100 have been applied in Northern Ireland, in line with EU legislation that applies in Northern Ireland under the NIP. Commission Implementing Decision (EU) 2021/1999  effects 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.

The administrative changes requested under RP1329 are implemented by Commission Implementing Decisions (EU) 2021/1161, 2021/1035, 2021/1185 and 2022/325.