

Consultation pack on amendments to Retained EU Law 1829/2003 and 619/2011 and extension to the tolerance period for traces of withdrawn GM oilseed rape products Ms1xRf1, Ms1xRf2 and Topas 19/2

The FSA is seeking stakeholder views on reinstating and correcting deficiencies in powers in retained EU Law (REUL) that are provided for in Regulation (EU) 1829/2003.

Launch date: 20 September 2022

Respond by: 4 October 2022

This consultation will be of most interest to:

Developers in the genetically modified organisms (GMO) industry, grain trade industry bodies, enforcement authorities, traders of oilseed rape, purchasers of oilseed rape products, other interested stakeholders with an interest in the policy and legislation regarding genetically modified (GM) food and feed and the supply chain of oilseed rape.

Consultation subject

The FSA is seeking stakeholder views on reinstating and correcting deficiencies in powers in retained EU Law (REUL) that are provided for in Regulation (EU) 1829/2003. These powers will enable regulations to be made in the future that will make the process of granting of an extension to the tolerance period of trace levels of the three withdrawn GMO products, Ms1xRf1, Ms1xRf2 and Topas 19/2 oilseed rape simpler and easier. These GMOs are currently under a transitional tolerance arrangement that permits a trace presence set at no higher than 0.1% until expiration on 31 December 2022. Once the tolerance arrangement expires, this would require all GM oilseed rape consignments to have an absolute zero detectable presence for the three withdrawn GMOs upon sampling and detection control measures.

These powers relate to provisions that allow the use of existing stocks of GM food and feed products, that may be applied for a limited period of time, upon having withdrawn the product from the market.

In addition, there is an ongoing failure of retained EU legislation to operate effectively due to an inconsistency between the transitional period in Article 2(b) of retained Regulation (EC) 619/2011 and the tolerance periods for the three withdrawn GMO products, Ms1xRf1, Ms1xRf2 and Topas 19/2 oilseed rape, set out in retained Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC. It is necessary to correct this inconsistency and amend these periods so that they align.

Powers granted by [The European \(Withdrawal\) Act 2018 \(EUWA\)](#) will be used to make the necessary changes described above.

The proposals in this consultation will apply in England, Wales and Scotland. In Northern Ireland, EU Food Law on GMOs continues to apply, under the current terms of the Protocol on Ireland/Northern Ireland (NIP). The tolerance period for the three withdrawn GM oilseed rape has been extended under [Commission Implementing Decision \(EU\) 2022/736](#) which is applicable in Northern Ireland under the NIP.

This consultation is open to stakeholders across the UK.

Purpose of the consultation

This consultation is to seek views on the proposed amendment to retained Regulation 1829/2003 on genetically modified food and feed, to reinstate Articles 8(6) and 20(6) that were omitted in error by the Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/705) and the correction of the ongoing inoperability in Article 2(b) of retained Regulation (EC) 619/2011. The provisions in Regulation 1829/2003 enable measures, on GM food and GM feed respectively, to be adopted on the trace tolerance of existing stocks of genetically modified organisms which have been withdrawn from the market after the authorisation has elapsed, that may be applied for a limited period of time.

This consultation is also to provide an opportunity for industry stakeholders, consumers and enforcement authorities to provide their comments on potential impacts which may arise should the extension in the transitional tolerance period for traces of the three withdrawn GMOs (Ms1xRf1, Ms1xRf2 and Topas 19/2 oilseed rape) not be extended beyond 31 December 2022.

How to respond

Responses to this consultation should be sent to:

Email: RPconsultations@food.gov.uk

Name: Regulated Products Approvals Team

Division/Branch: Regulated Services

Details of the consultation

Background

The withdrawal from the market of the three GM oilseed rape authorisations was undertaken by the European Commission (EC) in 2007 (under Decisions: [2007/305/EC](#); [2007/306/EC](#); [2007/307/EC](#)) with a transitional tolerance for trace levels of no more than 0.1% granted for a period of five years. The withdrawal from the market was triggered by the expiration of authorisation status of these GMOs. The reason for not seeking re-authorisation of the GM oilseed rape products was a commercial decision. When first authorised, the products were required to undergo a risk assessment before being authorised for the market.

Following the initial transitional tolerance measures taken for the three withdrawn GM oilseed rape in 2007, there have since been subsequent extensions that range from periods of three years to five years applied by the EC through the use of Regulation 1829/2003 provisions of Article 8(6) for food uses and Article 20(6) for feed uses.

As part of the measures taken by the transitional tolerance for trace levels, monitoring of the three withdrawn GM oilseed rape detection levels are administered by the GMO holder with the data supplied to the regulatory authority to inform of the progress on removing the residual remaining trace presence.

Positive detection in residual trace presence of the withdrawn GMOs has been shown in the most recent available monitoring data for 2019 – 2021. This has been explained by the biology of the oilseed rape seeds that can undergo dormancy for long periods, following the discontinuation of the intentional cultivation of these GM lines in the years preceding the 2007 transitional measures coming to effect.

Current status (with tolerance period) for the withdrawn GM oilseed rape products

The transitional tolerance measures applied by the EU Commission for the withdrawn GMOs under Decisions 2007/305/EC; 2007/306/EC; 2007/307/EC were retained in GB law post Implementation Period (IP) completion day. The latest extension in GB law is currently in place until expiration on 31 December 2022 as outlined in [REUL 2019/1562](#).

The tolerance level for traces of the three withdrawn GM oilseed rape products has been set at 0.1% under the prescribed sampling methodology. The most recent monitoring data indicates residual trace presence significantly below the 0.1% threshold. An absolute zero presence is difficult to achieve due to the length of seed dormancy and agricultural practices (including breeding methods).

The withdrawn GMOs were reported to have only been cultivated in Canada and therefore the transitional tolerance measures are made to apply only to imports of oilseed rape that are sourced from Canada. Oilseed rape is more commonly known as canola in Canada but can also be referred to as rapeseed and colza elsewhere.

The powers that have been used to set out and extend the tolerance period for the residual trace presence of the withdrawn GM oilseed rape products in the EU and Northern Ireland are set out in Regulation (EC) 1829/2003 under Article 8(6) for food uses and Article 20(6) for feed uses. Articles 8(6) and 20(6) were omitted in error from retained Regulation (EC) 1829/2003.

Northern Ireland

In Northern Ireland, EU Food Law on GMOs continues to apply, under the NIP. Since the UK left the EU, the EU has granted a further 3 year tolerance period for the three withdrawn GMO events, until 31 December 2025. The tolerance period for the three withdrawn GMO events has been extended under [Commission Implementing Decision \(EU\) 2022/736](#) which is applicable in Northern Ireland under the NIP. The extensions have been applied under Commission Regulation (EU) No.1829/2003 provisions of Article 8(6) for food uses and Article 20(6) for feed uses.

As part of the conditions for extending the tolerance period, monitoring of the three withdrawn GM oilseed rape detection levels is undertaken by the GMO holder. This data is supplied to the regulatory authority to inform of the progress on removing the residual remaining trace presence.

It is the European Commission's authorisation process, including renewals/extensions, that applies in Northern Ireland.

Policy proposal

Under powers granted by Article 8 of EUWA on dealing with deficiencies arising from the withdrawal of the United Kingdom from the European Union, an amendment of retained Regulation (EC) 1829/2003 is required to reinstate and recast Articles 8(6) and 20(6), to provide the powers to set and extend limited periods of time for existing stocks of products to be used up.

With the tolerance period for traces of the withdrawn GMOs in place until 31 December 2022, it is necessary to extend the tolerance period.

An extension of the tolerance period for another three years would be reflective of the same period of time that was granted by REUL 2019/1562, and on the previous occasion prior to this current extension. Three years is also the period of time granted within EU law, with Commission Implementing Decision (EU) 2022/736 applicable in Northern Ireland under the NIP.

Following responses received to this consultation, and in the event that a recommendation to extend the tolerance period end date for these withdrawn GMOs is agreed by UK Ministers, amendment is also needed to correct the ongoing failure of Regulation (EC) 619/2011, to ensure there is alignment with the tolerance periods for the withdrawn GMO products, and to ensure that the legislation as a whole can operate effectively.

Impacts

Trade of oilseed rape commodities and oilseed rape supply chain

Should the transitional period for tolerance of traces of the withdrawn GMOs cease from 31 December 2022, there would be a default requirement for zero tolerance of detection of the GMOs in the food supply chain entering GB. This would affect imports of GM oilseed rape commodities to GB from Canada. Due to the absolute zero detection set for GMOs that are not under authorisation, imports of oilseed rape consignments cannot be accepted for use in the food supply chain where trace elements of the withdrawn GMOs are found to be present. As a knock-on effect, rejection of large shipments of oilseed rape as a raw material at GB ports could mean that this impact is felt further along the food supply chain.

HMRC trade data shows that the quantity of oilseed rape seeds imported into the UK can fluctuate significantly from year to year. The same data source suggests that the quantity of oilseed rape seeds imported directly from Canada is negligible. However, in the HMRC trade data, details of imports are given according to the country from which the goods are consigned, which may not necessarily be the country of origin. Therefore, this data source may not reflect the trade of oilseed rape commodities that may have been taken as oilseed rape imports to the UK and sourced from Canada, but that have entered the UK via other countries (such as EU Member States).

The United Nation's ComTrade Database suggests that in 2016 (the latest year with any record of oilseed rape exports from Canada to the UK) Canada exported 6,300 tonnes of rape/colza seeds to the UK. ComTrade recommends that exporters record the country of final destination where possible. Whilst the two sources are not directly comparable, HMRC data shows that in total, the UK imported 53,568 tonnes of rape/colza seeds in 2016. This suggests oilseed rape imported from Canada could have accounted for as much as 12% of total imports in 2016. However, this may not be an accurate reflection of the current situation in 2022.

Northern Ireland

As EU Food Law continues to apply in Northern Ireland under the NIP, under the policy proposals within this consultation, there is a reduced possibility of regulatory divergence regarding the EU extension of the tolerance period for the withdrawn GMO events, as compared to 'doing nothing'.

If the recommendation, within this policy proposal, to grant an extension to the tolerance period for the three withdrawn GMO oilseed rape is agreed to by Ministers across the UK, the degree of regulatory divergence between Northern Ireland and GB will depend on the timings of such a decision. Should an extension not come into force prior to the expiry of the current extension in GB, there will be a temporary divergence between GB and Northern Ireland from 31 December 2022.

Should an extension to the tolerance period not be agreed upon in GB, there may be more prolonged divergence between GB and NI until at least the end of the tolerance period under EU law (which is currently stated as 31 December 2025).

Engagement and consultation process

A two-week public consultation is being launched across the UK to provide interested parties with an opportunity to comment on the policy proposals to reinstate Article 8(6) and Article 20(6) in retained Regulation (EC) 1829/2003 to have the appropriate powers to extend the transitional period for traces of the withdrawn GMOs in the food and feed chain in the future and to correct the ongoing inoperability caused by the inconsistency between retained Regulation (EC) 619/2011 and the retained Decisions and also to extend the transitional period for traces of the withdrawn GMOs.

This consultation period is relatively short in comparison to other, more complex, consultations, but is considered proportionate to the policy proposals. The proposed consultation length will allow the FSA to conclude the process with sufficient time to allow for the use of EUWA powers, which expire at the end of 2022. These powers would be used to implement the legislation in the event the consultation responses are supportive.

Any responses to this consultation will be given careful consideration and a summary of responses received will be published on the FSA website within three months of the consultation closing.

Questions asked in this consultation

1. Do you agree with the plans to:
 - a. reinstate Article 8(6) and Article 20(6) in retained Regulation (EC) 1829/2003 to have the appropriate powers to extend the transitional period for traces of the withdrawn GMOs in the food and feed chain in the future;
 - b. correct the ongoing inoperability caused by the inconsistency between retained Regulation (EC) 619/2011 and the retained Decisions; and
 - c. extend the tolerance period for the affected withdrawn GM oilseed rape products?
2. Please describe the potential impacts which may arise to your business or stakeholder sector should the extension in the transitional tolerance period for traces of the three withdrawn GMOs (Ms1xRf1, Ms1xRf2 and Topas 19/2 oilseed rape) not be extended beyond the 31 December 2022.
3. Please share any views or comments relating the approach as outlined under the Policy Proposal section.

Responses

Responses are required by close 4 October 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).

Please send response to RPconsultations@food.gov.uk

For information on how the FSA handles your personal data, please refer to the [privacy notice](#).

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,

Genetic Technology Policy Team
Policy Directorate

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
- Food and Drink Federation (FDF)
- Royal Highland and Agricultural Society of Scotland
- Scotland Food and Drink
- Scottish Quality Crops
- GM Freeze
- Beyond GM
- Gene Watch
- Farmers' Union Wales
- NFU Cymru
- Hybu Cig Cymru – Meat Promotion Wales
- Welsh Lamb and Beef Producers Ltd
- Quality Welsh Food Certification Ltd
- Ulster Farmers Union
- Northern Ireland Grain Trade Association
- Association of Port Health Authorities (APHA).