

## **EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK**

### **COM(2025)1030 FINAL: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATIONS (EC) NO 999/2001, (EC) NO 1829/2003, (EC) NO 1831/2003, (EC) NO 852/2004, (EC) NO 853/2004, (EC) NO 396/2005, (EC) NO 1099/2009, (EC) NO 1107/2009, (EU) NO 528/2012, (EU) 2017/625 AS REGARDS THE SIMPLIFICATION AND STRENGTHENING OF FOOD AND FEED SAFETY REQUIREMENTS**

Submitted by the Department for Environment, Food and Rural Affairs on 10<sup>th</sup> March  
2026

#### **SUBJECT MATTER**

1. This Explanatory Memorandum (EM) relates to proposed EU Regulation, COM (2025)1030. This instrument is part of a cross-cutting package of legislative simplification announced in the European Commission's 'Vision for Agriculture and Food'. The intention of this EU initiative is to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, and for the protection of human and animal health, and the environment. The proposal was made in response to ongoing requests from industry and European Union (EU) Member States to simplify and streamline certain requirements and procedures for products used in the production of food and feed. To achieve these efficiency and cost-saving objectives ambitions, this instrument seeks to amend and simplify particular provisions within and implementation of the following EU regulations:

#### **Regulation (EU)1829/2003 GMO**

- This regulation establishes the legal framework for the authorisation and supervision of food and feed containing, consisting of or produced from genetically modified organisms (GMOs).
- The proposed amendment to 1829/2003 will provide explicit confirmation that food and feed fermentation products obtained using genetically modified microorganisms (GMM) as processing aids are excluded from the definition of "produced from GMOs". Specifically, the proposal seeks to clarify the legal status of food and feed fermentation products obtained using GMMs as processing aids, to remove ambiguity and ensure consistent enforcement across the EU.
- 1829/2003 was retained when the United Kingdom (UK) exited the EU and became assimilated law in Great Britain (GB). The proposed changes do not apply to assimilated law in GB.

## **Regulation (EU) 1831/2003 Feed Additives**

- 1831/2003 establishes a common procedure for the authorisation and use of feed additives in animal nutrition, establishing rules for their placing on the EU market, labelling and use.
- This proposal amends several provisions in 1831/2003:
  - Removal of renewals: The current ten-year renewal requirement for feed additive authorisations would be removed, except for coccidiostats and histomonostats. Instead, it would allow these authorisations to remain valid indefinitely. The Commission would retain the power to modify, suspend or withdraw an authorisation at any time if new information shows that the conditions for authorisation are no longer met.
  - Simplification of administrative procedures: For name changes, businesses would only need to notify the European Commission and provide relevant information, after which the official EU Register of Feed Additives would be updated. It also provides the possibility for any interested party to submit an application for modification of an authorisation for which there is no specific holder (i.e., technological, sensory, or nutritional additives).
  - Labelling: Amends the rules on labelling responsibilities for feed business operators, so they align more clearly with Regulation (EC) No 767/2009 on the placing on the market and use of feed. Certain non-safety information (name and address of the responsible person, the approval number of the establishment, and batch details) would also be permitted to be provided in digital formats, reducing the amount of material that must appear on physical labels.
- Regulation (EC) No 1831/2003 was retained when the UK exited the EU and became assimilated law in GB. The proposed changes do not apply to assimilated law in GB.

## **Regulations 396/2005 Maximum Residue Levels (MRLs) of pesticides & 1107/2009 Plant Protection Products**

- This regulation makes amendments to two pieces of regulation which establish the EU regulatory framework for managing the sale and use of pesticides. The EU proposals entail numerous detailed refinements to this regulatory framework intended to collectively provide substantive reform and reduction of administrative requirements deemed burdensome by industry.

## **Regulation EU 528/2012 EU Biocidal Products Regulation**

- These proposals amend Regulation (EU) No 528/2012 on the making available on the market and use of Biocidal Products<sup>[1]</sup> (EU BPR).
- EU BPR regulates the placing on the market and use of biocidal products, which are a diverse range of products that control harmful organisms, such as insecticides, rodenticides and disinfectants. Active substances are those substances in biocidal products that give products their biocidal effect.
- These proposals affect the review programme for existing active substances (“the review programme”) which aims to systematically evaluate all active substances that were on the EU market on 14 May 2001. Following evaluation under the review programme, an active substance may be approved for a fixed period for the EU market, after which a renewal of the approval is needed.
- The review programme was originally due to be completed on 14 May 2010 but a new date of 31 December 2030 has been set. These proposals change the system of renewal for approved active substances to enable resources to be prioritised towards the review programme for its completion. A further proposal also simplifies the Union Authorisation process by amending requirements for publication in the EU Official Journal.
- The proposals are part of the cross-cutting legislative simplification package announced in the European Commission’s Vision for Agriculture and Food, which can be found [here](#).

<sup>[1]</sup> EU Biocidal Products Regulation (EU BPR): <https://eur-lex.europa.eu/eli/reg/2012/528/oj/eng>

### **Regulations (EU) 852/2004 and (EU) 853/2004**

- 852/2004 lays down general rules for Food Business Operators (FBO) on the hygiene of foodstuffs and Annex II lays down requirements for handling primary production. 853/2004 lays down specific hygiene requirements for FBOs manufacturing and handling certain Products of Animal Origin (POAO) such as meat, eggs, fish and dairy.
- The amendments to both regulations propose to simplify the notification procedure for Member States that wish to adopt national measures adapting the requirements laid down in Annexes II and III to those regulations respectively. The amendments propose to replace the specific notification procedure by the general notification procedure under Directive (EU) 2015/1535. The prescribed aim of any national measures adopted in accordance with the proposed simplified notification procedure will remain unchanged.
- Regulation (EC) No 852/2004 was retained when the UK exited the EU and became assimilated law in GB. The proposed changes do not apply to assimilated law in GB.

## **Regulation (EU) 2017/625 Official Controls (laboratories)**

- 2017/625 establishes official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and protection products. This regulation sets out rules for the designation of the laboratories carrying out analysis, tests or diagnoses for official controls and the conditions to be designated.
- National Reference Laboratories (NRLs) are specialist laboratories responsible for maintaining standards for the routine testing of feed, food and animal health. They provide advice and support on methods for official control testing, ensuring the delivery of risk-based and proportionate food enforcement to protect consumers.
- Regulation (EU) 2017/625 sets out requirements for the designation of NRLs. Currently, NRLs are required to include all the methods of laboratory analysis, test or diagnosis within their accreditation scope. To reduce the cost and resource demands for NRLs associated with this, it is proposed that laboratories may be designated, even if not accredited for every single method they use, and that accreditation under equivalent standards (e.g., ISO 15189) should be accepted for certain biological food safety hazards to avoid duplication and improve efficiency, without compromising reliability.
- Regulation (EU) 2017/625 was retained when the UK exited the EU and became assimilated law in GB. The proposed changes do not apply to assimilated law in GB.

## **Regulation (EU) 1099/2009 (Welfare at time of killing)**

The proposal includes targeted amendments to 1099/2009 on the protection of animals at the time of killing. These changes are intended to improve the clarity and efficiency of existing animal-welfare provisions without lowering established welfare standards.

- The proposed amendment removes an obligation in Article 18, paragraph 4 of Regulation (EC) 1099/2009 to submit an annual report on depopulation operations. This obligation is duplicated by reporting requirements in Regulation (EU) 2017/625 on official controls and other official activities (“the Official Controls Regulation” or “OCR”).
- The objective of these changes is to reduce unnecessary procedural complexity for Member State competent authorities, simplifying and modernising reporting and do not introduce substantive changes to the core animal welfare standards at slaughter.

## **Regulation (EU) 999/2001 (TSE)**

- Amendments to 999/2001, which sets rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (TSEs), are also introduced by this instrument.
- These changes are intended to support more consistent application of TSE controls and reduce unnecessary procedural requirements for competent authorities and industry, without altering the underlying standards for disease prevention or safeguarding public health.
- In particular, this instrument seeks to amend Articles 5, 6, 8 and 16 of Regulation 1099/2009 to provide technical adaptations empowering the Commission to adopt delegated acts to amend the list of rapid tests, surveillance requirements and the list of specified risk material. The aim of the proposal is to ensure proportionate and risk-based monitoring, flexible adaptation of subpopulations and age categories, and alignment with World Organisation for Animal Health standards.
- In practice, these amendments are not expected to have significant implications as the proposals are de-regulatory in nature, providing a more risk-based approach to surveillance.

#### **Regulation (EU) 2017/625 (OCR)**

- This instrument seeks to make several changes to the Official Controls Regulations (OCR):
- Firstly, Articles 41, 93, 100 and 144 of the OCR are amended to empower the Commission to adopt delegated acts concerning the cases - and the conditions under which - laboratories may be designated as official laboratories, national reference laboratories and EU reference laboratories, even when they are not operating or accredited in accordance with standards EN ISO/IEC 17025 and/or not being accredited for all the methods they use for official controls or other official activities.
- The purpose of these changes is to provide specific, rule-based flexibility that can be activated by delegated acts to (i) ensure continuity of official controls where fully accredited capacity is temporarily unavailable, (ii) enable faster designation of laboratories to avoid bottlenecks in high-demand or urgent testing situations, (iii) allow use of technically validated but not yet accredited methods in clearly defined circumstances with safeguards, and (iv) improve the overall responsiveness and resilience of the control system, without lowering protection for human, animal or plant health.
- These flexibilities are not automatically operative; operational effects arise only once the Commission adopts the relevant delegated acts. So, in practice, there will not be any immediate implications here as the accreditation change does not come into force until enacted by further legislation.

- Secondly, this instrument also proposes to make amendment to Article 50(3) of the OCR, to allow the competent authorities of Border Control Posts (BCPs) to split consignments of plant and plant products before the completion of all official controls, so compliant parts can be released while additional checks continue on the remainder.
- The purpose of this change is to reduce avoidable costs and delays for operators, particularly for perishable plant goods, by ensuring controls are carried out efficiently at Border Control Posts without causing unnecessary financial loss. This is expected to benefit businesses as it would mean that parts of consignments could move inland faster, which is a particular benefit for perishable goods such as plants and plant products.

## SCRUTINY HISTORY

2. There is no Parliamentary scrutiny history relevant to this Explanatory Memorandum.
  - **FSA** - There is no relevant scrutiny history in respect of these Regulations in the EU.
  - **HSE** - This Explanatory Memorandum is submitted to the relevant Parliamentary Scrutiny Committees to note the proposal, its significant policy context, and, specifically, its direct application and impact under the terms of the Windsor Framework.<sup>[1]</sup> Following EU Exit, the Great Britain Biocidal Products Regulation (GB BPR)<sup>[2]</sup> was assimilated in UK law. The assimilated version of this regulation can be found [here](#).

[1] Windsor framework: <https://www.gov.uk/government/publications/the-windsor-framework>

[2] GB Biocidal Products Regulation (528/2012): <https://www.legislation.gov.uk/eur/2012/528/contents>

## MINISTERIAL RESPONSIBILITY

### 3. Regulation 1829/2003 GMO

- The Secretary of State for Health and Social Care has responsibility for this area of food law in England.

### Regulation 1831/2003 Feed Additives

- The Secretary of State for Health and Social Care has responsibility for this area of feed law in England

## **Regulations 396/2005 Maximum Residue Levels (MRLs) of pesticides & 1107/2009 Plant Protection Products**

- Secretary of State for Environment, Food and Rural Affairs is responsible for pesticides legislation in England. Regulation 396/2005 is DAERA. The Health and Safety Executive in Great Britain (HSE), under Agency Agreement, delivers a number of Competent Authority functions on Defra's behalf.

## **Regulation 528/2012 EU Biocidal Products Regulation**

- The Secretary of State in the Department for Work and Pensions, advised by the Health and Safety Executive (HSE), is responsible for policy questions arising from this document that relate to GB BPR.

## **Regulation 852/2004 FSA and 853/2004**

- The Secretary of State for Health and Social Care has responsibility for this area of food law in England

## **Regulation 2017/625 Official Controls (laboratories)**

- The Secretary of State for Environment, Food and Rural Affairs and the Secretary of State for Health and Social Care have responsibility for this area of food law in England.

## **Regulations 1099/2009 (Welfare at time of killing), 999/2001 TSE & 2017/625 Official Controls**

- Secretary of State for Environment, Food and Rural Affairs.

## **INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)**

### **4. Regulation 1829/2003 GMO**

- This is a devolved area of policy. The responsible Government department is the Food Standards Agency in Northern Ireland (NI) and Wales, and Food Standards Scotland (FSS) in Scotland in conjunction with Scottish Government Ministers, Welsh Government Ministers and NI Executive Ministers who all have an interest in food and feed safety and hygiene law.
- This area sits within the scope of the Food and Feed Safety and Hygiene (FFSH) provisional common framework. Colleagues across all nations and devolved administrations have been consulted in the preparation of this EM.

## **Regulation 1831/2003 Feed Additives**

- This is a devolved area of policy. The responsible Government department is the Food Standards Agency in NI and Wales, and FSS in Scotland in conjunction with UK Government Ministers, Scottish Government Ministers, Welsh Government Ministers and NI Executive Ministers who all have an interest in food and feed safety and hygiene law.
- This area sits within the scope of the FFSH provisional common framework. All colleagues across the nations have been consulted in the preparation of this EM.

## **Regulations 396/2005 MRLs of pesticides & 1107/2009 Plant Protection Products**

- Regulation of pesticides is devolved in the UK and is subject to the provisional Chemicals and Pesticides Common Framework.
- The EU pesticide regulatory framework is listed in Annex 2 of the Windsor Framework and applies in NI. The Competent Authority and Enforcing Authority for pesticides regulation in NI is the Department for Agriculture, Environment and Rural Affairs (DAERA).
- The devolved governments have been consulted in the preparation of this Explanatory Memorandum and raised no concerns. DAERA has also prepared its own impact assessment of the changes for the Windsor Framework Democratic Scrutiny Committee.

## **Regulation 528/2012 EU Biocidal Products Regulation**

- EU BPR is listed in Annex 2 to the Windsor Framework.
- The Scottish and Welsh Governments have been made aware of these proposals.
- Regulation of chemicals in the UK engages a mix of reserved and devolved competence. Environmental protection and public health are devolved to Scotland, Wales and NI. Scottish, Welsh and NI Ministers therefore have an interest in elements of chemicals regulation that affect these areas.
- Regulation of chemicals in the UK, including EU BPR, falls under the Chemicals and Pesticides Provisional Common Framework, developed jointly by DEFRA, Devolved Governments including the NI Executive, HSE and the Environment Agency (EA). This framework facilitates cooperation between these parties to support regulatory consistency across the UK and enable the functioning of the UK Internal Market while acknowledging policy divergence.
- In NI, EU BPR applies under the terms of the Windsor Framework to enable its dual access to both the GB Internal Market and EU Single Market. Competency in NI for EU BPR lies with Department for the Economy (DfE).

## **Regulations 852/2004 FSA and 853/2004**

- This is a devolved area of policy. The responsible Government department is the Food Standards Agency in NI and Wales, and FSS in Scotland in conjunction with Scottish Government Ministers, Welsh Government Ministers and NI Executive Ministers who all have an interest in food and feed safety and hygiene law.
- This area sits within scope of the FFSH provisional common framework. All colleagues across the nations have been consulted in the preparation of this EM.

## **Regulation 2017/625 Official Controls (laboratories)**

- This is a devolved area of policy. The responsible Government department is the FSA in NI and Wales, and FSS in Scotland in conjunction with Scottish Government Ministers, Welsh Government Ministers and NI Executive Ministers who all have an interest in food and feed safety and hygiene law.
- This area sits within the scope of the FFSH provisional common framework. The EU proposal empowers the European Commission to bring forward delegated acts setting out further detail on the conditions and circumstances in which any flexibilities for laboratory accreditation may be availed. Further consideration will be given across the nations when more detail emerges on this aspect of the proposal.

## **Regulations (EU)1099/2009 (Welfare at time of killing), 999/2001 TSE & (EU) 2017/625 Official Controls**

- The Department of Agriculture, Environment and Rural Affairs (DAERA) in the NI Executive will have a particular interest in these proposals.
- Policy and regulation of animal and plant health is a devolved area in the UK. The Devolved Administrations were consulted during the preparation of this EM. UKG continues to engage with Devolved Governments following publication of the EU's proposal.

## **LEGAL AND PROCEDURAL ISSUES**

### **5.**

#### **i. Application of the Windsor Framework:**

The following Articles of the proposed Regulation are expected to apply in Northern Ireland under the terms of Article 13(3) of the Windsor Framework.

- Article 9 (Amendment to Regulation (EC) 1099/2009)
- Article 10 (Amendment to Regulation (EC) 999/2001)
- Article 11 (Amendment to Regulation (EU) 2017/625)

**ii. EU legal Basis:**

- The legal basis for the proposed Regulation is Articles 43(2), 114, 168(4)(b) and 192(1) of the Treaty of the Functioning of the European Union.

**iii. Voting Procedure:**

- The proposed Regulation is subject to the ordinary legislative procedure.

**iv. Application under the Windsor Framework**

- These Regulations are listed in Annex II to the Windsor Framework, therefore the proposed amendments will apply in Northern Ireland. The Northern Ireland Assembly conducts democratic scrutiny of relevant regulations under the terms of Schedule 6B of the Northern Ireland Act 1998.

**v. Timetable for adoption and implementation**

- The proposal has been submitted to the European Parliament and the Council for their review and proposed amendments. The proposals will come into force 20 days after publication in the Official Journal of the EU.

## **POLICY AND LEGAL IMPLICATIONS**

### **6. Regulation (EU) 1829/2003 GMO**

- The amendment to Regulation (EC) No 1829/2003 provides UK businesses placing products on the EU market with legal clarity by confirming that food and feed produced using GMMs as processing aids fall outside the GM food and feed authorisation regime (where the GMM has been removed and only non-viable, non-functional traces may remain).
- This amendment aligns with long-standing European Commission, UK and industry interpretations that fermentation-derived products not containing viable GMMs should not be regulated as GM food or feed.
- By setting explicit conditions, such as residue minimisation and the absence of technological effect, the amendment strengthens regulatory certainty for operators and reduces the risk of disproportionate authorisation or labelling obligations triggered by increasingly sensitive detection methods. This has important policy benefits as it supports competitiveness and innovation in the fermentation sector, ensuring proportionate oversight, and preventing divergent enforcement across NI and GB.
- Legally, the amendment harmonises the interpretation of “produced from” across the GMO framework and aligns definitions with Directive 2009/41/EC on the contained use of GMMs. It also ensures consistent treatment of biotechnology-derived products, thus securing the integrity and predictability of the UK market.

- There is no change to safety requirements for GMOs under this proposal. The proposed change does not alter authorisation, risk assessment, or labelling requirements for GM food and feed. It clarifies that products made using GMMs (with non-viable residues and no technological effect) are not considered “produced from GMOs”. It also confirms that the reference to GMMs in the definition of “produced from GMOs” applies only to micro-organisms in the biological sense and excludes animal and plant cells in culture.

## **Regulation (EU) 1831/2003 Feed Additives**

- Removal of Renewals: This proposal is welcomed for UK businesses placing feed additives on the EU market. Under the current regulation, businesses are required to submit full renewal applications every ten years, even when no safety concerns existed. Removing this requirement will reduce costs and administrative effort for UK businesses placing feed additives on the EU market.
- The proposal will bring NI closer to alignment with GB in relation to feed additives. GB removed renewal requirements for all feed additives, GMOs and smoke flavourings in April 2025 through a GB-wide statutory instrument, the [Food and Feed \(Regulated Products\) \(Amendment, Revocation, Consequential and Transitional Provision\) Regulations 2025](#).
- COM(2025)1030 does not propose the removal of renewal requirements for coccidiostats and histomonostats, meaning UK businesses placing these products on the EU market must continue to submit renewal requirements every 10 years. This differs from the GB approach, where renewal requirements for these products have been removed.
- Following the 2025 Reforms, GB can review and, if necessary, revoke authorisations where evidence - including decisions made in the EU on renewal applications for coccidiostats and histomonostats - indicates a potential safety concern. This ensures GB can respond proportionately and promptly to emerging risks while maintaining effective regulatory oversight.
- Simplified administrative procedures: Previously, any change to the authorisation-holder’s name (e.g., following an acquisition or a simple name change) required submitting an official modification request to the EU and adopting a formal regulation. The proposal should remove this burden for UK businesses seeking to update/change authorisation-holder details for feed additives on the EU market, introducing a more efficient and proportionate approach.
- The ability for any interested party to submit an application for modification of generic feed additive authorisations will be beneficial for UK businesses seeking to modify generic EU authorisations. The proposed amendment mirrors the simplified procedure for modifying holder-specific authorisations, providing a simplified process for adapting the specifications or conditions included in generic/non-holder specific authorisations. This avoids the need for operators

to submit a full application, making it easier to expand uses of existing generic additives, supporting flexibility and competitiveness. This will also allow multiple operators to benefit from generic authorisations.

- GB currently operates under assimilated EU law for feed additives, and the proposed amendments under COM(2025)1030 have not been introduced in GB. GB businesses must continue to follow the previous process set out under assimilated EU law. The divergence is procedural only, with minimal to no impact on UK businesses, and raises no concerns regarding trade.
- At present, GB does not intend to introduce equivalent simplification measures for amendments to holders of authorisations or for modifications to generic applications. The decision not to introduce equivalent measures at this stage is informed by wider UK policy considerations.
- Labelling: Digital labelling will apply only to non-safety information, ensuring that essential safety details remain on physical packaging. Businesses retain the option to continue using physical labelling for non-safety information if preferred. The amendment provides NI feed businesses with more flexibility, enabling operators to choose the most efficient and cost-effective method for their business.
- While digital labelling is positive for NI businesses, the proposal leaves room for the Commission to set additional rules for digital labelling, including what information can be digitised and which technologies can be used, through future delegated acts. Timely and transparent notification of any further proposals will be necessary to ensure consistent implementation across industry, and to help businesses make informed choices when investing in digital labelling. FSA will engage with industry to seek to address any lack of clarity.
- GB currently operates under assimilated EU law for feed additives. The proposed amendments to EU feed additive labelling have not been introduced in GB. GB businesses exporting to the EU will have the option to use digital labelling, providing them with more flexibility when exporting to the EU.
- Under the UK Government's commitment to unfettered market access, qualifying NI goods (QNIGs) have unfettered access to the market in GB. Feed additives despatched from a registered NI feed establishment are considered (QNIGs) and can move from NI to GB without SPS controls. Therefore, in GB there could be a dual labelling system, if NI businesses choose to employ digital labelling. To support this, GB enforcement authorities would need to be able to recognise and work with digital labels. This may require adjustments to established practices, including the ability to access information presented through QR codes.
- Digital labelling has the potential to introduce enforcement challenges, for example in the response to incidents where it is important to be able to readily identify batch numbers. The precise rules on the use of digital labelling will be defined in future Commission delegated acts and the FSA will monitor these developments to minimise any potential risks.

## Regulations 396/2005 MRLs of pesticides & 1107/2009 Plant Protection Products

- Regulation (EC) 1107/2009 (“PPP Regulation”) provides for the control of plant protection products (PPPs), through the approval of the active substances (i.e. the chemical ingredient(s) that go into the pesticide to provide the intended effect) and the authorisation of PPPs, i.e. the specific pesticide product. An active substance can be common to many different products, so as well as that active substance being approved, each individual product which contains the approved active substance must also be authorised within the Member State territory it is sold in and used.
- The key changes include moving to unlimited approval periods for most active substances with a prioritised renewal work programme; introducing a cap of targeted renewal and product authorisations not exceeding 15 years; and a package to accelerate access to biocontrol products (e.g. provisional authorisations, treatment as a single zone), alongside adjustments on the role of the European Food Standard Agency’, grace periods, grace recognition and data-protection rules.

### Approval and Renewal of Active Substances:

- The PPP Regulation also requires time limited approvals (typically 10–15 years) for active substances to ensure regular reevaluation based on evolving science. The changes proposed would remove this mandatory renewal cycle and would see a shift to unlimited approval periods, except in specific cases. This will allow for a renewal programme that targets the highest priority active substances to check whether certain approval criteria are still met.

### Treatment and Promotion of Biocontrol / Biopesticides:

- The PPP Regulation currently provides a framework for low risk and basic substances. The proposed changes aim to accelerate approval of biocontrol (biopesticide) solutions, providing faster procedures to give biocontrol products quicker market access, clarified definition of biocontrol substances, and provisional approvals based on draft assessment, risk and basic substances. The proposed changes aim to accelerate approval of biocontrol (biopesticide) solutions, providing faster procedures to give biocontrol products quicker market access, clarified definition of biocontrol substances, and provisional approvals based on draft assessment.

### Data Protection, Transitional Measures, and Grace Periods:

- Regulation (EC) 1107/2009 currently provides for strict timelines for withdrawing nonapproved substances and tightly limits grace periods. This proposal would allow for longer grace periods when approvals are wound down.

- The period of data protection for the studies supporting a pesticide, as set out in PPP Regulation, begins in each country when the first authorisation is granted in that same country. The proposal expands data protection rules so that data protection for pesticide studies are aligned across the EU simplifying the internal market.

#### Expanding role of European Food Standards Agency

- The proposal expands the role of the European Food Standards Agency (EFSA). Currently the regulation shares the regulatory workload between Member States allowing Member States to lead on assessments of active substances. This proposal would allow EFSA to take the lead on biocontrol active substances and contribute directly to Member State assessments. The intention is to provide more centralised support to address capacity constraints of Member States and provide consistency. This is unlikely to affect NI as the HSE, the regulator for pesticides in NI, cannot act as a lead Member State on assessments in accordance with the terms of the Windsor Framework.
- Regulation 396/2005 (“MRL Regulation”) provides for controls on how much pesticide residue is legally allowed to remain in food and animal feed. It does this by setting safe maximum limits for pesticide residues on food sold in the EU, to protect consumers. These are known as maximum residue levels (MRLs).
- The proposed changes aim to prevent the import of food with residues of certain hazardous pesticides not approved for use in the EU. To achieve this goal, the hazard-based criteria used for active substances from the PPP Regulation will be applied to MRL decision-making (including imports). It would also introduce pragmatic transitional measures for long shelf-life goods, alignment terminology (import tolerance [IT], Limit of Quantification [LOQ]), and streamline long-running monitoring-data MRLs.
- Bringing hazard criteria used for active substances in the PPP Regulation into the MRL framework to enable restrictions on imports of food produced in other countries would be internationally sensitive. Other changes (replacing the term ‘Limit of Determination’ with ‘Limit of Quantification’; amending the term ‘Import Tolerance’ to reframe it as setting MRLs based on good agricultural practice in third countries; more pragmatic transitional measures; streamlining of monitoring-data MRLs) are all proportionate and support clarity.
- Changes to the MRL Regulation are unlikely to have an impact on supply of food and feed treated with pesticides between GB and NI as the UK Internal Market allows for unfettered access of movements from NI to GB. The NI Retail Movement Scheme also allows for free movement of goods compliant with GB MRLs via the green lane, provided these are not at risk of moving into the EU market.

- For Northern Ireland, the reforms to the EU pesticides framework will apply directly because NI remains aligned with EU rules under the Windsor Framework. Changes to approval, renewal and import tolerance processes are therefore expected to affect which plant protection products and pesticide-treated food can be placed on the NI market. While unfettered access to the GB market mitigates impacts on internal UK trade, NI businesses will need to comply with updated EU requirements as they are implemented. The scale of impact will depend on the final drafting and timing of the EU legislation.

## **Regulation EU 528/2012 EU Biocidal Products Regulation**

- The policy intention of this proposal is to enable greater resources to be devoted to completion of the EU review programme by removing the requirement to renew active substances which have already been approved, other than in specific cases.
- Under the review programme, active substances can remain on the market through transitional measures until such time as an active substance has been evaluated. Following an evaluation, if an active substance is approved for the EU market, it is for an initial period not exceeding 10 years. Active substances with highly hazardous properties can be approved for lesser initial periods, up to 5 years for those that meet the exclusion criteria<sup>[1]</sup> and up to 7 years for those that are candidates for substitution<sup>[2]</sup>.
- At the end of the initial period, a renewal of the approval must take place. Active substances can be renewed for a period of up to 15 years and candidates for substitution for a period of up to 7 years.
- The review programme was planned to be completed by 14 May 2010, but it was extended for the first time to 14 May 2014, a second time until 31 December 2024 and more recently a third time until 31 December 2030. The delays have occurred due to various operational issues and the programme is currently 51% complete. However, active substances which were approved early in the review programme are now reaching their approval expiry dates due to the time lapsed since the original approval and require renewal. As an active substance will be removed from the market once the approval expiry date has lapsed if not renewed (subject to any phase-outs), these renewal applications have been prioritised.
- From a risk-based perspective, it is logical to prioritise evaluations of active substances yet to be approved under the review programme where there may be greater risk, instead of renewing existing approvals where the risks are already largely understood. This is especially important given that biocidal products containing active substances in the review programme which have not yet had their first review are allowed to remain on the market under pre-existing national legislation, where standards may be much less rigorous than under EU BPR.

- The proposal is to remove expiry dates from approvals so they are not time-limited. This does not include active substances that meet the exclusion criteria or are candidates for substitution. It also will not apply to active substances where the renewal evaluation is ongoing or where no renewal application was received on time.
- In order to maintain a high level of protection of human and animal health and the environment, it will still be possible for the European Commission to set time limits for approvals if found appropriate in the light of the outcome of the risk assessment prior to a decision on an approval. In addition, the proposal foresees that the European Commission may periodically select a number of active substances for which a renewal evaluation would take place while also maintaining the existing possibility to initiate early reviews if there are significant indications that the conditions of approval are no longer met, as set out in Article 15 of EU BPR.
- The proposed changes should result in a decreased workload on renewal applications facilitating resources to prioritising completion of the review programme.
- GB is facing similar challenges with an increasing number of active substance approvals elapsing and requiring renewal, whilst the GB review programme is ongoing with a similar backlog of first approvals to the EU. Moreover, where HSE is carrying out its own active substance evaluations, priority is already being given to first-time evaluations above renewals, except for renewals of high-hazard active substances, similar to the EU proposal. Therefore, the Government considers the EU's proposals to be reasonable.
- There is the potential for some short-term divergence between the EU and GB as a result of this proposal. HSE's recent consultation on chemicals reforms ([HSE Chemicals Legislative Reform Consultation Response](#)), also proposed removal of active substance approval expiry dates. It also included proposals that GB may recognise EU approvals and renewals, with an expectation that GB would align with the EU in the vast majority of cases. If there is a gap between EU proposals and the GB reforms subsequently enacted, renewal application could be necessary in GB but not in the EU. Applicants would make a cost benefit analysis of the renewal application based on the GB market alone. Further analysis will be required to understand the likelihood of this scenario and whether any additional mitigatory measures may be needed as part of the reforms, but it is still anticipated to be a small risk.
- A second proposal relates to publication requirements for Union Authorisations. The requirement to publish the Commission Implementing Regulation granting a Union Authorisation in the Official Journal of the EU includes a requirement to include the Summary of the Products Characteristics in all official languages of the EU. The European Commission states that this has proven to be cumbersome, leading to delays, and without added value considering that the decision is also disseminated on the ECHA website. Therefore, it is proposed

to simplify the publication requirements. Specifically, the individual decisions will take the form of Commission Implementing Decisions notified only to the applicants. Only summaries of those Decisions would be published in the EU Official Journal.

- Since EU BPR is listed in Annex 2 of the Windsor Framework, these new proposals will apply in NI subject to any Democratic Scrutiny process

[\[1\]](#) Exclusion criteria – Active substances that are carcinogens, mutagens and reprotoxic substances categories 1A or 1B according to the CLP Regulation, endocrine disruptors persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances.

[\[2\]](#) Candidate for substitution – More hazardous active substances, for example those meeting the exclusion criteria, or respiratory sensitisers, under GB BPR Article 10(1). These substances require comparative assessment and have restricted approval.

## **Regulations (EU) 852/2004 and 853/2004**

- The notification procedure will be simplified by removing the obligation for Member States to notify all other Member States and replacing this with a requirement to submit a single notification to the European Commission. Under the proposal, a standstill period will apply. While Member States are not required to provide comments, they may choose to submit comments or detailed opinions during this period.
- The change reduces administrative burden and supports subsidiarity by assisting Member States in tailoring hygiene requirements to local needs while maintaining food safety and protecting the integrity of the internal market.
- There is currently no impact as GB does not need to notify the EU of any national measures. As this is a procedural change, it has no impact on movement of food between GB and NI. It does not change hygiene requirements or introduce new obligations for food businesses in NI. NI has not made use of the existing notification procedure in recent years, and therefore no direct or practical impact on companies in NI is expected.
- The UK has communicated two notifications to the EU Commission (relating to meat and to food of traditional methods), since before EU Exit; NI has not made any relevant notifications in that time.

## **Regulation (EU) 2017/625 Official Controls (laboratories)**

- Currently, NRLs are required to include all the methods of laboratory analysis, test or diagnosis within their accreditation scope.
- To reduce cost and resource demands requiring reference laboratories to include all testing methods in their ISO/IEC 17025 accreditation scope, it is

proposed that laboratories may be designated, even if not accredited for every single method they use, and that accreditation under equivalent standards (e.g., ISO 15189) should be accepted for certain biological food safety hazards to avoid duplication and improve efficiency, without compromising reliability.

- This is a proposal to give the European Commission the ability to deliver this change via a delegated act at a later date. Full details are not available at this stage.
- Feedback on the proposals has been received from a limited number of laboratories within the FSA's network. While the proposed flexibility is welcomed as a means to reduce administrative burden and enhance operational agility, further detail on the proposal is required to enable a thorough assessment of its implications for NI. For example, clarification is needed regarding quality assurance arrangements, the scope of laboratories to which the proposal would apply, and the range of testing activities covered.

### **Regulation (EU) 1099/2009 (Welfare at time of killing)**

- The proposed amendments to Regulation (EC) 1099/2009 will remove the requirement from Member States (and NI) competent authorities for an annual report on depopulation operations carried out during the previous year to be transmitted to the Commission and made publicly available via the internet.
- This is usually recording of depopulation for animal health (disease control) purposes, including the methods of killing and any problems encountered. NI submit a depopulation report for their territory directly to the EU Commission, whilst under the assimilated regulation in GB, these figures are currently compiled by the Animal and Plant Health Agency and published online by Defra.
- The EU stated that, given its limited completeness and lack of comparability, the information provided under Article 18 of Regulation (EC) 1099/2009 has proven to be of limited value compared to the administrative burden of preparing the report.
- The information collection and reporting is also effectively duplicated by reporting requirements under Regulation (EC) 2017/625 on official controls (OCR), which will remain. Reports under the OCR cover official controls on the Regulation on the welfare of animals at the time of killing, including its provisions concerning depopulation operations, and are considered sufficient to verify compliance with Regulation (EC) No 1099/2009.
- Under assimilated regulations in GB the reporting requirements under both Regulations 1099/2009 and 2017/625 will remain, but there is no requirement to submit reports to the EU Commission.

### **Regulation (EU) 999/2001 TSE**

- Initial assessment of the proposed amendments to 999/2001 finds they carry minimal policy or legal consequences for both GB and NI. The most significant change is the introduction of a new article that enables the European Commission to update technical TSE provisions (including approving rapid tests, testing age thresholds, specified risk material rules, and amending annexes) through delegated acts rather than the traditional comitology procedure. The proposed amendments remove these detailed technical requirements from the articles, leaving them solely in the annexes. As annexes can now be updated more rapidly through delegated acts, this change is intended to create a faster, more streamlined mechanism for ensuring the legislation reflects the latest scientific developments. This shift is intended to reduce the administrative burden on Member State authorities, who will no longer need to initiate or vote on frequent technical updates. Compliance costs are expected to fall for economic operators, and the proposal is expected to help EU farmers become more competitive. This may negatively impact the UK's competitiveness if the EU is able to update trade requirements at a faster pace.
- The amendments also clarify that all gelatine and collagen products derived from healthy ruminants may be placed on the market without restriction. Previously, EU regulation only exempted gelatine and collagen produced specifically from hides and skins. The practical consequence is that very little changes for GB businesses moving goods to NI. NI gains improved access to the EU market for a broader range of gelatine and collagen products. Great Britain, however, continues to apply the UK-retained version of Regulation (EC) 999/2001, which still restricts the unrestricted category to milk, hides and skins, and gelatine and collagen derived specifically from hides and skins. As a result, GB businesses remain unable to move ruminant-derived gelatine or collagen (other than hide/skin-derived material) to NI without full certification and their competitiveness in the EU market may be hindered.

### **Regulation (EU)2017/625 Official Controls**

- The changes to articles 41, 93, 100 and 144 of the OCR have no immediate policy or legal impacts. These changes simply empower the Commission to adopt delegated acts concerning the cases, and the conditions under which, laboratories may be designated as official laboratories, national reference laboratories and EU reference laboratories. Impacts will only materialise once the Commission adopts the relevant delegated acts.
- The changes to Article 50(3) of the OCR, to allow the competent authorities of Border Control Posts (BCPs) to choose to split consignments of plant and plant products before the completion of all official controls, so compliant parts can be released while additional checks continue on the remainder.

- The EU has made this change in response to requests from Member States and stakeholders. The mixed nature of plant consignments can mean that part of the consignment clears controls more rapidly. Currently, the entire consignment is held until it is fully cleared from import controls. This can cause delays during which time goods can perish, resulting in financial loss for businesses. The amendments made to Article 50(3) will allow DAERA to make decisions on an individual consignment basis as to whether to release the compliant part of consignments whilst continuing to officially hold the remaining parts pending the outcome of further checks. This amendment does not impact how goods move under the Northern Ireland Retail Movement Scheme.

## **CONSULTATION**

7. The EU Commission ran a proportionate, targeted consultation to calibrate the proposed measures, drawing on ongoing exchanges with Member States and stakeholders, plus recent evaluations (in particular on the pesticides legislation and the feed additives regulation). In addition, the Commission organised a targeted Implementation Dialogue on the biocidal products regulation in July 2025. A Call for Evidence ran from 16 September to 14 October 2025, which gathered 6,440 responses overall. Nearly 6,000 came from citizens, mostly due through semi-automated campaigns, 318 from businesses and their associations, 52 public authorities, 107 from civil society, and 16 from academia. These stakeholders contributed 319 position papers with detailed, technical input. The evidence informed the problem definition, prioritisation of options, and safeguards.

### **1829/2003 GMO FSA / 1831/2003 Feed Additives**

- As this does not require changes to domestic legislation, no consultation with external stakeholders is required. The FSA will work with FBOs, and enforcement bodies as normal to notify and support them to adopt any changes as relevant. Should some of these changes be considered for adoption in GB as part of a wider regulatory change, a formal consultation will be carried out.

### **396/2005 Maximum residue levels (MRLs) of pesticides/1107/2009**

- No formal, public consultation has been undertaken regarding these newly published proposals.

### **Plant protection Regulation EU 528/2012 EU Biocidal Products Regulation (HSE lead)**

- The Commission states that in their responses, relevant industry stakeholders and several Member States prioritised completing the review programme and

simplifying renewals. NGOs and citizens expressed concern that streamlining could be perceived as deregulation and stressed that any adjustments must not reduce scrutiny of high-risk biocidal products or delay the evaluation of endocrine disruptors and should rather await the results of the full evaluation of Regulation (EU) No 528/2012.

- The UK Government has not consulted on this EU proposal
- The UK Government has consulted on the similar proposals as part of a larger package of chemicals legislative reform measures in GB.<sup>[1]</sup> The consultation response has been published [here](#). Further details of the findings and the next steps can be found in the consultation response

<sup>[1]</sup> HSE Chemicals Reform consultation - <https://consultations.hse.gov.uk/hse/chemicals-legislative-reform-proposals/>

### **852/2004 and 853/2004; 1099/2009 (Welfare at time of killing); 999/2001 TSE**

- As this does not require changes to domestic legislation, no consultation with external stakeholders is required.

### **2017/625 Official Controls (laboratories)**

- As this does not require changes to domestic legislation, no consultation with external stakeholders is required. The FSA will work with FBOs, laboratories, and enforcement bodies as normal to notify and support them to adopt any changes as relevant. Should some of these changes be considered for adoption in GB as part of a wider regulatory change, a formal consultation will be carried out.

### **2017/625 Official Controls**

- No formal consultation or impact assessment was carried out in GB or NI as this is a proposed change to EU regulations which do not apply in GB as retained EU law, having been made after 31st December 2020.

## **FINANCIAL IMPLICATIONS**

8. [EU press release](#) issued on 16 December 2025 estimated that the broader simplification package would deliver over €1 billion in total savings, including approximately €428 million per year for businesses.
9. There is no published financial cost estimate specific to the new regulatory clarification on GMM-derived food and feed. However, based on related EU reforms and established industry practices, the proposal is expected to reduce costs for both EU and GB food/feed sectors, primarily by avoiding unnecessary

GMO authorisations and reducing associated testing, documentation, and regulatory uncertainty.

### **1831/2003 Feed Additives**

The removal of renewal requirements for most feed additives will reduce costs and administrative effort for UK businesses placing the applicable feed additives on the EU market, as they will no longer be required to submit renewal applications every 10 years.

- However, UK businesses must continue to submit renewal applications for coccidiostats and histomonostats on the EU market, and therefore the administrative and financial burden remains for these feed additives.
- If NI businesses choose to employ digital labelling on feed additives and move these additives into GB under unfettered market access, GB enforcement authorities may be required to adjust established practices, including the ability to access information presented through QR codes. Therefore, there is the potential for increased financial costs for GB enforcement authorities.

### **396/2005 MRLs of pesticides & 1107/2009 Plant Protection Products**

The EU's assessment is not broken down in detail and covers the whole of the EU as well as multiple regulations so it is not possible to quantify the specific pesticide-related impacts for NI. However, many of the functions which are amended are not relevant as NI has more limited functions under the Windsor Framework compared to EU Member States. For industry there may be some benefits such as streamlining of bringing biopesticides to market. Restrictions of imports of food treated with pesticides not approved in the EU could impact food supply chains which would need to adjust. Net effects will depend on final drafting and timelines.

### **528/2012 EU Biocidal Products**

A full impact assessment was not produced by the European Commission. The proposed simplification measures do not alter core policy objectives or introduce significant new obligations. A reduction in costs to businesses who may otherwise have had to apply to renew active substances is anticipated. Under the terms of the Windsor Framework, Northern Ireland does not conduct active substance evaluations under the EU review programme. Therefore, no direct impact is expected on NI authorities, nor on the Health and Safety Executive in GB, who provide biocides technical support to NI.

### **852/2004 & 853/2004**

This procedural change will not apply in GB and therefore there are no financial implications. For NI, given this is a simplification of an administrative process which has had limited use in the past years, very limited impact is expected

### **2017/625 Official Controls (laboratories)**

While the proposed flexibility is welcomed as a means to reduce administrative burden and enhance operational agility, further detail on the proposal is required to enable a thorough assessment of its implications. For example, clarification is needed regarding quality assurance arrangements, the scope of laboratories to which the proposal would apply, and the range of testing activities covered.

- There may be a financial benefit to businesses from the proposed change to operations at Border Control Posts that will allow DAERA to release the cleared part of consignments for onward movement.

### **1099/2009 (Welfare at time of killing)**

There are no direct financial implications anticipated. The withdrawal of the requirement to report depopulation figures annually under Regulation 1099/2009 will ease administrative burdens on NI which currently submits this report for its territory to the Commission.

### **999/2001 TSE**

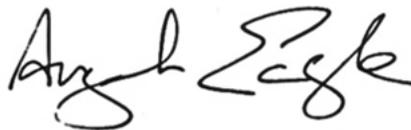
There are no direct financial implications anticipated. However, the removal of restrictions on gelatine and collagen products from all healthy ruminants, beyond the previous limitation to materials derived solely from hides and skins, will ease existing compliance requirements for NI. By permitting all such products to be placed on the market without restriction, the change is expected to reduce regulatory burden and associated costs for industry for NI.



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