

Summary – The European Commission’s proposal for a Food and Feed Safety Simplification Package

This proposal has been announced in the [European Commission’s Vision for Agriculture and Food](#) as a cross-cutting legislative simplification package in other areas than the Common Agriculture Policy that affect farmers, food and feed businesses and the related administrations. The aim of the package is to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, as well as for the protection of human and animal health and the environment. The proposal contributes to the Commission’s overarching objectives to: 1) streamline the EU regulatory framework in line with the [Communication on a simpler and faster Europe](#); 2) improve the competitiveness and resilience of the EU food and feed system, building on the Competitiveness Compass; 3) contribute to the achievement of the simplification targets of reducing regulatory burden by 25% for companies and 35% for Small and Medium-sized Enterprises –including cutting recurring administrative costs by EUR 37.5 billion by the end of the current Commission mandate, without undermining policy objectives.

The package comprises three separate legislative proposals:

- 1) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) No 528/2012 as regards the extension of certain data protection periods;
- 2) Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 98/58/EC and Directive 2009/128/EC of the European Parliament and of the Council as regards the simplification and strengthening of food and feed safety requirements, and repealing Council Directives 82/711/EEC and 85/572/EEC;
- 3) 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.

The content and objectives of the key measures proposed can be summarised as follows:

With **the first proposal listed in the box**, the Commission proposes **to extend until 31 December 2030 the period of protection for data for active substances used in biocidal products** which are still under assessment in view of their approval under Regulation (EU) No 528/2012 on biocidal products (the BPR). At present, Article 95(5) set an end date for the protection of such data at 31 December 2025. Business operators have flagged this as a serious concern as the ongoing review programme for all existing active substances in view of their first approval is substantially delayed and costly new data (e.g. related to the determination of endocrine disrupting properties) have only recently been generated or are still being generated. Without appropriate data protection, companies lose incentives to generate safety related data or competitors could benefit unfairly. The proposal for the extension of the data protection period, both in term of scope and duration, strikes a balance between the interests of review programme participants (data owners) and the interests of alternative suppliers of active substance, as well as producers and users of biocidal products, taking also into account the initial intentions of the European Parliament and the Council when setting the expiry of data protection in Article 95(5) of the BPR when the Regulation was adopted in 2012. It is important that this proposal is adopted with extreme urgency to limit the time during which relevant data are not protected.

Further targeted amendments to the BPR are included in the third proposal listed in the box to address two urgent issues that should be resolved without awaiting the full evaluation of the BPR, which has recently been launched¹ and is expected to be concluded by the end of 2027. As mentioned before, the review programme for existing active substances, which started in 2002, is significantly delayed. To date, only 53% of evaluations have been completed. This is mainly due to insufficient resources in Member States, delays in data generation by companies, and scientific complexity. As a result, many existing active substances continue to be placed on the market and used without having gone through a full safety assessment, while for others already assessed and approved earlier, renewal procedures are ongoing as currently all approvals are limited in time. These systematically required renewal procedures bind part of the limited resources in the Member States. In order to focus available resources on the completion of the review programme, the Commission has proposed that approvals can become unlimited in time, except for active substances with more hazardous properties (e.g. those meeting the criteria for exclusion or substitution). As a further safeguard for maintaining a high level of protection, the existing possibility to review approvals at any time if justified in the light of new evidence will be maintained. In addition, the Commission has proposed to simplify the administrative procedures for the granting of Union-wide product authorisations to accelerate market access for biocidal products.

In the second proposal listed in the box, the Commission has proposed to amend **Directive 2009/128/EC on the sustainable use of pesticides** to give Member States the possibility to allow the use of certain types of **drones for aerial spraying** of plant protection products without the need for individual derogations as is required today. The types of drones concerned will be identified by the Commission in a future delegated act based on technical work to be conducted by the European Food Safety Authority (EFSA) and Member States experts to determine which types of drones lead to comparable or lower exposure of humans and the environment than land-based spraying.

The Commission has also proposed to remove duplicative record keeping obligations in Directive 98/58/EC in relation to the use of veterinary medicinal products and observed animal mortalities and to repeal Directives 82/711/EEC and 85/572/EEC which have become obsolete in the light of more recent legislation on plastic food contact materials.

In the third proposal listed in the box above, the Commission proposes targeted amendments to a range of Regulations to reduce burdens on business operators and Member States administrations, in line with the aims of the Vision for Agriculture and Food.

Proposed amendments to **Regulation (EC) No 1107/2009 on plant protection products** intend to accelerate access to the market for **biocontrol active substances and products containing them** in order to expand and increase sustainability of the toolbox of solutions for pest-management for farmers. The Commission proposes (1) a clear definition of biocontrol active substances that is future oriented and covers innovative solutions, (2) prioritisation of the assessment of applications for approval of new biocontrol active substances and authorisation of products containing them; (3) the possibility for Member States to grant provisional product authorisations while approval procedures for new biocontrol substances are still ongoing; (4) reinforced zonal product authorisations and mutual recognition of national authorisations (i.e. tacit agreement if the 120-day deadline for decision-making is not met); (5) the possibility that EFSA can assume the role of rapporteur Member State for the initial risk

¹ The evaluation was launched with a call for evidence (available at: [Biocidal Products Regulation – evaluation](#)) and a public consultation (available at: [Biocidal Products Regulation – evaluation](#))

assessment (instead of a Member State) and additional resources for this task; (6) the waiving of the record-keeping obligations for farmers using products containing only biocontrol active substances.

Currently, all approvals of active substances are limited in time and the vast majority of resources in the Member States are bound by procedures for their renewal, practically all of which are significantly delayed, which leads to the need for extending existing approvals, while applicants for the approval of new (biocontrol) active substances must often wait several years before a Member State accepts the submission of applications. In order to enhance the capacity of Member States to assess applications for new (biocontrol) active substances, the Commission has proposed **that approvals of active substances can become unlimited except for more hazardous substances**, i.e. candidates for substitution or substances that are approved despite not meeting all approval criteria under Article 4(7) of Regulation (EC) No 1107/2009 (see next paragraph for more details), as well as substances for which the outcome of the risk assessment points to the need for a re-evaluation after a certain period of time. The proposal contains a number of **safeguards that ensure that the current level of protection of health and environment will be maintained**: all ongoing renewal procedures (for over 200 active substances out of the 420 approved) will continue and a decision on whether approvals can be renewed and the length of the renewal will be decided only upon their completion. In addition, product authorisations will remain time-limited and the Commission will be obliged to periodically identify – in cooperation with Member States and EFSA – active substances for full or targeted reviews, so that work can focus on cases where it really matters. As further safeguards, the possibility for ad-hoc review of approvals (Article 21 of Regulation (EC) No 1107/2009) and the adoption of emergency measures (Article 69 of that Regulation) remain unchanged.

In line with the announcement in the Vision for Agriculture and Food, that the Commission will carefully assess the availability of alternatives before banning active substances, the Commission has proposed to clarify and broaden the possibility to use **Article 4(7) of Regulation 1107/2009**, which allows for the approval for 5-years of active substances that do not meet all the approval criteria if such substances are essential to combat a danger to plant health because no alternatives are available. The Commission has also proposed that **Member States can grant longer grace periods** for the distribution and use of existing stocks of products when the approval of active substances contained therein cannot be renewed, but only when there are no immediate and serious concerns for health or the environment and when no reasonable alternatives are available. This should allow the Member States concerned to have more time to authorise alternative products so that they do not have to resort to emergency authorisations, as is often the case at present. The Commission has furthermore proposed to simplify **procedures for obtaining mutual recognition** of product authorisations and for the **extension of authorisations for minor uses** with the objective that farmers across the EU have more equal access to plant protection products. To further facilitate mutual recognition of product authorisations, the Commission has proposed to clarify that the latest EU-level assessment for an active substance is to be considered as current scientific and technical knowledge. However, if Member States consider that new evidence requires a reassessment of the active substance, they must inform the Commission accordingly.

The Commission has also proposed clarifying the existing provisions for the approval of **basic substances** and the placing on the market of products containing them, including in particular the possibility that basic substances can remain approved as such (and continue to be available to farmers) even if they are later approved as regular active substances. Further clarifications are proposed in relation to the provisions for **treated seeds** and for **data protection periods**, which are currently not applied in a harmonised way across Member States.

In relation to **Regulation (EC) No 396/2005 on Maximum Residues Levels (MRL)** the Commission has proposed to establish the possibility of implementing on a case-by-case basis the principle announced in the Vision for Agriculture and Food that **'the most hazardous pesticides banned in the EU for health and environmental reasons will not be allowed back to the EU through imported products'**, if considered justified in the light of the outcome of a case-specific impact assessment. In addition, as announced in the Vision, the Commission has launched a study which will inform a broader impact assessment that will consider the impacts of that principle on the EU's competitive position and the international implications and, if appropriate, will propose amendments to the applicable legal framework.

Further changes proposed relate to **the setting of MRLs based on monitoring data**, enlarged possibilities for **granting transitional periods** for products compliant with earlier MRLs at the time of production to avoid economic losses and food waste, and some **clarifications of terminology related to analytical verification of residue levels**.

Proposed amendments to **Regulation (EC) No 1829/2003 on genetically modified food and feed** aim at clarifying that food and feed produced through fermentation by using genetically modified micro-organisms (GMMs) are excluded from the scope of the Regulation if the GMMs are not present in the final product and that residues thereof are limited to non-viable cells, their presence is minimised and they have no technological effect on the food or feed.

Proposed amendments to **Regulation (EC) No 1831/2003 on feed additives** aim at easing the burdens related to the current obligation for the systematic renewal of authorisations of feed additives by foreseeing **unlimited duration of authorisations for all additives (except coccidiostats)** with solid safety safeguards. Further amendments intend to reduce burdens related to procedures for modifications of existing authorisations, and to allow digital labelling for certain non-safety information.

Proposed amendments to **Regulations 852/2004 on the hygiene of foodstuffs** and **Regulation (EC) No. 853/2004 laying down specific rules for the hygiene of food of animal origin** aim at removing duplicative requirements for the notification of specific national measures and streamlining these requirements into a single harmonised system under Directive (EU) 2015/1535 on the provision of information in the field of technical regulations (TRIS)(.

Proposed amendments to **Regulation (EC) No 1009/2009 on the protection of animals at the time of killing** intend to remove annual reporting obligations related to depopulation activities, as these are largely duplicative of reports required under Regulation (EU) 2017/2625 on official controls.

Proposed amendments to **Regulation (EC) No 999/2001 on the prevention, control and eradication of certain transmissible spongiform encephalopathies (BSE)** intend to modernise the framework, allowing rules to be updated swiftly and proportionately in line with the latest science and risk assessments. Surveillance and Specified Risk Material (SRM) requirements will be revised to target only at-risk populations. Trade restrictions are proposed to be aligned with international standards to ensure that EU measures are proportionate.

Proposed amendments to **Regulation 2017/625 on official controls** intend to establish a more pragmatic approach to border controls for plant products by the introduction of partial clearance of consignments at Border Control Posts for compliant parts (while other parts are checked further) and by allowing limited derogations from accreditation for reference labs, focusing requirements where they are most relevant.