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LIMITE

SIMPL	**DENLEG**
ANTICI	**MI**
AGRI	**FOOD**
AGRILEG	**FEED**
ENV	**SEMENCES**
PESTICIDE	**SAN**
PHYTOSAN	**CHIMIE**
VETER	**CODEC**

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus X: Omnibus on Food and feed safety – Presentation by the Commission (AGS on 12 January 2026)

Delegations will find enclosed a presentation as prepared by the Commission for the meeting of the Antici Group (Simplification) on 12 January 2026 regarding the Omnibus on Food and feed Simplification package (Omnibus X).

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Food and feed simplification package

Meeting of the Antici Group (Simplification)

12 January 2026

COUNCIL

JUSTUS LIPSIUS BUILDING

European Commission

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Background

Food and feed simplification package

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Goals

Contribute to overarching EC objectives:

- **Streamline and further harmonise** the EU regulatory framework
- **Increase competitiveness** and resilience of EU food and feed systems
- **Achieve the abovementioned simplification targets** of reducing regulatory burden by the end of the mandate.

Objectives

Faster access to markets and innovation under existing rules

Lower administrative burdens for economic operators and public authorities

Remove unnecessary complexity in risk management

Targeted simplification for safer, smarter, and more competitive food systems

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CLUSTER 1 -> FASTER ACCESS TO MARKETS AND INNOVATION UNDER EXISTING RULES

Regulation (EC) No 1107/2009	Biocontrol package
Directive 2009/128/EC	Aerial spraying of PPP

CLUSTER 2 -> LOWERING ADMINISTRATIVE BURDENS

Regulation (EC) No 1107/2009	Simplification beyond biocontrol
Regulation (EU) No 528/2012	Biocidal Products Regulation (BPR)
Regulation (EC) No 396/2005	Maximum Residue Levels (MRLs)
Regulation (EC) No 1829/2003	Food and feed obtained using GMMs
Regulation (EC) No 1831/2003	Feed additives
Regulations (EC) Nos 852/2004 & 853/2004	Notification of national hygiene measures
Regulation (EC) No 1099/2009	Depopulation reporting
Directive 98/58/EC	Record-keeping for farmers (treatments & mortalities)

CLUSTER 3 -> REMOVE UNNECESSARY COMPLEXITY IN RISK MANAGEMENT

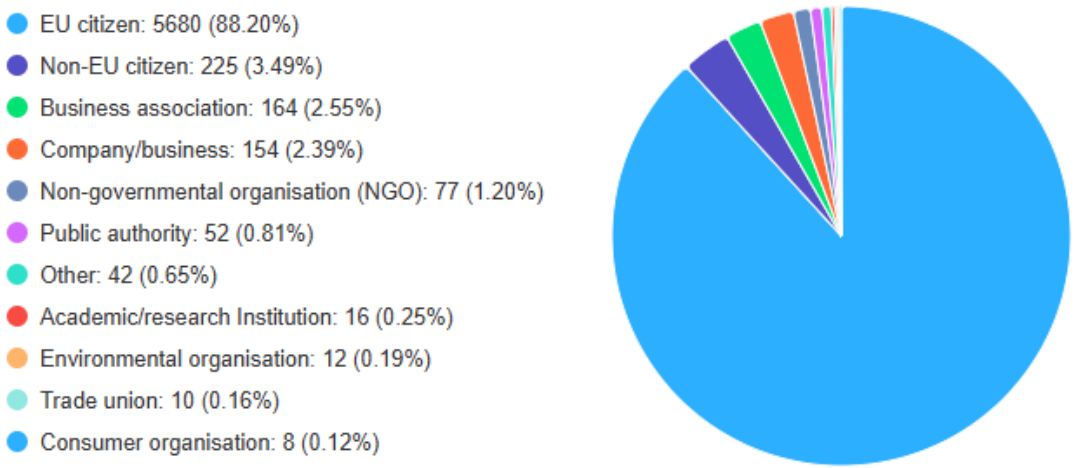
Regulation (EC) No 999/2001	Alignment of BSE rules
Regulation (EU) 2017/625	Official Controls Regulation (OCR)

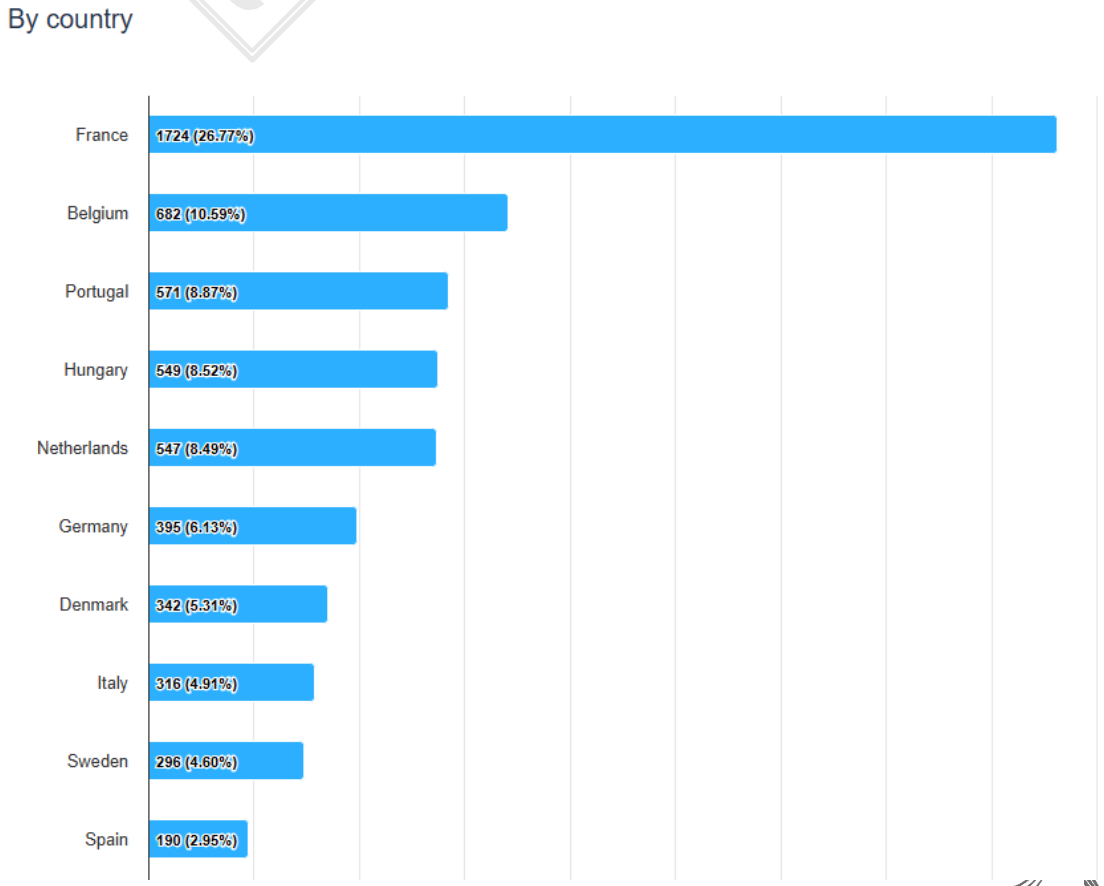
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Stakeholder input

Call for Evidence - 16/09/25 - 14/10/25

- 6440 responses:
  - nearly 6000 from citizens following NGO-led campaigns
  - 318 from businesses (association)
  - 52 from public authorities
  - 16 from research instutions
  - 107 from NGOs





Overall impacts & cost-savings

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LEAN, FASTER SYSTEMS LEAD TO SUBSTANTIAL SAVINGS

- Abolishing systematic renewals of approvals/authorisations contributes most.
- Streamlined procedures & risk-based controls also reduce administrative burden.
- **Cost savings:**
  - **€428 m/year (businesses, including €227 m/year for SMEs) +**
  - **€661 m/year (public authorities)**
  - **= > €1 billion/year**



CLARITY & PREDICTABILITY WITH A FOCUS ON RISK & ENABLING INNOVATION

- Remove grey zones or duplications as provisions are clarified.
- Faster time-to-market for innovative solutions: **SMEs benefit most**.
- Safety levels remain unchanged.
- Science-based assessment continues + review & withdrawal powers remain.

Food and Feed simplification package

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Organised in 3 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 EUROPEANPARLIAMENT 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 EUROPEANPARLIAMENT 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**

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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

Regulation (EU) No 528/2012 on Biocidal Products (BPR)

Lowering administrative burdens – data protection in the BPR:

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BACKGROUND

- "No data no market principle" applicable since 1 September 2015: to be allowed on the EU market, every active substance supplier must be listed either as a participant in the review programme of existing active substances, or as an alternative supplier that provides a letter of access to the relevant protected data from the review programme participant(s) or submits its own data package
- Purpose: cost compensation for companies generating safety data for active substances. To avoid disproportionate data protection periods a limit was set in the BPR as 31 December 2025 (10 years)
- Review programme for existing active substances started in 2000 but is suffering from major delays (only ~51% of evaluations completed today).
- As a consequence, the programme had to be extended repeatedly, now until 31 December 2030

ISSUE

- No data protection for data submitted in recent years on existing substances in the review programme, or still being generated and submitted now (particularly relevant for data related to endocrine-disrupting properties).
- The resulting free access to these data for alternative suppliers is a disincentive for participants in investing in the generation of studies to support biocides in the EU and potentially leading to the disappearance of potentially essential substances to protect human health or materials

Regulation (EU) No 528/2012 on Biocidal Products (BPR)

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SIMPLIFICATION MEASURE

- Extension until 31 December 2030 of the protection for all data of active substances still in the review programme in June 2018 (date when new criteria for endocrine disruptors became applicable)
- Adoption is of **high urgency** to limit gap in data protection

EXPECTED BENEFITS

- Balance considered for the scope of the data concerned by the extension of protection and the duration of extension, having in mind the different interests of active substance suppliers, biocidal product producers and users of these products as originally intended by Council and the EU Parliament when setting the current expiry date
- Avoidance of disproportionate protection and high administrative burdens for the implementation of longer data protection period.
- Maintain an appropriate level of data protection and keep incentive for the support of existing active substances in the EU

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

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Directive 2009/128/EC

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Faster access to markets and innovation - Application of PPPs by drones:

ISSUES

- Aerial spraying of PPPs is prohibited in general – Member States can grant individual derogations. Administrative burden of individual derogations is hampering development of application by drones (precision farming technology).

SIMPLIFICATION MEASURES

- Member States will be empowered to exempt certain types drones from the need for individual applications for derogation.
- Types of drones concerned to be defined in a future delegated act based on technical work to be conducted by EFSA and Member States experts.

EXPECTED BENEFITS

- Enabling innovation of drone technology under safe conditions will allow more targeted pesticide application and help protect human health and the environment.

Directive 98/58/EC

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Lowering administrative burdens - record-keeping for farmers:

ISSUES

- Farmers must keep records of medicinal treatments and animal mortalities.
- Requirements under Directive 98/58/EC overlap with those under Regulation 2019/6 on veterinary medicinal products and Regulation 2016/429 on transmissible animal diseases.
- Creates unnecessary paperwork without adding value.

SIMPLIFICATION MEASURES

- Amend Directive 98/58/EC to remove duplicate record-keeping obligations.

EXPECTED BENEFITS

- Simpler, more consistent legal framework without loss of transparency or animal welfare safeguards.

Repeal of Council Directives 82/711/EEC and 85/572/EEC

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Legal certainty – Plastic food contact materials and articles:

ISSUES

- Regulation No 10/2011 covers the matters regulated by Directives 82/711/EEC and 85/572/EEC.

SIMPLIFICATION MEASURES

- Repeal of Directives 82/711/EEC and 85/572/EEC for reasons of legal certainty.

EXPECTED BENEFITS

- Avoiding confusion about the rules applicable for testing the migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, including the list of simulants to be used to that end for specific food categories.

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

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Regulation (EC) No 1107/2009

Faster access to markets and innovation: biocontrol substances and products

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ISSUES

- New biocontrol products face long delays in reaching the market
- Farmers lack access to safer alternatives for crop protection while the chemical toolbox is shrinking

SIMPLIFICATION MEASURES

- Clear definition of biocontrol substances
- Member States must give priority to the assessment of applications for approval of new biocontrol active substances & authorisation of products containing them
- Possibility for Member States to grant provisional product authorisations while approval procedures for new biocontrol substances are still ongoing.
- One zone for product authorisations and reinforced zonal and mutual recognition (tacit agreement if 120-day deadline is not met)
- EFSA can take the role of rapporteur Member State for initial risk assessment (need for extra resources)
- Waiving of the record-keeping obligations for farmers for biocontrol products

EXPECTED BENEFITS

- Accelerated placing of biocontrol plant protection products on the EU market
- Reduction of burden for operators
- Strengthening innovation, sustainability, and competitiveness in EU farming

Regulation (EC) No 1107/2009

Lowering administrative burdens: further simplifications

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ISSUES

- Procedures for renewals of approval of active substances consume majority of resources in Member States and EFSA – leading to chronic delays and preventing innovative products reaching the market
- Mutual recognition not functioning properly; unequal access for farmers to plant protection products across Member States
- Legal uncertainty of provisions related to data protection, seed treatment, and basic substances

EXPECTED BENEFITS OF PROPOSED CHANGES (see next slides)

- Faster, more predictable processes for applicants
- Greater harmonisation and equal access to plant protection products across the EU.
- Reduction of burdens for companies, Member States authorities and EFSA without lowering safety

Regulation (EC) No 1107/2009

FURTHER SIMPLIFICATION MEASURES (1)

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- Possibility for unlimited approvals for active substances with exceptions:
  - candidates for substitution (substances with problematic hazard properties)
  - substances approved under the derogation possibility set out in Article 4(7)
  - active substances for which a limited period of renewal is set in the light of relevant uncertainties emerging from the risk assessment including as a result of data gaps
  - transition measure: ongoing renewal procedures (~200) will continue
- Safeguards to maintain high level of protection:
  - Product authorisations remain limited (maximum15 years) and subject to review and renewal
  - Obligation for Commission and Member States to periodically select substances with unlimited approval periods for full renewal or targeted reassessment (new provision – also applicable to substances with limited approval periods) – Possibility for review at any time (Art.21) and emergency measures (Art. 69) maintained.
- Article 4(7) derogation allows approval for 5 years of active substances not meeting all approval criteria if they are necessary to control a serious danger to plant health or plant production – substances with the most severe hazards are excluded from this possibility. The obligation for Member States to submit a phasing out plan is removed.
- Longer grace periods when no reasonable alternatives are available – max of 3 years instead of 18 months

Regulation (EC) No 1107/2009

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FURTHER SIMPLIFICATION MEASURES (2)

- Simplification for applications for extensions of authorisations to minor uses
- Restoration of EU-wide data protection periods (instead of 'per Member State')
- Clarification related to "current scientific and technical knowledge" for product authorisation assessments: latest EU assessment is applicable - if Member States consider that an update is needed they must ask the Commission to act to launch an appropriate procedure i.e. renewal, targeted reassessment or full review.
- Clarification of provisions for basic substances (including for product marketing and possibility for dual approval of basic/active substances) – currently Member States apply divergent rules.
- Clarification of provisions related to seeds treated with plant protection products, which Member States do not apply in a harmonised way.

Regulation (EU) No 528/2012 (the BPR)

Lowering administrative burdens - simplification for biocidal products:

A limited set of targeted adjustments in order to address specific issues already identified that require fast action ahead of the full evaluation of the BPR which is starting now.

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ISSUES

1) Active substances:
   - Review programme of existing biocidal active substances started in 2000: only ~51% of evaluations completed so far
   - 2021 Implementation report to Council and the EU Parliament: delays due to limited Member States resources, delays from companies, data gaps, new scientific ED criteria requirements in 2018, etc.
   - Due to the limited duration of approval, growing resource requirements for the evaluation of renewal applications while many substances are still not assessed under the review programme, and many biocidal products remain on the market without their safety and efficacy demonstrated according to BPR requirements

2) Union authorisation of biocidal products: Official Journal publication process of the whole product authorisation documentation adds complexity and delays.

Regulation (EU) No 528/2012 (the BPR)

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SIMPLIFICATION MEASURES

1) Active substance approval :
    - Unlimited duration of approval of active substances, except for substances that meet exclusion or substitution criteria or when otherwise decided in the approval decision
    - Possibility to select substances with an unlimited approval for which a renewal examination will be triggered
    - Transition measures: applications for renewals already submitted will continue to be evaluated
    - Possibility for review ‘at any time’ is maintained
2) Simplify procedure for Union authorisation of products: no longer a publication in the EU Official Journal of the full authorization documentation – instead: a notification to the authorisation holder + publication of a summary in the Official Journal.

EXPECTED BENEFITS

1) Better use of the available resources of companies and Member States authorities while maintaining a high level of safety
2) Resources freed up to ensure a faster completion of the review programme of active substances and of the authorisation of products according to BPR safety requirements, to achieve the objective of high level of safety for humans, animals and the environment
3) More efficient process for Union authorisation of products leading to faster access to market

Regulation (EC) No 396/2005

Lowering administrative burdens – Maximum Residue Levels:

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ISSUE

- Residues of substances not approved under Regulation (EC) No 1107/2009 due to particularly hazardous properties (*) may still be present in imported products if EFSA has confirmed that they are safe for EU consumers. This situation has been perceived as unfair by some stakeholders and some political groups in the European Parliament.

SIMPLIFICATION MEASURE

- Possibility for implementation on a case-by-case basis of 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 after an impact assessment
- Since the term “import tolerance” is often misunderstood, it is replaced for clarity by "MRL based on a good agricultural practice in a third country".

EXPECTED BENEFITS

- Clarity for stakeholders and authorities in the MRL setting process.
- Stronger alignment of production standards applied to imported products.

(*) Substances with mutagenic, carcinogenic, or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans and in non-target organisms. Also, substances persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB).

Regulation (EC) No 396/2005 – other issues

Allow for transitional measures in all cases where MRLs are lowered

- Continued marketing of products compliant with earlier MRLs is limited, which creates problems for long shelf-life products of high economic value such as wine, hops, oil that were compliant with earlier (higher) MRLs when produced, leading to economic losses and food waste.
- Allowing transitional measures in all cases is more proportionate, gives farmers and food business operators legal certainty and avoids food/economic losses.

Allow the setting of permanent (instead of temporary) MRLs based on monitoring data

- Currently, the MRL Regulation allows to set temporary MRLs based on monitoring data in specific cases
- A review of MRLs after a certain period of time is mandatory and requires resources, but is not meaningful for certain substances where no changes occur. Therefore, reviews should be done in a more flexible way, case-by-case. Since permanent MRLs can be reviewed at any time, it is not necessary to set temporary MRLs.
- This approach does not compromise the high level of consumer protection, while simultaneously alleviating administrative burdens for food business operators and Member States.

Align the terminology of the technical zero by applying the term limit of quantification (LOQ).

Currently, the MRL Regulation uses “limit of determination (LOD)”, while the correct analytical term is “limit of quantification (LOQ)”. This is confusing as the acronym LOD is also the abbreviation for the “limit of detection“, which is different.

Regulation (EC) No 1829/2003

Lowering administrative burden: food and feed obtained using GMMs

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ISSUES

- Uncertainty on whether Regulation 1829/2003 applies to certain food and feed obtained using genetically modified microorganisms (GMMs)
  - Impact on internal market by divergent enforcement and removal from the market of previously authorised products
  - Legal uncertainty for operators

SIMPLIFICATION MEASURES

- Clarify food and feed produced using GMMs are excluded from Regulation (EC) No 1829/2003 if:
  - the GMMs are not present in the final product
  - Residual presence of non-viable cells from the GMM is minimized and has no technological effect on the food or feed

EXPECTED BENEFITS

- Harmonised enforcement
- Legal certainty for operators

Regulation (EC) No 1831/2003

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Lowering administrative burdens: feed additives

ISSUES

- Authorisations are limited to 10-years and require renewal → high cost & workload for companies, EFSA, Member States and the Commission.
- Modification of authorisations (e.g. change of holder) unnecessarily complex.
- Only physical labelling allowed, unnecessarily rigid for companies.

SIMPLIFICATION MEASURES

- Unlimited duration of authorisation for all additives (except coccidiostats) with safety safeguards
- Simplification of procedures for modification of existing authorisations
- Allowing digital labelling for certain non-safety information

EXPECTED BENEFITS

- Significant cost and workload reduction for companies, EFSA, MS & COM, without lowering safety
- More flexibility and clarity for industry & COM
- More flexibility and reduced labelling compliance costs through digitalisation

Regulations (EC) No 852/2004 and 853/2004

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Lowering administrative burdens - national hygiene measures:

ISSUES

- Overlap between Hygiene Regulations (852/2004, 853/2004) and TRIS Directive (2015/1535).
- Unclear which notification procedure applies for national hygiene measures.
- Creates duplication and legal uncertainty.

SIMPLIFICATION MEASURES

- Streamline notifications into a single harmonised system under the TRIS Directive.

EXPECTED BENEFITS

- Simplifies compliance for Member States and operators
- Improves transparency through TRIS database
- Supports subsidiarity while reducing administrative burden

Regulation (EC) No 1099/2009

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Lowering administrative burdens - depopulation reporting:

ISSUES

- Regulation 1099/2009 requires annual reports on depopulation operations
- Information largely duplicative of reports required under the Official Controls Regulation (OCR)
- Reports are often incomplete, of limited comparability, and low added value.

SIMPLIFICATION MEASURES

- Remove obligation for separate annual depopulation reporting
- Rely on OCR reports to cover relevant animal welfare information

EXPECTED BENEFITS

- Reduced administrative burden for Member States authorities and Commission
- No loss of oversight, since OCR already covers depopulation operations

Regulation (EC) No 999/2001

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Remove unnecessary complexity in risk management: updating BSE rules

ISSUES:

- Current BSE framework outdated and inflexible.
- Misaligned with latest science and international standards (WOAH).
- Surveillance, Specified Risk Material (SRM) rules, and trade restrictions create heavy regulatory and operational burdens that are disproportionate to the current risk.

SIMPLIFICATION MEASURES

- Modernise legal framework to allow timely, proportionate updates.
- Revise surveillance and SRM rules in line with current risk levels.
- Ensure consistency across EU and alignment with international standards.

EXPECTED BENEFITS

- Major savings for operators and authorities.
- Reclassification of materials reduces waste and incineration costs.
- Maintains high standards of animal and public health.

Regulation (EU) No 2017/625

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Remove unnecessary complexity in risk management - flexibility in official controls:

ISSUES

- Consignments cannot be split at border control posts until all checks are finalised → delays, waste of perishable goods.
- Only one standard is recognised for laboratory accreditation, and reference laboratories must be accredited for all methods → unrealistic, i.e. rare / new methods.
- Leads to long-standing non-compliance and high costs.

SIMPLIFICATION MEASURES

- Allow partial clearance of consignments of plants and plant products at border control posts.
- Introduce limited derogations about standards and full accreditation for laboratories.

EXPECTED BENEFITS

- Faster trade flows and reduced financial losses for operators.
- Avoids destruction of perishable goods.
- More flexible, proportionate system for laboratories leading to significant savings.

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Thank you!