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signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of
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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE REFIT EVALUATION
of the
General Food Law (Regulation (EC) No 178/2002)
{SWD(2018) 38 final}

COMMISSION STAFF WORKING DOCUMENT

Fitness Check on the General Food Law (Regulation (EC) No 178/2002)

EXECUTIVE SUMMARY

Regulation (EC) No 178/2002 on General Food Law ('GFL Regulation'), adopted in 2002, is the foundation of a vast array of specific EU food and feed legislation. The present evaluation assesses whether the GFL Regulation including its principles as applied in subsequent legislation is still 'fit for purpose', taking also current trends and needs, and whether there is potential for simplification and the reduction of regulatory costs and burdens.

The fitness check was supported by two external studies carried out in the period 2014-2015.

Relevance

The evaluation indicates that the GFL Regulation **still remains relevant**. It is found adequate to address most of the current trends: growth and competitiveness and increased globalisation as well as the issue of 'dual quality' in terms of food safety and protection of consumers' interests. It is, however, less adequate to address food sustainability in general and food waste in particular.

Effectiveness

Overall, the GFL core objectives, *i.e.* a high level of protection of human health and consumers' interests in relation to food and the effective functioning of the internal market, have been attained.

Current food safety levels are more favourable than before the adoption of the GFL Regulation (*e.g.* decrease in salmonella, food largely free of pesticide residues and of veterinary medicinal product residues or below the EU legal limits, re-evaluation programmes of existing authorised substances in place *etc.*).

The **systematic implementation of the risk analysis principle in EU food law** has overall raised the level of protection of public health. The creation of the European Food Safety Authority (EFSA) has improved the scientific basis of EU measures. Major improvements in increasing EFSA's scientific capacity of expertise, the quality of its scientific outputs, its collection of scientific data and in the development and harmonisation of risk assessment methodologies have taken place. EFSA has also strengthened the cooperation with national and international scientific bodies as well as the information exchange between MSs, the Commission and EFSA. This cooperation has promoted a mutual understanding on risks, minimised the risk of duplications and limited the number of scientific divergences between EFSA and risk assessment bodies. EFSA's strict policies on independence, transparency and openness have also been regularly refined and strengthened. In particular, EFSA has one of the most advanced and robust systems ensuring its independence.

The **implementation** of the functional **separation** of the risk assessment and risk management at EU level, set out in the GFL Regulation, has been improved over time. Nevertheless, as Member States are not represented in EFSA's Management Board, EFSA's governance is not in line with the Common Approach on EU decentralised agencies.

EU risk managers have considered **other legitimate factors** in addition to the scientific opinions of EFSA in deciding the appropriate measures to be taken in **very few cases**. The use of legitimate factors in the EU decision-making process is not static and its exact range of factors and the weight attributed to them varies on a case-by-case basis depending on the subject matter and the measure concerned.

At EU level, the **precautionary principle** has been relied upon in a limited number of cases and applied in a proportionate manner to ensure the appropriate protection of public health. At national level, the rationale underpinning risk management measures is not always clear as to whether it is based on the precautionary principle or on other legitimate factors.

No **systemic inconsistencies in the application of the risk analysis principle as such** have been identified at EU level.

The food safety framework set up by the GFL Regulation has also served, in some cases as a **source of inspiration for non EU countries** developing their national legislation. The **superiority of the EU traceability system vis-à-vis other non EU countries** has also been acknowledged in a recent review of the existing food traceability regulations of 21 OECD countries.

EU emergency measures and existing crisis management arrangements have overall achieved consumer health protection and the efficient management and containment of food safety incidents. Nevertheless, the 2011 *E.coli* outbreak in sprouts in Germany has high-lightened the need to continuously re-evaluate the management of food crises.

Despite considerable improvements, human nutrition related issues and the protection of consumers' interests have been less well achieved than the protection of food safety through specific EU food legislation.

The GFL Regulation combined with a great degree of harmonisation in specific EU food legislation has contributed to the effective functioning of the internal market by creating a level playing field for all feed and food business operators ('FBOs') in the EU market and reducing disruptions of trade where problems have occurred. The value of the EU internal trade in the food and drink sector has increased by 72% over the past decade.

The GFL requirements including the science-based approach to food legislation, underpinned by the establishment and operation of EFSA and the commitment international standards, have contributed to the EU product safety recognition worldwide and to an improved quality perception for EU products in non-EU markets. This allowed the EU to achieve a more globally competitive position since 2003 vis-à-vis the main trading partners: the EU's external trade grew by 6.3%, far outweighing the growth of imports (0.5%), resulting in a positive balance: from less than EUR3 billion negative in 2003 to over EUR10 billion positive in 2012.

Nevertheless, certain shortcomings have been identified:

- National differences in the implementation of the GFL Regulation at Member State level have been observed creating in some instances uneven playing field of businesses in the following contexts: variable level of implementation of withdrawals amongst Member States with respect

to the determination of a food or feed as safe; in the few partly harmonised areas of food law, *e.g.* food contact materials ; food supplements and in foods with added vitamins and minerals; interpretation of the common definitions set out in the GFL; national differences in relation to information to the public on food safety incidents; variable national approaches to the implementation of official controls,; and, variable measures and penalties to address violations of food law. These national differences are not systematic but occur rather on a case-by-case basis.

- **Despite overall considerable progress, transparency of risk analysis remains an important issue in terms of perception:**
 - As regards risk assessment in the context of authorisation dossiers, EFSA is bound by **strict confidentiality rules** and by the legal requirement to primarily base its assessment **on industry studies**, laid down in the GFL Regulation and in the multiple authorisation procedures in specific EU food legislation. These elements **lead civil society to perceive a certain lack of transparency and independence**, having a **negative impact on the acceptability of EFSA's scientific work by the general public**. There is therefore a need to address these issues in order to protect the reputation of EFSA's work.
 - Risk communication has not always been effective with a negative impact on consumers' trust and **on the acceptability of risk management decisions**.
- A number of negative signals have been identified on the **capacity of EFSA to maintain a high level of scientific expertise**, *i.e.* difficulties encountered to attract new panel members, scientific expertise originates from a few Member States only, current trend of diminishing public administration budget, low finances dedicated to the outsourcing of EFSA's tasks to national risk assessors. These negative signals show the limitations of the current system to ensure in the long-term sufficient expertise and to fully engage all MS in scientific cooperation.
- Lengthy authorisation procedures in some sectors (*e.g.* feed additives, plant protection products, food improvement agents, novel foods, health claims) slow down the market entry process. This affects the innovation potential and the competitiveness of the EU food and drink industry as well as its capacity to address future challenges.

Efficiency

The overall benefits from the application of the GFL Regulation (*i.e.* increased protection of public health in terms of food safety, protection of consumers' interests, effective functioning of the internal market, increased competitiveness of the EU food and drink industry) accrue to the entire society. The GFL Regulation has resulted **in efficiency gains** through clear allocation of responsibilities between FBOs and public authorities along the food chain. The majority of the consulted FBOs considers that the benefits resulting from the primary responsibility principle and traceability outweigh the corresponding costs. The compliance costs aimed at preventing and managing crises are considered justified *vis-à-vis* the costs that full-blown food crises would involve. Overall, the few GFL general requirements imposed on operators are considered to entail a fair and proportionate burden.

The present fitness check has not identified any specific margin for simplification and burden reduction that would entail legislative action on the GFL. Many FBOs, including SMEs, already go beyond the GFL requirements *e.g.* on traceability. Adherence to private standards and certification schemes gained importance over the last decade and serve as the basis for integrating regulatory

requirements. At the same time, they add to the burden of FBOs, as they often lay down additional non-regulatory requirements.

The centralisation of the risk analysis at EU level has increased efficiency in terms of cost savings for national competent authorities and for operators, and pooling of scientific resources in EU and national assessment bodies.

Certain negative impacts on innovation and trade in relation to authorisation procedures are not directly attributed to the risk analysis principle as such, but to the specific design of those authorisation procedures in specific EU food legislation. Nevertheless, the centralised system of authorisations still results in efficiency gains compared to having multiple national authorisation systems for food.

The most burdensome information obligations stemming from EU food law are those associated with: certification of products or processes; cooperation with audits and inspection by public authorities; information labelling requirements; and, application for individual authorisation or exemption.

According to the SMEs, it is not the GFL requirements as such but rather detailed requirements in specific EU food legislation that contribute to their costs and burden. The share of administrative costs stemming from EU food law varies considerably amongst businesses (from 0-5% to over 20% of total administrative costs).

Coherence

The framework structure of the GFL setting out common definitions, general principles and requirements, which must consistently underpin the development of both EU and national food law have brought about **internal coherence** in this area. In the context of crisis management within the food chain, the possibility of adopting emergency measures under the GFL Regulation in conjunction, with specific EU food legislation has contributed to the internal coherence of EU food law, as one procedure applies across the board, eliminating discrepancies or inconsistencies.

The GFL Regulation has **proved complementary** to other Union interventions in the area of public health and food policy, especially with respect to the Common Agricultural Policy, where certain synergies have been identified.

EU added value

Finally, as regards the **EU added value**, the food law has the greatest impact when taken at EU level by ensuring a more uniform high level of protection of public health and consumers' interests across the EU as well as a level playing field for all FBOs in the food chain. The harmonised approach strengthens the competitiveness of the EU food and drink industry vis-à-vis its trading partners in the international arena. The EU added value of the GFL Regulation is further manifested through the EU-wide primary responsibility and the EU-wide traceability of food and feed which in combination with the EU-wide operation of RASFF and the enforcement of food law through a sophisticated system of official controls, the adoption of emergency measures and the possibility to enact a crisis management plan at EU level play a key role in preventing and managing food crises, limiting the

impact on public health and consumers' interests when such crises occur, thus maintaining consumers' trust in the long term and limiting unnecessary disruptions to trade.

Simplification and burden reduction

The present fitness check has identified some potential for simplification and burden reduction in sectorial EU food legislation: closing gaps in the few remaining partially harmonised areas, revisiting the modalities of the authorisation procedures to improve coherence and efficiency while accelerating market access, consideration of exemptions/simplified rules for micro-enterprises in line with a high level of protection of public health, and the impact of reviews of existing authorisations on the workload of EFSA.

Currently ongoing or planned evaluations on nutrition and health claims, plant protection products, food contact materials, food irradiation and feed additives will allow, amongst others, a more in-depth assessment of the way the GFL principles and requirements are translated into sectorial rules .

In parallel, a more detailed analysis of EFSA's operation and governance structure will be undertaken in the context of EFSA's external evaluation launched in 2017, building upon the findings of this Fitness Check and the specific issues of concern to EFSA. The possibility of strengthening the transparency, reliability and independence of studies underpinning EFSA's assessments, while protecting legitimate confidential business information should be further explored.