



Discussion Paper on the REFIT Fitness Check of Regulation (EU) N°178/2002

1. Background

Regulation (EC) N° 178/2002 (GFL) was adopted in 2002. It entered fully into force in 2005 but existing national and EU food principles and procedures had to be adapted at the latest by January 2007 to comply with the general principles (Articles 5 to 10) of the Regulation. Since its adoption, it has never undergone a comprehensive evaluation.

Food Law in the EU has evolved in several stages. Originally food law was principally directed towards the creation of an internal market for foods. The BSE crisis and other scares that followed brought to light many shortcomings in the existing body of European food law and it became clear that radical reforms were needed. In particular:

- Most technical rules governing the safety of food had been harmonised (probably around 90%) but the harmonisation process had been performed according to different policies and objectives (AGRI policy and Internal MARKET policy). The fragmentation of the legal and administrative system (at EU and national level) was considered as one of the causes for the underestimation of the BSE outbreak, the system lacking a global approach on the safety of the whole chain.
- Food law had to be risk based but the system did not provide for a systematic scientific assessment of the risk and when it did the instruments at stake (Commission scientific committees) lacked the capacity to provide the necessary scientific advice.
- The crises also demonstrated that the tools in place for preventing and managing crisis were not adequate (absence of traceability led to huge withdrawals and recalls making the crisis worse; RASFF system not sufficiently performing).

Regulation (EC) No 178/2002 pursued the following main objectives:

- To ensure a high level of protection of human health while also protecting consumers against misleading and fraudulent practices.
- To ensure a comprehensive and integrated approach of the food/feed chain as well as a common field for the free movement of foods by creating a harmonised framework for the development of all food law (EU and national).
- To ensure that Food Law is supported by high quality, independent and efficient scientific and technical support and to secure a science based approach of the risks.
- To ensure the prevention of crises (adequate prevention and management of emergencies in order to prevent that they develop into crises).



2. Objective of the evaluation

The evaluation aims to assess the effectiveness and efficiency of the General Food Law Regulation and of the RASFF, its relevance in delivering EU added value, its coherence with wider EU policy priorities (synergies/trade-offs) as well as to focus on simplification and the reduction of regulatory costs and burdens.

EFSA is not subject to the evaluation since it was already evaluated twice and will be re-evaluated in 2017 (evaluation each 5 years).

The evaluation implies checking whether the fundamental principles and definitions (that had to be applied by all public authorities through the entire spectrum of food law) were effectively implemented. It also implies checking whether the new responsibilities/requirements for operators as well as the new procedures and tools that were created in order to better prevent and manage emergencies and crisis were fit for purpose.

3. Indicative evaluation questions

Looking closer to the objectives pursued by the General Food Law Regulation the study could indicatively examine some of the following issues:

I. GENERAL PROVISIONS AND REQUIREMENTS OF GFL

a) With respect to the objective of high level of protection of health and of consumers' interests

Fulfilment of the objectives

- To what extent has the objective of protection of consumers' health and interests (including fair practices in food trade) been achieved (both in primary and secondary legislation)?
- To what extent have the provisions in food law legislation achieved a global approach taking into account the protection of animal health and welfare, plant health and the environment?
- To what extent have protection of other interests than those covered by Article 5 of Regulation (EC) N° 178/2002 been achieved? Which are mostly those interests?

Role of business operators and public authorities

- To what extent have the general obligations (in particular safety, verification, traceability, withdrawal/recall and notification) contributed to the placing on the market (including imports and exports) of safer and more compliant food?
- To what extent have these general obligations contributed to the performance of fit for purpose withdrawals and recalls by food/feed operators?



- How have the rules concerning the repartition of responsibilities in the food chain been applied? Have they contributed to a consistent allocation of responsibilities in the field of food law across the EU?
- To what extent have those obligations entailed a fair and proportionate burden on food business operators?
- To what extent have the public authorities applied measures and penalties in case of infringements?

Precautionary principle

- To what extent have the public authorities implemented the precautionary principle?

Others

- To what extent were the provisions of Regulation (EC) N° 178/2002 (GFL) instrumental in achieving a higher level of protection of consumers' interests, in particular through the prevention of fraud and of misleading practices?
- To what extent is the legislation considered as too prescriptive? Is the unique nature of Member States markets and different cultures taken into account?
- Are there inconsistencies/gaps in the interpretation and implementation of the provisions of Regulation (EC) N° 178/2002(GFL)?

b) With respect to the objective of establishing a harmonised framework when adopting food law measures

- Have the provisions in place ensured a comprehensive and integrated approach of the food chain? Was the scope correctly defined?
- Have the provisions in place ensured a consistent and efficient use of the risk analysis approach?
- To what extent has the adoption of harmonised framework (including in MS) ensured transparency through public consultation of stakeholders during the preparation, evaluation and revision of food law and through public information ?
- What is the European added value of the EU Food safety regulatory framework established by the General Food law Regulation? (compared to what could be achieved by MS at national and/or regional levels as well as international (Codex, OIE) level).



c) With respect to possible actions for simplification and reduction of regulatory costs and burdens

- Which specific concerns and burdens to business (particularly SMEs) and public authorities in the implementation of the General Food Law have been identified?
- Which actions (legislative, non-legislative) for simplification and reduction of regulatory costs and burdens can be implemented in the area of General Food Law?
- Which reduction of costs in quantitative terms can be achieved? What are the specific costs, benefits (quantitative and qualitative) and risks of these actions?

Other issues

Whilst the overriding aim of the GFL – that of ensuring a high level of protection of consumers from risks associated with the food chain—is as relevant today as in 2002, there have been significant policy developments over the last decade calling for the need to strengthen the sustainability of the EU food system. It could therefore be opportune to consider possible implications of these policy developments for the GFL.

Looking to the future, our food system will need to continue to ensure a high level of protection of human health taking into account animal health and welfare, plant health and environmental safety whilst --at the same time-- promoting sustainability and minimising food waste.

Given this context, would stakeholders consider it relevant to address the issues of sustainability and food waste as part of the overall evaluation of the General Food Law?

This could further support the ongoing analysis of the sustainability of the food system and identification of opportunities to strengthen and minimise food waste without compromising on food safety.

As the General Food Law provides the overarching framework for all legislation related to food and feed, this would then ensure a consistent approach in the integration of sustainability criteria across relevant legislation.

II. RASFF

The RASFF was set up by Regulation (EC) No 178/2002 as a network involving the Member States, the Commission and EFSA. The members of the network shall immediately notify the Commission when a serious risk for human health deriving from food or feed is identified, and of any measure, recommendation or rejection of food or feed related to it. The Commission shall immediately transmit the information to the network, and also any supplementary information received.

The evaluation of RASFF could indicatively examine some of the following issues:



- The role of the European Commission as manager of the system, the efficiency of maintaining the system and the capacity to keep the members interacting.
- The scope of the RASFF, its risk-based functioning and the role of EFSA in the RASFF.
- The participation of third countries, international organisations and other stakeholders in RASFF.
- Its effectiveness examining in particular to what extent the objective of the GFL to establish tools in order to better prevent and manage emergencies and crisis were achieved.
- Its efficiency and in particular whether the outputs and effects were achieved at a reasonable cost. Or to what extent were the time and efforts taken well used?
- Its EU-added value: what is the additional value resulting from the EU rapid alert system compared to what could be achieved by Member States at national and/or regional levels?
- Its complementarity with other systems (Member States, international organisations).