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COMMISSION STAFF WORKING DOCUMENT

Impact Assessment on the Revision of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety on the establishment of fees for EFSA

SUMMARY

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SUMMARY

The European Food Safety Authority (EFSA) produces scientific opinions which constitute the scientific basis of the European policies and legislation on food safety. It supports the European Commission, European Parliament (EP) and European Union (EU) Member States (MS) in taking effective and timely risk management decisions. Among other public interest tasks (scientific opinions of general interest, data collection and analysis on safety trends of the food chain, scientific support in case of emergencies/crises), EFSA performs the scientific assessment of regulated products/substances/claims/processes (hereafter "regulated products") marketed in the EU in the food and feed safety fields. The opinions resulting from these assessments are the scientific basis for the marketing authorisations granted by the risk managers or for their decision to maintain such regulated products on the EU market.

According to its founding Regulation (EC) n° 178/2002, EFSA shall be financed by the European Union's General Budget (and shall receive a contribution from any State with which the EU has concluded an agreement).

Regulation (EC) n° 178/2002 foresees, however, that the possibility to introduce fees with regard to the processing of authorisation applications presented by industry should be examined after the entry into force of the Regulation and in the light of the experience acquired (recital 57). More specifically, Article 45 provides for the publication of a report on the feasibility and advisability of the introduction of fees within three years following the entry into force of Regulation (EC) n°178/2002.

On this basis, the Commission issued on the 23 September 2010 the Report on the feasibility and advisability of putting forward a legislative proposal which would enable the Authority to charge fees for services rendered. In the Report the introduction of fees appeared, at first glance, a viable solution for the EU to best use public money without affecting EFSA's work and independence.

Considering the incompleteness of the data available, the Report stated however that it was not possible to draw any definitive conclusion and suggested to launch an Impact Assessment (IA) in order to perform a more in-depth analysis.

The EP and the Council agreed on the conclusion of the Report and urged the Commission to perform an IA in order to gather the information needed to allow a reasoned decision on the possibility of introducing a fee system.

With the aim of verifying the conclusions drawn by the report and driven by the political will to explore the possibility of optimising the use of EU public funds, the Commission performed an IA on the possible introduction of a fee system for regulated products.

Considering the key role of EFSA’s work on food safety, the analysis did not focus exclusively on economic aspects. The IA's final goal was to verify whether the putting in place of a fee system would result in a reduction of EU contribution to EFSA's budget while

preserving, at the same time, the good performance and efficiency of the system, as well as EFSA's reputation in terms of quality and independence of its outputs.

It is important to note that the reputational considerations related to independence are based mainly on perceptions expressed by stakeholders in the context of the current operating framework of EFSA.

Also, the analysis carried out in the IA relates to the current tasks of EFSA, without prejudice to future tasks that could be entrusted to EFSA.

Stakeholders, Member States and other interested parties were consulted throughout the whole process. EFSA was associated with the work carried out during the IA and consulted where appropriate.

After the exclusion of some of the options originally proposed, 4 options were considered for further scrutiny:

Option 1: No policy change;

Option 2: Application fee for all applicants for risk assessment of new and renewal applications (a sub - option 2, excluding sectors where initial assessment is performed by MS, was also analysed);

Option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and renewal applications (a sub - option 3, excluding sectors where initial assessment is performed by MS, was also analysed);

Option 4: Fees for additional services for all applicants and for new and renewal applications.

All the proposed options envisaged a 90% fee reduction for SMEs, in order to minimize regulatory burden for SMEs and incentivize them to apply.

The IA showed that the workability and practicability of establishing "a posteriori" a global fee system for EFSA is problematic due to:

- Complexity of the legal framework, embracing 19 different pieces of legislation;
- Heterogeneity of the authorisation procedures with different sharing of work between EFSA's staff, EFSA's Panels, Member States and EU Reference Laboratory (EURL);
- Limited number of dossiers, variable from one sector to another, received by EFSA for the scientific assessment of regulated products and an even smaller number of eligible dossiers for fees;
- Member States and EURL already charge fees in the framework of the same authorisation process in certain sectors;
- Two types of authorisations granted (generic and individual) providing different benefits to applicants;
- EFSA was created mainly as a provider of services to public authorities.

An in-depth analysis of the options, in the light of the criteria and limits set forth in the IA, showed that none of those proposing the introduction of fees would ensure EFSA a satisfactory income, nor would they result in significant savings for the EU budget. In addition, the fluctuating number of applications would give rise to some problems of

manageability of EFSA's budget, creating a risk, particularly in Option 2, that some resources for public interest tasks would be re-allocated to the assessment of regulated products.

With regard to applicants, the level of fees is considered burdensome in particular because in some cases the fees would be additional to others paid in the framework of the same authorisation procedure. Also, the needs and characteristics of each of the 19 sectors and related markets are not sufficiently taken into consideration in a global system of fees with potential negative effects in term of competitiveness, innovation and growth.

Finally, considering the current context, the introduction of fees could affect the perception of EFSA's independence.

More precisely, for option 2 the expected income would cover only roughly 48% of EFSA's current expenditures for regulated products activities and this would reduce the EU budget contribution by only 15% of the current funding. In addition, applicants for generic authorisations (authorisations benefiting all operators) and applicants for individual authorisations (authorisation holders with exclusive rights) are subject to the same fee regime, which is considered as an unequal treatment given that different benefits derive from the two types of authorisation. Also, the payment of fees for generic authorisations could encourage economic actors to wait for another company to apply (free riding).

Sub-option 2 would provide EFSA with 40% of the current expenditure for regulated products activities and would entail an EU budget saving of roughly 12%. The burden generated by a double system of fees (EU and MS level) would be avoided, but problems of fairness and competitiveness similar to option 2 would remain since the sectors excluded from the payment of fees are characterised by the issuance of individual authorisations.

In Option 3 EFSA's income would be shrunk to 23% of the current expenditure for regulated products, meaning that only 7% of the current EU contribution to EFSA would be saved. By charging a restricted number of sectors, the majority of which are already partly paying fees to MS or to the EURL in the framework of the same authorisation procedure, there is a higher risk of affecting the competitiveness of the concerned food and feed market.

Sub-option 3 appears to be the fairest one, since it applies only to authorisation holders who are not paying fees at national level and it would have a minimum effect on competition. However, the fee income would be very limited (covering only 7% of EFSA's current expenditure for regulated products and granting the EU a reduction of only of 2% to its current contribution to EFSA), especially if compared with the investment that EFSA would have to make in order to establish and to manage a fee system.

Option 4 would ensure EFSA 60% of the costs of the additional services foreseen but would entail an additional funding from the EU budget of roughly EUR 2 Million per year for services which are provided in the public interest. The services proposed would not represent a clear added value for applicants since parts of them are not tailored to the needs of the applicants of each specific sector.

These findings were confirmed by the majority of stakeholders and Member States, who also suggested the maintenance of the *status quo* as the best option.

The IA concluded thus that the funding system in place should be maintained since within the current context none of the options proposing the introduction of fees would bring a clear benefit either for EFSA or the EU institutions, or for stakeholders.

The full Impact Assessment is **available** on the SANCO website (…….).