



EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2012)

Opinion

Title **DG SANCO – Impact Assessment on the establishment of fees
for the European Food Safety Authority**

(draft version of 1 August 2012)*

(A) Context

Regulation (EC) n° 178/2002 provides that the European Food Safety Authority (EFSA) should be financed by the Budget of the European Union. It foresees, however, the possibility to investigate the feasibility of introducing fees with regard to the processing of authorisation applications submitted by industry. In September 2010, the Commission published a Report on the feasibility and advisability of putting forward a legislative proposal which would enable the Authority to charge fees for services (COM(2010) 496 final). The report concluded that, considering the complexity of establishing a fee system in the area of EU food legislation, it was not possible to draw any definitive conclusion and more reflection was needed on the range of options to be considered. This impact assessment therefore examines the feasibility and impact of the introduction of a fee system for EFSA.

(B) Overall assessment

The report should be improved in a number of respects. Firstly, it should explain why there is a need for the EFSA to explore charging fees, for instance by recalling the problems related to its performance as well as to the quality of applications. Furthermore, the report should present a detailed cost allocation related to the processing of applications and should explain any constraints stemming from the current full funding from the EU budget. Secondly, the report should present policy objectives and options that would better relate to the main factor(s) behind introducing fees and the corresponding key design choices, such as the extent of the cost recovery, fee differentiation and exemptions. Thirdly, it should better assess and substantiate, or present much more cautiously, the alleged negative impacts of setting the fees, particularly on discouraging applications or hindering competitiveness. In addition, negative impacts on the perception of the EFSA's independence should be further analysed and possible mitigating measures explored. The report should also better assess the cost-effectiveness of the collection system and the impacts on the EU budget. Finally, it should present the different views of stakeholders in a more balanced and differentiated manner, particularly of those in favour of setting fees.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Strengthen the problem definition. The report should present the problem in a more comprehensive and balanced manner by explaining why the EFSA should start charging fees in the first place, spelling out the underlying budgetary and policy considerations. In doing so, it should recall the problems identified in the 2010 Feasibility report and identify any changes compared to the previous analysis (e.g. regarding the perception of the EFSA's independence). The report should in particular explain if the EFSA currently receives the necessary funding to perform its tasks adequately and substantiate this with evidence, such as performance indicators on the timeliness of its opinions, pending cases, stop-the-clock etc. Furthermore, it should analyse if the current system sufficiently incentivises the applicants to submit complete and high-quality files and explain the high cost differentials in assessing applications from different sectors. The report should then present a detailed cost allocation related to the processing of applications, while duly reflecting their complexity and differentiating between direct and indirect, variable and fixed costs. In this context, the balancing contribution from the EU budget should be analysed in further depth (in particular vis-à-vis an unexpected increase in the EFSA costs/workload). The alleged risk of budget instability should be better substantiated (given that, as envisaged in the Feasibility report, a number of fixed costs can be funded from the EU contribution to stabilise the EFSA budget). Finally, the report should more extensively refer to the existing fee systems in the European Chemical Agency and in third countries, such as Australia or the U.S.

(2) Improve the presentation of objectives and options. The report should present a set of clear objectives that would better correspond to the rationale for setting fees and to the available key design choices, such as the extent of the cost recovery (i.e. full or partial), the fee differentiation between sectors, applicants or applications and the design of the collection system itself. On this basis, it should present a wider range of policy options that would credibly address all the identified policy objectives. For example, the report should present options based on partial cost recovery, exempting (upfront) niche products with minor commercial potential or the EFSA peer-review services, including reviews (or better justifying why they should be discarded without further analysis). It should also better explain why the fee systems of the European Chemical Agency or in Australia cannot be considered as either feasible or appropriate. Based on the improved problem definition and the revised policy objectives, the report should better explain the reasons for discarding a number of alternatives.

(3) Better assess and compare impacts. The report should provide a more detailed and balanced assessment of impacts, underpinned by examples and concrete evidence. In doing so, it should build on the experience with introducing fees at national and EU level or third countries and should present the fees in perspective (i.e. in relation to the turnover or profit margin for producers). In particular, the report should substantiate the assertions related to the discouraging effect on applicants, the risk of double-charging, negative impact on the applicants' competitiveness and outflow of investment from the EU. It should further analyse negative impacts on the perception of the EFSA's independence and explore possible mitigating measures. The report should also better assess the cost-effectiveness of the collection system as well as the impact on the EU budget of the different options. It should acknowledge any uncertainty or lack of evidence and clearly explain the limitations of the assumptions made. Finally, the report should present a clear comparison of the options in terms of effectiveness, efficiency and coherence.

(4) Better present stakeholders' views. The report should present the views of different stakeholder groups in a more differentiated and balanced manner, especially concerning the problem relevance, refined options and the expected impacts. In particular, it should present the views of those in favour of fees (including the EFSA) and of Member States that already charge fees. The report should also clarify whether the European social dialogue committees

in the relevant sectors were consulted and present their views.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

In order to facilitate the reading for non-experts, the report and its Annexes should include a description of the functioning of the EFSA, its organisational structure and the way it shares work with Member States.

(E) IAB scrutiny process

Reference number	2012/SANCO/007
External expertise used	No
Date of IAB meeting	19 September 2012