



## Business panel



## SME PANEL ON EFSA FEE BACKGROUND DOCUMENT

### 1. Context

According to Regulation 178/2002<sup>1</sup>, 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, the European Commission should investigate the **opportunity to introduce fees with regard to the processing of authorisation dossiers presented by industry to EFSA.**

The legal framework imposing authorisation procedures for foods, substances, processes, or claims used in the food chain is mainly aimed at granting general approvals for the benefit of all operators. Under the current situation, the scientific assessment of regulated products in the food and feed sectors is entirely covered by the EU budget.

The applicant bears the cost of preparation of a dossier, which varies depending on the characteristics of the application and the sector to which it relates.

In certain cases, the authorisation is not generic but granted to specific authorisation holders that derive particular economic advantages from the authorisation system.

The processing of authorisation dossiers by EFSA is paid for by public money, even if the authorisation is also expected to benefit the applicant and more widely the producers and users of

<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT>

the authorised substance, process, test or claim. Therefore the question arises whether public money should be used for private interests.

EFSA has to process applications that fall under different pieces of legislation requiring scientific assessment and/or reassessment through mechanisms which, unlike the pharmaceutical or chemical sectors, have not been designed to integrate a requirement for a cost-recovery system.

There are in total 18 sectors concerned by the possible introduction of fees along the food chain. Each sector presents its own characteristics in terms of actors involved in the application process, different role of Member States, EFSA, European Commission, different value and structure of the market.

The authorisation of regulated product has an important impact on the European food market and the introduction of fees should be evaluated in the light of the impact on innovation, access to the market and competitiveness of European industries.

The distribution of potential costs and of the benefits of the proposals will depend on the size of the business. For this reason, it is important to establish to which extent the different options considered in the impact assessment (mandatory fees for all applicants, mandatory fees only for authorisation holders or administrative fees for all applicants) will affect the competitiveness of SMEs and micro-businesses, their business environment and all the other aspects related to the potential introduction of an additional financial cost (fees).

The preliminary analysis carried out has shown that, while part of the market in some areas is highly concentrated (presence of 4/5 big industries operating on the market) others are characterized by a high number of SMEs (90%).

In the context of the ongoing Impact Assessment (IA) on the possible introduction of fees for EFSA, it is therefore relevant to gather data on the Small and Medium-sized Enterprises operating in the 18 sectors, which could potentially be affected by the introduction of fees for authorisation applications to EFSA.

The data gathered will have a double use. On the one hand the data will be used to evaluate and quantify the potential impacts on Small and Medium-sized Enterprises of the selected policy options and on the other, they will be used to perform the SME-test required by the IA.

The objective of the consultation is to gather information and quantitative data on the characteristics of the Small and Medium-sized Enterprises operating in the 18 sectors (number of employees, turnover, costs related to the preparation of a dossier to be submitted to EFSA , investments in research and development, possible barriers to access to the market, capacity to innovate).

In light of the results of the survey, the Impact Assessment will foresee a particular regime and/or exception for Small and Medium-sized Enterprises for the options contemplating the payment of fees to EFSA for the submission of authorisation application dossiers.

Please note, it is extremely important that the questionnaire is addressed to the Small and Medium-sized Enterprises that are **producers and/or importers** in one of the 18 sectors listed below:

1. Plant Protection Products: active substances (PPP)
2. Maximum Residues Levels (MRL) of PPP
3. Genetically Modified Organisms (GMO)
4. Flavourings
5. Smoke flavourings
6. Extraction solvents
7. Food enzymes
8. Food contact materials
9. Food additives
10. Nutrient sources
11. Feed additives
12. Transmissible Spongiform Encephalopathy (TSE) tests
13. Animal by-products
14. Antimicrobial treatments
15. Health claims
16. Novel foods
17. Infant formulae
18. Food allergies

**NACE classification:**

NACE 10.11 : Processing and preserving of meat

NACE 10.12 : Processing and preserving of poultry meat

NACE 10.13 : Production of meat and poultry meat products

NACE 10.20 : Processing and preserving of fish, crustaceans and molluscs

NACE 10.31 : Processing and preserving of potatoes

NACE 10.32 : Manufacture of fruit and vegetable juice

NACE 10.39 : Other processing and preserving of fruit and vegetables

NACE 10.41 : Manufacture of oils and fats

NACE 10.42 : Manufacture of margarine and similar edible fats

NACE 10.51 : Operation of dairies and cheese making

NACE 10.52 : Manufacture of ice cream

NACE 10.61 : Manufacture of grain mill products

NACE 10.62 : Manufacture of starches and starch products

NACE 10.71 : Manufacture of bread; manufacture of fresh pastry goods and cakes

NACE 10.72 : Manufacture of rusks and biscuits; manufacture of preserved pastry goods and cakes

NACE 10.73 : Manufacture of macaroni, noodles, couscous and similar farinaceous p NACE

10.81 : Manufacture of sugar Products

NACE 10.82 : Manufacture of cocoa, chocolate and sugar confectionery

NACE 10.83 : Processing of tea and coffee

NACE 10.84 : Manufacture of condiments and seasonings

NACE 10.85 : Manufacture of prepared meals and dishes

NACE 10.86 : Manufacture of homogenised food preparations and dietetic food

NACE 10.89 : Manufacture of other food products n.e.c.

NACE 10.91 : Manufacture of prepared feeds for farm animals

NACE 10.92 : Manufacture of prepared pet foods

NACE 11.02 : Manufacture of wine from grape

NACE 11.05 : Manufacture of beer

NACE 11.06 : Manufacture of malt

NACE 11.07 : Manufacture of soft drinks; production of mineral waters and other bottled waters

NACE 20.12 : Manufacture of dyes and pigments

NACE 20.13 : Manufacture of other inorganic basic chemicals

NACE 20.14 : Manufacture of other organic basic chemicals

NACE 20.15 : Manufacture of fertilisers and nitrogen compounds

NACE 20.16 : Manufacture of plastics in primary forms

NACE 20.53 : Manufacture of essential oils

NACE 20.59 : Manufacture of other chemical products n.e.c.

NACE 21.10 : Manufacture of basic pharmaceutical products

NACE 22.21 : Manufacture of plastic plates, sheets, tubes and profiles

NACE 22.22 : Manufacture of plastic packing goods

NACE 22.29 : Manufacture of other plastic products