



EHPM Response to the Commission Consultation Paper on Potential fees for EFSA

The European Federation of Associations of Health Product Manufacturers (EHPM), represents the interests of specialist health products manufacturers, in particular food supplements, in Europe. The EHPM brings together 26 associations from 22 European countries and represents more than 2000 health product manufacturers including large pan-European companies and many SMEs. We are grateful for the opportunity to reply to the Commission consultation on the feasibility and advisability of presenting a legislative proposal enabling EFSA to receive fees for processing authorisation files.

The European food supplements industry contains a very high proportion of SMEs, about 85% of companies in trade association membership. The industry relies on innovation to reflect emerging science in the areas of nutrition, dietetics and health. In view of this, and in accordance with the Lisbon agenda, we are not favourable to the addition of a financial burden to the already high cost of compliance with the series of newly adopted legislation and changes to existing requirements that particularly challenges the SMEs of our sector.

We would like to offer the following detailed comments to the consultation paper:

1&2. Tasks rendered by EFSA and scope of the consultation

At present, we understand from the consultation that EFSA envisages raising fees for the delivery of opinions in the following areas of interest to our sector:

1. Assessment of nutrients and their sources for addition to the positive lists contained in Directive 2002/46/EC on food supplements, Directive 2001/15/EC on nutrient sources for foods for particular nutritional uses (PARNUTS) and Regulation (EC) N^o 1925/2006 on the addition of vitamins, minerals and certain other substances to foods.
2. Assessment of the scientific substantiation of health claims under Regulation (EC) N^o 1924/2006
3. Assessment of referrals from the European Commission or member state competent authorities on issues pertaining to the authorisation of novel foods or novel food ingredients.

We note that the financial impact of potential EFSA's fees has not be taken into account in the impact assessments conducted prior to the adoption of these legislation and that therefore charging fees would be contrary to current better regulation policy of the Commission.

It is reported that some EFSA tasks may bring direct profit to individual natural or legal persons, notably in cases where EFSA assesses authorisation files under centralised Community procedures culminating in the granting of a marketing authorisation for a product or substance.

We believe that in the areas of assessment identified above, it would not be the case. In the majority of the cases, the submissions made are of a general nature and intended to culminate in the granting of an approval and addition to a general positive list of substances that benefit all operators. This is for example the case for the granting of approval to use a nutritional substance, which has been subject to a favourable EFSA evaluation, and its addition to the positive lists under the annexes of the Food Supplement Directive, hereby allowing it to be used by any manufacturer of food supplements. No exclusivity, nor protection of proprietary data is provided to the submitter, thereby making it difficult to identify a specific direct benefit for the applicant.

Therefore we are of the opinion that the legislative texts requiring authorisation procedures for foods or ingredients, and involving an evaluation by EFSA, are mostly resulting in the granting of general approvals for the benefit of all food operators. These should not be subject to fees.

3. Situation at community level

3.1 European Medicines Agency

The Consultation document refers to the experience of the EMEA. This agency is very different from EFSA in terms of competences and notably given that it provides authorisation to market medicinal products, a competence that can be considered as providing a direct benefit for industry applicants, especially as exclusive data protection is granted to the applicant. EFSA acts as a European risk assessor providing opinions to the risk managers, and therefore does not directly provide a benefit to industry applicants since, even if it has provided a positive opinion, there is no guarantee that the risk manager will give an authorisation to market. This has been illustrated recently by some member states' refusal to endorse the authorisation to use boron in food supplements, despite a favourable EFSA opinion on its safety of use.



3.2.3 Novel Foods and Novel Food Ingredients Regulation EC 258/1997

As stated in the Consultation Paper, some member states have imposed fees for the assessment of the dossier. These fees can range from euro 2,000 to 26,000, which is already extremely high. It is unclear from the Consultation Paper whether the members states' fees would cover the referrals from the member state competent authority or the European Commission of the whole or part of the dossier to EFSA for an opinion. This needs to be clarified as a fee from EFSA for an opinion could impose an additional and un-budgeted financial burden on the applicant.

4. Options for identifying those liable to pay fees

4.1 & 4.2 - Options 1 & 2

In the case of the assessment of nutrients and their sources for addition to the positive lists contained in Directive 2002/46/EC on food supplements, experience with the provision of derogations for substances under Article 4 of Directive 2002/46/EC on food supplements has shown that a very high proportion of the applications were for generic rather than proprietary substances. In the particular case of this Directive's derogations, there was a diverse range of applicants for the generic substances, including trade organisations. Such cases are envisaged in the second indent of Option 2 of Section 4.1 of the Consultation Paper.

It is accepted that applicants for proprietary ingredients for which they have a monopoly in the form of either having patents or an unique process could possibly be considered as falling into a fee-paying category. However, as many of such applicants are innovative SMEs, the fees should at least be fairly low (e.g. euro 1000 – 5000) so as not to discourage innovation.

4.3 Questions

The above commentary outlines the specific problems faced by the European food supplements industry and we therefore cannot accept Option 1, i.e. that all applicants must pay a fee.

Option 2, i.e. that only applicants with profits specifically vested in the authorisation must pay fees, is preferred for the reasons outlined above. Indeed, we believe fees should possibly only be charged for



applications where the applicant would have a monopolistic advantage and also provided that a realistic and low fee structure is applied to SME applicants who form the majority of the supplement industry.

5. Options – advantages & disadvantages of charging fees

5.1.2 - Option 1 - Disadvantages

We cannot agree with the assertion that if EFSA's procedures are entirely free of charge, there is no financial risk for the applicant who submits an invalid file and that fees would limit the submission of frivolous application.

SMEs are already often lacking the necessary procedural expertise to prepare dossiers for submission to EFSA and must have recourse to external expertise for preparing files. They would be further penalised if EFSA would also charge them for its review of the files. So preparing a file entails a real financial risk for a SME.

As for frivolous dossiers, a simple solution is for EFSA to produce clear guidance on the necessary information and format for submission of files, as is already the case for additives authorisation for example, and to return immediately files that are not submitted in accordance with the guidance and format.

5.2.1 – Option 2 - Advantages

We would like to point out that the lack of resources of EFSA in the 2007-2013 budget is the result of the budgetary restrictions voted by the Council and the Parliament and that industry should not have to pay the costs of the lack of support from the national governments and parliamentarians. Our sector is supportive of an overall increased budget for EFSA through the general budget, given the key role EFSA has to play in relation to the general public health and notably food safety.

The consultation paper states that fees result in highly professional quality for services rendered and a better and faster assessment of innovative products. We would strongly argue that if fees are adopted, there must be clear timings set for the delivery of opinions and a transparent procedure for the assessment of files, with a formal right of dialogue between the applicant and EFSA before the adoption of an opinion. This guarantee for a transparent and clear procedure, allowing the applicant to judicially challenge EFSA in case of non-respect of the



procedure is currently lacking as was pointed out by a recent case of the Court of Justice case¹ on the Food Supplement Directive.

Also if fees are adopted, we agree that any fee system must be based on real costs of service rendered which must be measured by appropriate analytical instruments, and that practical specific measures for SMEs must be considered. In that respect, we regard the experience of EMEA measures in favour of SMEs (p 5) as worth considering, in particular regarding the reduction and exemption of fees, as well as postponement of fees until the end of the assessment procedure.

5.2.2 – Option 2 - Disadvantages

The Consultation paper also indicates that the size of the European market reduces the economic impact of the fee as firms granted a centralised authorisation would have access to all 27 member states market. This is not the case for SMEs who often do not have the resources to market in more than one or two neighbouring countries because of the costs incurred. This also ignores the fact of existing barriers to trade for food products in various non-harmonised areas preventing SMEs to enter other markets.

Besides, we note that the advantages listed (more appropriate funding for complex and costly scientific assessment, incentive for scientific excellence, enhanced opportunities for co-operation and synergy between EFSA and national agencies, disappearance of processing gaps) are all of a general nature and are equally applicable to EFSA's general interest activities.

5.3 Questions

As already stated, a fee structure applied indiscriminately for all assignments undertaken by EFSA will have a serious impact on innovation in the important areas of nutrition and health.

In response to the questions in 4.3 (above) it is accepted that a realistic and low fee structure may possibly be appropriate in cases where the applicant will have a monopolistic advantage and the authorisation is very specific to the applicant.

However, in the majority of cases, and particularly in the food supplement industry, applications are likely to be more generic and we can not agree that fee be required for applications benefiting all operators.

¹ Case C-154/04 of 12 July 2005.



Therefore the EHPM has to prefer Option 1 (5.1), i.e. no fees for processing authorisation files, with the proviso that modest fees could possibly be applied to applications for the authorisation of proprietary substances / claims where the applicant benefits from a direct advantage over its competitors, although this determination remains very difficult in practice.

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Conclusion

EHPM firmly believes that the lack of funding for EFSA should be resolved through an increase in the General Community Budget and not through the setting up of a general fee system for the delivery of EFSA's opinions.

We consider that there are no compelling arguments in the consultation paper justifying the charging of fees for authorisation files benefiting all operators and that where fees could be justified for an applicant gaining a specific advantage, specific measures for SMEs applicants should be envisaged.

We are very concerned that a fee charging policy would be particularly detrimental for SMEs and would not encourage innovation.

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