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PLATFORM FOR INGREDIENTS IN EUROPE

PIE response to the Commission consultation paper on the feasibility and advisability of presenting a legislative proposal enabling the EFSA to receive fees for processing authorisation files

Contributor

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Sector of activity : trade association of nutritional food ingredients manufacturers.

General comments

We have reservations about the structure of the consultation document, since the options for identifying those liable to pay fees are considered before the options on advantages and disadvantages of charging fees. We would find it more appropriate to start with the second part of the consultation, and our contribution is built accordingly.

Advantages and disadvantages of charging fees

Q: Which option do you prefer, and why?

→ **PIE members believe that Option 1 is the most adequate, i.e. EFSA is not entitled to charge fees for processing authorisation files.**

The consultation document adequately addresses the **advantages** of such an approach, if combined with the paragraph 5.2.2., i.e. the disadvantages of Option 2¹ as follows:

- “Risk of a perceived reduction in the independence of EFSA’s scientific opinions. EFSA could more easily be exposed to charges of lack of independence if it is partially funded by industry”.

Actually, the EFSA’s alleged “lack of independence” has been pointed out at several occasions over the past months, which proved to be detrimental both for European institutions and for applicants: this is unfortunately a very sensitive issue, that can be easily exploited for political reasons. **We sincerely believe that the Authority needs to be**

¹ i.e. EFSA is entitled to charge fees for processing authorisation files.

beyond reproach since it is essential for its credibility. Even partial funding of EFSA's activities by industry will open the door to criticism in that respect, and will serve neither the interests of the European Institutions, nor the interests of industry.

It is paramount that a centralized risk assessment by EFSA is accepted by national agencies, which means an absolute need for trust and confidence in EFSA assessments. A partial funding of EFSA by industry may reduce this confidence and trust, especially in Member States where such fees are not currently applicable.

- *"Companies applying for authorisations incur additional costs, i.e. the payment of the fee, before being able to place their products on the market, which may undermine their competitiveness."*

This is particularly true for SMEs.

- *"The introduction of fee charging for every file assessed may not always guarantee a stable annual EFSA budget, since the number of files for assessments may vary unpredictably from year to year. In addition, fee charging may provide grounds for reducing public funding even though such contributions are necessary for stable and efficient management of all of EFSA's scientific activities of general interest."*

We deeply regret that the funding for EFSA for 2007-2013 is 15/20 % below the amounts considered by EFSA as necessary to cover the tasks foreseen by its mandate. **We believe that EFSA is a key organisation in the risk assessment as part of food and feed safety, and we consider it paramount that it beneficiaries from an adequate funding from the European Union.**

It should also be pointed out that the administrative recovery of fees would lead to additional administrative costs to EFSA.

We disagree with certain statements made in the section "disadvantages" of this Option 1:

- *"The public budget continues to fund activities conferring special benefits on certain firms, whereas these public funds, restricted by definition, could more usefully be devoted to activities of general interest."*

We would remind that the EFSA activities result from the implementation of the European food and feed legislation, and industry applicants are not be blamed if the legislator decides to engage public funds in those activities (which we besides consider to be of general interest!).

Also, we would point out that risk assessments undertaken by EFSA are mandated by the Commission, the European Parliament, the Member States and at their own initiative, not by firms directly.

- *"The lack of fees make the concept of individualised service less obvious and may not be conducive to bringing in more efficient and more modern methods of managing authorisation files."*

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If we understand correctly, this statement assumes that the EFSA is possibly not putting currently enough efficient and modern methods of managing authorization files: should it be the case, we do not see to what extent fees could help solving what would appear more as an EFSA internal organizational matter.

- *“The absence of costs for applicants may in some cases culminate in files submitted by industry which are not adequately supported by proper scientific studies. If EFSA’s assessment procedure is entirely free of charge, there is no financial risk to an applicant who submits an invalid file. If EFSA cannot charge fees, it cannot retain file-processing fees either. This state of affairs means unjustifiable costs and wasted time, to the detriment of other public-interest tasks. National fees, even fairly small ones, introduced for the processing of files on items such as novel foods and ingredients have the added advantages of limiting the submission of frivolous applications”.*

Manufacturers of e.g. novel food ingredients generally have no interest in such “frivolous” applications.

Q: if Option 1 is chosen, what factors could, in your opinion, mitigate against the loss of this potential source of finance?

First and foremost, it might be useful to recall that the EFSA ‘s mandate is related to **food and feed safety**. Additional tasks in the general framework of public health might be wished, but the financial resources should be primarily affected to the core activities of the Authority. In that respect, the prioritisation of the EFSA’s tasks for 2007-2013, keeping the initial mandate in mind, might contribute to solve part of this funding issue.

One of these priorities should be the safety assessment of new substances such as new food ingredients. This is essential in a perspective of continuous development of the European ingredient industry, who dedicates considerable efforts in the Research & Development of innovative food ingredients, some of which need the “safety” rubber stamping of EFSA before being used by the food industry, and further benefit to the consumers.

It should be noted that more and more tasks are given to EFSA as a consequence of recent Regulations in the field of nutrition (claims, nutrients profiles etc), however without allocated the necessary additional resources.

We would recommend a **better interaction between EFSA and the originator of the request** (very often the European Commission) at the very early stage of a possible request for a risk assessment: actually, appropriate discussions between EFSA and the originator of a possible request would be helpful to assess if there is a real need for EFSA to be involved in the matter, and to what extent this involvement would be necessary (i.e. is an opinion necessary, or is a statement in the minutes of a meeting be enough to clarify the matter?): this could help restricting the number of requested opinions to those for which the need is real.

Also, in line with the EFSA six key priorities, a **better scientific cooperation and networking with Member States** may help taking advantages of national expertise and resources, and avoid duplication of assessments.

Finally, the **rationalizing** of the EFSA Panels meetings location and the increasing use of electronic work may be useful to make better use of EFSA resources.

Options for identifying those liable to pay fees

As explained previously, **we consider that the consultation on these options is not relevant if the previous choice is in favour of Option 1.**

However, we would offer the following comments in principle:

Q: Are the factors listed above the most important ones for identifying the advantages and disadvantages of the two options? If not, indicate other essential factors.

The consultation paper gives a good overview on the two options. However, it does not include very clearly the provisions of the legal regime for fees, as is described in page 3 : public *versus* private goods, according to which - if we understand correctly - only a well identified beneficiary from the services can be submitted to fees.

Q: Which option do you prefer, and why?

We consider that none of the two options is adequate.

→ Even if a well identified applicant is at the origin of the request for a new substance, the authorisation might benefit in the short term (generic authorisation) or in medium term (specific authorisation) to all interested manufacturers: it would not be fair that a single manufacturer be penalised for its innovative efforts.

→ Intellectual property rights such as patents funded by the applicants are time-limited. Although they are intended to give the exclusive right to the inventor to use the invention, in practice this protection may be weak: actually, unless the substance as such is covered by the patent, the patent infringement is not easy to prove, specifically as regards substances produced in third countries: hence, the protection granted by a patent covering the production process or the product application, as is the case for most food ingredients, is far from being absolute.

→ In the case of generic authorizations, an approach “by sector” would simply not be realistic! Numerous food ingredients are not organized by sectors – hence there would be “orphan” substances. Also, this approach does not take account of the confidentiality aspects surrounding the R&D activities of manufacturers who would be understandably reluctant to share their dossier to EFSA with their competitors on the grounds of a “sector” approach.

→ Arbitrary implementation of fees to EU industry would lead to a distortion of competition in the international market. Fees for the assessment of a substance and its subsequent authorisation in the EU would be paid by the EU manufacturer, which would be put in competition with importations of the same substance produced in third countries and not subjected to the assessment fee.

→ Reference is extensively made to the EMEA, which receives fees paid by pharmaceutical companies for the assessment of authorisation files on medicines for human or veterinary use. We consider that the comparison of the assessment of active pharmaceutical substances and food ingredients is simply not valid: intellectual property rights are much more substantial in the

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pharmaceutical industry than in the food ingredients industry; the application dossier for an active pharmaceutical substance is by nature significantly more extensive than the dossier for the authorisation of a food ingredient; finally, costs of medicines are partially reimbursed to the patients from public funds, which could possibly be seen as a rationale for establishing fees paid by pharmaceutical companies.

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