



FEFANA contribution to the consultation paper on the feasibility and advisability of presenting a legislative proposal enabling the European Food Safety Authority (EFSA) to receive fees for processing authorisation files.

Interest for the consultation.

FEFANA is the EU Association of Feed Additives and Premixture Manufacturers. The membership of the association covers the whole range of additives included in the scope of Regulation 1831/2003, with the exception of anticoccidials. FEFANA representing one of the sectors identified for being possibly submitted to an EFSA fee system (i.e. section 3.2.2 of the consultation paper) has a direct and major interest in the consultation.

Summary position

FEFANA is opposed to the proposal that EFSA should levy fees from applicants presenting dossiers for consideration for authorisation of additives pursuant to Regulation (EC) No 1831/2003 for legal, practical and political reasons.

Answer to Question 1.

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. Which option do you prefer and why?

In the consultation document – section 4.3 – it is asked which option for levying fees is preferred, based on holder specific / non-holder specific or profitability basis. Neither is preferred for the reasons listed below.

1. **Legal basis for raising fees:** FEFANA challenges the legal interpretation of 178/2002 which is used as the basis for this consultation. The consultation document states it is based on Article 45 of 178/2002 which refers to the feasibility and advisability of legislation on fees received by EFSA. The reference in the consultation omits the full sense of Article 45 which goes on to state that such legislation on fees relates to “other services provided by it (EFSA)”. EFSA is **mandated** to provide community institutions with “...the best possible scientific opinion in all cases provided for by Community legislation and on any question

- within its mission...” It is quite apparent that the review of dossiers is one such activity provided for by Community legislation and does not constitute “other services provided by EFSA”, and as a result fees cannot be considered for dossier review.
2. **Scope of EFSA:** EFSA’s mandate is related to food and feed safety. Additional tasks it undertakes in the general field of public health may be envisaged, but re-directing some of its scarce resource to recouping income is clearly out of scope. There will certainly be increasing pressure on these resources over the next 3 years as the date for re-authorisation of almost all additives looms. FEFANA believes EFSA’s resources should be focussed fully on ensuring the process of dossier review is as seamless and accurate as possible. Collecting fees from the industry is an unnecessary and potentially hazardous diversion.
 3. **Rationale:** The rationale for levying fees from applicants seeking authorisation of a feed additive is fundamentally flawed. If the fee is nominal then there is little point in its collection since it will cost as much to administer as it will collect, yet this process will add an additional administrative burden to the regulatory process for no gain. If the fee is designed to fully recover the costs of the review process in total, then the costs would be sufficient as to stifle competition. For example, SMEs would be even less able to afford the EU regulatory process. This would drive operators to consider seeking registration and sale of their products outside of the EU, where no such hurdle exists. Moreover, FEFANA believes this proposal is simply a means to address a budgetary problem within EFSA which is not of the industry's doing. The activities for which EFSA are requesting industry funds are driven by implementation of the legislation put in place by the EC, not through activities of the industry. As a result FEFANA cannot see the justification for levying fees to address a possible short-fall in funding in an EU organisation for an activity which has been mandated by the EU.
 4. **Precedent:** The precedent for such a proposed fee structure is not good. The CRL fees levied for auditing methods of analysis of feed additives, which has not been actively opposed so far by the industry, is already considered for revision to higher amount. This fee is now clearly seen as a direct tax on the industry, which might raise several legal concerns. This is an unacceptable situation, and with no fair arbitration process for control of the fee scale levied, it is likely to quickly get out of hand. The industry should not be seen as a direct source of finance for governmental bodies.
 5. **Anticompetitive effects:** Levying of any fees will be anticompetitive. In the case of products under non-holder-specific authorisation, the first to market the product will bear the full fee schedule whereas the followers will reap the benefits with no similar costs. Furthermore in the case of innovative products where EFSA would need time to understand a novel product/process, the innovator would presumably be levied a fee which is disproportionate to subsequent copycat producers. The levy structure itself may be seen to be anticompetitive. If SMEs were charged as much as large corporations this would constitute a relatively larger hurdle for them to overcome. If large corporations were charged more than SMEs, it would be hard to justify the differential fees for delivery of exactly the same service when the fee setting criteria was based solely on size of the applicant. The justification that the industry makes profits on the products which are subsequently sold ignores the fact that some are linked to low volume or low margin products whereas others are more profitable, independently of the size of the applicant.
 6. **Poor examples of successful fee collection:** Continued comparison with the pharmaceutical and agricultural chemicals industry is also not legitimate – the very scale of these industries is an order of magnitude removed from that of the feed additive industry, with the result that their ability to cope with fees is much greater. In addition, the pharmaceutical and feed

additive industries work in a very different environment. Pharmaceuticals by their very nature require far more extensive dossiers than feed additives, and costs of medicines are partially reimbursed from the public purse, not industry, which is possibly seen as a rationale for establishing fees paid by pharmaceutical companies. The hurdle of an extra fee for dossier review will, in FEFANA's opinion, fundamentally change the landscape and range of additives offered in the EU unless a very complex system were put in place.

7. **Lack of any benefits:** One comment in the pre-amble of the EU document states that an additional benefit of such fees would be to reduce the number of frivolous dossiers submitted for review. FEFANA is frankly at a loss with this statement. The costs of the studies necessary for registration of a feed additive are onerous, and as a result no company would invest the amount of time and money required to get a product placed on the EU market without paying a great deal of attention to the dossier contents. Rather than introducing fees to improve dossier quality, FEFANA would be far more appreciative of clearer guidelines and guidance so that the contents of dossiers readily address not only the requirements for proof that the additives are safe for all concerned but also EFSA's evolving expectations.
8. **Conflict of interest:** FEFANA does not believe that it is a healthy situation where the regulatory authorities or their proxy may end up relying on the industry for a substantial portion of its funding. This will leave the regulatory authorities open to accusations of bias in some decisions by the general public, which will damage the credibility of EFSA as a truly independent authority, and as a result FEFANA strongly opposes such a position.
9. **Prioritisation and resourcing:** If fees are levied for review of the dossier, then how will EFSA prioritise this work against other activities that EFSA are tasked with? Would dossiers take precedence on resources as a result of their direct funding and presumably contractual status or would they be subjugated compared with EU tasks? Either situation has unhealthy ramifications which FEFANA believes will bring EFSA, the EU and the industry into disrepute. There will also likely be time periods where there will be significantly more needs for review than others. FEFANA sees the period of 2008 to 2010 being particularly busy due to re-authorisation of most of the notified 2500+ additives whose registration expires in 2010. After this period there will be a relative lull. If funding from the industry became a significant part of EFSA's resourcing then there would be unmanageable fluxes in income.
8. **Financial accountability:** With ever greater scrutiny of accounts and invoices, the industry is rightly challenged to ensure that any payment for a service or product can be justified and audited. If a fee were to be levied then the industry would need a detailed account of precisely what it is getting for the money spent – i.e. the activities for which it has paid. Presumably there would need to be a contractual agreement stating these deliverables, which would get the industry and regulatory authorities into legal obligations with one another. This, in the view of FEFANA, would be inappropriate. The alternative would be to consider the fees as a tax, what would obviously raise conflicts with the Treaties.
9. **Reduction in categories covered.** The implementation of a fee schedule will force companies to re-evaluate the economic viability of supplemental dossiers for categories of animals which do not represent a large volume of sales. In FEFANA's view this will lead to orphaned categories of animals, where the availability of additives will be severely limited for some of the smaller segments of EU agriculture

For these reasons, FEFANA considers that no applicant should be charged any fee by EFSA for authorisation of dossiers.

Answer to Question 2.

Which option [EFSA is entitled to charge a fee or not] do you prefer and why? If option 1 is chosen, what factor could, in your opinion, mitigate against the loss of this potential source of finance?

FEFANA supports the option 1 (EFSA is not entitled to charge fee for processing authorisation files). All of the arguments which are presented in the document which support levying fees are addressed in sections 1-9 above. In particular, FEFANA is alarmed by the assertion in 5.1.1 para. 3 that “fees usually result in highly professional quality criteria for services rendered.” If this is not the case today then EFSA is not meeting its requirements set by the COM.

Regarding mitigating factors, the first point is that we do not see the fee as a potential source of finance as detailed under point 1 above. An alarming conclusion that FEFANA draws at present is that the EFSA should not be forced to consider this ill-considered route to right a funding shortfall. This is presumably a problem even today, and is a result of potentially inadequate consideration of EFSA’s needs by the EU in its conception. FEFANA is not only concerned for the future, but present-day capabilities of the EFSA as a result. Approaching the industry to address this issue is not an appropriate route in FEFANA’s view.

All companies which are registered and trade in feed additives in the EU pay towards EFSA and the EU through taxes. It seems untoward that additional funds are being requested by a regulatory body from the very industry that it is charged to regulate. As new additives are brought to the market they benefit far more than the additive industry itself. The feed industry benefits, indeed the public at large as additives bring sustainable production and jobs, and moreover are essential for minimising wastes and maximising efficiencies of energy and protein utilisation in the production of farm animals. If the additive industry is faced with yet additional costs for bringing forward innovative products, then the rate of introduction of new products will slow and the EU will become less competitive and more wasteful in its production of animals. This is a situation that neither the authorities nor the industry should aspire to. FEFANA is therefore suggesting that the resources of the COM and EFSA focus on simplification and clarification of the evaluation of safety of additives on the market through delivery of clear guidelines and guidance notes, and refrain from increasing hurdles and costs in the process of feed additive authorisation.

Contact person:

Didier Jans
Secretary General
FEFANA Asbl
Av. Louise 120 Box 13
B – 1050 Bruxelles.
dja@fefana.org