



European Food Safety Authority

Chair of the Management Board

DRAFT LETTER

Dear Robert,

The Management Board of EFSA has examined in detail the European Commission's public consultation paper considering the feasibility and advisability of Co-Decision legislation on fees to be received by EFSA for its activities in line with the provisions of Article 45 of Regulation (EC) 178/2002, which was published in November 2006. The Board very much appreciates the flexibility of the Commission in enabling EFSA to comment beyond the cited deadline to enable it to have a full discussion of its views on the implications of fees to EFSA.

The Board would like to emphasise the need for EFSA to be sufficiently funded to deliver its mandate according to its Founding Regulation. EFSA has to be able to be responsive to new and emerging issues and provide risk managers with robust risk assessments based on the best available science. It has to be able to act independently of political, economical or other undue influences and to be seen to be so acting. Only with independent and scientifically excellent scientific risk assessments can risk managers build confidence in the decisions they take.

Although the Board would like to express its views on the consultation document, it also understands that the source of EFSA's funding is clearly a matter for risk managers. EFSA would like however to be consulted at all stages of any follow-up actions which may result in changes to EFSA's funding structure.

With this in mind the Board has focused on 7 key points resulting from the issues raised in the consultation paper:

1. EFSA needs to be adequately funded. This needs to be true whether or not a fee system is introduced so that EFSA can deliver scientific risk assessments across all its remit, and continue to communicate on its findings.
 - EFSA may need more income in the future to fund all its activities which increase with almost every legislative act in the areas covered by it. This is important whether this comes from the EU budget, which is the case at the moment or supplemented by a fee for a specific authorization service. In the Community system the amount of a fee must be proportional to the

cost of the service rendered so there would be no benefit to EFSA's other activities. If fees were to form part of EFSA's funding the amount available for this element would vary depending upon the number of dossiers submitted which would introduce an element of uncertainty to resource allocation and planning. It is therefore not clear whether charging a fee would indeed assist with the overall EFSA budget. EU Agencies will continue to be placed under financial scrutiny and have to keep a tight rein on expenditure. Thus it is probable that the Budgetary Authority would in fact reduce its contribution to EFSA's budget *automatically* to take account of any income accrued from fees.

2. The introduction of fees should not result in a skewing of EFSA's priorities themselves.
 - EFSA has to be able to play its part in building confidence in the European food supply and the system that underpins EU food and feed law. This includes working in those areas that would not attract fees. EFSA has to be able to determine its priorities based on public health, plant or animal health and welfare needs, the needs of the legislative programme as well as providing evaluations of substances or products which may lead to authorisations for their marketing. If fees are to be part of EFSA's funding it should be clear that the important self tasking work which enables EFSA to develop new risk assessment methodologies, or determine the significance of an emerging risk should not be put under pressure by the need to meet the demands of those paying fees for evaluations of substances or products. EFSA thus needs to be able to maintain a balance across all its activities when determining its work programmes.
3. There must be no detriment to EFSA's independence or the perception of its independence which could reflect on the overall EU system for food and feed law.
 - It is possible that under a fee system industry may require EFSA to produce an evaluation to its time line which may not be conducive to the application of a full scientific process and this may indeed be a real threat to EFSA's ability to carry out full and independent scrutiny and risk assessment. Even if EFSA resisted this and any other such pressure and maintained its independent stance – the *perception* could be that as EFSA is partly funded by industry, it may not be able to be impartial. The Board would therefore like to stress that the introduction of a fee charging system should not result in any real or perceived threat to EFSA's independent status.
4. Thought should be given to whether indeed the time is right to introduce a fee system while EFSA is still establishing its reputation and working practices.

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- The possibility of EFSA charging fees should be considered in light of the fact that EFSA is already under scrutiny on its real and perceived independence and is a young organization which is still developing its trust profile with its stakeholders, institutional partners and consumers.
5. If a fee system is introduced it must not be cumbersome, complex or expensive to run.
- The balance of costs between the fees charged and the monies needed to establish and manage a fee system has to be looked at in more depth than is indicated in the paper and in collaboration with EFSA. Only certain areas of EFSA's work would potentially attract a fee and it would be necessary to put in place within EFSA specific procedures and management systems to establish and manage the fees which would be in addition to the infrastructure currently in place to manage the rest of EFSA's work.
6. There is the need to assess the relevant legislation and fees systems that exist in EFSA's area and find a common and harmonised approach.
- There are currently some areas of EFSA's work that attract fees but in some instances these are paid to the Member States' authorities which undertake initial evaluations. It is mooted that the fees that EFSA would charge would be in addition to the fees paid to Member States. There are in fact several different system and if not harmonized these could result in several different charging structures in EFSA.
7. The Board believes that more thought should be given to considering a fee for the whole authorisation process – that is, the risk assessments carried out by the Member States and EFSA and the risk management elements undertaken by the Commission.
- EFSA understands the view expressed in the paper that it is appropriate to consider fees where a private entity benefits directly from the type of public expenditure involved in the overall evaluation and authorisation. Fees are seen as legally justifiable for the authorization of products or substances that may bring direct profit to individual natural or legal persons (in practice, firms applying for marketing authorizations for products or substances). The Board believes that based on this principle, consideration should be given to all parts of the approval process, including those parts undertaken by Member States and/or the Commission to bring a product to market. Indeed it may be more appropriate for the Commission itself to collect the fee and apportion this accordingly thus removing any direct financial arrangements between EFSA and the industrial entity and avoid calling into question EFSA's independence.

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In closing the Board would like to stress its view that it is the decision making bodies – the Commission through its proposals, the EP and Member States through Council – which will ultimately construct the systems with the budgetary authorities for EFSA to function. The source of the funding may not be an issue for the Board's further concern provided that the issues above, particularly in relation to its independence and accountability to the community system are considered as adequately covered by the legislators if fees are introduced.

Patrick Wall

Chair