



FEFANA response to EFSA evaluation report generated from stakeholder comments by Bureau van Dijk Management consultants

This review provided a great deal of information with regards to the perception, from the stakeholders involved, of EFSA's performance over the 2 years following its formation. The review is certainly more positive than negative by a large margin, although from the specific viewpoints of the feed additives industry there are some points of concern that need to be addressed.

Many activities of EFSA are welcomed and recognised by FEFANA. The industry is particularly at pains to recognise the significant improvements in the regulatory process brought about through the inception of EFSA. The previous process, in which member states had a large role in scientific evaluation, was sometimes/often inconsistent across member states, unpredictable in terms of timeliness, was lacking in scientific credibility and moreover the process did not capture all additives. Consistency and international scientific credibility are the key benefits that are recognised by the industry today. As a result, it is expected that public perception of the EFSA and its activities will continue to improve and thus lead to increased public confidence in the process of regulation of additives. The general structure of EFSA and the increasingly open nature of its activities are conducive to an excellent working environment with all stakeholders concerned.

The areas of concern with regards to the evaluation of the EFSA can be distilled into three subjects

1. Lack of resource
2. Location
3. Co-ordination / communication

It is worthwhile noting that the majority of these issues are not a criticism of the personnel within EFSA, or in large part, of the operations of EFSA, rather a criticism of the conditions under which EFSA has been asked to operate. FEFANA appreciates that this is the case and recognises the significant personal efforts that EFSA staff and scientists have to date put into their activities.

1. Lack of resource – Personnel and funding.
 - a. The original plan to have 340 staff in place by the end of 2005 is woefully behind schedule (195) and is not likely to remedy soon. The reason for such a poor result is put down to the high standards required for applicants, the lack of financial incentives, and the recent downgrading of 19 positions within EFSA by the EP which has reduced the attractiveness of EFSA positions to potential candidates. The result of this lack of resource is already apparent in terms of slippage of timelines in non-regulatory requests, but the true situation is likely worse than perceived to date due to many EFSA personnel working at an unsustainable rate.

This situation is expected to deteriorate dramatically as more requests are placed on EFSA if significant increases in resources are not realised. Whilst there are some solutions offered in the report such as improvements in work practices, better prioritisation of tasks and postponement of some activities, FEFANA is of the view that all such measures should be secondary to the central need for an adequate scientific resource at EFSA to allow it to respond to all tasks which are covered in its remit. FEFANA is concerned not only for the impact such lack of resource may have on its own area of concern, the regulation of feed additives, but also the effect it may have on the public perception of EFSA at large. FEFANA recognises that the value of the regulatory environment is only as good as the faith that the public place in such a process and institution. If EFSA fails in any significant role as a result of lack of resource, the fallout will damage all involved in processes which rely on EFSA's judgment. This cannot be allowed in FEFANA's view and we therefore urge the authorities to re-consider the budgetary constraints on EFSA. One of the suggestions provided in this report was that tasks should recover costs from the industries involved through a fee structure. FEFANA has the view that such a proposal will leave the EFSA open to criticism with respect to its independence and will create another level of bureaucracy where transparency is required. Furthermore, EFSA's evaluations do not always relate to the interested of a specific stakeholder, which will significantly complicate the establishment of a fair and equitable fee structure.

- b. Location. The recent move of EFSA to Parma has created significant problems for recruitment of staff, not only due to the expense and isolation of the location, but also due to the disturbance created during the transitional period. Whereas the transitional disturbance has passed, the current location of EFSA still poses problems, and moreover has created a logistical problem for any involved in meetings with EFSA. The report clearly acknowledged the widespread frustration of all involved in meetings based in Parma due to the need to allocate 3 days travel for a 1 day meeting. This is a considerable burden on the scientists involved in the panels, and on the stakeholders wishing to hold meeting with EFSA. The Authority clearly did not foresee these problems and has not implemented any strategy to offset the considerable efficiency losses that this has undoubtedly brought about. FEFANA is encouraged by the pragmatic suggestions with regard to video-conferencing, longer, more inclusive meetings etc, but for stakeholder involvement in critical meetings FEFANA encourages more off-site meetings in accessible cities such as Brussels.
- c. Communication. Within EFSA, the report notes that the evolution of EFSA from a small, tightly knit organisation to one that is considerably larger and heterogeneous in its activities. This has reduced the ability of EFSA to balance resource demands with resource allocation, and to identify overlap in decision-making activities between scientific panels, for example. As a result a call has been made for improved planning, consolidation of systems of management (software in particular) and greater accountability of time management. FEFANA sees such process improvements as key in improving the interface between the EFSA and the outside world. Such activities will result in a greater degree of consistency and predictability in decision making within and between expert groups/panels and as a result minimise the number of situations which may arise where more than one panel is tasked to deliver on a particular issue. Between EFSA and DG SANCO, the Commission and Member states, it is clear that communication is not as good as it could be. The standing of EFSA in the public eye and the clarity of its role (e.g. as to where its role of risk assessor crosses over to that of the risk management of the EC) relies on transparent communication of its actions and decisions. FEFANA believes that with proper resourcing of the EFSA and more active involvement of some MS, the commission and DG SANCO where such activity is lacking, these problems can be minimised.

The report fails, however, to cover some aspects of EFSA's work practices which FEFANA feels is not particularly well defined or justified and which has a significant and variable impact on the industry. These include self-tasking on regulatory areas, the lack of a resolution or arbitration processes when there is disagreement, its scope on certain regulations and the perception of potential conflicts of interest in the panels.

1. The self-tasking process is particularly difficult for any industry to deal with since it literally can come out of the blue. FEFANA feels that this process should be more inclusive of the industry concerned to ensure that a holistic approach to such tasks is taken. Self-tasking should also avoid invading regulatory areas.
2. Further concerns of the industry relate to resolution of issues or even disputes between the EFSA and a company/industry body. Two example situations come to mind.
 - a. FEFANA has in the past invested considerable time and effort on collaborative work with EFSA in the subject areas of QPS, Antibioresistance and carotenoids. A great deal of information transfer took place with the EFSA on each of these topics but there was no clear process or discussion with FEFANA as to why some information was acted upon and other information passed aside. FEFANA finds this process exasperating and would very much prefer a more inclusive process whereby we at least understand the reasons behind EFSA's decisions. In general, the scientific justification of the decisions taken and rejection of alternative options or elements submitted is also an important factor in maintaining EFSA's credibility; accountability of opinion should be clearly included in the management process
 - b. With respect to individual company interaction with EFSA, it is obvious that with scientific discussions there is never agreement on an optimum solution for all problems. FEFANA is aware that in cases where disagreements with EFSA arise over, for example, the description of an acceptable technique for proof of efficacy, there is currently no arbitration process. Whereas we recognise the scientific excellence of current EFSA staff and panel scientists, it is also the case that none are infallible. An arbitration process under such circumstances would be very much welcomed.
3. In some areas there has been "scope creep" of EFSA authority, particularly in relation to the guidance documents for implementation of Regulation No 1831/2003 on additives in animal nutrition, where it is clear that some of the guidance notes are more like the guidelines which should be prepared by the commission who have responsibility for risk management. FEFANA would very much prefer to see EFSA concentrating on its area of expertise and refrain from moving into areas which become more political.
4. When it comes to defining the extent and type of data to be provided for assessment of products in regulatory authorisation processes, there is a perception from the industry that active involvement of the members of panels in providing such data might entail some conflict of interest. While conflicts of interest are - given the professionalism of all involved - possibly manageable when it comes to judging a file in a pre-defined assessment environment, the panels should preferably be kept away from designing the "rules of the game", particularly with reference to minimum numbers of trials required for proof of efficacy. We understand that this was the purpose of the legislator when he clearly entrusted the Commission with the governance of the scientific assessment, under consultation with EFSA scientific staff. We also noticed that "shadow experts" are called by the panels to prepare file assessment, from reserve lists. For the sake of transparency and conflict of interest issues, we believe that these experts should be clearly identified in the reports.

Conclusions

In short, it seems that the review has highlighted 3 issues which are seen by FEFANA as areas of concern for the additives industry. It is clear that all 3 areas of concern are, to varying degrees, due to budgetary constraints imposed on EFSA. FEFANA recognises that EFSA's role is critical for the future of a publicly supported regulatory environment, and that neither the commission nor the industry can expect EFSA personnel to continue working at an unsustainable pace. FEFANA therefore calls for remedy to the budgetary constraints that have been imposed on the EFSA so that it can continue and build on its considerable successes to date.

FEFANA would also like to bring attention to further areas of concern not covered by the review, and asks that the EFSA considers these points for future discussion and action.