European Food Safety Authority

TIMEFRAMES FOR EFSA'S SCIENTIFIC WORK

1. The purpose of this paper is to seek the endorsement of the Board for EFSA's position on this key issue, to indicate certain problems which are now arising and to agree the proposed way forward as a position which can be used in communication with the European Council and Parliament.

EFSA'S POSITION ON TIMEFRAMES

2. EFSA has on its own initiative sought to set timeframes for all its work (including cases where this is not required by legislation), to make these publicly available (e.g. via the website) and as far as possible to meet these timeframes. Any timetable set by EFSA is largely based on the workload of the relevant Panel and on the priority attached to the new activity on the basis previously agreed by the Board.

3. This action reflects our belief that :
   i) Interested stakeholders in a particular issue have the democratic right to know when the relevant EFSA opinion may be expected so that they can prepare whatever steps they would wish then to take ;
   ii) Public health could suffer if an opinion is unreasonably delayed. Equally, there is a potential cost to the industry which is not justifiable if opinions are delayed for no good reason ;
   iii) The efficient management of the Authority requires that its business should be transacted according to preset timeframes and that its performance can be monitored accordingly both internally and externally. This issue will be covered when proposals for EFSA performance indicators are put to the Board.

4 . The above principles have however to be applied reasonably and to allow for exceptional situations because:

i-) Setting of arbitrary timeframes which bear no relation to the expected timeframe of a particular process will simply lead to frustration and

inefficiency. EFSA's external experts have to be able to schedule their work in which allows their other external commitments and EFSA's own staff have to have the time to properly present the material on which scientific judgments need to be made;

ii-) Instances will arise where the clock needs to be stopped to allow for further data to be sought from the applicant company for an authorization. This is sometimes but not always provided for in the relevant legislation. (eg. the current Council proposal of 25 March 2004 for the regulation of pesticide MRLs does not recognize this facility. Whilst it is a responsibility of EFSA's external experts to use the ability to seek further data responsibly, denial of this facility is likely to lead to opinions that lack scientific credibility and indeed to the possibility that no conclusions will be reached by the panel. A large number of such outcomes is clearly not in either the public interest or arguably the longer term commercial interest of industry.

iii-) With many applications and issues dealt with by EFSA will be straightforward and thus adhere to properly set timeframes, issues will arise which are novel and/or hotly contested from a scientific point of view. It is essential that panels should have the opportunity to explore such issues in the depth required if we are to retain the high quality of our external experts and to reach genuine consensus, where this is available, as opposed to a proliferation of minority and disputed opinions which will do nothing to enhance consumer or other confidence in EFSA's risk assessments. Similarly occasions will occur where the initial analysis for discussion need to be translated or redone or both or where the Panel finds it needs additional external expertise.

NEW LEGISLATIVE DEVELOPMENTS

5. EFSA has consistently maintained for the reasons set out above that whilst it respects the principle of observing timeframes, this cannot be at the price of providing inferior science. Perhaps as a response to this, amendments have appeared in two items of prospective legislation which would give the Commission the right to review EFSA's decisions, including at the request of third parties, seemingly either as to their substance or as to a failure to act within a set time-limit. The two relevant examples are annexed: the source of the amendments is unknown to EFSA.

6. As previously indicated the concerns which presumably underlie these amendments are fully appreciated by EFSA's staff and we accept responsibility for trying to prevent such complaints except in the circumstances set out in paragraph 4 above. However the nature of these amendments should in our view be a subject of public objection by the authority as a challenge, whether intended or not, to its independence and also as being of little practical effect. The reasons for this are set out below.

7. It is difficult to understand how the Commission could review "a decision…taken under… the powers vested in the Authority" given that technical competence in the area concerned will have been specifically withdrawn from the Commission and vested in EFSA. If the Commission were to demand that the Authority 'withdraw its decision', the Authority would be left in a situation where the judgments were essentially to be formally in the public domain only if the Commission did not object to them. This of course is completely contrary to the system created by Parliament and Council whereby EFSA gives independent advice which is made public and the Commission and Member States then decide what risk management option, if any, they wish to pursue. Effectively the entire system of risk assessment and risk management would return to the control of the Commission. This would also conflict with the Commission position in its Communication on the operating framework for the European Regulatory Agencies, COM(2002)718 final[1]. Whilst highlighting, under the section on Controls, the importance of special relations between the Commission and agencies, it states: "*Obviously, this is not a question of giving the Commission powers of legal supervision; i.e. empowering it to issue instructions to the regulatory agencies or quash or oblige them to withdraw certain individual decisions*" – see paragraph 4.3, page 12.
Apart from this fundamental objection of principle, there is a rather obvious difficulty of understanding how an EFSA decision could be withdrawn since an EFSA risk assessment, once published, would clearly continue to exist in its own right even if EFSA were legally prevented from maintaining it, thereby creating major legal uncertainties vis-à-vis the applicant or notifier.

[1] http://europa.eu.int/comm/governance/docs/comm_agence_en.pdf

8. The related proposed power to allow the Commission to require "the Authority….to remedy its failure to act within a set time-frame" is equally of little value. If EFSA fails to respect timeframes for no good reason, the EFSA Management Board itself will no doubt wish to take corrective action; The Commission similarly could and no doubt would complain in such circumstances: The Authority, which under its founding Regulation is subject to the judicial supervision of the European Court of Justice, could certainly face legal action in relation to such a failure. However if there is good reason why a timeframe cannot be met, the European Commission has hitherto followed the principle that protection of public health has to take priority over timeframes. Hence even if this particular power were to be enacted, it would seem to have no real effect.

PROPOSED WAY FORWARD

9. There are issues of very great importance here both in terms of ensuring the Authority gives a proper service to its clients and in ensuring that its independence and commitment to a high standard of science can be preserved in the interest of protecting the European consumer. If the Board shares our analysis, they are invited to authorize the Chairman to write to the appropriate legislative bodies stressing that:-

i) EFSA is committed to delivering work against reasonable timeframes as a matter of institutional efficiency and meeting the legitimate interests of its stakeholders;

ii) Exceptions to properly established timeframes need to be justified and documented and may include situations. Where new data has to be requested or there is in depth scientific discussion which has to take place and cannot be accommodated within the given timeframe.

iii) Proposed powers to allow the Commission to review and require withdrawal of EFSA's decisions are unnecessary, contrary to the principle of separation of function between EFSA and the Commission and unlikely to have any practical value. Similarly there are already sufficient potential sanctions on EFSA should it generally fail to respect properly set timeframes and the additional proposed power for the Commission is pointless.

ANNEX

TWO EXAMPLES OF « ADMINISTRATIVE REVIEW » PROVISIONS FOUND IN FUTURE LEGISLATION

1. **Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin**
   [Council of the European Union, document no 7737/04, circulated in preparation for the working party on agricultural questions (pesticides residues) meeting, 7 April 2004]

   Article 21 bis Administrative review

   Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member States or from any person directly or individually concerned.

   For that purpose, a request shall be submitted to the Commission within two months after the day on which the party concerned became aware of the act or omission in question.

   The Commission shall take a decision within two months requiring, if appropriate, the Authority to withdraw its decision or to remedy its failure to act within a set time-limit.

2. **Proposal for a Regulation of the European Parliament and of the Council on materials and articles intended to come into contact with food**
   [Council of the European Union, document no 7781/04, text agreed by the Permanent Representatives Committee at its meeting on 24 March 2004]

   Article 11b Administrative review

   Any act adopted under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned.

   To this effect a request shall be submitted to the Commission within two months from the day on which the party concerned became aware of the act or omission in question.

   The Commission shall take a decision within two months requiring, if appropriate, the Authority to undo its act or to remedy its failure to act.