European Food Safety Authority

Evaluation of EFSA

Annexes

Contract FIN-0105

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Annex 1: EFSA intervention logic

In our view the intervention logic describes the logic of the different levels of objectives of the Authority, that are also related to the inputs of the EFSA as well as to the context in which the Authority works and develops.

1. Objectives

We distinguish **three levels of objectives**:

- Overall objectives, referring to EFSA efforts towards a high level of protection of human life and health. Such objectives are not specific to EFSA but concern all institutions involved in food safety policy. EFSA alone is not able to achieve such strategic objectives, which overcome the Authority.
- Specific objectives: those objectives are univocally related to EFSA. They reflect the 'raison d'être' of the Authority and its mission. They support the overall objectives.
- Operational objectives translated into activities generating outputs: such activities are defined according to the various priorities of the EFSA. They support the specific objectives.

Our review of the Regulation 178/2002 and of several documents presenting the activities[1] concludes on the following hierarchy of overall objectives, specific objectives and operational objectives.

Overall objectives	◆ To **contribute to a high level of protection of human life and health**, and in this respect to take account of animal health and welfare, plant health and the environment ◆ To **improve consumer confidence** by acting as an independent scientific source of advice, information and risk communication ◆ To **contribute to the smooth functioning of the European Union's internal market** by acting as an independent scientific point of reference in risk assessment		
Specific objectives	SCIENCE - To provide *scientific advice* and *scientific and technical support* that will serve as the scientific basis for the drafting and adoption of Community measures. - To *collect and analyse data* needed to allow *characterisation and monitoring* of risks. - To promote *uniform risk assessment methodologies*.	COMMUNICATION - To communicate on risks and, in doing so, to act in close collaboration with the EC and the MS to promote the necessary coherence in the risk communication process. - To provide the public and interested parties with reliable, objective and comprehensible information.	NETWORKING - To establish a network of organisations operating in similar fields. - To improve international cooperation and develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.
Operational objectives	- Provision of scientific opinions and studies, guidance and advice in response to questions received from the EC, the EP, the MS or the Authority itself (self-tasking). - Assessing the risk of regulated substances and monitor specific risk factors, zoonoses and animal diseases. - Contribution to the harmonisation of scientific approach and methodologies for risk assessment: development of guidance or harmonised approaches, harmonised database of national experts. - Participating in the Commission's rapid alert system.	- Continuous update of the website. - Publications (EFSA news, annual reports, etc). - Public meetings, stakeholders consultations and scientific colloquia. - Contacts with the media	- Networking of the national agencies through the Advisory Forum (AF) and its three working groups (Communication, Information Technology and Scientific Work). - Development of the academic, institutional and stakeholder networks of the Authority. - Dialogue with and consultation of stakeholders (Stakeholder Consultative Platform). - Regular contacts with other EU institutions and participation in meetings. - Establishment of links with partner organisations in third countries and international organisations.

[1] *Draft 2005 Management Plan of the EFSA, EFSA Annual Reports 2003 and 2004, EFSA Information Pack, Presentation 'Risk Communications in Europe' of February 28 2005.*

2. Inputs

The inputs are financial, human or organisational inputs. The availability of these inputs is an important parameter possibly influencing the achievement of the objectives.

- Financial resources: the following table compares the EFSA's budget as forecasted in the Commission document COM 7162, the Community's subvention and the total expenditures in million € for the years 2002 to 2005:

	2002	2003	2004	2005
Forecasted budget (million €)	9	24.9	32.2	44.4
Community's subvention (million €)	NC[3]	10.3	29	36.7
Total expenditures (million €)	NC	10.2	21.6	n.a.

There are several issues related to the financial resources of EFSA.

The first one relates to the origin of EFSA's resources, which is DG SANCO. A first implication is that EFSA's resources are fully dependant on the orientations affecting the Commission's budget, which are currently rather restrictive.

The second one deals with the current discussions and future consultation about the possibility and appropriateness for EFSA to perceive fees for the processing of authorisation files. This would allow EFSA to increase their revenues, like it is for EMEA, but there are fears that it would also reduce its independency. The draft EC consultation paper discusses the advantages and drawbacks of a fees system. We refer to it in section 3.1 of the main evaluation report.

In 2004 total expenditure was lower than the Community's subvention, itself lower than the budget forecasted. The Community's subvention was not entirely committed.

- Human resources: according the Commission document COM 7164, 'the resources needed for the EFSA to carry out its tasks effectively would be 339 staff'. The following table compares the forecasted staff to the effective staff over years:

	2002	2003	2004	2005	Year ?
Forecasted staff	35	111	168	255	339
Effective staff (end December)	NC	72	127	n.a.	n.a.

2003 shows a deficit of about 40 between forecasted staff and recruited one. This is said to be due to the fact that EFSA has effectively started in 2003 and that there were uncertainties concerning its definitive location. This deficit is the same in 2004 meaning that it has been neither increased nor recovered. For 2005, the perspective is that the gap increases, as the targeted staff figure is 194 (gap of 61 compared to forecast) and that this figure might not be reached.

Organisational arrangements: The report of the Court of Auditor[5] for the 2003 financial year observes deficiencies in the validation of the accounting systems, the systematic checks on the determination of the

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[2] *COM (2000) 716 final, Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food. In the present document we qualify all figures coming from COM (2000) 716 final as 'forecasted'.*

[3] *NC= Not Communicated*

remuneration (particularly salaries) and on the financial entitlements of newly recruited staff as well as concerning the strengthening of the IT system to match the increases in its activities. The Authority as a response took several measures afterwards.

The annual report 2004 also indicates that the Human Resources department devoted a large amount of work to establishing structures, policies and procedures of a wider nature, in order to facilitate day-to-day management and increase work process efficiency. Also the legal department was active in procurement and contract management, in both handling of individual projects and establishing EFSA's procedures related to planning, functioning and monitoring of this activity.

3. Context

For EFSA, the realization of its objectives depends importantly on its **environment,** and notably on the following aspects:

- The fact that risk assessment and risk management are carried out by distinct organisations whose relationships have to be progressively built.
- The quality of cooperation between the Authority, Commission – mainly DG SANCO - and Member States to promote the effective coherence between risk assessment, risk management and risk communication functions.
- The close cooperation between the Authority and the competent bodies in the Member States carrying out similar tasks.
- The need for the Authority to be recognised as a point of reference by virtue of its independence, scientific excellence and the transparency of its procedures and methods of operation.
- The 'tension' between two logics: EFSA as an autonomous institution and EFSA mainly busy with answering requests from the Commission.
- The restrictive budgetary context.
- The regulatory context for recruitment of personnel, for contracting out, etc. that is adapted to established public institutions but not to starting agencies.
- The location in Parma and its impacts.
- The large diversity of expectations on EFSA from governments, consumers, industry, ngo's, etc.
- Differing perceptions of what 'science' entails.

4. Summary

There is an inherent complexity in EFSA intervention logic that makes it difficult to attribute responsibility in the achievement of its objectives. The components of this complexity are:

- A limited control by EFSA on its workload mainly determined by its DG 'de tutelle'.
- The fact that the overall objectives are well beyond the reach of EFSA alone.
- The need to cooperate with MS bodies that have their own logic, in a context where confidence and legitimacy have to be built.
- A restricted budget and procedures not adapted to a starting agency.

[5] *REPORT on the annual accounts of the European Food Safety Authority for the 2003 financial year together with the Authority's replies (2004/C 324/06), Official Journal of 30.12.2004*

Annex 2: Some issues related to assessing EFSA performances

This annex is a result of the desk research. It reports our processing of EFSA official[6] indicators in view of objectively assessing EFSA performances.

In search of a 'firm ground' to judge EFSA performances, i.e. quantitative and objective data, we have a rather limited set of indicators available:

- The staff numbers, globally, per grade level (A, B, C, D), per category (permanent, temporary, auxiliary, detached, etc.) and per activity.
- The numbers of scientific opinions requested and adopted, globally, per requesting institution, per Panel area.
- Various indicators about the interest in EFSA's website.
- The budgetary figures, currently not broken down on an activity basis.

To compare the actual EFSA inputs and outputs figures with a baseline, we refer to quantitative indicators making part of the 'Financial Statement' of COM (2000) 716 final7. This is indeed to our knowledge the only available baseline, as EFSA does not seem to proceed with yearly quantified indicators8. The table below illustrates this.

	Forecasted[9] indicators	EFSA indicators	Comparability
Inputs			
Staff	Projection of staff up to 2005 (n+3), plus per activity and area for this year.	Nbr of staff recruited.	- Comparison possible for total staff level (and per area on basis of doc 'who does what at EFSA').
Budget/ expenditures	Budget and costs per category and activity.	Budget and expenditures per category and very rough Activity Based Budgeting.	- Differences between the distribution of the 'administrative' and 'operational' forecasted costs in COM (2000) 716 final, p. 71, and the chapters and sub-chapters of the EFSA budget. - COM (2000) 716 final proposes also a rough budget distribution per sector of activity while the EFSA annual reports 2003 and 2004 present very rough, non comparable, activity-based budgeting.

[6] *See notably documents MB 16.12.2004 – 8a and 8b, MB10.03.2005 – 7 and MB 13.09.2005 – 7 on EFSA Performance/Progress indicators.*

[7] *Proposal for a Regulation of the EP and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food.*

[8] *There seems also there is not a kind of 'Rolling programme' like for Consumer policy 2002-2006, whose execution can be unambiguously monitored and judged.*

[9] *The word 'forecasted' systematically refers to the figures presented in COM (2000) 716 final.*

Outputs			
Scientific opinions	Projection of requests for 2005 (n+3) per area.	Opinions requested and adopted, with the following details: per quarter, requestor, area, timeliness.	- Comparison possible.
Move to Parma	Not considered when drafting COM (2000) 716.	Number of staff installed in Parma.	- No comparison possible because absence of a baseline.
Communi-cations	Various indicators (not quantified): press releases, campaigns, etc.	Interest in EFSA web site.	- No comparison possible due to difference of indicators and absence of a quantified baseline. However the Annual report presents figures on articles and media coverage.
Other outputs	Information gathering and studies (Task 2), Technical advice (Task 3), Identification of emerging risks etc. (Task 4).	No indicator available.	- No comparison possible due to lack of indicator.

Comparing EFSA actual with forecasted inputs and outputs is thus only possible for a couple of indicators.

We carry out such comparison for some indicators and draw preliminary conclusions. The forecasted figures for 2004 are either directly extracted from COM (2000) 716 final, or they are estimated on the following way: estimation 2004 equals 73 % of forecasted figure for 2005, as 2004 forecasted budget equals 73 % of 2005 budget.

	Forecasted figures 2004	Actual figure 2004	Comment
Staff	168	127	Actual figure amounts to 76 % of forecasted one. Staff figures can also be splitted per category of staff, functions (administrative, scientific, communications) and Panel area.
Budget (million €)	32,2	29,1 (appropriations) 21,3 (commitments)	Actual commitments amount to 66 % of forecasted one. Budget figures can also be splitted per category of staff, functions (administrative, scientific, communications) and Panel area.
Scientific opinions requested	224 (estimation for large & medium files)	180	Actual figure amounts to 80 % of forecasted one.
Requestors of scientific opinions: EC MS EP EFSA/Other	 76 % 10 % 12 % 2 %	 84 % 5 % 1 % 11 %	Much less requests from MS and especially EP than expected.
Scientific opinions adopted	224 (estimation for large & medium files)	158	Actual figure amounts to 71 % of forecasted one.
Scientific opinions adopted per Panel: AFC FEEDAP PPR GMO NDA BIOHAZ	(estimations) 66 13 40 43 15 12	Requested Adopted 51 49 39 32 9 7 15 7 31 31 18 16	- FEEDAP workload is larger than forecasted due to Regulation (EC) N°1831/2003, which foresees in particular in Art. 10 a notification of all existing additives before Nov. 2004; close to 9.000 notifications were made and have to be reviewed by FEEDAP. - For PPR and GMO it is the opposite situation - NDA has twice the workload forecasted

CONTAM AHAW SC	12 14 9	4 9 4	10 6 1	- GMO and AHAW, probably for different reasons, seem to face problems in delivering the requested opinions. - SC has to deal with horizontal issues what implies a longer preparatory work.

Thus the forecasted figures can be used as a first baseline to assess EFSA situation as to their inputs and performances. However this baseline has not been used so far by EFSA. This has probably to be understood in a context where few voices claim for a more elaborated system of indicators.

- EFSA resources: COM (2000) 716 final, p. 73 characterises the EFSA forecasted budget in year n+3 (i.e. 2005) as moderate. A 'wider scope and range of tasks to be undertaken by EFA' in comparison to EMEA is translated into a larger number of staff: 255 for EFSA versus 210 for EMEA. The EMEA larger budget per staff member (238 000 € for EMEA, 174 000 for EFSA) can nearly be fully explained by the difference of the cost of living between Belgium and UK10.

  But the EFSA actual subvention figure for 2005 – 36,7 million € - remains well below (83 %) the 'moderate' figure of 44,4 million € forecasted for 2005, despite the fact that this last figure did not include impacts of the move to Parma (with its cost increases, direct – cost of living – and indirect – missions, etc.).

- The EFSA 2004 Annual report makes an interesting reference to Activity Based Budgeting (ABB), by splitting the 2004 expenditures in science, communications and administration related activities. In addition to a traditional cost-based operating budget, ABB is a powerful tool to monitor EFSA performances.

  The purpose of ABB is to show the connection between the resources an agency plans to consume and the outputs it plans to produce. This provides the agency's leadership with a vehicle to make allocation decisions. The budget decision-making process can then focus on maximizing outputs critical to the success of the agency.

  The starting point for the ABB budget process is the customer. Each unit or service determines the customers they serve - the public, other government organizations or other services within the agency - and what the customers expect to receive from each unit or service. These desired services are the outputs for the agency activity-based budget.

  Once outputs are identified, it is possible to determine the activities that are required to produce the outputs. Activities are processes that consume resources, such as time and money, to produce a given output. The goal is to clearly identify the activities that must be performed to produce critical outputs and then determine the level of resources that must be committed to successfully complete the activity. Once this is done, it is possible to determine how various funding levels affect the outputs produced.

  The decisions on resource allocation are thereby focused on determining which outputs will be produced. The management can then manage resources in such a way as to maximize the agency's outputs to its customers. The ABB process provides management with the quality information necessary for sound decision-making.

  By EFSA, currently, there is only a basic ABB, as shown by the 2004 Annual report. The apparent distribution of ABB expenditures 2004 – 72 % science, 21 % administration and 7 % communications – invites to examine efficiency in science in priority: number of scientific opinions delivered, timeliness of these opinions, staff involved and budget involved. This analysis could be made for 2003 and 2004, per Panel and in comparison with the forecasted figures.

[10] *According to EC rules for experts, daily allowance for Belgium amounts to 149,63 € i.e 75 % of 199,21 € (allowance for UK).*

Annex 3: Results of the survey

The survey was addressed to 152 people, some of them having transmitted the questionnaire to other people or member organizations. The number of completed questionnaires received amounts to 80. The table below highlights the number of people targeted and the questionnaires received according to the categories of stakeholders. A list of stakeholders having responded to the survey is provided at the end of the present Annex.

Categories of stakeholders	Nbr of questionnaires sent	Nbr of questionnaire received	% received	Comments
Advisory Forum	28	18	64	
EFSA Scientific Panels, Committee and Expert Services	20	0	0	Most addressees decided not to answer, claiming they were part of EFSA staff or committee. Some of them have been interviewed.
EFSA Expert Panels	9	6	67	The 9 Chairs were demanded to forward the questionnaire to the members of their Panel.
EP: Committee on Environment, Public Health and Food Safety; Committee on Fisheries; Committee on Agriculture	3	4	na	The Secretariat of each Committee was demanded to forward the questionnaire to their members
Commission services	10	5	50	
Consumer organisations	40	17	43	
NGO's	5	3	60	
Private companies	12	12	na	The figure is positively biased by three companies contacted through ILSI
Trade associations	12	11	92	
Trade Unions	1	0	0	
Press	7	2	29	
Scientific Committees of DG SANCO: Committee on Consumer Products; Committee on Health and Environmental Issues; Committee on Emerging and Newly Identified Health Risks	3	1	33	
EU Agency (ECDC)	1	0	0	
Other	1	1	na	The respondent is an independent expert
TOTAL	**152**	**80**	**53**	

These figures inspire three conclusions:

- The overall rate of return is very satisfactory compared to similar surveys.
- The rate of return of companies and trade associations shows a substantial interest in EFSA from this category of stakeholders.
- The very low number of questionnaires received from the EP could reflect a weak interest for EFSA or at least for the present survey foreseen by Regulation 178/2002.

A specific email survey on international cooperation has targeted international organisations (WHO, FAO, OECD, OIE) as well as organisations from third countries (FDA, Health Canada, ANZFS). The survey was launched on 11 May and a reminder was sent on 23 May.

Contact was established with FAO, OECD, WHO, FDA, Health Canada and ANZFS, and answers were provided by OECD, WHO, FDA, Health Canada and ANZFS.

The analysis presented hereafter focuses on the answers to the survey, including comments made, of the most representative groups i.e. 18 members of the Advisory Forum, 17 members of consumer organizations, 22 representatives from industry and 8 representatives of the press and chairs of Panels.

1. General comments and highlights

- Among all groups of stakeholders, industry and trade associations seem the most involved in EFSA matters compared to other groups such as consumers, Advisory forum, NGOs. This concerns both the rate of return of questionnaires as well as the richness of comments specifying the answers provided.

- Overall, the judgement is that EFSA is doing well, that the situation is better than before but considering that EFSA operates since 2003 it is too early to judge. Some say they expect proofs that will come in the next years.

- There is a majority of respondents to state that there is no increase of consumer confidence in the last 12 months.

- A major issue stressed by members of AF and by representatives of industry is the need for a closer collaboration between EFSA and the MS national agencies/authorities. A real networking of organisations – that is more than an IT networking - is still to come. E.g. from the analysis of the AF questionnaires there is clearly an issue of communication from MS to EFSA, and of (or including) coordination between EFSA and MS on procedures to minimise divergent opinions and reduce duplication of work. The accuracy of the information of some members of the AF on the EFSA missions and achievements could seriously improve.

- Considering the opinions expressed by the consumer organisations, the first conclusion is a rather positive general judgement on EFSA even if they expect that EFSA addresses more often their own concerns such as appropriate diets. However on a number of issues there is no really clear trends but instead fragmented and in some cases diverging views.

- The representatives of industry have in general a positive appreciation of EFSA. The main areas for improvement they mention are a closer coordination between EFSA and the EU institutions on one hand, the national ones on the other. This notably concerns risk communication (strategies, procedures, criteria, etc.). They would also be interested in getting a more direct access to the Panels' work.

- Independently of the stakeholder categories there are areas where improvements are needed:

  → More visibility of EFSA that should become recognised as the reference of the European risk assessment network.

  → To address the issue of the understaffing of EFSA, notably the Scientific Expert Services: with more senior scientists, EFSA could better support the work of the Panels and fulfil its obligations referred to in the Regulation such as scientific and technical assistance, monitoring of emerging risks, etc.

2. Members of the Advisory Forum (N=18)

Scientific opinions

For all Panels, the scientific opinions are in most of the cases judged as 'relevant' to 'highly relevant' to the AF members needs, i.e. the assessment work in their own countries. Due to the sensitive character of opinions on GMO, two members stress the higher expectations about this Panel.

Most of the members (16 on 18) have no opinion on the issue of timeliness of the scientific opinions requested as they have not requested any opinion.

EFSA cooperation network

Most of the members (14 on 18) qualify the AF performance regarding exhaustiveness of information exchanged as 'good' or 'very good', especially the information going from the EFSA to the Member States. One AF member states that presently the information is mostly one way, from EFSA to MS, and that the other way is (only) active when MS are asked by EFSA. Another stresses that EFSA is very young, that each side has to gain experience, and that things are better now than 2 years ago and will further improve with the implementation of regulation 2230/2004 (networking with MS bodies).

As regards the timeliness of the information exchanged most of the members (14 on 18) qualify the performance as good especially the information going from the EFSA to the Member States. One member is very happy to receive opinions in advance of publication by EFSA. Another one suggests, for a good preparation of the AF meetings, to receive earlier the information to be dealt with.

Concerning the frequency of use of cooperation mechanisms by AF, 8 respondents say 'often' and 9 say 'occasionally'. The mechanisms referred to range from scientific colloquia to video-conferencing i.e. different ways of scientific cooperation and in particular the networking of scientific data. A slight majority of respondents (10) qualify as 'fair' the contribution of these mechanisms to more reliable risk assessment. 4 respondents claim a 'little contribution'. The profile of responses is similar concerning the contribution of the mechanisms to a more rapid communication. One respondent stresses that cooperation takes time what requires optimised communication channels.

For 10 respondents, initiatives have been taken to promote, coordinate and/or develop uniform risk assessment methodologies as horizontal activities of the Scientific Committee. The example mentioned is the assessment of genotoxic and carcinogenic substances. 8 respondents have no opinion on this matter. 8 respondents consider as 'fair' and 6 as 'high' the added value of the Scientific Expert Services concerning risk assessment methodologies.

Most respondents do not know how many procedures to minimize divergent opinions and reduce duplication of work between national bodies and EFSA, are discussed, prepared, etc. and the other ones do not agree on the numbers concerned. One respondent considers that there is too little coordination in that matter.

EFSA contribution to a high level of protection of human life and health

When asking whether EFSA has taken appropriate preventive actions for situations that may have led to a food safety crisis, the majority of respondents (12) consider that EFSA does better than when food crisis matters were handled by DG SANCO and the Members States. The role of EFSA is judged more positively for situations that may have led to the perception of a crisis than to a crisis as such.

EFSA added value in this matter is illustrated by the following comments: EFSA acts with care especially regarding risk perception; more than once, EFSA risk assessment has prevented food scares; EFSA has reacted quickly in case of emerging risks such as acrilamide, semi-carbazide and phtalates.

Half of respondents (9) considers that during the last 12 months the consumer confidence in food safety hasn't changed. 3 respondents think it has increased and 6 have no opinion. The fact is that no respondent mentions facts or figures on this issue for the last 12 months.

Independent centre of scientific excellence

The overall organisation of EFSA as well as the related scientific structures is assessed as 'good' to 'very good'. For one respondent EFSA is seen as a model that could inspire others. Another stresses that the organisational structure supports the formation of opinions. A third respondent stresses that even if the overall organisation and the related scientific structures are adequate there is a lack of manpower and experts. One member of AF states that EFSA needs to develop a scientific secretariat for the Scientific Committee and the Panels in order to prepare the scientific opinions at the secretariat's level. A last one states that there is a need to better integrate the smaller Member States and establish a 'day to day' level of communication, in addition to the more formal approach and suggests that a support desk would be a good start.

Concerning risk assessment, EFSA is recognised by a large majority (17) as an important player at European level, as independent and as a centre of excellence. The picture is nearly the same concerning risk

communication except for 2 respondents raising doubts on EFSA independence at that level. One AF member considers there is a need for the future to develop strategies and scientific criteria for risk communication.

Most respondents (17) consider EFSA as 'compliant' to 'fully compliant' with its transparency obligations as listed in article 38 of Regulation 178/2002.

The confidence in the transparency of EFSA regarding the scientific opinions issued and the decisions taken by the Management Board is considered as 'fair' to 'high'. The transparency of the functioning of EFSA is mostly (10) judged as 'fair'. One respondent states that in some cases the data basis for risk assessment is not fully transparent because applicant's data are not part of the opinion.

Again, as to the number of mechanisms or processes (e.g. for the selection of Panel members) implemented by EFSA to guarantee scientific independence and excellence of scientific expertise, the majority of respondents (8) have no opinion. One says that even as member of the AF he is not aware of these mechanisms. As to the level of guarantee offered by these mechanisms or processes, 6 judge it as 'high' and 2 as 'fair'. One respondent claims for more scientific support by EFSA staff.

The level of AF members'confidence in EFSA internal and external scientific expertise in food/feed safety is 'high' to 'very high' for the large majority of members. One respondent says he would have liked to answer between 'high' and 'low' concerning the internal scientific expertise. The availability, quality and scope of expertise perform a bit better than its legitimacy.

EFSA risk communication

The risk communication as regards sharing and exchange of information and knowledge on food safety is mainly judged as simply 'effective'. This concerns communications with risk managers as well as with press, consumers and industry associations. One respondent states that communications may be a bit too technical for the average consumer.

Concerning the experience of difficulties between EFSA as risk assessor and risk managers in the distribution of communication tasks, the respondents do not agree: 6 claim that they have never experienced that, while 6 others have occasionally faced such situations, notably concerning mercury in fish. One member of the AF suggests that clear and transparent rules on each other responsibilities should be laid down in an agreement between EFSA and the Commission.

A majority of respondents consider that the EFSA IT system contributes to improve the networking with MS and other stakeholders: this refers to video conferencing, extranet and secure exchange of scientific data.

And all respondents say that the website fulfills this role. Three respondents have much hope in the future added value of the tools, not yet fully operational: they could be further developed, e.g. search tools for the website, or their use could be extended, e.g. the secure extranet for all EFSA Panels and working groups.

EFSA scientific expertise

Does the Advisory Forum contribute to the well functioning of EFSA? A majority (9) consider a 'fair' to 'low' added value concerning the scientific advice on the projects, the priority setting and the feedback to EFSA proposals. The judgement is much more positive concerning the contribution to networking the experts, except for two members stating a low added value and waiting for the implementation of regulation 2230/2004.

Is the current EFSA internal scientific expertise adequate to provide scientific and technical advices/assistance in addition to the scientific opinions issued by the Panels? For nearly all the Panel areas a majority (60 %) of respondents answers 'yes' while the others have no opinion. The proportions are inversed concerning the Animal Health & Welfare Panel. Three respondents stress the need to strengthen in-house scientific expertise for all Panels.

EFSA beneficiaries and stakeholders

For 16 respondents the EFSA priorities and outputs are ''fairly'' to 'fully' in line with their expectations.

15 respondents considers EFSA as ''fairly'' to 'fully' compliant with the legal requirements as regards the consultation and information of stakeholders.

EFSA added value

For three criteria (*specialised expertise and know-how, response to questions or inquiries, setting up of comprehensive networks*), for at least 13 respondents, there is clearly an improved situation with EFSA compared to the past.

Concerning the *credibility of outputs as a result of greater independence* and the *effective involvement of stakeholders*, the situation is more nuanced: 55 % vote an improvement but 35-40 % say 'no change'.

For the *flexibility in outsourcing tasks*, the respondents are perfectly shared between the two opinions.

Finally 55% of respondents have no opinion on the *benefit/cost ratio*.

As to whether an option alternative to EFSA would have provided more added value, a large majority of AF members have no opinion.

EFSA intervention logic, objectives and activities

EFSA's support to uniformisation of risk assessment methodologies is expected to contribute to more consistent decision making in other institutions: 44% of respondents claim a 'fair' contribution, while other ones refer either to a 'strong' contribution or to a 'little' one. One respondent states that EFSA consistency of approach and guidance documents are followed in his national institution.

Does the independent character of EFSA scientific advice contribute to ease policy-making by the Commission, the EP and the MS? The answer is 'yes' as 5 respondents claim a 'strong' contribution and 8 a 'fair' one. The AF member having responded "little contribution" has commented that decisions are generally dictated by political and economic concerns. The importance of the scientific aspect is secondary although certainly not insignificant. One AF member tells that EFSA opinions are frequently referred to in their own risk assessments presented to their national risk managers.

3. Consumer organisations (N=17)

Scientific opinions

Scientific opinions issued are assessed as 'relevant' or 'highly relevant' for most Panel areas. The judgement seems to be a bit less positive for the Animal feed Panel and especially for the Animal Health & Welfare one.

EFSA contribution to a high level of protection

A slight majority of the answering organisations estimate that the situation is better with EFSA concerning the taking of appropriate preventive actions in cases that may have led to the perception of a food safety crisis by the public. For situations that may have led to a crisis, 5 organisations consider that the EFSA has not brought a clear improvement.

One organisation indicates that transparency has increased and that involvement of consumer organisations is better. Another considers that with EFSA coordination has increased.

For 70%, consumer confidence in food safety did not increase. One organisation mentions that consumer still do hardly trust in 'European' agencies. Another one states that the information does not reach the public except the scientific community.

Independent centre of scientific excellence

At least two thirds of organisations consider the EFSA overall organisations and related scientific structures as 'good' to 'very good'.

Some criticisms are formulated by some consumer organisations. They concern the poor representation of consumers in the different structures of the EFSA, the difficulty to get a balanced scientific view in some cases due to narrow scientific Panels, the lack of traceability in the way EFSA comes to scientific opinions, the implications of consumer and environmental NGOs as observers while having a word to say in the appointment of internal and external experts

75% of organisations judge the performance in risk assessment as 'good' to 'very good'. Concerning risk communication, 6 organisations consider EFSA as not being enough important on the European scene.

10 organisations estimate that EFSA is 'fairly' to 'fully' compliant with its transparency obligations.

The organisations are very confident in the transparency of the EFSA's functioning, a bit less in the one of the decisions of the Management Board and of the scientific opinions issued. One organisation would like more transparency about the different scientific opinions. Another one comments that stronger consumer representation would boost confidence.

If the consumer organisations are very confident in the quality of EFSA expertise, some (3 to 4) doubt about its availability, scope and legitimacy.

EFSA risk communication

The views diverge concerning the real contribution of EFSA risk communication to sharing and exchange of information and knowledge on food safety. This relates particularly to communication to press, consumers and industry associations. A slight majority of consumer associations have no opinion concerning the communication with risk managers.

EFSA management systems and processes

9 organisations mention they have experienced difficulties between risk assessors and risk managers in the distribution of communication tasks. One of them wonders about the role of bureaucracy in the appearance of such difficulties. Another one complaints about a lack of transparency and communication from the national correspondent body of EFSA.

A slight majority considers that the EFSA website contributes 'fairly' to improved networking with stakeholders. 7 organisations consider instead a little contribution. One consumer organization comments that the website should not be upgraded beyond the capacity of small organisations and ordinary consumers to access it easily and quickly. Another indicates that it's not a website which can contribute to improving networking with stakeholders, but meetings, conferences and accessibility of documents.

EFSA's beneficiaries and stakeholders

For more than half of the organisations, EFSA outputs are in line with their expectations. The other ones have no opinion or have a critical judgement. Concerning EFSA priorities, opinions are a bit less positive. One Consumer organisation stresses that progress is slow. Often Council will ask EFSA for an opinion. By the time an opinion has been formed and then acted on by Council, the food industry has often mobilised to introduce initiatives that challenge consumer confidence in an opinion. Any potential legal changes are pre-empted by industry which leads to them being watered down.

2 organisations mention they wait for more communication.

47 % of organisations are satisfied of their relationship with EFSA regarding ease to provide inputs, meetings with the Authority. 35% have indicated "low satisfaction" to "very low satisfaction" regarding participation to EFSA consultation. For two of them this is explicitly related to their insufficient level of resources needed to participate and come to meetings. One of them indicates that interactions are done through intermediaries like BEUC and the FSAI.

EFSA added value

No organisation mentions that the creation of EFSA has brought shortcomings. A majority mentions improvements in terms of *specialised know-how and expertise* and *credibility of outputs as a result of a greater independence*. The views are more balanced concerning *responses to questions or inquiries, effective stakeholder involvement, setting up of comprehensive networks for the gathering and exchange of information*, 'No opinion' answers prevail regarding the *flexibility in outsourcing of tasks* and the *benefit/cost ratio*.

4. Representatives from industry (RI) (N=22)

This point summarizes the answers of 9 private companies, 10 trade associations and 3 catering/hospitality service providers.

Scientific opinions

9 RI mention the little relevance of the opinions issued by the Animal Health & Welfare Panel. Concerning the other Panels, highest satisfaction concerns the opinions of the Food Additive Panels (16 mentions 'relevant' or 'highly relevant'), the Contaminants Panel and GMO (14 mentions each), the Animal Feed, and Pesticide Panel (13 mentions each).

One RI comments that 'the relevance of EFSA scientific opinions is generally good. Further improvement could come from providing access to the information used to develop the opinion. Also in cases where no firm conclusion can be reached, this should be declared. This point coincides with the comment made by one consumer organization on the lack of traceability in the way EFSA comes to scientific opinions. Another RI mentions that 'The opinions of all of the Panels cited are relevant, but should be given more weight relative to contrary opinions issued by Member State food safety agencies. There should at least be evidence of coordination'.

EFSA contribution to a high level of protection of human life and health

13 RI mention the situation is better with EFSA in what concerns the taking of appropriate preventive actions to reduce any unnecessary disquiet. No RI believes that the situation is worse. One RI believes that better performances come from applying a precautious approach at an early stage in the risk assessments.

One RI mentions that the effectiveness of EFSA would further benefit from improved collaboration between DG SANCO, EFSA and the MS agencies; another one highlights that the issues of main concern relate to actions of the national authority and their interpretation of EFSA risk assessments.

About the consumer confidence in food safety, the majority of the RI (13) mentions no change. 3 RI highlight the impact the MS may have on the consumer confidence as illustrated e.g. by the inconsistent Member State reactions to recent cases of non-permitted colorants (e.g. Sudan 1 and Para Red) in the food chain.

Independent centre of scientific excellence

Most of the RI (20) mention that the EFSA overall organization and related scientific structures are 'good' or 'very good'. One RI regrets the lack of formal consultation mechanisms with regard to EFSA opinions both at central level as well as at Panel level.

About EFSA performance in risk assessment, 14 RI mention 'good' or 'very good' performance. Depending on the respondent, the reason for weaker performances is the deficiency in the expertise of certain Panel scientists (e.g. in material science), the over-cautious character of EFSA causing unnecessary delay when issuing scientific opinions, the need for more interaction with other scientific committees such as CVMP from EMEA or with JECFA from Codex or the need for better coordination with national Safety authorities so as to limit further contesting/duplication of EFSA work at national level.

At least 11 RI consider that EFSA performance in risk communication is 'good' or 'very good' as regards its importance, independence and excellence. 7 RI mention weak performance and indicate the need for improvement in risk communication to the public (overall communications about food safety risks), a perceived lack of cooperation between the various regulatory elements of the risk communication process or the lack of respect for confidential data on the private companies.

Most of the RI estimates the EFSA is 'fairly' to 'fully' compliant with its transparency obligations and they are generally confident in the transparency of EFSA. Three RI make suggestions for improvements in what concerns the publication on the EFSA web site of 1° agenda well in advance of meetings, 2° minutes of

meetings as soon as adopted and 3° opinions as soon as adopted[11], the protection of proprietary and confidential data and the accessibility to Scientific Panels.

EFSA risk communication

Half of the RI is satisfied with the effectiveness of EFSA risk communication as regards sharing and exchange of information and knowledge on food safety.

For improved effectiveness, one RI indicates that EFSA opinions should be conclusive enough to allow the risk manager (Commission) to easily (and therefore rapidly) adopt accordingly a legislative measure. For him, acknowledgement in practice of EFSA opinions by national safety agencies is also paramount.

Another RI mentions the semi-carbazide issue as a prime example of complete failure of effective risk communication.

EFSA management systems and processes

7 RI have occasionally experienced difficulties between risk assessors and risk managers in the distribution of communication tasks. 6 RI have experienced such difficulties often or very often. 9 RI do not have any opinion on this issue.

More generally on the cooperation between risk assessors and risk managers, one RI refers to the semi-carbazide issue that highlighted general problems with the interface between risk assessment and risk management and the acceptance of EFSA outputs as valid science. One RI mentions 'the need for EFSA to be fully within the process of Inter Services Consultation to enable scientific comment on the appropriateness and practical workability of regulatory proposals'.

Most of the RI mentions a fair to strong contribution of the EFSA website to improved networking with stakeholders. One of them comments on the need not to put too much information on the website. Another one stresses that even if the website is a good tool, it does not contribute to networking with stakeholders.

EFSA scientific expertise

A majority of the RI has no opinion on the adequacy of the EFSA internal scientific expertise. For the cases when the RI has an opinion, the EFSA internal expertise is generally considered as adequate.

One RI is however of opinion that the EFSA is clearly understaffed so that it is difficult to meet deadlines, what is greatly detrimental for the industry. Suggestions from two respondents are that the EFSA scientific expertise (contaminants) could be improved with industry representation and that for larger requests (more than € 100 000) a consultation process should be established.

EFSA beneficiaries and stakeholders

Most of the RI (20) says that the EFSA priorities are fairly to fully in line with their expectations. 12 RI also believe that EFSA outputs are fairly in line with their expectations while 6 RI mention they are weakly in line. 3 RI mention their wish to have more timely opinions.

A majority of RI (14) mentions that EFSA is fairly compliant with the legal requirements regarding the consultation and information of stakeholders. One RI hopes that the future Stakeholder Consultative Committee will provide additional forum to improve the dialogue (in particular in the field of food additives). Two of them mention that improved accessibility of interested stakeholders to Scientific Panels would be desirable and favour a more structured consultation with stakeholders and support the creation of a consultation forum.

RI are generally fairly to highly satisfied regarding their relationships with EFSA. This is truer for the possibility of meeting the Authority than for the ease to provide inputs, for which 6 RI mention a low level of satisfaction. Also 5 RI were not satisfied concerning the participation to consultations.

[11] *The RI mentions that opinions are usually published 1 month after their adoption and there is no way to get information on their content in the meantime.*

EFSA added value

The creation of the EFSA has brought added value primarily regarding the *specialised expertise and know-how* (mentioned by 16 RI), the *credibility of outputs as a result of greater independence* (15 RI), the *effective stakeholder involvement* (14 RI) and the *response to questions or inquiries* (13 RI). Respectively 11 and 13 RI do not have opinion about the EFSA added value regarding *flexibility in outsourcing of tasks* and *benefit/cost ratio*.

As commented by one RI, 'the new system is clearly an improvement on the previous situation and is moving towards the required objectives. My perception is that co-ordination between risk assessment, risk management and risk communication needs to be improved but it is not EFSA role to do this but the role of each agency to better co-ordinate their actions'.

An alternative option would have provided more (even more) added-value regarding the 'effective stakeholder involvement' (12 RI) the 'specialised expertise and know-how' (8 RI), the 'response to questions or inquiries' (8 RI) and the setting up of comprehensive networks (6 RI).

As far as RI have commented their responses, it seems that such alternative option does not mean 'replacing EFSA with something different' but well 'keeping the Authority and improving it' e.g. by recruiting additional experts, encouraging the EFSA Panels and dedicated working groups to dialogue with industry and to meet the applicants/notifiers on a bilateral basis so as to facilitate the exchange of scientific and technical information, shortening the time lines to make the industries able to stay competitive in a global market.

5. Some views of the press and of Chairs of Panels (N = 8)

Relevance of scientific opinions issued

Opinions are relevant but they could be made much more relevant i.e. by being more incisive, by being written in a clearer style and by giving the conclusions in a far less technical way in the summary of the opinions. The opinions should more clearly reflect the importance of an issue. Top priority for the most important opinions (danger to human health) should be reflected in the calibre and length of the opinion. Opinions of a lower importance could be much briefer. In all the summaries, it is important to be relevant to the non-technical reader.

Timeliness of scientific opinions issued

Panels respond within timeframe agreed with petitioner. Timeframes inserted into EU legislation are not always agreed with EFSA in advance - this should be addressed.

Initiatives taken as regards uniform risk assessment methodologies

These initiatives refer to creating working groups of the Scientific Committee on specific items such as exposure assessment or genotoxic and carcinogenic substances, as well as inter-Panel Working Groups.

Added value of the scientific expert services

The Scientific Expert Services are an essential component of the risk assessment process because they provide for the ongoing daily scientific work of EFSA to complement the regular scientific advice of the Panel members. There is an urgent need to expand these services in order to fulfil the growing workload in risk assessment.

Establishment of procedures to minimise divergent opinions and reduce duplications of work

EFSA staff is trying to encourage Member States to let EFSA know when they are working on a particular topic (procedure in preparation), especially if it is a topic already on the EFSA list of questions (procedure in place).

Appropriateness of preventive actions by EFSA

Risk Communication at EU level has been substantially improved by EFSA. Effective action has been taken in a number of areas e.g. semi-carbazide, contaminants in farmed salmon, Bt 10. The ongoing communication of scientific advice to risk managers and stakeholders is effective.

In some cases, EFSA has taken action, which has led to a co-ordinated approach and meant that there has been less unnecessary alarm. However, in other instances, EFSA could have been much more proactive. E.g. EFSA has not issued statements on Para Red, Sudan 1 and salmon fish. While EFSA cannot issue risk assessments on every hazard that is in the news, it needs to make some statements on some well-chosen issues.

EFSA overall organisation

Much of EFSA organisation and scientific structure is very good despite understaffing, but EFSA is handicapped by its inability to recruit more scientific staff and more experienced staff due to Commission budget constraints. When BSE was raging, the Commission promised a high calibre authority with the necessary staff. It has failed to deliver on the staffing promise.

The involvement of stakeholders needs to be better defined but a lower involvement is related also to a higher independence.

EFSA performance in risk assessment

EFSA could do more to have a higher profile. If networking with Member States is essential, EFSA needs perhaps to do more to establish its own identity, which would ensure its independence.

The risk assessments from EFSA do seem to carry more weight in the EU and be cited beyond the EU (e.g. in the USA) compared with those from the previous Scientific Committees attached to DG SANCO. This is partly due to better publicity of EFSA opinions via the Internet, the greater independence of EFSA from the Commission and the increased number of Panels compared with Committees, enabling input from more scientists.

Heavy workload of the Panels together with resources limitations endangers the excellence of EFSA work.

Indeed there is insufficient internal scientific support from EFSA (understaffing) and shortcomings in the availability of external experienced experts whose time for EFSA assignments is finite.

EFSA performance in risk communication

EFSA needs to be a bit clearer in its risk communication and to use simple, straightforward language that everyone understands. It should not be frightened of talking about scientific uncertainty.

EFSA transparency

In the next round of selection, more scientists with different views should be included i.e. for GMO someone with some sceptical tendencies should be on the Panel. The opinions need to be written more clearly, particularly the summaries. The board meetings seem transparent but it might not be concentrating on some of the important issues - it is steered into a 'cul de sac' of administration. The real issues are not always tackled, so in a way transparency is irrelevant.

The weakest point at the moment is the relationship with national agencies. It took a too long time for EFSA to take care about that major point as any discrepancy between opinions from EFSA and national agencies and any duplication of work create a discomfort and a lack of confidence for consumers.

EFSA expertise

The GMO Panel could do with the inclusion of at least one person who is a bit sceptical from a scientific point of view about GMO and the Biohazards Panel could draw more on some of the scientists in the UK regarding BSE because there is a lot of expertise there and it would avoid duplication.

There is a serious understaffing of the EFSA scientific services. There is an urgent need for experienced senior scientists.

External expertise: EFSA has secured a very wide range of high quality independent experts in the Panels and working groups. Internal expertise: EFSA has a small number of very high quality independent experts. Many more high quality senior scientists are needed across a range of areas of expertise.

On the internal staff attached to the Panels: they are all very competent but too overburdened with administrative tasks in running the Panels and Working groups that they have little time (and the Commission

and EFSA give them little freedom) to address scientific issues. There is a need for a relaxation of the current requirement that all questions coming into EFSA have to be answered by a Panel.

In food safety area, problems are often interdisciplinary (e.g. toxicology, nutrition, microbiology) and the present structure of Panels has no longer a common platform[12].

EFSA contribution to a more consistent decision-making

It is still early in the life of EFSA but there are clear indications that EFSA is setting the standards for risk assessment in Europe and globally. This will lead to greater consistency in decision-making at EU level, at Member State level and in international institutions.

The independence of EFSA from Member States, the EC and stakeholders is critical to its function. All agencies and institutions acknowledge this independence and EFSA advice is universally seen as an objective input into decision-making on matters of food policy.

6. Survey on international cooperation

A specific email survey on international cooperation has targeted international organisations (WHO, FAO, OECD, OIE) as well as organisations from third countries (FDA, Health Canada, ANZFS). The answers provided by OECD, WHO, ANZFS, FDA and Health Canada are synthesised hereafter.

FSANZ

The establishment of EFSA as the risk assessor for the European Union has resulted in a series of well-balanced scientific opinions that have become well regarded by other food regulators around the world. The EFSA scientific opinions are now sought out by stakeholders in Australia and New Zealand and are compared with those of FSANZ.

Executed:

- Visits of high-level staff to each other.

- EFSA routinely supply FSANZ and other food regulators with early warning of the release of their impending scientific opinions or issues that might also affect them.

Future:

- To place staff from both organisations on secondments to foster cooperation and undertake specific tasks of mutual benefit to our respective organisations.

FDA

FDA values the scientific relationship it has built with representatives of EFSA. Both FDA and EFSA have been involved in a number of regulatory cooperation initiatives related to food safety issues, including information sharing on risk assessments. These activities have the added value of increased consumer protection, and exchange of scientific expertise.

Executed:

- Bilateral meeting in Brussels, June 2004, to share and exchange information on their respective organizations.

- Bilateral meetings in December 2004 to assist EFSA in defining a strategy for microbial risk assessment and all day meeting to inform EFSA about the FDA process for identifying, selecting and managing 'major' risk assessments.

[12] *This last comment seems to ignore the role of the Scientific Committee.*

Future:

- To continue dialogue with EFSA to facilitate regulatory cooperation and the sharing of information.

Health Canada

Up to now, the cooperation between EFSA and Health Canada has consisted of two activities.

1° Workshop on Risk analysis/Risk communications, Ottawa, Ontario, Canada, March 23-24, 2005.

This workshop fostered open communications between Health Canada and other national and international collaborators. During this workshop Health Canada met with Dr. Herman Koeter, Executive Scientific Director and Deputy Director of EFSA. They exchanged on preferred risk mitigation and risk communication strategies used by both parties with regards to Acrylamide, Furan and other chemicals in foods. As a direct output of this workshop, a working group of international members was formed for information sharing, and terms of reference are being developed. This will enable future open dialogue between EFSA and Health Canada (amongst other International organizations).

2° Product Assessment

The Food Directorate of Health Canada has had many very beneficial and productive discussions with various EFSA members regarding a number of risk assessment issues (e.g., parabens as food additives, furan, food allergens), but to date there has not been specific cooperation in projects. EFSA and Health Canada are currently laying the framework for more formalized collaboration efforts that should be valuable for both organizations.

WHO

The cooperation between EFSA and WHO has consisted in exchanging scientific information on specific topics, with the effects of keeping each other informed of activities and avoiding duplication of work.

The cooperation instances are e.g.:

- FOS/WHO has shared all INFOSAN notes in advance with EFSA.
- EFSA has shared its papers on *Enterobacter sakazakii* in infant formula with FOS.
- EFSA is participating in the FAO/WHO E-mail discussion group 'Virus in Food'.
- With PCS/WHO, there have been several interactions such as: on the pesticide evaluation programme to compile table of available evaluations and planned programme; on the contaminants side discussion of outcome of the 64th JECFA meeting; provision of draft monographs on acrylamide and on PBDEs to EFSA scientific staff.

OECD

Cooperation between EFSA and OECD in the area of pesticides (with the Environment, Health and Safety Division) originated in June 2003. Instances of cooperation are the participations of EFSA in OECD's working group meetings and in a workshop in Washington.

Specifically in the area of pesticide risk assessment, EFSA seems active in identifying who is doing what (which national organisations). EFSA has also exchanged reviews with Health Canada and FDA.

List of stakeholders having responded to the survey

Advisory Forum

Country	Name	Organisation
Austria	Dr. Roland Grossgut	Austrian Agency for health and food safety (AGES)
Belgium	Mr. Charles Crémer	Federal Public Service – Public Health, Safety of the Food Chain and Environment
Cyprus	Dr. Constantinos Michael	Food Safety Board – State General Laboratory
Czech Republic	Dr. Milena Vicenova	Food Authority, Ministry of Agriculture
Denmark	Dr. Hans Peter Jensen	Danish Institute for Food and Veterinary Research
Estonia	Hendrik Kuusk	Ministry of Agriculture
France	Paul Merlin	French Food Safety Agency (AFSSA)
Germany	Susanne Kaus	Federal Institute for Risk Assessment (BfR)
Hungary	Prof. Peter A. Biacs	Hungarian Food Safety Office
Iceland	Elin Gudmundsdottir	Environment and Food Agency
Ireland	Dr. Alan Reilly	Food Safety Authority of Ireland
Italy	Prof. Enrico Garaci	Ministero della Salute – Istituto Superiore di Sanità
Latvia	Vinets Veldre	Food and Veterinary Service of Latvia
Malta	Dr. Martin Seychell	Food Safety Commission
The Netherlands	Dr. Benno H. ter Kuile	Voedsel en Waren Autoriteit
Slovenia	Marusa Adamic	National Institute of Public Health
Sweden	Dr. Leif Busk	National Food Administration
Switzerland	Dr. Michael Beer	Swiss Federal Office of Public Health

EFSA Expert Panel

Name	Function
Dr. Susan Barlow	Chair EFSA AFC Panel
Dr. Philippe Vannier	Chair EFSA AHAW Panel
Prof. John D. Collins	Chair EFSA BIOHAZ Panel
Dr. Josef Schlatter	Chair EFSA CONTAM Panel
Dr. Harry Kuiper	Chair EFSA GMO Panel
Prof. Albert Flynn	Chair EFSA NDA Panel

European Parliament

Name	Function
Oliver Emmes	Advisor on food safety and quality in GREEN/EFA Group
Conceição Gonçalves	Principal administrator of the Secretariat of the Environment Committee
Vittorio Prodi	Member of the European Parliament – Committee on the Environment, Public Health & Food Safety
Michel Somville	Advisor on genetic engineering issues in GREEN/EFA Group

Commission Services

Name	Commission Service
Isabelle Peutz	AGRI DG
Juergen Helbig	Environment DG
Kathryn Tierney	Environment DG
Elke Anklam	JRC
Guy Van den Eede	JRC (Ispra)

Consumer organisations

Country	Name	Organisation
Austria	Birgit Beck	Verein für Konsumenteninformation (VKI)
Austria	Petra Lehner	Chamber of Labour Austria – Consumer policy department
Belgium	Francesco Montanari	EURO COOP
Belgium	Robert Remy	Test Achats
Cyprus	Rodoula Papalambrianou-Karavella	Cyprus Consumer's Association
Czech Republic	Karel Pavlik	Consumers Defence Association of the Czech Republic
Finland	Maili Mustonen	Kuluttajat-Konsumenternary
Germany	Thomas Isenberg	Federation of German Consumer Organisations
Greece	Nikolaos Tsemperlidis	Consumer Protection Centre
Hungary	Livia Domolki	OFE Budapest
Ireland	Dermott Jewell	Consumer's Association of Ireland
Italy	Maria Luisa Villa	Altroconsumo
Latvia	Maria Zeltina	Latvian National Consumer Right Protection Association
Poland	Elzbieta Sieliwanowicz	Polish Consumer Federation
The Netherlands	Ir. Gerard Kramer	Consumentenbond
Slovenia	Marjana Peterman	Slovene Consumer Association (ZPS)
U.K.	Christine Coupe	National Consumer Council

NGOs

Name	Organisation
Dil Peeling	Eurogroup for Animal Welfare
Adrian Bebb	Friends of the Earth Europe
Christoph Then	Greenpeace

Private companies

Name	Company
Karin Goodburn	Chilledfood UK
Dr. Geoff Thompson	Danone Group
Bart Brands	Dow Europe GmbH
Dr. Piet Wim Van Dijck	DSM
Colum Hatchell	Mac Donald Europe
François Chastellain	Nestlé
Yasmine Mortajemi	Nestlé
Peter van Vladeren	Nestlé
Paul Synquintyn	Quick Restaurants
Roy Mkirby	Unilever
Peter Oldring	Valspar
Mark Kerr	Whitbread

Scientific Committee of DG SANCO

Maria del Pilar Aguar Fernandez	Scientific Secretary of the SC on Emerging and Newly Identified Health Risks

Trade Associations

Name	Organisation
Beate Kettlitz	CIAA
Franz Jozef Feiter	Copa – Cogeca
Susanne Kofoed	Danish Agricultural Council
Dr. Friedhelm Schmider	ECPA
Hervé Maryse	ELC
Noëlle Vonthron	EuroCommerce
Astrid Meesters	FEFAC
Michael Hunt	Food & Drink Federation (UK)
Suzanne Zänker	IFAH Europe
Nico Van Belzen	ILSI
H. Kenigswald	L'Alliance 7

Press

Name	Organisation
Kate Trollope	EU Food Law
Lindsey Partos	Novis Group

Other

Mogens Thomsen	Independent expert

Third countries and international organisations

Name	Organisation	Function
Dr. Paul Brent	FSANZ	Acting General Manager – Product Safety Standards
Barbara Ward-Groves	FDA	MPH, Associate Director, Office of International Programs, Office of the Commissioner
Ron Burke	Health Canada	Director, Bureau of Food Regulatory, International and Interagency Affairs Food Directorate
Dr. Angelika Tritscher	WHO	WHO Joint Secretary to JECFA and JMPR, International Programme on Chemical Safety
Richard Sigman	OECD	OECD Environment, Health and Safety Division

Annex 4: Case study concerning BSE/TSE

How do EFSA as a whole and the Scientific Panels and Scientific Expert Services handle TSE/BSE (Transmissible Spongiform Encephalopathy/Bovine Spongiform Encephalopathy) and Risk Communications?

1. Introduction and Objectives

The main objective of this case study is to measure the "added value" brought by EFSA by comparing how EFSA has been handling this very sensitive issue for the last 24 months with how the BSE/TSE issue was handled, before the start of EFSA, in the UK and in France, two countries directly concerned by the BSE/TSE issue. More recently, EFSA has had to deal urgently with the potential TSE-related health risk of consuming milk and milk-derived products from goats; so this case study will be analysed also in order to measure the "added value" of EFSA.

Some stakeholders and members of the European Parliament have told us that the BSE/TSE issue was in fact the reason why EFSA was created. This of course is not true as the first cases of "Mad cow disease" occurred in the UK in 1985 and a link between BSE and Creutzfeld-Jacob Disease (CJD) in humans was suspected in the UK as early as 1986 following the first two human deaths in May 1995.The link between BSE and nvCJD was confirmed in March 1996.

BSE was a driver for the establishment of EFSA. Indeed at EU level the BSE issue led to:

- The establishment of the Multidisciplinary Committee followed by the European Steering Scientific Committee (SSC) to advise the Commission.
- An increasing recognition in Europe that a consumer focused on risk assessment on all sorts of food related issues was needed.

And this resulted in the establishment of the EFSA.

2. Methods and Information Sources

The methodology used to reach the objectives is based on different ways to measure the "added value" of EFSA by comparing before and after establishment of EFSA and this via the following themes:

- Comparison of EFSA with National Agencies/bodies issuing Statements and Scientific Opinions on TSE/BSE, with a focus on the TSE issue (section 2.1).
- Interviews with key stakeholders (consumers but also the meat/milk producers and retailers), at EU level (European Trade Associations) and also at National Level in France and the UK (section 2.2).
- Interviews with some Scientific Community leaders who are experts in BSE/TSE, including members in EFSA of the BSE/TSE and Biohazards Units (section 2.3).
- Opinions via interviews with Press and desk work on press review (section 2.4).

Table 1 on next page shows that we interviewed 16 persons: 6 Scientific experts on BSE/TSE, 2 members of AF, the UK delegate to AF and a French scientific expert who is also a member of AF; 2 journalists; 4 trade Association representatives, including a retailer; 2 MEP's and 1 European Consumer association.

Our target was also to interview more AFSSA experts; but both the AFSSA Director and Vice Director resigned during the evaluation period. Fortunately, we were able to interview Dr M. ELIASZEWICZ, the new AFSSA delegate to the Advisory Forum, but she was also member of the "Committee of experts specialized in Transmissible Subacute Spongiform Encephalopathies" (ESST) and her comments were those of AFSSA in general and not her personal ones.

Table 1: List of interviews

Organisation	Interviewee	Qualification	How?	Date
CERVA-CODA	Dr E. VANOPDENBOSCH	Head BSE Unit at CERVA Member of BIOHAZ Panel	F2F	27/04/05
EFSA	Dr Bart GOOSSENS	Scientific Coordinator BSE/TSE SES and BIOHAZ	F2F	03/06/05
AFFSA+AF	Dr M. ELIASZEWICZ	Director in charge of RA in general at AFSSA	Phone	07/06/05
DEFRA (UK)	Frances RADCLIFFE	Head of BSE Unit	Phone	03/06/05
Dépêche Vétérinaire	Dr Michel JEANNEY	Journalist on animal health issues	Phone	24/05/05
AUZALIDE communication	Dr Vincent DEDET	Managing Director Journalist	Phone	24/05/05
Industry	Dr Jean VIGNAL	Reg. Affairs NESTLE	Phone	01/06/05
Retailer	Dr Peter WIGHT	Director Reg. Affairs MARKS & SPENCER	Phone	07/06/05
CIAA	Mr D. TAYMANS	Chairperson Task group EFSA evaluation	F2F	21/03/05
FDF- UK	Mr Roy KIRBY	Food Safety Unilever UK	Phone	05/06/05
FSA	Mr Alan HARVEY	Head of TSE Division	Phone	03/06/05
AF-FSA	Mr A. WADGE	Delegate to Adv Forum	Phone	15/03/05
FSA	Dr James HOPE	Head TSE research at the Vet Lab Agency UK	Phone	14/06/05
EP	Mrs D.ROTH-BEHRENDT	VP Committee Public Health and Food Safety	F2F	18/04/05
EP	Mrs C. JACKSON	Member Comm. Envir. (ex Consumers)	Phone	23/03/05
Consumers	Mrs B. KETTLITZ	Food safety expert	F2F	15/03/05

In addition to those interviews, we had the opportunity to discuss our draft case study with 2 experts and we thank them for their comments:

- Dr Danny MATTHEWS, TSE Programme Manager, Veterinary Laboratory Agency, UK.
- Dr Koen VANDYCK, Vet. Administrator, DG SANCO, who is dealing in particular with the TSE/BSE issue.

Table 2: list of most important documents consulted in the BSE/TSE case study

* 12 Scientific Opinions BIOHAZ and 3 statements of BIOHAZ on BSE, including the Opinions on BSE/TSE goats.
* 7 Opinions from SSC concerning BSE/TSE in sheep and goats from 1988 to end 2001.
* 9 Opinions ("*Avis*") from AFSSA since July 2004 on BSE/TSE.
* FSA website with "BSE" and different sites such as "What is BSE" and "Links".
* Different Volumes of the Report "BSE inquiry into BSE and variant CJ in UK", mainly Volume 1 "Findings and Conclusions", MAFF, 2000.
* BSE Risk Assessment in France: Muriel ELIASZEWICZ AFSSA, Namur June 2004.
* Press Review "EFSA provides update on plans to assess the safety of goat meat and goat meat products with regards to BSE/TSE" 28/01/2005, Communications Department EFSA.
* Press Review "EFSA provides further assessment on health risk of goat meat and goat meat products with regards to BSE/TSE" 28/06/05, Communications Department EFSA 18-07-05.
* Different press cuttings collected in Professional Press Veterinary Record UK- Dépêche Vétérinaire F- Semaine Vétérinaire- Kraftfutter (D) and in Lay press (e.g. Le Monde-Le Soir): 1986 -2005.

2.1. Comparison of EFSA with National Agencies/bodies issuing Statements and Scientific Opinions on TSE/BSE, with a focus on the TSE issue

In this paragraph, we analyse and compare, for both the BSE in bovines issue and the BSE/TSE issue in goats, the Scientific Opinions from EFSA with those from AFSSA and FSA:

2.1.1. BSE issue

EFSA

Since March 2004 till early May 2005, i.e. nearly 14 months, EFSA has published 26 opinions issued by its Scientific Panel on biological hazards (BIOHAZ), of which 12 concerned BSE. It also issued 3 statements (1 deals with BSE and 2 with BSE/TSE in goats). So nearly 50% of the Opinions issued by BIOHAZ concerned BSE/TSE.

In addition, EFSA has published the results of diagnostic tests and GBR assessments (Geographical BSE Risk assessments of countries) issued by the BSE/TSE Unit of the Scientific Expert Services (SES).

Those Scientific Opinions and Statements are then sent to DG SANCO in charge of Risk Management (RM).

Comments

The comments received from the Scientific Community show that the Opinions are generally considered as "scientific and limited to the Risk Assessment issues"; exactly what EFSA should do.

AFSSA

The French Agency, AFSSA, publishes "Opinions" ("*Avis*") based on reports issued by its "Committee of experts specialized in Transmissible Subacute Spongiform Encephalopathies" (ESST). We consulted 9 opinions on BSE/TSE which AFSSA has published since July 2004. Only very rarely they refer to Opinions issued by EFSA (See section 2.1.2 for a detailed case related to the BSE/TSE goat issue). These Opinions are then sent to the "*Direction Générale de l'Alimentation*" (DGAL) at the French Ministry of Agriculture which is charged with RM.

Comments

Even if the "border line" RA/RM is sometimes difficult, it is interesting to note from contacts and interviews, that most interviewees considered AFSSA "Opinions" as a "mix of RA and RM": often the AFSSA "Opinions" end with "proposals" and "suggestions to guarantee the best consumer protection". This is considered by most of our contacts and interviewees as "instructions to RM". This can be explained by the different status of AFSSA versus EFSA: there where the EFSA limits its work to RA Opinions, the rules in France foresee that AFSSA has to be consulted on legal proposals; and therefore their opinions can "touch" RM measures, since they are requested to do so.

FSA

The Food Standard Agency (FSA) website is general public-orientated with sections on "What is BSE?" and a Q/A document .It summarises issues such as banning Specific Risk materials (SRMs) from cattle and the Over Thirty Months Rule (OTM) making the BSE control test mandatory for all cattle aged more than 30 months at slaughter. The site provides a list with the number of BSE cases in the EU MS and outside the EU for the last 3 years and the total since 1987 ("BSE incidence worldwide"), and the results of BSE testing in the UK and EU.

FSA has to refer to their government's advisory committee on spongiform encephalopathies, the Spongiform Encephalopathies Advisory Committee (SEAC): this is the rule as the results of the opinions or conclusions of studies conducted by FSA are always passed to the SEAC. For transparency reasons, the SEAC meetings are even open for the public.

Under 'BSE' and 'Links' the FSA website lists "Other UK and European sites concerned with BSE, TSE's and CJD". These include "European Commission-Food safety BSE" and "BSE groups" in the Irish, German and

Spanish Ministries. This "link" to the European Commission is the only reference to the European dimension, even if the "Food Safety" site to which FSA refers also contains a list of EFSA Opinions for BSE and TSE.

Comments

FSA is independent of the Ministry DEFRA and the opinions referred to in the website deal with the RA; but, as confirmed in our Interviews, FSA publishes a lot of information on its website intended to show consumers the work performed to guarantee their safety.

How to measure the added value brought by EFSA in BSE?

The analysis of EFSA Opinions and Statements, and the fact that it was only dealing with RA is in line with Opinions expressed both in France and the UK. But this does not provide, as such, an evaluation of the "added value" brought by EFSA. It only confirms that EFSA is doing what it should do: issue good scientific Opinions and limit it to the RA issue. The difficulty to prove an added value of EFSA, versus AFSSA and FSA, is that BSE is no longer perceived as a "hot issue"; mainly as the actions taken by EFSA (and also AFSSA and FSA) deal more with general approaches to prevent new cases, such as the withdrawal of SRM (Specific Risk Materials) and the testing of animals prior to slaughter.

The reduction in cases of BSE is certainly, but indirectly, an added value due to EFSA whose experts recommend to DG SANCO to improve and stricter the RM measures; but as those measures were already initiated by the Scientific Steering Committee from DG SANCO(SSC), and "refined" by EFSA, it is difficult to estimate the exact EFSA added value. As an example of measures, we consulted a presentation by Dr M. Eliaszewicz, AFSSA in Namur, June 2004. It gives a summary of ten topics for assessing the risks of BSE, identified by SCC/EFSA in their Risk Assessment an implemented via DG SANCO, as RM, throughout the EU to control the number of BSE cases among animals slaughtered and the transport of meat which could carry prions to humans.

The Commission mandated on several occasions EFSA to update previous opinions in the light of new scientific evidence or based on the improved situation due to the stringent risk management measures in place for several years. The effects of these measures are seen in the number of BSE cases in EU MS which are falling everywhere and in the number of cases of new nvCJ cases in humans which does not increase.

Most of these positive results were already noted before EFSA was started; but the measures are now "refined" on a regular basis at the EU level and implemented, later on via RM measures, in the different MS. This can be seen as a key role for EFSA, and as such another indirect added value, which is not always understood by the outsiders to EFSA and the National experts.

2.1.2. BSE/TSE in goats

We proposed in our tender to study in more detail the Opinions expressed on this issue as it is a relatively recent event; even if the goat found in France died in 2002, BSE/TSE was only diagnosed in November 2004 due to the time needed to obtain the results (nearly 2 years) of the *in vivo* test (in mice) to confirm infectivity.

We could consult 8 opinions (*"avis")* concerning BSE/TSE in goats and issued by AFSSA since early 2002 and also 2 statements and one Opinion issued by BIOHAZ Panel since 2003.But it should be remembered that EFSA started in reality only in 2003; so in an evaluation of the "added value" of EFSA, we should also refer to the 7 Opinions on small ruminants expressed earlier by the Scientific Steering Committee (SSC).

The opinions from AFSSA show clearly that they have been considering the potential presence of BSE in goats since 2002. In January 2005, just after that France informed EFSA of the diagnosis that the agent found in the goat that died in 2002 was BSE, the EFSA, following a mandate received from the European Commission, published the BIOHAZ Statement with an update to its plans to access the safety of goat meat and meat products with regards to BSE/TSE.

This was followed by the AFSSA "Opinion" of 19/04/2005 on the same issue: AFSSA refers to the EFSA Opinion of 28th January 2005 and concluded that in their opinion, as EFSA, it is "unlikely" ("*peu probable*") that milk and dairy products from small ruminants present a risk of contamination with TSE/BSE as long as the milk comes from healthy goats.

In fact, EFSA referred first to their statement of 26 Nov 2004 and reiterated that *"in light of the current scientific knowledge and irrespective of their geographical origin, milk and milk derivates from small ruminants are unlikely to present any risk of TSE contamination provided that milk is sourced from clinically healthy animals*" and added "*important information gaps do not allow, at this stage, the quantification of BSE-related risks with regards to the consumption of goat milk*".

By July 2005 the BIOHAZ Scientific Panel was hoping, after having been able to assess new data (*"monitoring results and further experimental and epidemiological data")* to be able to provide further advice relating to safety of goat meat and meat products. This statement also provided an overview of the actions taken by EFSA following the announcement by the French Authorities of a suspected case of BSE infection in a goat. It was interesting to see that EFSA sent letters to the members of the EFSA's Advisory Forum (AF) in order to request MS and their national reference lab and research institutes to provide EFSA with all information related to this issue. Virtually no responses were received from the MS for the simple reason that the request was for information on goats, an issue where there simply wasn't any data – it is no surprise that there were no replies from MS. EFSA eventually had all the key experts at its working group, and therefore was able to access unpublished data that would never have been put in writing via competent authorities.

Comments on the Added value brought by EFSA in the BSE/TSE goat case

As EFSA only started to become really active on the TSE/BSE issue in 2003, it is important to note that "preliminary work" had been made by the former Scientific Steering Committee (SSC) in DG SANCO, which already expressed 7 opinions on small ruminants since 1998 till end 2001. This was a good basis for EFSA.

The TSE/BSE case in a goat is more recent than the BSE issue, as it emerged at the time that EFSA was created; and as such it is easier to evaluate whether there was an EFSA "added value". As the Commission will not act on the basis of an Opinion from a National scientific body, the intention of the European Commission to mandate the EFSA on the goat milk issue and to request a Quantitative Risk Assessment of the consumption of goat meat products was to provide the scientific basis for risk management measures to be taken at EU level. The "added value" brought by EFSA in this case was to assure that the French goat case became a European issue, which made it possible to implement measures on an EU level.

In addition, the "added value" brought by EFSA in the TSE/BSE goat issue, even if it not really measurable, was to refine the Opinions already expressed by the SSC in DG SANCO before EFSA was created.

2.2. Interviews with the key stakeholders in the BSE/TSE issue (consumers but also the meat/milk producers and retailers), at the EU level (European Trade Associations) and also at a National Level in France and the UK

The objective to evaluate the "added value" by EFSA during interviews with key stakeholders was probably unachievable for two main reasons with which we were confronted during the interviews:

1) Firstly the EFSA remit followed principles largely established by the Scientific Steering Committee (SSC) in DG SANCO before EFSA was created. This is clearly demonstrated under point 2.1 here above: EFSA simply took up this role, and in its first two years has probably had too big a burden to make its own mark on the process as far as TSE's are concerned.

2) Secondly, by selecting the UK and France as indicators of the impact of EFSA, we choose, maybe, the least appropriate countries because they both had well established procedures for handling risk assessments.

   Therefore the selection of countries that did not have the historical infrastructure to thoroughly evaluate risks may have resulted in a much more positive outcome. But as the National food safety agencies are relative young in most of the other countries, this would have been difficult.

But during our interviews with the key stakeholders in the BSE issue (consumers and producers) other issues than "consumers' confidence" were brought up and "added values" due to EFSA could be identified. The list of interviewees are identified in **Table 1**.

2.2.1. EU level

The outcome of these interviews is that the general opinion expressed by stakeholders (Industry, consumers and retailers) is "*EFSA Scientific Opinions are very accurate and scientifically based*".

Both at the EU level (European Trade Associations, industry, consumers) and in France and the UK, those interviewed agreed on this. This is true in general for most of the issues with which the EFSA is dealing.

How EFSA is perceived in the specific case of its handling of BSE/TSE is difficult to assess as it is considered by most of the people interviewed as "under control" ("*BSE is no longer a problem"*) and also as the comparison should be versus the perception in different MS (see below) for UK and France; and, as explained above, this parameter could not be "measured" during those interviews.

2.2.2. United Kingdom

1) On a "hot" topic for UK such as BSE/TSE, this positive opinion on EFSA is confirmed. When we interviewed a UK stakeholder on the question *"Has consumer confidence increased since EFSA exists?",* the direct response was to give figures on beef and meat consumption. In his opinion and for the first time since the end of the 1980s, the consumption of beef has "recovered" to the level seen before the BSE issue. The problem is that this "recovery" to almost the levels seen before the BSE crisis is not due only to consumer confidence in authorities as EFSA and FSA.

   Even if some stakeholders identify the "added value" of EFSA in the increase of beef consumption in UK, we have to add the nuance that several factors have to be taken in account e.g.:

   - The "OTM measures"(Over 30 Months) exclude all over 30 months animals from food and feed chain.
   - The surveillance data in UK, but also in Europe, clearly shows a decline pointing out to an infection in the past. This will influence the perception that BSE is of "lesser importance".
   - The announced number of cases of nvCJD was not confirmed; so the initial fear was calmed down.

   In the opinion of other UK stakeholders, the FSA opinions are less "clear" and as example, in their opinion, the position taken by FSA on the BSE issues did not improve the confidence of UK consumers in beef.

   Here it should not be forgotten that this was in the past before EFSA existed: the press cutting analysis (see section 2.4) shows that in nearly 90% of cases the references are made with regard to National Statements, such as FSA for UK, rarely to EFSA.

2) For other stakeholders "*FSA is the important body, not EFSA*". EU trade associations such as EUROCOMMERCE do not refer very often to EFSA. But EFSA is recognised to be still in its early days.

Comments

Two different views from two different industry representatives; it seems that one group is far more European oriented, where the second group remains a typical representative of the UK point of view.

3) UK consumers

   The responses from consumers were nearly the same: satisfied with the handling of the BSE cases in recent years, but without "proof" of added value expressed in confidence and consumption in animal products.

   Some people told us that the attitude of the UK citizen is also a consequence of the "Phillips report", the "BSE inquiry into BSE and nvCJD in UK" from 2000.This "inventory" on how the BSE case was handled in the UK was very critical for the UK authorities. Consumer confidence thereafter increased in 2001 and 2002, before the benefits brought by EFSA since 2002 can be assessed. But other interviewees told us that Consumer Associations (some highly political associations) mostly and other lobby groups do value having another independent watchdog in place, such as EFSA, with a more global remit than the FSA in the UK.

   Consumption of beef held up quite well post-1996, mainly because prices were reduced for beef. Consumers were by 1997, and before Phillips report, already buying more beef, and indeed there was adverse consumer reaction in November 1997 when Government decided to ban beef on the bone due to an estimated risk that one consumer could be infected with BSE by eating dorsal root ganglia. Consumers responded by buying beef on the bone illegally, and demanded to be informed of the risk, but allowed to

make their own decisions as to whether to accept the risk. The "impact" of the Phillips report was via the process which led to the establishment of the FSA, even before the Inquiry was complete.

Comments

The fact that the perception by UK consumers of Authorities as FSA and DEFRA is more positive than versus EFSA cannot be linked as EFSA was only created 2 years ago.

2.2.3. France

A good example of consumer confidence is the statements issued by the French trade association of goat owners "ANICAP" which stated "*many protective measures had been taken by the administration long ago to face any possible BSE case…we are not worried*". They used to refer to AFSSA and not to EFSA: see 2.4.

Comments

Based on our interviews and desk work, the added value of EFSA cannot be shown in France, even in the more recent TSE goat issue; and this was confirmed by interviews of French journalists. At the end, the EFSA should be satisfied as far as it related to increased consumer confidence, if its "messages" are using the local Agencies as "relay"; this is also an "added value" especially in countries, as France, where the "cultural background" favours national approaches.

The issue here is how EFSA identifies the most appropriate sources of information, and communicates with the MS. This should be done via AF, but the structures of AF are not yet fully operating. Frequently a request to central government in individual countries does not necessarily identify the appropriate agencies or individuals, especially if roles and responsibilities of individual Government Departments and their staff vary from country to country.

2.3. Interview with some Scientific Community leaders who are experts in BSE/TSE

2.3.1. EFSA

In order to measure the "added value" of EFSA, we had the opportunity to meet for interview two Experts in BSE/TSE for an interview:

- On the question as to what EFSA has brought as "benefits", both agreed and clearly saw a difference: now there is a "clear cut" difference between RA and RM and the scientific community can express its opinion clearly. As a consequence the work at DG SANCO is facilitated.
- In addition to official contacts with DG SANCO and the Unit "Relations with the EFSA and Rapid Alert System" and this mostly via the Scientific Committee, there is also now, in specific cases and where needed, an increasingly direct relation with the respective Head of Units in DG SANCO. This sometimes means that a question from DG SANCO can be formulated more clearly and helps EFSA and its SES start work without delay when a question comes from DG SANCO.
  But there is still an uneasy and unresolved issue as to how the EFSA should respond to a remit that it considers inappropriate. It is beginning to get better at replying that a DG SANCO request cannot be delivered because of absence of data, although it is sometimes under clear pressure to evaluate non-existent data and turn it into precise recommendations.
- The members of the Panel in the BIOHAZ Unit dealing with BSE/TSE are well appreciated by their colleagues. Scientific opinions expressed by scientists in private industry are also taken into account. As an example, in the 'gelatine' Working Group the chairperson is working in a private company. This is known by all the members of this WG and the chairperson declared his "interest" in industry.

2.3.2. AFSSA

- AFSSA, who has considerable experience with health issues and is well known and appreciated by French stakeholders(including French industry and consumers), is satisfied in general terms with the creation of EFSA. The recent BSE/TSE case in goats has been an opportunity to increase collaboration with EFSA and its SES and the EFSA BIOHAZ Unit.
- A proposal from some National Food Safety Agencies is that EFSA should share the research work with national Agencies and certainly avoid duplication of work. Even if this issue is far broader than the

BSE/TSE case, it is certainly of importance in the BSE/TSE case: a lot of European Community MS are faced with the BSE/TSE issue and collaboration in "sharing" the work with other National Agencies and with EFSA would be of benefit for everyone. This was confirmed also in UK (see below 2.3.3).

2.3.3. FSA and DEFRA

1) UK was the first MS confronted with the BSE issue. The members of FSA's BSE Unit and of the UK SEAC (Spongiform Encephalopathy Advisory Committee) are satisfied with the way EFSA is handling BSE issues and with the Risk Assessment Statements and Scientific Opinions which are published as Risk Communications.

   FSA foresees in the future an increased role for EFSA which could reduce the advisory role of the SEAC in advising FSA on negotiating positions and information. This is already beginning to happen in UK for issues that are common to other MS.

2) DEFRA agrees that EFSA activities have added value/made changes to DEFRA activities.

2.3.4 How EFSA's handling is perceived?

From these interviews summarised here above with Experts from the EU, French and British Scientific Community, it is nearly impossible to measure how EFSA is perceived: nearly all interviewed are members of EFSA and/or of Panels or Groups working in EFSA. Most important is the clear cut between RA and RM.

But, even if EFSA is relatively recent, they all appreciated the actions taken by EFSA, even if most are just "refinements" of Opinions already expressed by the SSC and implemented in EU via RM measures.

Not directly for the BSE/TSE case study, but for the future, there is a need for a better "flow" of communications from both EU and National sites, the comments made by National Food Safety Agencies and also the fact that EFSA would like more support from National Agencies are important. AF has a key role to play here and once it will be on "full speed", this flow of communication should still improve.

2.4. Opinions via interviews with Press and Desk Work Press review

2.4.1. Interviews of French and British Press

What the national French papers and magazines reproduce is symptomatic: 9 out of 10 of Food Safety issues concerning BSE/TSE refer to AFSSA Opinions and only once to EFSA. One journalist even told us that BSE/TSE "*it is no longer an issue for the media*".

Industry point of view is that not enough attention is given in the UK press to what EFSA is doing.

2.4.2. How EFSA's handling is perceived in the Press

General

Difficult to judge as in most MS, "*BSE is no longer an issue"* and no longer makes the headings in the press:

- The purpose of the desk work on press cuts was to collect and study both press cuttings from the periods covering the press releases/documents issued by DG SANCO in the past, and now by EFSA and DG SANCO. Even if the first BSE crisis was real (several months, very substantial economic impact on the market) and while the goat issue was more a "sensitive issue", not a real crisis, this survey should allow measuring how the press reported the cases, in relation to "added value" of EFSA.
- The key role of the media was confirmed: as long as humans were dying from nvCJ and that the link with BSE in beef meat was supposed, that was a "hot issue". But now that the number of humans dying from nvCJ is no longer increasing, "mad cow" disease is no longer a front page topic. On the food safety issue, the National press more often reports Opinions from these National Agencies than from EFSA.
- The outcome could have been quite different in other countries than France and UK: AFSSA in France, and SEAC in the UK, have provided historical risk assessments, and FSA in the UK is a mouthpiece and no more in relation to those risks. Relationships have therefore been established between media and

these agencies, but probably not with EFSA yet. All EU institutions are likely to be considered remote by the national press.

Before 2002 and the start of EFSA

We started with a review of press cuttings from before the establishment of EFSA as an independent European Agency in January 2002. Press cuttings came from both the professional press: e.g. Semaine Vétérinaire (F)/ Veterinary Record UK)/Kraftfutter-Feed Magazine (D) and general press from France, Belgium and UK.

The main concerns before 2002 concern the links between new variant Creuzfeld-Jacob Disease (nvCJD), meat intake and the number of cases of BSE-positive cattle in the different MS of the EU.

In the UK, where the first cases of BSE were found, the media provided a great deal of coverage at the start. It appears clearly that it was more emotional than reality and the potential "transfer of mad cow disease to humans" was the most emotional factor with articles speaking about "millions of humans under threat of dying from mad cow disease". The initial fear was mainly due to the fact that with the increase of BSE cases there should be also an increase of nvCJD cases; in reality fewer than 200 humans were diagnosed nvCJD positive, who unfortunately all died.

BSE again became a key issue for the media in some MS when the first cases were diagnosed in their own country (Spain, Germany and Italy, in November 2000 for the first two countries and in January 2001 in Italy).

From 2002 onwards after start up of EFSA

BSE.

The press cuttings from 2002 onwards are far less numerous, and this both in the professional press and in the general press and media. The fact that the number of cases in cattle fell is certainly one of the main reasons for this, but also the number of cases of nvCJ which did not increased. We were told that "*BSE is no longer an issue for the media*" (see above in chapter Interviews).

BSE/TSE in goats

The new "event", disclosed late last year after the first BSE/TSE case was confirmed in a goat in France, allowed some press coverage; but the number of press cuttings is relatively small and can be summarized as "*it is too early to analyse the risk from goat meat and further checks are needed*". So, for the media it is not a real issue worthy of the front page in magazines and newspapers.

It is worth remembering that the "French goat" was actually killed in 2002, as was the flock of origin. So in effect the result was about a potential risk two years earlier and this had a significant impact on interpretation. If the goat had been identified a couple of months before the announcement it could maybe have generated a different press response.

Two press reviews performed by the EFSA Communications Department both demonstrate that the EFSA "messages" come through as " a message of EFSA" or as supported by National Food Safety Agencies:

1) One after the EFSA statement (Scientific Panel BIOHAZ) on 28 January 2005 which provided "an update on plans to assess the safety of goat meat and goat meat products with regards to BSE/TSE". At the request of the DG SANCO, the members of the BIOHAZ Scientific Panel were asked to provide scientific advice on the human health risks related to the consumption of goat milk and goat meat after studying the data obtained in their analysis since 26 November 2004 in which they concluded that " in light of the current scientific knowledge and irrespective of their geographical origin, milk and milk derivates from small ruminants are unlikely to present any risk of TSE contamination provided that milk is sourced from clinically healthy animals."(See point 2.1 Release of Scientific Opinions by EFSA and by AFSSA and FSA for more details).

   Practically two months later, they confirmed that "important information gaps do not allow, at this stage, the quantification of BSE-related risks with regards to the consumption of goat milk". The statement of 28/1/2005 was an update of their statement of 26/11/2004, concluding that "nothing new" is yet available; but that by July 2005 the BIOHAZ Scientific Panel was hoping, after having been able to

assess new data ("monitoring results and further experimental and epidemiological data") to be able to provide further advice relating to the safety of goat meat and meat products. This statement also provided an overview of the actions taken by EFSA following the announcement by the French Authorities of the confirmation that for the first time BSE was found in a goat.

Press Review - international - of the Press Statement of EFSA

The press review performed by the EFSA Communications Department assembled 55 press cuttings ("Media Results") in the week after the EFSA statement of 28th January (including 35 from EU MS and 9 from US-Canada). Most referred to the exact sentences of the Statement of 28th January ("*too early to analyse the risk…*" and "*important information gaps do not allow...*").

Interestingly, the Commissioner Markos KYPRIANOU was quoted many times "*I want to reassure consumers that existing safety measures in the EU offer a very high level of protection*"

Press Review in France of the Press Statement of EFSA

In that same week, French media quoted from an interview with the chairperson of the BSE working Group at AFSSA, Prof. Marc ELOIT that "*there is no proof for the moment that contamination of milk of goats would be possible*" and this was taken up by the French trade association of goat owners "ANICAP" who stated "*many protective measures had been taken by the administration long ago to face any possible BSE case…..we are not worried*".

Not surprisingly, in the Press review performed by the EFSA Communications Department after the EFSA statement of 29 January 2005, of the 35 press cuttings, 10 were from the French media the week after the EFSA statement (but EFSA- Commission was referred to around in half and 8 times reference to AFSSA). This illustrates the statement made by French journalists who told us that for both BSE and TSE in goats the French press refers not very often to EFSA: in their opinion, once in 10 times only and the 9 other times to AFSSA (See interviews in section 2.4.1 here above).

Press coverage in the UK of the Press Statement of EFSA

On the basis of the interviews it is clear that press coverage in UK has been minimal, mainly because it was "relative good news" and this is, normally, not a 'Key Issue' to be reported! Nevertheless, the Press review performed by the EFSA Communications Department after the EFSA statement (BIOHAZ Scientific panel) on 28 January 2005, reference to the goat BSE/TSE issue could be found in 5 Press cuttings (as many as in Italy and Germany) out of the 35 press cuttings coming from the MS. This does not include the Commission's press coverage on BSE, only the press review in the UK in this case.

2) One after that EFSA provided, on 28 June 2005, "further assessment on health risks of goat meat and goat meat products with regards to BSE": the Experts concluded " Low risk for BSE in goats, but more research is needed" and " EFSA's opinion on BSE and goat meat is partly reassuring, but data available must be completed to allow quantitative risk assessment".

Press coverage of the Press Statement of EFSA

It was an objective reporting from the EFSA position. This press review referred to 21 articles; all but 2 articles quoted either statements of EFSA's press release or comments made by speakers at the EFSA Press Conference. The articles came from 6 European Countries: 4 from Germany, 3 from France, 2 from Italy, Spain and Portugal, 1 from Belgium. Three came from Pan European Press. There was no press coverage in the UK press, at least during the week after the EFSA Opinion.

The majority of the articles reiterate the EFSA position that the risk to human health related to the consumption of goat meat and goat meat products is considered to be low at the moment; but that further research on BSE in goats is necessary.

"Added value" brought by EFSA

From the analysis of the press, the added value brought by EFSA could not be found as in most cases the press refers to Opinions expressed by National Agencies. As EFSA was set up only 2 years ago this is

understandable and EFSA will keep a low profile as long as no new "food crisis" occurs and EFSA is not campaigning to get a better profile. But as long as the "message" from EFSA comes through, directly or indirectly via the National agencies, the goal of communication by EFSA, increase consumer confidence in meat products, is reached.

The fact that there are no divergent opinions between the EFSA's conclusions and the statements in the National Press is nevertheless an "added value' of EFSA: this can be seen as a result from a well harmonised strong scientific based communication.

3. Conclusions

The key outcomes from the interviews and data collection are summarised below.

3.1. Comparison of EFSA with National Agencies/bodies issuing Statements and Scientific Opinions on TSE/BSE, with a focus on the TSE issue

The analysis of EFSA Opinions and Statements shows that:

- They were in line with opinions in F and UK.
- EFSA dealt only, as it should, with RA (not RM).

The difficulty to prove an "added value" of EFSA, versus AFSSA and FSA, is that BSE is no longer perceived as a "hot issue"; mainly as the actions taken by EFSA (and also AFSSA and FSA) deal more with general approaches in recommending measures to prevent new cases, such as the withdrawal of SRM (Specific Risk Materials) and the testing of animals prior to slaughter.

The reduction in cases of BSE is certainly an indirect "added value" due to EFSA whose experts recommend to DG SANCO to improve and stricter the RM measures; but as those measures were already initiated by SSC, and "refined" by EFSA, it is difficult to estimate the exact "added value" from EFSA.

The "added value" brought by EFSA in the TSE/BSE goat issue, even if it not really measurable, was:

- To make of it an European issue what enables EU level RM.
- To refine the Opinions already expressed by the SSC in DG SANCO before EFSA was created.

3.2. Interviews with key stakeholders (consumers but also the meat/milk producers and retailers), at the EU level (European Trade Associations) and also at a National Level in France and the UK

The outcome of these interviews is that the general opinion expressed by stakeholders (Industry, consumers and retailers) is "*EFSA Scientific Opinions are very accurate and scientifically based*". Interviewees agreed on this at EU level (European Trade Associations, industry, consumers) as well as in France and the UK.

How EFSA is perceived in the specific case of its handling of BSE/TSE is difficult to assess as this issue is considered by most of the people interviewed as "under control" ("*BSE is no longer a problem"*) and also as the comparison of EFSA's "added values" should be versus the perception in different MS (UK and France). This parameter of "added value" of EFSA could not be "measured" during those interviews. Most of the "renewed confidence" in meat products was already in place in the MS when EFSA was created.

Even if EFSA is recognized by many stakeholders as "a bonus" which contributes to EU consumer confidence in food, including beef meat and goat milk, these "added benefits" could not clearly be demonstrated in the BSE/TSE case study in comparison with the situation existing before EFSA was set up. The main reason is that EFSA's remit followed principles largely established by the Scientific Steering Committee (SSC) in DG SANCO before EFSA was created two years ago.

But the decrease of the number of cases of BSE cannot be denied and even if not only due to EFSA, this demonstrates that EFSA, based on the good basic work performed by SCC, could recommend stringer measures which allowed Risk Managers to "refine" and improve some of the measurements.

We have identified also that consumer confidence in beef has increased since the installation of EFSA. Even if other factors have played a role, the European consumer has more confidence in bovine food products and fewer fears about BSE/TSE. But this increased confidence of consumers is difficult to measure in the case of BSE/TSE. Even if some "facts" confirm this:

- BSE/TSE is no longer a key issue, either in the press or as a priority dealt with by European Trade Associations representing consumers.
- The fact that the industry, both at the EU level and in MS such as UK and France, is in general satisfied with the beef sales is further proof of this confidence.

Of course, the National Food Safety Agencies also played a role in increasing this confidence.

The only "sword of Damocles" is what could happen if more goats and sheep die from BSE. The analysis shows that due mainly to EFSA, the EU is "ready for action"… would more positive BSE/TSE goats be found in the EU.

3.3. Interview with some Scientific Community leaders who are experts in BSE/TSE

The scientific community considers that the Scientific Opinions and Statements issued by EFSA are accurate, scientifically based and "based on good risk analysis". Nearly everyone is happy that "finally" RA is separated from RM. Also, EFSA Risk Communications are considered as very good.

From the interviews with Experts from the EU, French and British Scientific Community, it is nearly impossible to measure the added value of EFSA: nearly all interviewed are indeed members of EFSA and or of Panels or Groups working in EFSA. But, even if EFSA is relatively recent, they all appreciate the positions taken by EFSA, even if most of them are just "refinements" of Opinions already expressed by the SSC and implemented in EU via RM measures.

As one expert told us *"The EFSA Panels and Units have taken on the SCC remit, and if EFSA didn't exist, then something like it would have to be invented"*.

3.4. Opinions via interviews with Press and desk work on press review.

From the analysis of the press, the added value brought by EFSA could not be found as in most cases the press refers to Opinions expressed by National Agencies. As EFSA was set up only 2 years ago this is understandable and as long as no new "food crisis" occurs, EFSA will keep a low profile.

The fact that there are no divergent opinions between the EFSA's conclusions and the statements in the National Press, is nevertheless an "added value" of EFSA: this can be seen as a result from a well harmonised strong scientific based communication.

As long as the "message" from EFSA comes through, directly or indirectly via the National agencies, the goal of communication by EFSA, i.e. the increased consumer confidence in meat products, is reached. At the end, the EFSA should be satisfied as far as it related to increased consumer confidence, if its "messages" are using the local Agencies as "relay"; this is also an "added value" especially in countries, as France, where the "cultural background" favours national approaches.

3.5. Attitudes of the national food/feed authorities.

And, as an additional outcome of the evaluation, we added a fifth parameter: as it is clear that National Food/Feed Safety Authorities have a key role in increasing consumer confidence, how do they consider the role and the potential added value of EFSA.

There is a wish to see more collaboration and common research projects on topics such as BSE/TSE: there is a request by some MS to collaborate with the EFSA and the National Agencies ask to share the work; FSA is even already planning to reduce their staff now that EFSA is in place. From our interviews, it appears clearly, in the UK at least, that discussion on key issues is happening in Europe so quickly that it undermines any attempt to conduct the assessment separately in one MS. The expectation of FSA is that EFSA will eventually determine EU policy in terms of its recommendations to DG SANCO. The speed of this transfer to EFSA, coupled with the increasing confidence with SSC/EFSA opinions, means that Government Departments in UK

are prepared to wait for such an opinion. They may also prefer at times to ask for an EFSA opinion rather than a national opinion, especially where UK believes that the EU agenda may be easier to handle than a local perspective: e.g. in response to the requests for consideration of the relevance of "atypical scrapie" in the context of breeding for resistance, UK recognises that this issue cannot just be solved in the UK.

This is another proof of an "added value" thanks to EFSA; but it remains to be seen if this can be generalised to other MS.

Annex 5: Case study on GMO

1. Introduction

This Case study was prepared as an example to show EFSA's in-depth involvement for its first 24 months of operation in managing GMO approvals and issues at EU level. The Objectives, Methods, Outputs and Reporting Format have been agreed by the Steering Committee for the Evaluation of EFSA.

2. Objectives

The main objectives of this GMO case study are to provide a measure of the performance of the EFSA GMO Panel from the scientific point of view, give a summary of some independent perceptions of the Panel and its outputs and examine the attitude of stakeholders to the validity and reliability of these outputs, in terms of food safety and consumer confidence. EFSA has had to deal urgently with the potential food safety risks of the accidental illegal importation of Bt10 maize into the EU and the validity, relevance and impact of EFSA's response to this will also be examined.

3. Methods

The methodology used to reach those objectives includes:

- Assessment of EFSA's performance in issuing statements and scientific opinions on GMOs, as available on EFSA's web-sites.
- Interviews with key stakeholders in this issue.
- Analysis of contents of those interviews.
- Desk work: collecting and studying the press releases/documents issued by EFSA and press cuttings taken from those periods.

3.1. Assessment of EFSA's performance in issuing Statements and Scientific Opinions on GMOs

Between 25.11.2003 and 6 July 2005, EFSA's Scientific Panel on GMOs ('GMO Panel') adopted 13 opinions on notifications or applications for placing GMOs on the market, one statement on a toxicology test of a GM maize, 4 opinions on legal matters including 3 invocations of Article 23 of directive 2001/18/EC, a Guidance Document and an opinion concerning this, and one self-task initiative. See **Table 1** below. In addition, a further 17 assessments of applications and 3 self-tasked projects are still in progress as at 15.7.2005. The addendum to the Guidance document, Draft new chapter 11.4 on General surveillance of the impact of the GM Plant, has recently been published for consultation.

Added value of EFSA

Although still at an early stage, since almost all submissions to GMO Panel have been reviewed by one or other MS at national level and there is therefore already a position established before the GMO Panel has assessed them, the added value of EFSA can be perceived in terms of the different nature of the opinion process. It is regarded as a good thing that, whereas previously, national authorities made decisions and EU scientific committees were involved as a 'last resort' in cases of disagreement, now the EFSA GMO Panel comes to an opinion at the start of the process, which is then submitted to the Commission for decision. From the perspective of most MSs, however, it seems that GMOs are still not regarded as an issue to be determined by centralised committee but as national issues to be determined nationally, whatever the EFSA GMO Panel may decide.

Table 1: Opinions and statements issued by GMO Panel

Type of work	EFSA-Q- ref no	Subject matter
Reg 1829/2003	2004-159	Monsanto insect- and herbicide-tolerant maize MON863xMON810xNK603, and food and feed use
Reg 1829/2003	2004-154	Monsanto insect- and herbicide-tolerant maize MON863xNK603, and food and feed use
Reg 1829/2003	2004-112	Monsanto insect-tolerant maize MON863xMON810 for food and feed use
Reg 1829/2003	2004-087	Pioneer-HiBred/Mycogen Seeds insect-tolerant maize 1507 for food use
Dir 2001/18	2004-072	Pioneer-HiBred/Mycogen Seeds insect-tolerant maize 1507 for import, feed and industrial processing and cultivation
Dir 2001/18	2004-012	Syngenta insect-tolerant maize Bt11 for cultivation
Dir 2001/18	2004-011	Pioneer-HiBred/Mycogen Seeds insect-tolerant maize 1507 for import and processing
Reg 1829/2003	2003-089	Monsanto insect-tolerant maize MON863 and MON863xMON810 for food use (new application to cover new safety information)
Reg 258/97	2003-121	Monsanto insect-tolerant maize MON863 and MON863xMON810 for food and feed safety (animal feeding trial required)
Dir 2001/18	2003-089	Monsanto insect-tolerant maize MON863 and MON863xMON810 for import and processing
Dir 2001/18	2003-078	Monsanto herbicide-tolerant oilseed rape GT73 for import and processing
Dir 2001/18	2003-003	Monsanto herbicide-tolerant maize NK603 for import and processing
Reg 258/97	2003-002	Monsanto herbicide-tolerant maize NK603, food and feed safety (Novel Foods Directive)
General questions	2005-055	Hungary – invocation of Article 23
	2004-062	Austria & Greece – invocation of Article 23
	2003-005A	Guidance document for the risk assessment of GM Plants and derived food and feed
	2003-004	Guidance notes to Part B of Annex II of Directive 90/219
	2003-001	Austria – notification of national legislation
Self-tasking	2003-109	use of antibiotic resistance genes as markers
Statement	-	evaluation report on MON 863 submitted by Germany

Source: EFSA web-site http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html

3.2 Interviews with key stakeholders

We were able to interview 15 persons, whose affiliations are shown in Table 2 below.

We also reviewed a joint industry document submitted by EuropaBio to the Director General of DG SANCO in March 2005, which makes also relevant comments on general aspects of EFSA evaluation.

Table 2: List of interviews

Organisation	Interviewee	Qualification	How?	Date
Member State Authorities	Dr Steven Hill	Head of Science Advice & Liaison Team, Defra; previously Secretary to ACRE, the UK's Advisory Committee on Releases into the Environment	F2F	13.6.05
	Dr Claire Baynton	Head of Division, Novel Foods, Additives and Supplements, FSA	F2F	13.6.05
	Dr Alex Lawrie	Head of Novel Foods Unit FSA	Phone	5.7.05
	Neil Martinson	Director of Communications, FSA	Phone	4.7.05

Scientific experts	Prof. Derek Burke	ex-Chair of UK Advisory Com on Novel Foods and Processes	F2F	15.6.05
	Prof. Mike Gasson	Science Director, Institute of Food Research, Norwich UK; current Chairman of UK ACNFP; member of EFSA GMO Panel	Phone	14.7.05
Media	Geoffrey Lean	Environmental Editor, Independent on Sunday	Phone	6.7.05
	Sean Poulter	Consumer Affairs Editor, Daily Mail	Phone	27.6.05
Biotech Industry	Dr S Waters	Member of Plant Biotechnology Unit of EuropaBio, Brussels; Regulatory Affairs Director Monsanto Europe	F2F	6.6.05
	Dr J Vanhemelrijk	Secretary General EuropaBio, Brussels	F2F	14.6.05
Food Retailers	Peter Wight	Director of Regulatory Affairs, Marks & Spencer, UK	Phone	7.6.05
	David Gregory	Technical Director, Marks & Spencer, UK; Chair of UK Defra's LINK Programme for Food Quality and Innovation	Phone	1.7.05
NGOs	Vicki Hird	Senior Food Campaigner, Friends of the Earth, UK	Phone	24.6.05
	Emily Diamand	Senior Food Researcher, Friends of the Earth, UK	Phone	27.6.05
	A.Bett	Senior Food Researcher, Friends of the Earth, Germany	Phone	01.04.05
Others	Dr Sandy Primrose	Head of BTM, a traceability and food labelling consultancy	Phone	24.6.05

3.3. Analysis of interview contents

3.3.1. Scientific opinions and statements by EFSA Scientific Panel on GMOs

There was an overall view that the *scientific opinions and statements* were RELEVANT or HIGHLY RELEVANT, though we were told of "small scientific mistakes" in the opinion on antibiotic resistance markers, some lack of clarity in opinions perhaps because of lack of precision in drafting of text, and difficulties in knowing exactly how the Panel had reached its conclusions. Criticism included comments that opinions were not based on sound science, they raised more questions than they answered, did not set out the uncertainties, gaps and assumptions well enough and were not relevant to the retail food sector. However, "The fact that the Commission acts on GMO Panel opinions points to their high relevance", "Opinions are helpful for MS authorities when formulating responses to hostile media" and "Industry welcomes the role of GMO Panel in generating guidelines and guidance documents and would like these to be issued more rapidly".

We consistently heard adverse comments about the *move to Parma* and its likely impact on quality of scientific output – "a 1-day meeting now takes up 3 days and a plenary takes up the whole week", doubts that sufficient skills and resources are available in the locale and a view that the added time pressure will disbar top-rank people from being involved. EFSA should make more use of videoconferencing and round-table telephone conferencing to overcome this.

There are some problems with *reduplication of effort at MS level*, since there should now be no need for MSs to do their own in-depth review of approvals, as if under the 'old' system. Respondents perceived problems with *timeliness* and delays for validation of dossiers for approval. Early delays have now improved but there is still no way to get information about the progress of a dossier. Respondents would welcome a reduction of the validation scope to cover only completeness of data provision, rather than quality or adequacy of data.

Transparency of process was an important concern for our interviewees, scored SOMEWHAT COMPLIANT to NOT CONFIDENT AT ALL. Because it is difficult to see what information and evidence has been used and how a particular opinion has been reached, it is not always possible for some respondents to decide if a MS's specific concerns have been taken into account. A clearer itemisation of the evidence used, and ensuring that the logical process for the opinion was better-stated, would be of great value. A specific case of NO CONFIDENCE was mentioned, the GMO Panel's dismissal of Germany's concerns over Monsanto's feeding

study on MON863xMON610. This concern was raised in spite of the communication from EFSA (letter of 19 January 2005) reiterating its support of the scientific work performed by the members of the GMO Panel. *Monitoring emerging risks* is an important role but little evidence has been seen to date, according to our interviewees. For example, a very important issue is microbial contamination of food, and standards of identifying and reporting this are widely variable across the EU. EFSA could usefully adopt a horizon-scanning approach to emerging needs.

Most respondents stated that it was national food authorities who were responsible for *contribution to a high level of protection of human life and health* rather than EFSA. We heard that the GMO Panel's activities might have contributed to human life and health, had the Councils of Ministers and the MSs agreed to allow GM crops and foods onto the market. Certainly the Panel's deliberations were seen as having a positive impact on the perception of safety of GM feed ingredients.

3.3.2. Risk communication

The overall view was that not enough was done in *risk communication*, with scores from NOT EFFECTIVE AT ALL to VERY WEAK, including a comment that "EFSA is conspicuous by its absence". At national level, risk communication and management information will come from national bodies, such as Leatherhead Food International and the British Retail Consortium in UK, or European bodies such as EuroCommerce. The view was that EFSA's role should be to communicate risk upward to the Commission, and leave other risk communication to national authorities. The view was that EFSA is not covering risk analysis, the assumptions made in coming to an assessment, or the sensitivity (reliability in context) of the assessment. Respondents commented that *risk assessment and risk management* were not separate activities but were part of a continuum including risk communication, underpinned by science, and so should be a valid activity for EFSA and GMO Panel. Overall, "Risk Assessment in context is more for EFSA than for EC, but is currently not well-covered in the EFSA-EC relationship"; EFSA staff attendance at RM meetings in Brussels would be useful in this context.

The *provision of information* was scored as SHORTCOMINGS WITH EFSA - "When EFSA is dealing with controversial issues or popular foods, there is a need for more consultation that can go beyond the opinion itself." More details would be helpful at EFSA Communications Advisory Group about forthcoming opinions and statements, not just a list. *Advance warning for MSs* would be appreciated; providing the opinions and statements under embargo to MS authorities more than 3 days before EFSA release would help in preparing positions, generating cohesion and reducing divergence across MSs. At the other end of the process, the opportunity for MSs to be consulted on *draft final opinions* and statements would be very helpful, though the tight time lines would need to be fully recognised.

More workshops could be held to provide *engagement with the wider public*, real consultations rather than a series of presentations with little opportunity for discussion; more use should be made of videoconferencing and round-table conferencing for MS and public on topics of interest. There were expressed concerns that the *Press Office and Secretariat* do not pass enquirers onto scientific experts for detailed discussion – "We have contacted the GMO Panel Secretariat but find them neither easy to contact nor open to the idea of better contact. We were instructed to send our questions to the Director of EFSA and they would then be passed to the appropriate persons." Other interviewees commented that the output of the press office was "too technical" and did not show an *understanding of how to engage with the wider public and consumers*, with scores of MODERATELY EFFECTIVE to NOT EFFECTIVE AT ALL, and suggested that greater *accessibility* of the GMO Panel would be helpful when there is a need for discussion of safety assessment data packages or ongoing technological innovations. However, "If EFSA can improve its performance, it has the potential to be a VERY IMPORTANT player in Risk Communication". Briefings on a regular basis would be welcomed by the media. The web-site was regarded by most respondents as not as easy to use as it could be; a more focused email alert service using key words of interest and information-filters was suggested.

3.3.3. Management systems and processes

Scientific support staff, though approachable and helpful, were scored 4/10 (NOT VERY SATISFACTORY) to 0/10 (NOT SATISFACTORY AT ALL), though the situation has improved since EFSA was established, boosting the number of secretariat and support staff with scientific expertise is needed, as recognised in the 2005 Management Plan; "Too much very routine work is done by GMO Panel members", and "Adequately-qualified support staff are needed to organise, review and summarise information for panel members and assist members to prepare draft and final opinions". One useful comment was that the creation of an explicit Rapid

Response process for a food crisis which does not rely on a meeting of a committee or Panel, as part of the existing Rapid Alert System, would be very helpful.

Overall there is HIGH to VERY HIGH confidence in the availability and excellence of *Panel member expertise*. Respondents stressed that reduction of divergence could be encouraged by more use of *national expert resources* as part of the proposed co-operation network or as external consultants, or encouraging members of MS competent authorities to apply for positions on EFSA panels, or inviting chairs of national bodies to be observers at EFSA. We received comments from several different interviewees that *environmental questions* and environmental safety are an integral part of assessment of GMO crops and food, but the low number of environmental experts on the panel means that the environmental part of the opinion is not trusted so much, and MSs do their own in-depth review, possibly leading to divergence from the GMO Panel's opinion.

Transparency of membership scored from CONFIDENT IN INDEPENDENCE through LOW LEVEL OF GUARANTEE OF INDEPENDENCE to NOT CONFIDENT AT ALL, the latter based on views that Panel composition reflected a core of 'career-comitologists' with insufficient independence. We were told that the last stages of the *selection process* (criteria for selection), the length of appointments, performance assessment criteria and removal of panel members for poor performance could all be more transparent. Industry noted that co-option was often necessary to get the right calibre and expertise. There were concerns that there was a lack of *consumer representation* and lack of *open meetings*, and "Transparency should no longer be an issue for discussion within EFSA, it needs to act in order to build confidence."

Co-operation mechanisms have started to work well - workshops, concertation events, Post-Marketing Monitoring [PMM] events and inviting MS authority representatives to GMO Panel meetings are helpful in moving MSs together. EFSA should capitalise on such meetings to help bring MSs and EFSA closer. A network of scientific support across EU would be helpful in reducing the pressure on individual members of the Panels. The *GMOEFSANET system* has had a strong contribution to a more rapid communication of risk assessments and email links are also very useful.

3.3.4. Relevance to stakeholders

Respondents stated that EFSA is *highly relevant* because food trade is international and a common approach must be established and there is a need to reduce or remove the variability in food hygiene and standards across the EU. EFSA should do more in terms of *harmonising approaches across MSs* and some respondents voiced concern that MSs can still ignore the GMO Panel's opinions - "each time a MS refuses an authorisation, it costs the industry more than €10 million to refute the failure to make a decision and try to rebuild consumer confidence". EFSA could do more to assess risk management across EU after it has issued its risk assessments, to review the outcomes and develop more harmonised approaches. It is too early to claim that EFSA is *legitimated as a key player* in food safety in the EU, according to our interviewees, though performance so far has been encouraging, in spite of difficulties in producing a 'European view', for example on antibiotic resistance markers, when there are clearly still deeply-held national differences.

The GMO Panel's outputs were seen as being IN LINE or FULLY COMPLIANT WITH *EC policies*. Nevertheless there was some concern about *meeting stakeholders' needs*, with scores from NOT IN LINE AT ALL WITH EXPECTATIONS and VERY LOW SATISFACTION with relationship. We heard concerns that EFSA has not worked with industry to identify issues for future action; there seems to be an overall nervousness to engage with industry and perceptions of an "adversarial approach with EuroCommerce" – EuroCommerce being the body that represents retailers at EU level.

3.3.5. Added value

There has been little or no direct *impact on Member State actions*; though, in UK for instance, some procedural changes have occurred, the consistency of decision-making has not decreased or increased since EFSA, mostly because the systems were so well-established already. It was stated that ACNFP (the UK's Advisory Committee on Novel Foods and Processes) will now take on board the opinions of GMO Panel in food and feed areas without further substantial work, except where there is lack of clarity or where it might seem that the UK viewpoint has not been taken into account.

EFSA's system of producing an agreed opinion and its rapid responses were regarded as *added value* by most respondents, compared with previous systems of MS decisions and Scientific Committees responsible only to

EC, although industry would like a stronger role for EFSA in securing a harmonised, risk-proportionate approach to food safety across the EU. *Activities of scientific expert services* and *encouragement of uniform methodology* have added value, through events such as workshops and PMM meetings, and the Guidance on Risk Assessment. *Additional coherence* would be achieved if EFSA had a 2-weekly rolling email alert report or 'forward plan' to give MS authorities better interplay with EFSA panel activities and alignment of their own schedules and activities.

However, EFSA has made no direct impact on *improving consumer confidence*, according to interviewees; in UK , for instance, consumer surveys show a 10-15% fall in confidence in the UK food retailers' ability to 'sell food you can trust' since March 2003, but this concerns pesticides, obesity and school meals, not GM foods. Overall, in UK, it is consumer perceptions and confidence that produce the decisions that are made, rather than EFSA's Risk Assessment opinions, but there is a belief that EFSA would contribute to improved consumer confidence in future, especially when the first full list of *de novo* approvals come through the GMO Panel. On a European basis, the actions of MSs in refusing to agree to EFSA GMO Panel's opinions on safety and acceptability has meant no increase in consumer confidence in GM foods at all. Media attention towards EFSA is either simple abstracts from the press release with a web-link to the full opinion, or commentary that highlights adversarial aspects of the opinions; neither of these approaches assist in promoting consumer confidence, EFSA's image or harmonisation.

3.4. Desk work

We studied the Scientific Opinions produced by EFSA GMO Panel, the related press releases issued by EFSA and the subsequent press coverage. The primary purpose was to evaluate process, and to check how often EFSA was mentioned as the source of the information, and whether the press coverage appeared to represent fairly the conclusions of the opinions and EFSA press releases.

3.4.1. GMO opinions and statements

We reviewed 19 GMO Panel responses to EFSA Questions, spanning EFSA-Q-2003-001 to EFSA-Q-2005-055, looking at periods of validation and review, and delay to publishing the opinions, according to the information available on EFSA's web-site:

- Validation periods may reflect completeness of data at the time of submission of a request for assessment and opinion, or may reflect internal processes; they appear to be reasonably short (in 9 cases, accepted when submitted) although the biotechnology industry has complained about lengths of time between submission of dossiers and acceptance. But during this validation period the CRL (Contract Research Lab) has to perform its own work and sometimes there is no contact between the two processes of CRL work and the administrative review by the Unit in EFSA: other applications not yet determined have validation periods of 1 month to 6 months or more, mostly 4-6 months (see EFSA web-site, register section). The bioindustry's concerns may therefore be relevant for these.
- Review periods for applications are variable but most (9/13 = 69%) are less than 6 months. Only 2/13 (15%) are less than 3 months. Review periods for legal matters (invocations of Article 23 and notifications of national legislation) are naturally shorter, all less than 2 months.
- EFSA has given itself the target of producing a press release 'immediately' on an opinion being adopted by its Scientific Panels. There is no definition of the practical level of 'immediate' but in common parlance it can be taken to mean within 1-2 days. This target has not been achieved - 11 opinions have been published in the period from 6-19 days and 7 after at least one month.

We also reviewed five statements from EFSA, issued from 20.10.2004 to 09.09.2005. These appear to have been timely in relation to the events stimulating the statements.

3.4.2. Press releases issued by EFSA and media coverage

77 Press releases were reviewed, spanning the period 18.06.2003-21.06.2005. 9 of these concerned management topics, selected because they set out EFSA's intentions, against which achievements might be measured, as well as providing firm statements defending EFSA and its activities when such statements seem necessary. The topics included: stressing requirements for openness and transparency; the intention to create a stakeholder forum; the principle that meeting deadlines cannot be at the price of inferior science, undermining scientific excellence and that EFSA would oppose legislative proposals from the Commission that would allow the EC to withdraw EFSA decisions; the tabling of the 'Paeps Report', which was the result of a series of

interviews of stakeholders, to determine the early views on the image and performance of EFSA, carried out between March and April 2004; the decision to undertake the 2-year review; the conclusion of the Advisory Forum's first large-scale public event on risk assessment and risk-benefit analyses; the Management Board's support for independence and transparency of scientific panels in response to a report by the Friends of the Earth of 26 November 2004; the confirmation in the 2005 Management Plan of an increase of staff from 102 to 194, and 'continued recruitment of senior scientists with a high level of scientific expertise'; and the establishment of the Stakeholder Consultative Platform. Formal evolution of stakeholder engagement appears to have taken 2 years, rather a long time given the very early commitment to this, which may be due to a combination of early days of overstretched resources followed by the need to recover from the move to Parma.

Of 68 other Press Releases available on EFSA's web-site, 12 (18%) concern GMO issues specifically. Interviewees said that the press releases encapsulate the summaries of the GMO Panel opinions in a straightforward and relatively simple way.

98 items of media coverage were reviewed, including some transcripts of radio broadcasts and off-prints of web-pages, including 55 from international media and web-sites based in EU and US, 10 from UK, 9 from Italy, 6 from US, 5 each from Germany and Spain, 2 from Hungary and individual items from a number of other EU countries. Some media items were a response to a particular situation, such as: the GMO Panel's first opinion, on 1507 maize; the move to Parma (including interviews with G Podger); the interchanges between Friends of the Earth Europe and EFSA's Management Board (including extracts from S Slorach's statement of support); allegations concerning inappropriate conflicts of interest of GMO Panel members (including a focus on 3 German experts); the Bt10 case; and the case of the rat study for MON 863 and allegations that EFSA GMO Panel ignored bad science and positive pathological findings. In such cases, the media press releases contained some detail, often with additional information not included in the press release from EFSA. In most other cases, there tended to be no substance to the press coverage apart from a brief extract of the key statements in the EFSA Press Release associated with a specific opinion. Some media items, such as those from the Food Industry Environmental Network and from EU Food Law are barely more than *verbatim* EFSA material. Italian and Spanish coverage tended to include context of GM technology, crops, general information on regulatory regimes. German, Hungarian, some UK media tended to cover issues from an anti-GM viewpoint. Apart from the media coverage engendered by Greenpeace and Friends of the Earth, EFSA was reported at worst neutrally and on a few occasions positively. The GMO Panel *per se* was not often mentioned. Even if a media item concerned GMOs and the EU, a mention of EFSA was not always guaranteed.

3.4.3. The report by Friends of the Earth Europe, of 29.11.2004

EFSA has been *responsive to stakeholder concerns*. A recent example concerns a publication by Friends of the Earth Europe "*Throwing Caution to the Wind: a review of the European Food Safety Authority and its work on genetically modified foods and crops.*" This claimed that the European Commission, under pressure from the biotechnology industry and the United States, used EFSA GMO Panel's opinions to 'create a false impression of scientific agreement when the real situation is one of intense and continuing debate', ignored arguments on safety made by Member States and allowed members of the Panel to have unacceptable biotech industry connections. The Management Board gave the report a full discussion on 16.12 2004. In an unexpectedly strong response from EFSA, the Management Board released the text of a letter to FoE Europe, sent on 19.1.2005, reaffirming EFSA's strong support of its GMO Panel in terms of its scientific excellence, its transparency and its independence; noting important areas where FoE had misinterpreted the legislation; and agreeing to strengthen the process of obtaining and publishing declarations of interest from Panel members and *ad hoc* experts, and to have specific discussions with FoE as part of the stated programme of stakeholder engagement. Thus, EFSA responded within 5 working weeks, allowing for holiday periods. Although there was press coverage of the original publication of FoE report and EFSA's immediate rebuttal, there does not seem to be significant coverage of EFSA's January letter *per se*, rather a shifting of attention away from the general report, towards certain issues raised by the MON 863 rat feeding study. This can be counted as a successful outcome.

3.4.4. The Bt10 case

The 'Bt10 case' concerned the discovery of inadvertent import into the EU of maize seed for research purposes, mislabelled as Bt11 but containing the unapproved Bt10 event, with an ampicillin resistance marker gene as well as a gene encoding insecticidal toxins of *Bacillus thuringiensis* (Bt). EFSA was formally notified of the import of unapproved seed on 23.3.05 and immediately called on the GMO Panel for an assessment. For

this case, we examined the sequence from the release of information by the US EPA on 21 March 2005, one day before publication in *Nature* of the discovery, to EFSA's second statement on Bt10 on 9 June 2005.

By far the majority of press releases in this period were stimulated by NGO press releases and questions, asking for urgent investigations. The Guardian mentioned the GMO Panel's self-task initiative on antibiotic resistance market genes on 01.04.2005; EFSA's statement of 12.04.2005 was reported *verbatim* in Food Law News; on 14.04.2005, Food Navigator (www.foodnavigator.com/productnews/news.asp?id=59391&k=illegal-gm-ingredient) reported on EFSA's statement (describing it as an opinion) that Bt10 maize was unlikely to pose a threat to health or the environment; and also noted that the European Commission was pushing ahead on a ban. Other press items focused on the actions of the Commission or importing countries such as Japan. EFSA was able to provide a statement within 14 working days (12 if the minimum Easter period is taken into account). It is not clear if this time could have been shortened had EFSA had the necessary scientific expertise available within its support staff or secretariat, rather than needing to consult the GMO Panel. Overall, NGO commentators were given more media mention than EFSA except in European web-based media. Any impact of EFSA's statement was quickly overshadowed by the Commission and MSs decisions to move ahead with a ban. In our interviews, we also heard that "the Bt10 statement issued by EFSA was of no importance, since it made little or no difference to the real situation in MSs and again did not provide a transparent basis for statements and opinions in terms of identifying the evidence reviewed".

3.4.5. "Added value" brought by EFSA in media activities

EFSA's impact appears better in response to media issues such as the Bt10 case, the Friends of the Earth report or the Greenpeace statements about MON 863 safety, or when there is something independently newsworthy to discuss, such as the move to Parma, than in the "day-to-day" work of getting opinions and their impact understood and widely disseminated. Some media have a constructive approach to relevant topics (reporters who bring in other detail and facts to add value to the EFSA starting point), and they should be listed in order to identify those who could be cultivated by EFSA. Others, who appear to content themselves with extracts and *verbatim* outline reporting, are in effect no better than the EFSA web-site itself and probably worse, because they may not be providing the factual context of the GMO Panel opinion. These should either be avoided or trained. On the Bt10 issue, in spite of the low level of quoting of EFSA, the statement by EFSA introduced a harmonised scientific opinion of 'no expected risk' into what had threatened to become an overheated debate. However, responses to the EFSA statement do suggest that more attention could usefully be paid in future to showing how a recommendation or an opinion was reached and what assumptions and data gaps exist.

4. Outputs

The key outcome from the interviews and data collection are summarised below.

4.1. EFSA GMO Panel - the handling of requests

The GMO Panel has handled requests in a manner that can be mainly regarded as *relevant, generally accurate and timely.* Opinions are on the whole regarded as authoritative, although some respondents would like to see more clarity so that readers are sure of the evidence that has been reviewed, the thought-processes by which the conclusions have been reached, and the assumptions and gaps that have been considered. Significantly lower scores are however provided by NGOs and media, who question the validity of the science base and claim an institutionalised pro-GM bias of experts. Some respondents do not like delays experienced between submission of dossiers and validation (and have a suggestion on how to reduce these, namely collaboration between the Unit in EFSA and the CRL and focus on the presence of data in the sections, not on its quality). Others would like more advance warning of opinions and statements so that they can prepare for answering their own questions from local NGOs, media and Government Ministers. The Panel's guidelines and other scientific and technical activities are welcomed and the GMOEFSANET is seen as invaluable and is definitely regarded as added value. Co-operation systems are seen as just starting and will need improvement.

4.2. Explanation of findings to consumers

EFSA appears to have made little impact here. Press releases are regarded as too technical and not written in a way that recognises the risk communication requirements for the wider public. EFSA could perhaps address

the issue of whether it has a role in addressing and engaging consumers in general, or should do this via a more consumer-orientated communication effort aimed through national food safety authorities.

4.3. Consumer confidence

According to interviewees, the vital points for consumer confidence are *transparency, independence and proper management of conflicts of interest.* Since these are three of the key targets of EFSA, it should be possible to see EFSA as instrumental in delivering consumer confidence about food within the EU. However, as seen with the case study on TSE/BSE, the National Food/Feed Safety Authorities have a greater impact on consumer confidence than EFSA *per se*. In addition, it is these three points that are regarded as in doubt by some NGOs. On the food safety issue, the National press more often reports opinions from National Agencies than from EFSA.

4.4. Structural Issues

Currently, a spotlight has been shone on the role of EFSA in providing Risk Assessments, because of the failure of the EU Council of Environmental Ministers to agree the Commission's proposals concerning acceptance of GMOs considered safe by EFSA. This is regarded as indicating a lack of coherence in Risk Assessment, Communication and Management between EFSA, EC and MSs. Respondents did not agree with the division set out by the Commission, with Risk Assessment the remit of EFSA GMO Panel, Risk Management the remit of the Commission and the home for Risk Communication not clearly spelt out. As we saw for the TSE case study, the work performed in GMOs over the last two years is considered as excellent by stakeholders who are aware of the European dimension; but not yet at a National level where consumers rely far more on National Food Safety Authorities. EFSA must increase its visibility and campaign if it wishes to get a profile at this level. More interaction between GMO Panel and relevant members of MS authorities is indicated; mechanisms might include joint meetings, increased use of IntraNet, use of MS expert committees to prepare draft first opinions on dossiers, increased possibilities for secondment between MS authorities and EFSA Scientific Panels, increased use of video- and telephone-conferencing. Authorities in some MSs would be happy to be involved in activities to support added coherence between MSs. There is some alarm about the impact of the move to Parma, which needs addressing constructively.

5. Conclusions

Since we are now only just getting to the stage where EFSA's GMO Panel is assessing direct submissions, rather than responding to submissions already assessed by individual MSs under previous legislation, it is premature to make definitive conclusions about ways of working and efficiencies: the next audit or assessment will be more important in this respect. Nevertheless, "Added Value" of EFSA with respect to the management of GMO-related activities could be identified.

From the data and comments that we have obtained it is clear that:

- There is great value seen in the system of obtaining a harmonised opinion as the starting-point.
- Respondents believe that EFSA produces scientifically highly-relevant RA opinions on GMO topics.
- The work on general technical and scientific support is valued (Guidance Documents) and more should be produced, as rapidly as possible.
- Divergence of opinion and lack of consistency between MS and EFSA's scientific committees reduces the added value of EFSA GMO Panel.
- The ability of MS political authorities to ignore the EFSA GMO Panel opinions is seen as detrimental to added value and to consumer confidence.
- GMOEFSANET has made a strong contribution to cohesion and is well-valued – and it could be used for the 2001/18 system as well.

- Some MSs have accepted that they do not need to conduct their own in-depth reviews of approvals when EFSA GMO Panel is doing this. However, there is a belief by some stakeholders that the environmental expertise on GMO Panel is not adequate in number and depth of knowledge, so MSs will still make their own environmental reviews; this needs addressing.

- There is strong concern that the move to Parma might undo the progress made in the last 2 years in adding value, and that more strenuous efforts are needed by EFSA Management Board via appropriate expansion of scientific support system, communications systems and its Secretariats, to overcome these negative impacts.

6. List of most important documents consulted

- Scientific Opinions from GMO Panel, via EFSA's web-site (see Table 1).

- Statements from GMO Panel and/or EFSA on GMO topics (see Table 1).

- EFSA Press Releases on GMO Panel opinions, via EFSA web-site.

- EFSA Press Releases on general management developments, with relevance to GMO topics, via EFSA web-site (see under "desk work").

- Media articles concerning EFSA's opinions and statements on GMO issues.

- Media articles concerning the MON 863 rat feeding study, the Bt10 case, (such as www.guardian.co.uk/gmdebate/Story/0.2763,1449796,00.html) and the disagreements between EFSA, EC and Council of Ministers.

- Information on EFSA Post Market Environment Monitoring Working Group and reports of its consultation workshops, via EFSA web-site.

- GMOs and Food Safety, an Introduction of the European Food Safety Authority (EFSA) – a presentation given by Herman BWM Koëter.

- Throwing Caution to the Wind: a review of the European Food Safety Authority and its work on genetically modified foods and crops, Friends of the Earth Europe, November 2004 & the response from the EFSA Management Board to Dr Martin Rochol of FoE Europe, dated 19 January 2005, ref SR/CM/AC/HK/SS(2205) MB/1.

- The Review of Regulation EC No 1829/2003, EuropaBio March 4th 2005, a letter to Mr R Madelin, Director General SANCO, EC Brussels.

- Stakeholder Interviews: Image and Performance of EFSA Frederic Paeps, FPA 2004; also presentation at EFSA's 2nd Colloque: http://www.efsa.eu.int/stakeholders/colloque_2/695/v06_paeps1.ppt November 2004.

Annex 6: List of interviewees

Organisation	Interviewees	Interviewer	Date	How
EFSA	G. Podger, Executive Director	Bureau van Dijk	31/08/05	F2F[13]
EFSA	H. Koeter, Deputy ExecutiveDirector and Director of Sciences	Bureau van Dijk	30/08/05	F2F
EFSA	Prof. V. Silano, Chair of the Sc. Committee	Arcadia	4/10/05	Phone
EFSA staff	N. Poupart	Bureau van Dijk	07/07/05	F2F
EFSA staff	F. Monnart	Bureau van Dijk	04/07/05	F2F
EFSA staff	Ch. Majewski	Bureau van Dijk	31/08/05	F2F
EFSA staff	6 staff of Sc Committee Unit and 8 Heads of the 9 expert Panels	Arcadia	20/06, 21/06 & 01/09/05	F2F
EFSA staff	Head of Sc Exp Service BSE/TSE	Arcadia	03/06/05	F2F
EFSA staff	Head of Sc Exp Services Epidemiology	Arcadia	21/06/05	F2F
EFSA staff	A.-L. Gassin	Bureau van Dijk	19/07/05	F2F
EFSA staff	A. Cuvillier	Bureau van Dijk	18/07/05	F2F
EFSA staff	Th. Beniflah	Bureau van Dijk	12/07/05	F2F
EFSA MB	B. Sangster	Bureau van Dijk	14/9/05	F2F
EFSA MB	E. Bobek	Bureau van Dijk	15/09/05	Email
Head of Expert panel	A. Chesson	Arcadia	25/08/05	F2F
Member of Expert Panel	J. Hope	Arcadia	08/06/05	F2F
DG SANCO	R. Madelin	Bureau van Dijk	02/09/05	F2F
DG SANCO	R. Vanhoorde, J. Vergnette & Alii	Arcadia & Bureau van Dijk	05/07/05	F2F
DG SANCO (non food unit)	P. Wagstaffe	Arcadia	13/06/05	F2F
DG SANCO (formerly)	B. Gminder	Bureau van Dijk	25/08/05	F2F
DG SANCO	M-P. Benassi & R. Vanhoorde	Bureau van Dijk	12/07/05	F2F
ECDC	Z. Jakab	Arcadia	14/07/05	Phone
EEA	J. Mc Glade	Arcadia	27/06/05	Phone
Advisory Forum – UK – FSA	Dr Wadge	Arcadia	22/09/05	Phone
Advisory Forum – F – AFSSA	M. Eliaszewicz	Arcadia	07/06/05	Phone
Advisory Forum – Hungary	P. Biacs	Arcadia	04/0705	Phone
Advisory Forum – Germany	Viell	Arcadia	07/07/05	Phone
European Parliament	Ph. Whitehead	Bureau van Dijk	27/04/05	F2F
European Parliament	D. Roth-Berend	Arcadia	18/04/05	F2F

[13] *Face to face.*

European Parliament - COCOBU	J. Mulder	Bureau van Dijk	29/08/05	F2F
BEUC	J. Murray	Arcadia	09/06/05	F2F
Euroconsumers	R. Remy	Arcadia	14/06/05	F2F
EUROCOOP	F. Montanari	Arcadia	27/06/05	F2F
CIAA	CIAA Evaluation task force	Arcadia	28/06/05	F2F
Danone	G. Tompson	Arcadia	15/06/05	Phone
Nestlé	G. Kayaert	Arcadia	13/06/05	F2F
Unilever	D. Toet	Arcadia	28/06/05	F2F
COPA-COGECA	R. Feller	Arcadia	22/06/05	F2F
EUROPA BIO	J. Vanhemelrijk S. Waters	Arcadia	16/06/05 6/06/05	F2F F2F
FEFAC	A. Doring & A. Meesters	Arcadia	17/06/05	F2F
FEFANA	D. Jans	Arcadia	29/04/05	F2F
Agence France presse	B. Pinon	Bureau van Dijk	24/08/05	Phone
EU Food law	K. Trollope	Bureau van Dijk	30/8/05	Email
Agra	H. Cuisinier	Bureau van Dijk	06/09/05	F2F

Annex 7: Terms of reference of the evaluation

1. Justification, purpose and objectives of EFSA's evaluation

The obligation to evaluate the Authority is enshrined in Article 61 paragraph 1 of its founding Regulation. This article states:

Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level. The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation reports and the recommendations shall be forwarded to the Council and the European Parliament and shall be made public.

The purpose of the evaluation is to present, in an independent way, the achievements of EFSA as compared to the established objectives, possible shortcomings and possible improvements necessary to its structures and working practices. It could in principle lead to a series of operational changes and possibly also to changes to the Authority's legal framework. Full account should be taken of the relatively short time span EFSA has been operational.

2. Evaluation Questions

Be it at general or operational level, the evaluation questions are derived from the positioning, mission and tasks (intervention logic) which were designed for EFSA in the Regulation 178/2002. They are associated with expected effects measured by success criteria and quantitative or qualitative indicators. This is supposed to allow measuring (i) to what extent the expected result has been achieved and/or (ii) to identify the reasons for partial achievement. The evaluation questions address the following issues: efficiency and effectiveness, relevance, added value, and coherence, complementarity and synergy.

In the main report, the evaluation questions listed below have been organised in four groups in order to ease the understanding of the evaluation. The table below illustrates the grouping of the questions identified by their number and the success criteria considered.

Organisational set-up, management & resources
- Q9 a & b : Management Board - Q9 c, d, e : EFSA other structures - Q1d: Setting up of EFSA scientific structures - Q8 : Management systems & processes - Q12.2: EFSA intervention logic - Move to Parma

Delivering independent and excellent science
- Q1 : Delivering scientific opinions - Q2 : Networking with MS and other organisations - Q3 : Avoiding food crisis - Q4: Independent centre of scientific excellence - Q5: Data collection and emerging risks - Q6: Technical and scientific assistance - Q11a,b,c,e,g: Scientific added value

Communicating on risks
- Q7 : EFSA success in risk communication - Q8c: Relations RA - RM - Q12.3 : Coherence RA, RM, RC

EFSA and Stakeholder needs
- Q10 : Requirements on EFSA - Q11 d, f : EFSA added value - Q12.1: EFSA intervention logic

2.1. Efficiency and effectiveness

Q1: Has the Authority issued the relevant scientific opinions, in a timely manner and at a reasonable cost in terms of the financial and human resources deployed? If yes, to what extent and why? If not, why?

List of success criteria:

a. Relevance of scientific opinions issued.
b. Time frames for issuing scientific opinions and decision making process.
c. Planning and setting priorities in scientific activities.
d. Efficiency in setting up internal and external scientific resources for the purpose of issuing the scientific opinions.

Q2: Has the Authority succeeded in setting up an effective cooperation network with Member States national food bodies and other organisations operating in the fields within its mission, in accordance with its mandate? If yes, to what extent and why? If not, why?

What has been the contribution of this network towards the attainment of the Authority's objectives in these fields?

Does this network help to enhance common approaches and coherence?

List of success criteria:

a. Efficiency of the communication network with the Members States and stakeholder organisations.
b. Effective cooperation mechanisms exist in order to ensure effective risk-assessment and rapid networking on risks with national agencies, other Community Agencies (EMEA, EEA), EU scientific committees and the Commission Services (DG RTD, JRC).
c. Establishment of a network of organisations operating in the fields within EFSA's mission and responsibility for its operation.
d. Established cooperation with international organisations and third countries.
e. Promotion, coordination and development of uniform risk assessment methodologies.
f. Establishment of procedures in order to minimize divergent opinions and reduce duplication between national bodies and EFSA.
g. Added value to the work of national bodies.

Q3: Has EFSA contributed to a high level of protection of human life and health? If yes, to what extent and why? If not, why?

List of success criteria:

a. Recognition that on matters which may have led to a food safety crisis or the perception of one, EFSA has dealt with this properly and in such a way as to reduce any unnecessary disquiet.
b. Preparedness of EFSA for a crisis, appropriate systems put in place.
c. Evolution of consumer perception and confidence in food safety issues, recognising that such trends are not specific to EFSA's role per se but rather to the effectiveness of the ability of risk assessors and risk managers to address effectively consumer concerns.
e. EFSA's decision making processes concerning priorities take into account overall risk to health.
f. Compliance with the legal requirements in terms of openness and transparency and relationship with stakeholders.

Q4: Has EFSA succeeded in establishing itself as an independent centre of scientific excellence? If yes, to what extent and why? If not, why?

List of success criteria:

a. Effectiveness in setting up EFSA's overall organisation and related scientific structures.
b. Recognition by consumer associations and other stakeholder organisations of the importance, independence and excellence of EFSA's work in relation to risk assessment, communication and food safety.
c. Confidence in the transparency of EFSA.

d. Setting up of mechanisms and processes to guarantee scientific independence and excellence of scientific expertise.
e. Confidence in EFSA to deliver appropriate science which addresses the risks to human health from food, feed and other matters dealt with by EFSA.

Q5: Has EFSA succeeded in collecting and analysing data to identify, characterise and monitor (emerging) risks? If yes, to what extent and why? If not, why?

List of success criteria:

a. Mechanisms in place to collect and analyse data.
b. Mechanisms in place to identify emerging risks.

Q6: Has EFSA succeeded in implementing technical and scientific assistance? If yes, to what extent and why? If not, why?

List of success criteria:

a. Mechanisms in place to implement technical and scientific assistance.

Q7: Has EFSA succeeded in risk communication? If yes, to what extent and why? If not, why ?

List of success criteria:

a. Mechanisms in place setting up risk communication processes.
b. Effective sharing and exchange of information and knowledge pertaining to food safety through risk communication mechanisms.

Q8: Do EFSA's management systems and processes contribute to the effectiveness and efficiency of its operations? If yes, to what extent and why ? If not, why ?

Indicative list of success criteria:

a. Specific, realistic and operational objectives as well as indicators for outputs, results and impacts contained in the work programme.
b. Activities (and resources) of EFSA focused on priority objectives. This criterion relates to the 'system' that ensures that activities are prioritised and resources allocated accordingly.
c. Communication and dissemination strategy towards interested parties and public at large is well established between risk assessors and risks managers.
d. Internal communication systems contribute to focusing on core operational objectives and to enhance productivity.
e. Monitoring system allows EFSA to collect relevant data on inputs, outputs, results and impacts (where possible).
f. IT management systems facilitate the networking with Member States and stakeholders.
g. Responsiveness of EFSA to a crisis.

Q9: Does the Authority's organisational set-up contribute to the effectiveness and efficiency of its operations? If yes, to what extent and why ? If not, why ?

Are the number, mandate, role and composition of EFSA's Scientific Committee, Scientific Panels and other Expert Groups adequate and proportionate to their tasks?

List of success criteria:

a. The size, composition and context of the Management Board strike a reasonable balance between the need to retain an effective decision-making body and the need to ensure the full range of necessary skills, backgrounds and geographical balance.
b. Management Board provides clear strategic direction and sets priorities. Appropriate indicators of performance: Board meetings are focused on issues of strategic importance, delegation of tasks to the Executive Director.
c. The added value of the Advisory Forum in terms of scientific advice on projects, priority setting, feedback and expert networking.

d. Support mechanisms to the Scientific Committee and Scientific Panels in terms of managing overflow of work.
e. And investment in food science by development and reinforcement of the internal scientific expertise.

2.2. Relevance

Q10: Do EFSA's activities, mission and tasks correspond to the requirements of the beneficiaries and stakeholders and benefit to the Community policy on food and feed? Are there areas where changes are necessary in scope, management systems or processes? If yes, to what extent and why? If not, why?

The answers to this question will be derived from the comparison between the results of the impact assessment made in connection to the proposal to the legal basis of EFSA and the results of the present evaluation.

List of success criteria:

a. The clients, beneficiaries or stakeholders of EFSA are satisfied with the results of its activities (dialogue, scientific input…).
b. EFSA's activities have been instrumental to the delivery of Community policy in the area to which the Authority's activities pertain.

2.3. Added value

Q11: **Des the transfer of the risk assessment, zoonoses and BSE – TSE testing issues to EFSA provide added value compared to possible alternative options of implementing the activities in question (e.g. through the Commission Services themselves, the contracting out of individual tasks, etc.).**

If yes, to what extent and why ? If not, why ?

What are the improvements or shortcomings compared to the previous system of scientific and technical support within the European Commission?

List of success criteria:

a. Enhanced specialised expertise and know-how.
b. Timely and relevant and clear response given to questions or inquiries made by EU institutions or other stakeholders.
c. Credibility of EFSA's outputs enhanced as a result of greater independence.
d. More effective stakeholder involvement (e.g., consumer organisations, food industry, other interested bodies ….).
e. Setting up of comprehensive networks for the gathering and exchange of information.
f. Cost/saving assessment of EFSA's activities on the budgetary framework of the European Union as a whole.
g. Flexibility in the implementation of outsourced tasks achieved.

2.4. Coherence, complementarity, synergy

Q12: Do the intervention logic, objectives and activities of EFSA support or contradict those of other public interventions i.e. those of the relevant European Institutions involved in food safety policy – eg the Commission and the European Parliament, and the member state's national bodies.

If yes, to what extent and why? If not, why?

Are the elements of EFSA's intervention logic complementary, mutually supportive and non contradictory? If yes, to what extent and why? If not, why?

How successful has EFSA been in promoting the necessary coherence between the risk assessment, risk management and risk communication functions in collaboration with the Commission and Member States?

List of success criteria:

a. Coherence and consistency ensured with regard to the overall strategic objectives in the Community policy (Strategic Planning and Programming).
b. Internally coherent hierarchy of objectives established (from the Regulation down to the Annual Work Programme).
c. Consistency ensured between high-level objectives in the founding Regulation [178/2002] and the resources, responsibilities and competences entrusted to EFSA.
d. Integration of EFSA into the EU institutional environment e.g. in view of EFSA's need for more input into legislative proposals which affect it.
e. Development by EFSA of a coherent approach to food safety assessments enabling consistency in decision making in the other institutions.
f. Coherence in policy making enhanced through EFSA's actions and providing independent scientific advice.
g. Effective strategies are in place to ensure the consistent dissemination of risk communication messages throughout the Community following risk assessments published by EFSA.
h. Quality of the dialogue between risk assessors and managers on risk analysis issues.

Annex 8: Documents consulted

BEUC, the role of consumers in the risk analysis process, and in particular risk assessment.
CIAA, l'autorité européenne de sécurité des aliments, vision de l'industrie alimentaire, Dominique Taeymans, directeur, affaires scientifiques et réglementaires, 26 mars 2004
Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food.
Court of Auditors - Report 2003.
DG SANCO – Maximising the contribution of science to European health and safety – Discussion paper – July 2005-10-05
DG SANCO D5 2003/450134 "Guide for preparation of requests for scientific opinions of EFSA".
Diverse presentations made at the 14th Annual European Food law Conference – 28-29 June 2005, Brussels.
EC Regulation N° 1304/2003 of 11 July 2003 concerning the procedure applied by EFSA to the demands of scientific opinions.
EFSA - Absence of conflict of interest form.
EFSA - Annual Management Plans 2003 – 2006.
EFSA - Budget 2004 – 2005; Project of 2006 Budget.
EFSA - Assessment of the current image of the EFSA (Paeps report, 2004).
EFSA - AF – Discussion of the role of the AF members as EFSA contact points in the MS (AF 08.04.2005).
EFSA - Budget & Establishment Plan 2005 (MB 16.12.2004 – 10).
EFSA - Decision concerning the establishment and operations of the Scientific Committee and Panels – MB 17.10.2002 – 3 adopted.
EFSA - Information Pack, 2005.
EFSA - Decision of MB implementing means of transparency and confidentiality (MB 10.03.05).
EFSA - Reports of Plenary Meetings of EFSA Scientific Committee 15-16/12/2004 and 28/2/2005.
EFSA - Stakeholder Consultative Committee – Terms of Reference (MB 10.03.05).
EFSA 2003 and 2004 - Annual Activity Reports.
EFSA - Expert selection procedure.
EFSA - Financial reports.
EFSA - Performance indicators and progress indicators (MB 16-12-04 8a and 8b; 10-03-2005; 13-09-2005).
EFSA - Investing in food science: priority projects and cooperation with national research centers, Doc. AF 13.02.2004-3.
EFSA - MB letter to Friends of the Earth of 19 January 2005.
EFSA - MB meetings of 16th December 2004 and 10th March 2005; including all the attachments and documentation and the EFSA performance indicators.
EFSA – MB: Note to the Management Board on issues related to the functioning of the Scientific Committee and Scientific Panels (MB 27.10.2005 – 3)
EFSA - Meetings of the AF, including Berlin 8-9/11/04 and information note "Making RA more transparent: information note to the AF (AF 3-4/02/2005)" and press release "Creating a European Network to enhance risk assessments regarding the food chain: where does EFSA's Advisory Forum stand today" 8-11-2004.
EFSA - Recent scientific opinions from different units of the Expert Panels.
EFSA - Timeframes for EFSA's Scientific Work (MB 27.04.2004).
EFSA - Who does what at EFSA?
European Commission - Proposal for a regulation of the EP and of the Council laying down the general principles and

requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food – COM(2000) 716 final.
European Commission - White paper on food safety, COM (1999) 719 final.
European Commission decision of 21-11-2002 amending Decision 94/652/EC as regards updating the inventory to tasks to be undertaken within the framework of cooperation by MS in the scientific examination of questions relating to food (2002/916/EC).
European Commission decision of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management.
European Commission : draft document de consultation sur la possibilité et l'opportunité d'établir par voie législative la possibilité pour l'EFSA de percevoir des redevances en matière de traitement des dossiers d'autorisation, 2005.
GMO's and food safety, an introduction of the European Food Safety Authority, Herman Koëter, Deputy Executive Director and Director of Science, 2004.
Melissa – D. Demortain – L'autorité des agences sanitaires européennes – 13 novembre 2003
Optem – Les perceptions des risques alimentaires liés à la présence de mercure dans le poisson – Octobre 2004
Regulation (EC) N°178/2002 of the EP and of the Council of 28/01/2002 updated by: - Regulation (EC) N°1642/2003 of the EP and of the Council of 22/07/2003. - Commission Regulation N°2230/2004 of 23 December 2004 laying down detailed rules for the implementation of EP and Council Regulation N° 178/2002 with regards to the network of organisations operating in the fields within the EFSA's mission.
Risk communications in Europe: the role and experience of the EFSA – Presentation of 28 February 2005 by Anne-Laure Gassin, Communications Director at EFSA.
Sectorial legislation on authorisation procedures involving EFSA: in particular Regulation 1831/2003 (feed additives); Regulation 1829/2003 (Genetically Modified food/feed); Directive 2001/18 (GMOs); Regulation on smoke flavouring N° 2065/2003; Regulation on food contact materials N° 1935/2004; Commission proposal COM (2003) 424 final on nutritional and health claims.

Annex 9: List of abbreviations

ABB - Activity Based Budgeting	GBR - Geographical BSE risk assessments of countries
ACNFP - Advisory Committee on Novel Foods and Processes	GMO - Genetically Modified Organisms (Panel)
ACRE - Advisory Committee on Releases into the Environment	GMOEFSANET – EFSA Network on GMO's
AF - Advisory Forum	ILSI – International Life Sciences Institute
AFC - Food additives, flavourings, processing aids and materials in contact with food (Panel)	IT – Information Technology
AFCSA - Agence Fédérale pour la Sécurité de la Chaîne Alimentaire (B)	JECFA – Joint Expert Committee on Food Additives
AFSSA - French Food Safety Agency	JRC – Joint Research Centre
AGES - Austrian Agency for health and food safety	MB – Management Board (EFSA)
AHAW - Animal Health and Welfare (Panel)	MEP – Member of European Parliament
AI - Avian Influenza	MS – Member State
ANICAP - Association Nationale Interprofessionnelle Caprine	NDA – Dietetic products, nutrition and allergies (Panel)
BEUC - Bureau Européen des Unions de consommateurs	NGO - Non Governmental Organization
BIOHAZ - Biological Hazards (Panel)	nvCJD – New Variant Creutzfeld Jacob Disease
BSE/TSE - Bovine Spongiform Encephalopathy	OECD - Organisation for Economic Co-operation and Development
CIAA - Confédération des industries agro-alimentaires	OIE - World Organisation for Animal Health
CJ - Creutzfeld-Jacob	OTM - Over Thirty Months
CJD - Creutzfeld-Jacob Disease	PBDE - Polybrominated diphenyl ether
CONTAM - Contaminants in the food chain (Panel)	PCS/WHO
COREPER - Comité des représentants permanents	PMM - Post-Marketing Monitoring
CMPV - Committee for Medicinal Products for Veterinary Use	PPR - Plant Health, Plant Protection Products & their Residues (Panel)
DEFRA - Depart. for Environment, Food and Rural Affairs (UK)	PR - Para Red
DG - Directorate General	PRAPeR - Pesticide Risk Assessment Peer Review Unit
DGAL - Direction Générale de l'Alimentation	QPS - Qualified Presumption of Safety
ECDC - European Centre for Disease Prevention and Control	RA - Risk Assesment
EFSA - European Food Security Authority	RM - Risk Management
EMEA - European Agency for the Evaluation of Medicinal Products	RC - Risk Communication
EMRISK - Emergent Risk	RI - Representative of Industry
EP - European Parliament	SC - Scientific Committee
EPA - Environmental Protection Agency (USA)	SCENIHR - Scientific Committee on Emerging and Newly identified Health Risks
ESST - Transmissible Subacute Spongiform Encephalopathies	SCHER - Scientific Committee on Health and Environmental Risks
EU - European Union	SCPP - Scientific Committees on Consumer Products
EUROCOOP - European Community of Consumer Cooperatives	SEAC - Spongiform Encephalopathies Advisory Committee
FAO - Food and Agriculture Organisation	SES - Scientific Expert Services
FDA - Food and Drug Administration	SRM - Specified Risk Materials
FDF - Food and Drink Federation	SSC - Steering Scientific Committee
FEEDAP - Panel on additives and products or substances used in animal feed (Panel)	SWOT - Strengths, Weaknesses, Opportunities, Threats
FELASA - Federation of European Laboratory Animal Science Associations	ToR – Terms of reference
FoE - Friends of the Earth	USDA - United States Department of Agriculture
FOS/WHO - Food Safety Department/World Health Organization	VKI – Verein für Konsumenteninformation
FSA - Food Standard Authority (UK)	VLA - Veterinary Laboratories Agency
FSAI - Food Safety Authority of Ireland	WG - Working Group
FSANZ - Food Standard Australia New Zealand	WHO - World Health Organisation