ECONOMISTI ASSOCIATI

IDENTIFICATION OF KEY IMPACT INDICATORS MEASURING THE EFFECTIVENESS OF EFSA IN RELATION TO ITS SUPPORT TO RISK MANAGERS IN THE EUROPEAN COMMISSION

Final Report

submitted by:

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Table of Contents

EXECUTIVE SUMMARY

1. *Following the EFSA Management Board decision to monitor impact indicators as a tool to assess responsiveness to risk management needs, and to track down the number and percentages of opinions and other scientific outputs taken into account for risk management purposes, it was proposed that a more detailed analysis of twelve case studies be carried out to validate the indicator reliability of measuring usefulness for risk management and to have more precise insight on the determinants of usefulness.*

2. *The Terms of Reference for this study therefore envisaged that the exercise would be based on twelve case studies and the three feedback reports provided so far by the Commission to EFSA, and that it should provide:*

- *a quantitative and qualitative description of the overall usefulness and relevance of EFSA's scientific advice to Commission services;*
- *more detailed insight into the features deemed to be of different use to risk managers and their related degree of satisfaction,*
- *identification of the determinants of risk managers' confidence in using EFSA outputs, including data reliability and suitability to risk management purposes.*

It was intended that the exercise would not examine or comment upon the appropriateness of risk management processes or the consistency of related decisions with EFSA scientific outputs.

3. *The exercise was carried out based on a sample of twelve case studies, one per each panel, plus the PRAPeR and SC&AF units, inclusive of a very exhaustive set of possible outputs. These ranged from requests from Parliament and Member States to self-tasks, from opinions involving the organization of public consultations and advisory fora to mandates jointly implemented by different panels, and to two notable opinions that included a minority vote. The case study selection criteria therefore reflect the widest possible range of occurrences spanning from extremely complex authorization dossiers to extremely simple ones, rather than attempt to be roughly representative of the average case dealt with by any given panel. The exercise was based on triangulation of sources: desk research on the selected case studies, an interview program with relevant EFSA scientific staff and finally an interview program with Commission risk managers and representatives of national risk management institutions and stakeholder groups.*

4. *The results demonstrate that all the case studies have assisted the risk management process and have been taken into consideration by risk managers. However, in order for the proposed indicator to reasonably serve as a proxy for perceived usefulness, a clearer distinction should be made in the existing feedback mechanism between opinions the Commission has decided not to take action on and those whose underlying policy issue has yet to be removed from the policy agenda and remains pending. In fact, EFSA scientific outputs can be useful to risk managers for a number of reasons, including providing reassurance that an action is not necessary, or confirming the validity of a decision made before but not officially formalized in the policymaking process. There are no instances in the sample of opinions where EFSA outputs were not taken into consideration due to late arrival which rendered them too late to be of use, although was theoretically possible in a couple of cases.*

5. *In all but three cases, opinions were found to be useful and fully fit risk management needs. This allowed them to be used as a basis for authorization procedures, or to contribute to the regulatory process either directly, by providing elements on whether action was needed or not, or indirectly, by confirming a previous decision. Opinions which included a minority vote have also proven useful*

in that they provided sufficient elements and evidence of uncertainty to justify a precautionary approach. So the proposed indicator targets appear realistic and achievable.

6. *The opinions that failed to be of adequate usefulness are two cases, where little or no previous practical experience existed on how to approach the issue and where EFSA and the Commission were unable to reach an agreement on how the expected result should be achieved and the type of evidence needed to draw conclusions. In one of these cases, risk managers themselves acknowledge the misunderstanding originated in the way the Terms of Reference were drafted which was not subsequently redressed due to lack of interaction with EFSA. In the third case, it was the authors of the opinion who claimed they did not have enough time to adequately cover the subject area and requested another mandate.*

7. *So reasons for dissatisfaction can be categorized as broadly linked to the type of subject covered (a novel issue) and the inconclusive content of the output (an opinion asking for another mandate on the same subject). There are no examples among the case studies reviewed of lack of usefulness linked to the timing of delivery, although this may have resulted from an unintended bias in the sample selection. In a number of cases, issues related to the relevance of contents were reported, where some opinions addressed only part of their mandates due to lack of data, but this never translated into a final assessment of insufficient usefulness. To sum up, in terms of overall usefulness of the twelve cases considered – including those deemed to be poorly useful – an average score of 4.1 on a scale of five resulted from the analysis, which appears relatively high. However, the scope and significance of the analyses, which includes relevance issues, was given a lower 3.4.*

8. *The determinants of confidence in EFSA outputs (data completeness, methodological reliability, etc) can often only be appreciated by risk managers on an ex post basis when criticism is received from outsiders once the opinion has been released. This explains why some risk managers proposed keeping track of the number of requests for clarification sent by the Commission on any given opinion as a rough, complementary indicator of the degree of the Commission's confidence in a given output and satisfaction with methodological clarity, data completeness and scope of analysis. This would help capture aspects which are currently not covered by the proposed indicator.*

9. *In more analytical terms, the quality features that more strictly correlate with overall perception of usefulness to risk managers are the quality of conclusions and recommendations and then the scope and significance of analysis. The adequate review of alternative explanations to data and a refutation of possible counterarguments is another appreciated quality feature. Also the executive summary appears very useful for risk management purposes, but its overall quality is quite uncorrelated to the overall usefulness of the output. On average, there is a good degree of satisfaction with all the quality features of an opinion, though with different levels of room for improvement perceived.*

10. *There are notable variations in the perceived level of usefulness of the features of an opinion both among risk managers, EFSA staff, and between the two groups. On average, risk managers appear slightly more interested in conclusions and recommendations, the executive summary and the scope and significance of the analysis. Whereas EFSA staff appear slightly more concerned with methodological considerations and data transparency issues. However, the single item risk managers and EFSA staff diverge the most on in their assessment is the importance attributed to background and context, which is of limited importance for the former and is notable for the latter.*

11. *Based on a comparison of the assessments made by the two groups it can be concluded that the proposed indicator is bound to provide some added value and complementary data to the existing EFSA management information system, as it captures aspects not necessarily covered by the existing internal quality review system, which is largely based on self-assessments and internal peer reviews.*

12. *Overall usefulness is a key determinant of perceived value for money from the risk managers' perspective, but there are also instances when this perceived value is low either because the current scientific opinion process appears too heavy and burdensome for the task at hand or is disproportionate to the information needs. Therefore a more streamlined and simplified method of operating would be preferred, though it is acknowledged this is often not possible due to regulatory constraints.*

13. *Different levels of satisfaction with the features of an opinion frequently result from diverse causes. As a result, suggestions for possible improvements may appear contradictory or may seem that they are not shared by all risk managers. Consequently, there is hardly such a thing as a set of unanimous findings from this exercise that unequivocally leads to recommendations on how to improve utility for risk managers. In particular, the views of those involved with authorization dossiers tend to diverge from those dealing with other scientific opinions.*

14. *For the time being it can be concluded that there is substantial consensus on the need to:*

1) *strengthen the EFSA autonomous data gathering capacity and improve access to unpublished sources, research-in-the-making, or other unofficial sources of information. This aspect could also be worth monitoring through a separate indicator;*
2) *ensure a stricter enforcement of guidance on content, structure and the format of documents, including provisions to ensure that all key elements underpinning the main line of reasoning are adequately highlighted and referenced in the text and that more extensive cross-referencing is made to the terms of reference or the relevant regulations when needed;*
3) *receive guidance on the harmonization of terminology used to qualify the magnitude of risk from the Scientific Committee;*
4) *further strengthen co-operation procedures in finalizing the terms of reference, including ways to prevent the mandate from becoming a report with a number of pages that are barely manageable from an operational point of view;*
5) *maintain the current use of a rigorous and highly specialized language and avoid oversimplification for communication purposes in the main text.*

0. INTRODUCTION

0.1. Putting the Exercise into Context

Background. EFSA has begun to develop a **set of indicators** to measure the impact of its activities in order to assess its effectiveness in supporting the European regulatory system. In particular, the EFSA management board has recommended the adoption of a set of impact indicators to complement the current performance indicators in an effort to better understand strategic priorities and generate preliminary feedback on effectiveness. Issues about the practical expediency of collecting these indicators and their different significance for authorization-related procedures and the other scientific dossiers have been raised during the debate and have led to a first set of proposals.

A preliminary set of impact indicators was proposed for monitoring. The indicators selection criteria were reportedly inspired by three main principles:

- *visibility;*
- *usefulness in assessing EFSA value and overall impact;*
- *the possibility of further developing qualitative performance indicators.*

The Board defined impact broadly by including contributions to the food law system at both the European and Member State level, on the behavior of institutions at both levels, and on the perception and confidence of stakeholders and consumers.

Among the pilot indicators proposed for testing in 2011, one includes the:

- *Number and percentage of Opinions and other scientific outputs taken into account in Risk Management actions at EU level*

to which two separate targets are attached, namely:

- *100 % of opinions directly relating to authorization of dossiers translated into European level risk management actions*
- *80% of other outputs translated into European level risk management actions*

The overall objective is to have insight into the usefulness of EFSA's opinions, their timeliness, quality and value for money.

To validate and better fine tune the indicator and align it to other available management information the Board proposed carrying out **a number of case studies** to investigate the utility of selected opinions to risk managers, the parts that were concretely used for risk management decisions (including non-action), and an assessment of the reasons why other parts were not used. A distinction was to be maintained between authorizations and other scientific outputs.

It is worth noting that both in developing the indicator and in its subsequent refinement work, **different wording was used** and consequently the indicator is not defined with precision. First the proposed indicator was described as the number of opinions "*taken into account*" for "*actions*" which appeared to be a fairly broad definition. Targets were also expressed in terms of "*direct*

translation into action" and the case studies were intended to investigate the uses made – including "*non-action.*"

As a basis for this indicator, EFSA plans to use the **feedback from the Commission on the follow-up** actions taken in relation to EFSA scientific outputs over a three-year period of time. This represents the continuation of a quality feedback mechanism long discussed with DG SANCO[1] that was originally intended to inform the Panels about the ultimate outcome of the authorization dossiers they process, but which has now been extended to all the opinions.

In fact, beginning in 2009 the Commission started to provide EFSA with feedback on the follow-up given to their scientific outputs. **Three such reports have been delivered.** The first covers the 2006-2009 period and the next covers the second semester of 2009. A third feedback report has just been delivered with updated information on the June 2009 – June 2010 period with preliminary feedback on the second semester of 2010. Until the last report this feedback did not typically cover pesticides evaluated under the PRAPeR procedure or include information about the EFSA Scientific Commission's opinions. The first report actually appears to be a collection of different DG SANCO units' feedback drafted based on their own criteria and with a slight variation in content, although the latest versions have become more harmonized. Much of the emphasis of the text, however, remains on pure factual follow-up activities rather than quality feedback.

The Mandate. This exercise is to **gather complementary information on these indicators** in order to better assess the information they capture and their related limitations in use, as well as to have a more detailed understanding of the way EFSA opinions[2] are concretely utilized by risk managers.

The terms of reference for this study envisaged carrying out **twelve detailed case studies**, including both authorization dossiers and other opinions. In analyzing the selected case studies the following results were expected:

1) *a quantitative and qualitative description of the overall usefulness and relevance to Commission services of EFSA's scientific advice;*
2) *more detailed insight into the features that were deemed differently useful for risk management purposes and related degree of satisfaction,*
3) *the identification of the determinants of risk managers' confidence in using EFSA outputs, including data reliability and suitability to risk management purposes.*

It was intended that the exercise would not enter or comment upon risk management processes or decisions.

In other words this report is to focus on the following three aspects:

1) *how, and in which respects, have EFSA's outputs assisted risk management processes. Including a detailed overview of how the scientific outputs have been useful to the European Commission and other risk managers, including whether EFSA outputs had been useful in other ways (e.g. to give assurance to risk managers that action is not necessary).*

[1] Back in 2006 DG SANCO's Director General proposed the adoption of a joint format to facilitate interaction between risk assessors and risk managers and provide a quality feedback mechanism. See S. Gobbi *The Interaction between Risk Assessors and Risk Managers* European Food and Feed Review 3/2007 p134

[2] In this report Opinions will be often used as a synonym of scientific output, without entering into the procedural details differentiating the various possible typologies of EFSA outputs. When this is relevant, the distinction will be made clear in the text

2) *the reasons why these outputs or parts of them have not been useful (e.g. the relevance of the content of the output, the timing of its delivery, the nature of the output or the type of subject covered - as for example where there is a degree of uncertainty and conclusions that may require further scientific insight).*
3) *a clear analysis of findings leading to recommendations of possible ways to increase the utility of EFSA's scientific outputs to the European Commission and other risk managers. Additionally, to identify areas for improvement in the way outputs are developed and presented to risk managers, and assist and inform EFSA's overall planning and prioritization.*

Finally, to the extent possible the study would provide insight not only on quality issues but also on the underlying **value for money**.

0.2 The Selection of Case Studies

The Process. Out of a long list of some 36 possible case studies suggested by DG SANCO, a final shortlist of twelve opinions were selected, **in agreement with EFSA**, to provide one case study per relevant panel/scientific unit. An alternate list of another twelve case studies was considered in case difficulties arose in interviewee availability or data gathering, but this did not prove to be the case. The main list of selected case studies is reported in the table below.

Table 0.1 – List of Selected Case Studies

Panel	Publication Date	Opinion
AHAW	06/06/2007	Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds (hereinafter avian influenza vaccines).
ANS	22/06/2009	Chromium picolinate, zinc picolinate and zinc picolinate dihydrate added for nutritional purposes in food supplements (hereinafter picolinates as supplements).
BIOHAZ	22/02/2007	Assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE (hereinafter fishmeal as ruminant feed).
CEF	30/09/2010	Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A (hereinafter Bishenol A).
CONTAM	29/05/2009	Review of the criteria for acceptable previous cargoes for edible fats and oils (hereinafter edible fats and oils).
FEEDAP	02/07/2007	Maximum Residue Limits for Clinacox 0.5 % (diclazuril) for turkeys for fattening, chickens for fattening and chickens reared for laying (hereinafter Clinacox).
GMO	30/07/2009	Applications (EFSA-GMO-RX-MON810) for renewal of authorization for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto (hereinafter MON 810 maize).
NDA	31/07/2009	Plant Stanols and Plant Sterols and Blood LDL-Cholesterol - Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission and a similar request from France in relation to the authorization procedure for health claims on plant stanols and plant

		sterols and lowering/reducing blood LDL-cholesterol pursuant to Article 14 of Regulation (EC) No 1924/2006 (hereinafter plant stanols and sterols).
PLH	29/06/2008	Evaluation of a pest risk analysis on Thaumetopoea processionea L., the oak processionary moth, prepared by the UK and extension of its scope to the EU territory (hereinafter oak processionary moth).
PPR	08/07/2009	Updating the opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Toxicological and metabolism studies (hereinafter toxicological and metabolism studies).
PRAPER	11/05/2009	Potential risks for public health due to the presence of nicotine in wild mushrooms (hereinafter nicotine in mushrooms).
SC&AF	24/07/2008	Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals including the two updates (hereinafter animal cloning).

The Main Features of the Case Studies. The sample resulting from this two-tiered selection process is inclusive of **various different possible typologies of opinions** (scientific opinions strictly speaking, EFSA statements on MRL, authorization dossiers, requests from the Commission, Member States and Parliament, self tasks, different mandates grouped under a single opinion, joint opinions processed by different panels, etc.). However, due to the limited size of the sample, the case studies **were never intended** to be **statistically representative** of the activities of any given EFSA panel or unit.

For instance, there are **just three authorization dossiers** (picolinates, clinacox and MON 810 maize), the assessment of which is based mainly on data submitted by applicants, whereas the remaining cases require direct data gathering efforts by EFSA. In reality, the largest majority of opinions by far of EFSA's day to day activities are related to authorization dossiers and do not require any direct data gathering effort. Even panels and units that almost exclusively work with authorization dossiers - like NDA or PRAPeR - had very atypical case studies selected. Then of the twelve case studies, three were published in 2007, two in 2008, as many as six in 2009 and just one in 2010. On one hand, this means the **various procedural improvements introduced over the years are reflected differently in the analysis** and results of the assessment could depend on factors that have since been modified. On the other hand, this distribution can **underestimate eventual problems with overall timing and timeliness in delivery that occurred in the past** due to resource bottlenecks and sudden jumps in workflow.

The **case studies present a number of notable features** and represent in certain policy areas very special cases, namely:

- *Avian Influenza Vaccines* is an opinion drafted following an **emergency situation** and resulted from the fairly atypical participation of a number of representatives of various international and European organizations in working group activities;
- *Picolinates as Supplements* is a routine authorization-related opinion on a substance some **Member States had raised reservations about** in a parallel separate procedure;
- *Fishmeal as Ruminant Feed* is one of the very few requests for an opinion that came from the **European Parliament**;
- *Bisphenol A* is a case involving precautionary measures taken at the Member State level on the basis of separate risk assessments. An unusually large role was thus played by consultation with the Advisory Forum. The EFSA process ended with a **minority opinion**;

- *Edible Fats and Oils* is a case of a request for assessing the abstract **conformity** of proposed international principles with European criteria rather than concretely assessing a substance;
- *Clinacox* is an authorization request for a given use followed up by a **subsequent application** on the same subject;
- *MON 810 Maize* is one of the very few cases of authorization request for GMO cultivation, thereby including major **environmental assessment considerations**;
- *Plant Stanols and Sterols* is a **regulatory-aimed request** jointly coming from both the Commission and a Member State **to subsequently make a private health claim possible**. Not being an authorization dossier in its own right it therefore required autonomous EFSA data gathering efforts;
- *Oak Processionary Moth* is a fairly atypical and unprecedented case of an **endogenous pest** moving across Europe rather than inside Europe from abroad for which little agreed analytical methodology existed. Related risk management decisions can therefore have an impact on the **internal market** and conflict with Member States commercial interests. Also in this case a **minority opinion** resulted from the process;
- *Toxicological and Metabolism Studies* is a case of a **self-task** accomplished in an extremely short period of time because of its perceived urgency at that time;
- *Nicotine in Mushrooms* is possibly one of the very few cases of a PRAPeR output unrelated to an authorization dossier, and which also required substantial **inter-panel co-operation** under a very stringent deadline. It raised the issue of conflicting methodologies used by different panels;
- *Animal Cloning* is an opinion on a new technology with a very broad scope, which encompassed the responsibilities of different panels and was eventually entrusted to the Scientific Committee. It included one of the few cases of **public consultation** managed by EFSA and its subsequent **annual updates** have been released as **EFSA Statements** rather than as scientific opinions.

0.3 Implementation of the Assignment and Structure of this Report

Implementation of the Assignment. The implementation of the assignment has followed a methodological approach whose main guidelines were already **defined in the Terms of Reference**. The exercise had to be based on twelve case studies and carried out through the analysis of the following sources of information:

- information provided by EFSA on **the feedback given by the Commission** concerning the usage made of EFSA's scientific outputs over the past three years (the three follow-up reports);
- **desk research** on the selected case studies;
- face to face **interview programme with relevant EFSA staff** that was carried out in the March 10- March 21 period;
- Face–to-face interview programme with relevant **risk managers in the European Commission** (31 March – 6 April);
- Final phone interviews during the month of May with representatives of three **key stakeholder groups**, and representatives of three Agencies of food safety in three **Member States**;

Details about the interview programme are included as appendix A to this report. The semi structured interview questionnaire to risk managers is included as appendix B.

Structure of this Report. This report is structured into **three chapters**, each including a section on conclusions and final considerations.

The **first chapter** summarizes main findings concerning **overall usefulness** to risk managers and compares this information with the **feedback available from the Commission follow-up reports** to highlight the information captured by the proposed indicator, its possible limitations and possible linkages, or lack thereof, with existing performance indicators. Possible alternative indicators will also be reviewed. Separate considerations will also be made for **timing** and **value for money** that represent two possible aspects of existing resource constraints.

The **second chapter** will enter into more detail about the **determinants of perceived satisfaction**, the parts that are deemed useful, not useful or even redundant. The analysis will also cover the perceived relative importance of the various possible determinants of quality.

The third chapter will **compare** some of the findings above **with EFSA staff's own self-assessments** in order to obtain a first rough idea about areas of agreement and disagreement and of the extent to which self-assessment or internal quality control arrangements can be trusted as a reasonable proxy of risk managers' feedback, as well as of the **possibility of integrating EFSA performance indicators with the feedback received from the Commission**.

CHAPTER 1 - OVERALL IMPACT AND USEFULNESS FOR RISK MANAGERS

Introduction. This chapter first reviews the evidence available from the Commission written feedback report. The objective is to validate the proposed indicator and understand its implications in the light of the evidence collected during the case studies. The main findings of the case studies in terms of overall usefulness, relevance, timing and value for money aspects will then be presented. Possible linkages with available performance indicators to better track usefulness will finally be explored and possible alternatives / complementary measurements will also be proposed in the conclusions as tentative recommendations for further action.

1.1 The Feedback Received from the Commission through the Follow-Up Reports

The Status of Available Written Evidence. The table below (tab.1.1) summarizes the feedback received from the Commission in tabular format as follow-up information on the selected twelve case studies.

Table 1.1 - Follow-up Feedback Received from the Commission on the Twelve Case Studies.

PANEL	TITLE	SOURCE	FEEDBACK
AHAW	**Opinion of the Scientific Panel on Animal Health and Welfare (AHAW) related with the vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds (EFSA-Q-2006-309).**	Commission participation to EFSA Panels/Follow-up 2006-2009	
ANS	**Chromium picolinate, zinc picolinate and zinc picolinate dihydrate added for nutritional purposes in food supplements (EFSA-Q-2005-077-EFSA-Q-2005-094-EFSA-Q-2005-110-EFSA-Q-2006-231)**	Commission Feedback to EFSA on requests for scientific advice June –December 2009; Commission Feedback to EFSA on requests for scientific advice June 2009 –December 2010	Regulation (EC) No 1170/2009 of November 30, 2009 amending Directive2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (Text with EEA relevance), OJ L 314, 1.12.2009,p. 36–42; http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0036:0042:EN:PDF;
BIOHAZ	**Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE (EFSA-Q-2006-130)**	Commission participation to EFSA Panels/Follow-up 2006-2009	Allowing fishmeal to young ruminants.
CEF	**Opinion on Bisphenol A: evaluation of a study investigating its neuro-developmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A (EFSA-Q-2009-00864; EFSA-Q-2010-00709; EFSA-Q-2010-01023)**	Commission Feedback to EFSA on requests for scientific advice June 2009 –December 2010	Opinion considered in the amendment of Directive 2002/72/EC as regards Bisphenol A.
CONTAM	**Review of the criteria for acceptable previous cargoes for edible fats and oils (EFSA-Q-2009-00236)**	Commission Feedback to EFSA on requests for scientific advice June 2009 –December 2010	EFSA Opinion used as the basis to establish the EC position in relation to the list of acceptable previous cargoes which is under discussion in the framework of Codex Alimentarius. The next session of the Codex Committee for Fats and Oils is scheduled to take place in February 2011. In order to update the

			current legislation a follow-up mandate has been sent to EFSA.
FEEDAP	**Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the Maximum Residue Limits for Clinacox 0.5 % (diclazuril) for turkeys for fattening, chickens for fattening and chickens reared for laying (02.07.2007) (EFSA-Q-2006-134)**	Commission participation to EFSA Panels/Follow-up 2006-2009	Negative opinion, MRL cannot be set for tissues from turkeys and chickens (new data submitted, see opinion of 16-04-08).
GMO	**Renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto (EFSA-Q-2007-150; EFSA-Q-2007-153; EFSA-Q-2007-164)**	Commission participation to EFSA Panels/Follow-up 2006-2009	
NDA	**Plant Stanols and Plant Sterols and Blood LDL-Cholesterol - Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission and a similar request from France in relation to the authorization procedure for health claims on plant stanols and plant sterols and lowering/reducing blood LDL-cholesterol pursuant to Art. 14 of Regulation (EC) No 1924/2006 (EFSA-Q-2009-00530; EFSA-Q-2009-00718)**	Commission Feedback to EFSA on requests for scientific advice June –December 2009; Commission Feedback to EFSA on requests for scientific advice June 2009 –December 2010	This opinion was necessary as further advice to support the authorization procedure with regards to the positive claims on plants stanols and sterols and reduction of LDC cholesterol. It was in particular needed to define the Conditions of Use for these health claims.
PLH	**Evaluation of a pest risk analysis on Thaumetopoea processionea L., the oak processionary moth, prepared by the UK and extension of its scope to the EU territory (EFSA-Q-2008-711)**		
PPR	**Updating the opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Toxicological and metabolism studies (EFSA-Q-2009-00615)**	Commission Feedback to EFSA on requests for scientific advice June –December 2009 Commission Feedback to EFSA on requests for scientific advice June 2009 –December 2010	Revision data requirements on-going and expected to be finalized in 2010. Revision data requirements on-going and expected to be finalized in 2011.
PRAPER	**Potential risks for public health due to the presence of nicotine in wild mushrooms (EFSA-Q-2009-00527)**		
SC&AF	**Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals including the two updates (EFSA-Q-2007-092)**		

As can be seen the table does not contain feedback for SC and PRAPeR scientific outputs, as this is available only starting from the latest June 2009-December 2010 feedback report. The table therefore looks **less exhaustive than it would appear based on the current reporting standards**. Moreover during the interview program the AHAW unit showed written evidence of further feedback received from the Commission according to which the opinion on avian influenza

vaccines was used for the authorization of avian vaccination programs proposed by some Member States. No information on oak processionary moth is reported in the tables because the first meeting to discuss the opinion was held after the related feedback report was delivered and no update was then provided. At any rate no final decision has been taken and the issue is still open.

Reporting Criteria. It should be noted that the **different DGSANCO units** use slightly **different language and levels of detail** in filling in these feedback documents. Some of them report about specific normative acts be they proposed or approved, others about the expected result in broad policy terms, and finally a few enter into a bit more detail about the steps undertaken in the policymaking process. In certain cases a direct link is established between the opinion and the policy result, in other cases indication is given simply of the policymaking context without establishing any link. It is **unclear** whether **the same feedback criteria** are consistently applied across the various units. For instance the PPR opinion on toxicological and metabolic studies is reported in connection to a revision of data requirements for the related Council Directive first expected to be finalized in 2010 and then postponed in 2011, i.e. with reference to a detailed step a policymaking process in the pipeline. In the feedback provided on other opinions, the distinction between whether no action has been taken, deemed necessary or is planned in the future but not reported yet is not always clear when the cell is simply left blank.

Relation with the Proposed Impact Indicator. The proposed impact indicator can then reflect different underlying possible situations. **A distinction clearly exists between authorization-related opinions and other scientific outputs**. In the case of an application, three final outcomes are possible: 1) the authorization is granted, 2) the authorization is denied / the request is withdrawn, 3) the request is sent back to the applicant because not enough data was provided for assessment. An intermediary stage is possible when the opinion has been delivered and the request is still under discussion at the relevant Standing Committee, but this condition is temporary and the related "open" status should become clear at some point. A **more complex** situation exists for the **"other scientific opinions"** where the decision making tree includes a number of different options. First, it should be understood whether the issue deserves some type of policy action or not, and whether the opinion is just "one" of several possible elements taken into consideration in this decision. The case studies on fishmeal as a feed for ruminants and animal cloning provide evidence of instances where an EFSA opinion is just one of the inputs, sometimes not even the most important one, that steers the policy debate.

There is also the case where EFSA **results are inconclusive** or not enough data exists to reach a conclusion and where a decision must still be taken whether this justifies an action based on the **precautionary principle**; where the possible consequences in terms of potential harm are considered sufficiently serious to justify an intervention. This would still register as an impact, though the underlying level of satisfaction with the usefulness of the scientific output may not necessarily be high. Finally, **timing considerations** may also influence impact; for example, the opinion could come too late in a decision-making context influenced by external factors (e.g. emergency situations, international deadlines, etc.).[3]

The Possible Various Understandings of the Indicator. These preliminary considerations are needed to understand the **various possible meanings** of "taken into consideration" or "translated into action" for indicator purposes in light of evidence gathered during the case studies. Opinions are requested when an issue has already entered the policy agenda, so they are **"taken into consideration"** almost by default by the originating service or upon the request of a political body

[3] The same kind of constraint would theoretically apply to authorization-related opinions if authorizations were granted (or denied) if regulations ever envisaged this as a default case after a certain maximum period of time has elapsed from the applicant's request.

capable of influencing the policy agenda such as the Parliament or a Member State. There are cases of opinions not "taken into consideration" in **setting the policy agenda** but these are typically self-tasks or refer only to the "recommendations" component. "**Translated into action**" can be understood as if some kind of **formal act** were required of risk managers as a consequence of their request – which is something the vast majority of interviewees considered totally inappropriate and as a misleading impact indicator. Alternatively, it could be understood as a synonym for a **"closed" or "decided" issue**, removed from the agenda at least until new evidence arises.

The following example (tab. 1.2) better illustrates the point. **All the outputs** analyzed in our sample of case studies clearly **met the criterion for "taken into consideration"** in the broad sense, even if they were **not all deemed useful**. However, not all suggestions to include items in the policy agenda (either by formulating suggestions for other requests for an opinion or by requesting that studies be carried out or other actions implemented) have been followed up. Authorization-related opinions formally **met the 100% "translation into action"** benchmark, as well as the other scientific opinions with their 80% benchmark, but **the consequences in terms of usefulness appear ambiguous**. In fact, both opinions on Bisphenol A and Animal Cloning could theoretically have resulted in no action at all of risk managers and therefore the 80% benchmark would not have been met, at least if the current reporting format is followed. The concrete significance of this in terms of EFSA impact remains unclear, as the indicator on "other scientific opinions" could be understood in terms of measurement of risk managers' threshold reaction level to any perceived risk and of their propensity to ask for risk assessment expert opinion in case of doubt.[4]

Finally **"translated into action"** can be understood in terms of whether a **final decision** has been taken on what to do or not to do on the subject matter, so the issue is eventually removed from the policy agenda or remains there **undecided, as an "open" issue**. When compared to authorization dossiers a subtler distinction should then be made between cases where the issue is no longer open from the Commission risk management perspective because a proposal has been made on the course of action, and cases where it remains open from a broader European policymaking perspective because agreement has not been found with the Council or Parliament as could be the case with proposed regulation on animal cloning as novel food.

Table 1.2 - Impact of the Twelve Case Studies According to the Proposed Indicators

Case Study	Taken into Consideration	Influenced Agenda as Intended	Action Reported as Taken	Issue Still Open	NOTE
Avian Influenza Vaccines	☑	☑	☑		Influenced approval of action plans
Picolinates as Supplements	☑		☑		
Fishmeal as Ruminant Feed	☑	?	☑		Confirmed decision already taken
Bisphenol A	☑		☑		
Edible Fats and Oils	☑		☑		
Clinacox	☑		☑		Decision postponed to subsequent more complete application
MON 810 Maize	☑		?	☑	

[4] Moreover a logical asymmetry would be created between authorization-related outputs where impact can be both measured in terms of lives saved or enhanced quality of life (in case of denial) and of economic utility (authorization granted), while the no action option resulting in lower costs and regulatory burden for society would not be considered in the impact of the other opinions.

Case Study	Taken into Consideration	Influenced Agenda as Intended	Action Reported as Taken	Issue Still Open	NOTE
Plant Stanols and Sterols	☑		☑		
Processionary Oak	☑		?	☑	Preliminary discussions held but no final decision taken
Toxicological and Metabolism Studies	☑	NO	☑	☑	Action reported as in the pipeline
Nicotine in Mushrooms	☑		☑		
Animal Cloning	☑	?	☑	?	Issue considered closed from a Commission risk management perspective because a regulatory proposal has been submitted to Parliament and Council, although not approved ?

The table above (tab. 1.2) has been drafted by **integrating and updating the data missing** in the Commission written follow-up, based on the factual evidence gathered during case studies. It is unclear whether the meetings held on the oak processionary moth or maize Mon 810 would consistently qualify for "action taken" according to current reporting standards.

1.2 Evidence of Usefulness Gathered from the Case Studies

Judgment Criteria. Commission's relevant risk managers have been asked to comment on their overall **degree of satisfaction** with the twelve scientific outputs received from EFSA in terms of their **overall usefulness** and their degree of contribution to providing clarity and surety to the decision making process. They were also asked about the opinion's **overall relevance** to the scope and meaning of the mandate and the eventual flexibility of the underlying management mechanism in ensuring that their information needs are adequately addressed. On top of their qualitative considerations, a quantitative ranking of the overall opinion fitness for purpose on a scale from one to five was requested.

Main Findings. An **average score of 4.1 out of five on overall satisfaction level** resulted from the exercise and in only three cases were substantial reservations raised on the practical usefulness of EFSA outputs for risk management purposes. In two of these cases the opinion was acknowledged to be below typical panel standards and hardly representative. In two of these cases previous experience with the problem was missing. In **all the other nine opinions** considered, the scientific output was deemed **fully fit for purpose**, with just minor comments on possible quality improvements for specific aspects. The three negative assessments relate, respectively, to: an opinion whose **very limited informational content** was deemed out of proportion with its ambitious scope, one that did not report enough elements to assure about data gathering procedural transparency and compliance with scope of regulatory requirements and also failed to provide elements necessary to reassure about the **rationale behind conclusions**, as two different sets of conclusions were included. Lastly, a case of a mandate where - faced with the novelty of the situation - the Commission and the Panel could not reach a mutual understanding on the **scope and aim of the analysis** and what was really expected in terms of informational content. In this last

case, the **misunderstanding originated in the mandate-drafting phase**[5] and could not be redressed during the discussion due to **lack of interaction**. So it appears both to be a case of limited usefulness and of Commission difficulties in articulating their information needs, as risk managers acknowledged.

Relevance. In a much higher number of cases reservations were expressed about **relevance issues**, in that the opinion was deemed not to have adequately covered and explored all the items originally included in the mandate and information on certain aspects was simply missing or found to be less well developed than it should have been. These limitations obviously apply to non-authorization related opinions only. In the majority of cases EFSA claimed that the underlying studies or basic information was not available, although it can also be exceptionally stated that there was not enough time or resources to retrieve it. At any rate the distinction between sheer impossibility and practical difficulties appears blurred to some risk managers and it is often not clear to them whether the information was not really there or was simply not found. It is interesting to note that EFSA staff interviewees substantially agree with this assessment and acknowledge that EFSA is better structured and organized to react to information provided by applicants as happens with the authorization procedures rather than **seeking unpublished evidence** on its own.

There are a number of case studies (e.g. avian influenza vaccines, fishmeal as ruminant feed, processionary oak, animal cloning) where **access to raw data and unpublished studies clearly emerges as a key issue**. Notable improvements in this respect have been reportedly recorded over time and traditional reliance on working group members' contributions has been increasingly complemented by recourse to specialised outsourced services. More internal resources have also been devoted to data gathering purposes. However, some heads of units were explicit in conceding that if given the ability they would trade off resources to invest more in data gathering and that procedures to improve dialogue and data sharing with the scientific community about on-going studies deserves further improvement, a view also shared by a number of risk managers within the Commission.

For their part, risk managers have increasingly focused their **mandates with explicit formal requests for specific data gathering efforts**, and as a result have steered the allocation of resources along these lines and have more EFSA staff specifically devoted to this information gathering task. This is the case, for instance, in one of the mandates on Bisphenol A that expressly required an extensive review of literature, or in the update mandates on animal cloning that explicitly mentioned the need to consider unpublished data. In other cases (e.g. toxicological and metabolism studies) the recommendation to concentrate resources and data gathering efforts in certain areas only remained more informal.

1.3 Timing and Value for Money Considerations

Timing. Timing considerations do not play a major role in influencing usefulness in the sample of case studies considered. The overall **average satisfaction score, 4.25, is fairly high** and basically there are no cases where the timing of the opinion is considered insufficiently aligned with needs. This is due to the fact that when **delays are agreed upon in advance**, Commission services find them justified by the circumstances and there are no cases in our sample of serious or otherwise unexpected delays. Only in the case of food supplements has a broader general issue of delays due

[5] This latter case also highlights instances of a possible broader problem unrelated to quality issues but that appears here and there in other case studies, namely that before assessing any specific case, a general agreement should be reached between EFSA and the Commission on the criteria through which the underlying problem should be analyzed, because this broader methodological framework is perceived to have in itself a risk management dimension.

to structural problems with lack of resources been recorded and the level of compliance with the subsequently agreed upon timetable in that case was deemed sufficient. It has yet to occur that an opinion arrived too late to be of use in the policymaking process, even though this was theoretically possible in the case of edible fats and oils or with avian influenza vaccines. However, an interviewee mentioned that current EFSA procedures do not sufficiently address emergency situations - for which there are no emergency adoption procedures. This is particularly the case when the underlying regulation explicitly requires an opinion rather than an EFSA statement which is typically used in similar cases of emergency situations. Some risk managers, without complaining about timing, have noted that the approval process could have been shorter if leaner and more streamlined procedures were adopted – particularly in the panel plenary meeting phases.

It is worth noting that **most respondents would have been happy to trade off further delays in opinion delivery if this ensured a broader coverage of issues** and filled in the gaps to better address the scope of the mandate. However they deem the time devoted to the effort fully adequate to the results achieved in all but two cases where it was acknowledged a bit more time should have been granted to implement the assignment. The proposed impact indicator could not serve as a reliable instrument to evaluate ex post the correct prioritisation of requests for an opinion, as the fact that a decision has not been made after a certain number of months or years on the follow-up to give to a certain opinion is not a reliable indicator of a wrong prioritisation when this was requested. Moreover, the most patent example of an opinion where this could seemed to have been (but actually was not) the case, i.e. Toxicological and Metabolic Studies is actually a self-task proposed by the Panel itself.

Value for Money. Outputs that do not pass the overall **usefulness** test also generally do not meet the risk managers' own overall **value for money criteria**, as it is not difficult to conclude that too many human resources and too much expertise were invested to justify the result achieved. There was only one additional case in our sample where the value for money was deemed insufficient for an output, but was otherwise considered very useful. This was due to the fact that the EFSA **standard scientific opinion procedure** was deemed **disproportionate to the needs** in terms of quality and amount of expertise mobilised, something with which relevant EFSA staff also agreed. In all other cases value for money was considered fair, or presumed so when respondents did not have enough elements to conclude otherwise.

However, there are a number of cases with no clear indication of insufficient value for money, but in which a need for **better allocation of resources** has been indirectly highlighted. This was sometimes the case with the **exceedingly large amount of academic and scientific detail** devoted to issues not relevant for decision making purposes and which sometimes led to overly lengthy text. In authorisation-related opinions for example, analysis of issues was sometimes made that was not originally intended by the underlying regulation and was deemed not to be relevant. On the other hand, more resources could have been spent to **broaden the scope of data gathering** as previously mentioned, and to incorporate a wider range of sources (including raw data, unofficial and unpublished sources) into the analysis,. This is also acknowledged as necessary by some EFSA's Heads of Unit.

1.4 Summary of the Main Conclusions

- Visibility of the follow-up given to an opinion is certainly a motivational tool appreciated by all panels and scientific units. However, in a **number of cases this information was already shared** in plenary meetings or through other informal means, and often with a greater level of

detail. Feedback is of little help in improving planning of activities and prioritisation of requests for an opinion, which would require sharing detailed annual work plans in advance.

- For the proposed indicator to serve as a reasonable proxy of usefulness, a **certain consistency in factual reporting across the different DG SANCO units would be required**. Most importantly the key discriminatory criterion should not be whether action has been taken or not, but whether the **issue is still in the agenda** of risk managers long after the opinion has been released. This criterion appears to be a fairly reliable proxy indicator of possible usefulness and as such of some interest for EFSA management purposes. On the contrary, a decision to take no action is not necessarily relevant to accomplishing EFSA aims. The proposed indicator is at any rate unlikely to capture softer instances of problems with timing or relevance that would require additional complementary information. However, in certain cases the indicator is likely to overestimate possible problems actually due to other parallel unrelated inputs in the decision making process.

- The proposed **targets appear realistic and achievable**, although possibly overestimated as far as authorisation-related procedures are concerned. In fact, in the sample under consideration, the usefulness criteria are considered as met in 75% of the cases.

- **Self-tasks** capacity to raise issues in the policy agenda would probably require a separate more detailed ad hoc study because the problem hardly lends itself to being appreciated through a routine DG SANCO-driven monitoring system, as policy agenda setting mechanisms are typically complex and involve several different actors (Parliament, Member States, Stakeholders, etc.). Along the same lines, the impact indicator is unable to capture the degree to which **recommendations have been taken up** by different services of the Commission (e.g. DG Research, the Joint Research Centre when relevant, etc.) which appears to be fairly low *prima facie*, but would also require a separate study.

- The sample considered does not provide conclusive evidence on possible synergies between the proposed impact indicator and other existing **EFSA performance indicators** on compliance with deadlines in drawing conclusions on usefulness. As suggested by some interviewees, complementary information on usefulness and relevance could be gathered by **keeping systematic track of the Commission's subsequent written requests for clarification**, including follow-up requests for an opinion not justified by the appearance of new scientific evidence.

- Overall **usefulness appears to overestimate value for money** that is deemed satisfactory in 66% of cases in the sample. To compensate for this bias, a very rough performance indicator can possibly be represented by the ratio between the number of studies reviewed and referenced and the number of external expert/days required for non authorisation-related opinions. Conversely, the number of unpublished sources and data referenced could be considered a substantial gain in value for money terms, as they would represent novel elements in the decision making process typically appreciated by risk managers. The reliability of these tentative indicators would however require further pilot testing to be validated.

CHAPTER TWO – THE USEFULNESS OF THE VARIOUS PARTS

Introduction. This chapter deals in more detail with the usefulness of various components of EFSA's scientific outputs. The purpose of this analysis is to provide a more analytical feedback on the perceived determinants of quality and on the degree of satisfaction with the various parts. The chapter is structured in three sections. The first describes the judgment criteria used and how they were construed, the second summarizes main findings as far as usefulness is concerned, and the final section summarizes the main conclusions.

2.1 The Judgment Criteria

Rationale Behind Methodological Approach. The terms of reference expressly mention the need to assess the relative usefulness of the various components of EFSA scientific outputs and the reasons why. The assumption to be verified was that **certain parts** of the documents, e.g. the executive summary and conclusions, could possibly have greater weight than other parts of the main text in **determining perceived usefulness for policymaking purposes**. During the kick off meeting it turned out that EFSA was interested in a broader understanding of the subject, inclusive of the procedural aspects linked to the opinion formation process and the scope of analysis was extended accordingly.

The problem of assessing the usefulness of the various parts was split into two parts. First risk managers were asked to score the **perceived importance** they attached to certain **quality features** of the opinion or the opinion-making process in general terms. This was intended to provide elements for ranking the relative importance and measuring dispersion of subjective opinions - including the possible existence of outliers among respondents - as it was expected that a certain degree of variability would be found. Then a more specific and articulated assessment was requested about their specific **degree of satisfaction** with the same quality features in the specific case under consideration and of the reasons why.

Definition of Quality Features: The identified quality features to be investigated in more detail were agreed upon in the inception phase as follows:

1) The quality of the *executive summary* defined in terms of adequacy of the **informative contents** to the intended reader and **inclusion of all the relevant elements** to be highlighted.

2) The quality of the information on *background and context* in allowing the reader to put the EFSA scientific output into adequate context and consequently **understand the rationale behind the mandate** and the contents of the terms of reference.

3) The perceived quality of the scientific assessment in terms of *data transparency and completeness,* including the presence in the text of a **clear description of sources used and their possible limitations, the existence of clear and exhaustive referencing, and transparent justification for the possible omission** of apparently relevant data or other major sources.

4) The perceived quality of the scientific assessment in terms of *methodological transparency and appropriateness,* including considerations on the presence of an adequate **description of the methodology** adopted in the text, a clear **justification of the assumptions made** and **the line of reasoning followed**, a clear explanation – whenever relevant – of the modeling and calculations

made, compliance with internationally recognized methods, and - more generally speaking - recourse to the best available science.

5) The perceived quality of the scientific assessment in terms of *scope and significance of the analysis*, including **identification of all the relevant issues** for decision makers and related exhaustive analysis, clear **prioritization of aspects deserving attention in the text**, adequate exposition and possible confutations of **alternative explanations of data**.

6) The quality of *conclusions and recommendations* in their being **clear, succinct and operationally-oriented**, as well as sufficiently **justified by the underlying analysis** and in clearly indicating their possible limitations (methodological assumptions, areas of uncertainty and other data gaps).

7) The overall quality of *presentation aspects* both in terms of **overall readability** and **length of the text** and as concerns the degree of accessibility of the **specialized terminology** used.

8) The quality of the *interaction with EFSA* in terms of addressing information or **clarification needs** during the process and of warning in advance about possible problems in executing the mandate.

9) The perceived adequacy of the arrangements made to ensure *interaction with Member States and relevant stakeholders* on substantive matters and **information exchange**.

2.2 Main Findings

General Importance of the Different Quality Features for Risk Managers. The table below (tab.2.1) summarizes the perceived importance of the different quality features of a scientific output for risk managers in general terms, i.e. with no specific reference to the case studies under review. Average, and median values as well as outliers are separately reported to allow the reader to appreciate the dispersion in judgments on a scale from one to ten by increasing order of importance. As can be seen, **conclusions and recommendations are confirmed as the single most important part** of scientific opinions with overwhelming consensus among respondents and little variation in answer. The **executive summary** follows as the second most important item though with a slightly lower degree of consensus and one notable dissenting view among the interviewees.

The quality features of the underlying scientific assessment follow in order of importance, with a slightly more prominent role played by **the scope and significance of the analysis** over stricter methodological and data completeness considerations. Interaction with risk managers is *de facto* attributed an importance more or less equal to methodological aspects, while **arrangements to involve Member States** and **stakeholders** appear as the most **controversial** quality feature with substantial variation in feedback provided by interviewees with fairly divergent views. There seems to be a division between those who are concerned stronger involvement of external actors will end up endangering the panels' independence, ultimately interfering with their activities, and those in favor of a much greater use of current procedures (advisory forums, public consultations), though this represents a substantial cost burden. The rationale of the latter is that the sooner reservations about EFSAs preliminary orientations and challenges to its conclusions come to light, the better it is for risk management purposes. In a similar vein there are also mixed views on applicant **hearings** which, from a procedural point of view, should be carefully managed in order not to represent an undue incentive to trade off written evidence or incomplete files for oral explanations.

Presentation aspects and the information provided to put the exercise into **context** are generally deemed **the least important parts**, although with notable **variation** among respondents as well.

Table 2.1 - Assessment of the Overall Importance of Quality Features as Determinants of Usefulness for Risk Management Purposes

	Average Score	1	2	3	4	5	6	7	8	9	10
Executive summary	**8,83**						○	——	——	●	——
Background and context	**5,00**	○	——	——	——	●	——	——	○		
Data transparency and completeness	**8,25**					○	——	——	●	——	——
Methodological transparency and appropriateness	**8,30**					○	——	——	●	——	——
Scope and significance of the analysis	**8,58**					○	——	——	——	●	——
Conclusions and recommendations	**9,25**							○	——	——	●
Presentation aspects	**6,83**			○	——	——	——	●	——	——	
Interaction with Risk Managers	**7,18**					○	——	——	●	——	——
Interaction with Member States and Stakeholders	**7,64**		○	——	——	——	——	——	●	——	——

Note: scale from 1 to 10 in increasing order of importance. Median value indicated as ●, outliers as ○.

Degree of Satisfaction with the Various Components of Quality. The average degree of satisfaction with the main perceived components of quality appear fairly good as reported in the table below (tab. 2.2) showing the various features ranked in order of perceived importance and the related average score on a scale from 1 to 5.

Table 2.2 - Overall Degree of Satisfaction with the Various Quality Features in the Case Studies Considered

Quality Feature	A = Ranking by Perceived Importance (from 1 to 10)	B = Average Degree of Satisfaction (from 1 to 5)
Conclusions and Recommendations	9.25	3.85
Executive Summary	8.83	3.85
Scope and Significance of the Analysis	8.58	3.40
Methodological Transparency and Appropriateness	8.30	3.50
Data Transparency and Completeness	8.25	4.17
Interaction with Member States and Stakeholders	7.64	4.50
Interaction with Risk Managers	7.18	4.50
Presentation Aspects	6.83	3.95
Background and Context	5.00	4.50

Conclusions and Recommendations represent the quality feature that **more strictly correlates with overall usefulness**, in that there is a one to one correspondence between opinions deemed insufficiently useful in general terms and a low degree of satisfaction with the way conclusions are drafted. This can be variously motivated by lack of clarity, lack of operational-orientation, insufficient evidence of how conclusions were arrived at from the analysis and poor methodological surety or a combination of these factors. It is worth noting that a lower score can be due to some **lack of terminological clarity about the magnitude of risk** appreciated also in otherwise useful opinions. Finally more emphasis on the degree of uncertainty attributed to various statements along with more tentative statements themselves would be welcome provided that levels of uncertainty and underlying data quality were made clearer, possibly in quantified form. Some risk managers have reservations in principle with the idea that **recommendations** are included in the text[6]. In fact, to them the decision to fund a study or carry out further research on a given subject appears to correspond with the first step of possible risk management actions and, as such, should be left to the Commission's discretionary assessment without written input from EFSA. As recommendations and conclusions strictly correlate, so should related qualifiers. In other words, the sheer existence of a recommendation should be consistent with the language used for the related conclusion. If this is not the case then, it is deemed that the recommendation should be dropped.

The quality assessment of the *Executive Summary* - despite its perceived importance in its own right - appears quite **uncorrelated to the overall assessment of usefulness**. This is evident in cases where opinions score fairly high in terms of usefulness yet the executive summary *per se* is deemed badly drafted and to be of little use. There are also cases of good quality executive summaries in opinions deemed to be of poor usefulness. When major complaints were voiced, these usually pertained to the "scholastic" or "academic" **drafting style** of the executive summary or its poor reflection of the underlying **relevant contents** for policymaking. Various and sometimes contradictory opinions on language and style were also recorded as possible areas of improvement in instances where the level of satisfaction is high overall.

Scope and Significance of the Analysis is the single quality feature where problems of a different nature tend to concentrate, which contribute to the lowest score of satisfaction recorded in the analysis. First of all, this component, together with the conclusions and recommendations component, is the only other one where a clear **two way correspondence can be found with the overall degree of usefulness**. So opinions deemed generally not useful always have problems with insufficient satisfaction with the scope and significance of the analysis and vice versa. Thus the relatively low score may also reflect the already mentioned problem of **coverage of analysis** and parts of the mandate not addressed due to lack of data. In the case of authorization-related opinions issues of scope are raised as well in cases where the analysis does not strictly stick to regulatory requirements but also covers other unnecessary areas. Finally complaints were voiced about the **significance of text** that was exceedingly distracting to the reader and that mixed pages together of little relevance with small sections that were extremely important, without a clear hierarchy established in the text to help the reader move from key issues to less important ones within the same chapter.

[6] This is in line with scholar research on the precautionary principle-related regulatory tools. A "funding more research precautionary principle" is identified as the first step in risk management and linked to minimal reasons for concern. Subsequent steps would be represented by the "Information Disclosure Precautionary Principle" and the "Economic Incentives Precautionary Principle" . See R.B. Stewart, *Environmental Regulatory Decisionmaking under Uncertainty*, Research in Law & Economics, 71, 76, 2002 or Cass. R Sunstein *Laws of Fear – Beyond the Precautionary Principle*, Cambridge University Press 2005.

Finally the significance of the analysis is also a feature particularly influenced by external feedback and stakeholders' comments and is thus of a fairly reactive nature. Whenever the opinion is challenged on some grounds the issue immediately arises whether enough elements can be found in the text to reply to it, or whether there is at least evidence that the comments have been taken into consideration.

Methodological Transparency and Appropriateness is a quality issue, partly influenced by the experience risk managers have with the panels, and by their attitude following the opinion formation process. The longer this experience is, and the more assiduous their presence to the working group meeting is, the easier it becomes for them to **follow the line of reasoning** in the text (see box 2.1 below) and understand the assumptions and other methodological considerations. Otherwise it can happen that only the more experienced among them will spot the elements spread in various parts of the text, reconstruct the methodological approach and rationale behind it, and debrief colleagues accordingly. In the worst of these cases, key elements can be included in an annex or be clearly understood only if one has followed the opinion formation process, which makes the main **text not self-contained** and difficult for outsider readers. The adequate representation of **various possible scientific views** on a subject also appears to be an issue on occasion.

Data Transparency and Completeness is an item where notable improvement has been reported over time due to **improved guidance** and where there is a tendency to trust EFSA unless serious challenges come from outsiders. In only one case was there a problem considered serious enough by a respondent that it had a direct impact on the overall usefulness assessment .

Interaction between EFSA and Risk Managers is generally **deemed very satisfactory** apart from the somewhat grey area before the mandate is formally issued where procedures are poorly formalized and unexpected events can still occur. Since the useful practice of negotiating the contents of the mandate in advance to avoid misunderstandings and clarify expectations has begun to take place, the contents of mandates have begun to improve over time, and reasons for discontent remain related to the uncertain timing of the process and to the limited predictability of mandates of a cross-cutting or ambiguous nature, that can end being entrusted with another panel than originally expected thereby nullifying all the previous efforts.

Interaction with Member States and Stakeholders and related arrangements are also considered **generally very satisfactory** and adequate to requirements. However, as mentioned before, this is possibly the quality feature where respondents' ranking of importance differs the most, and those who consider the item very important still see room for further improvement, especially with regard to public consultations and procedures to incorporate related feedback.

Presentation Aspects are considered **very good as far as the language and the terminology** adopted is considered, and interviewees generally agree that it should be addressed to a public of highly specialist readers deserving the highest possible scientific rigor. Contrary to expectations, any attempt to simplify the language for broader communication purposes was not particularly welcome and, on the contrary, is a possible cause for complaints about "*excessive trivialization*" of issues. The **length of the text should be manageable for operational purposes** and should reach a maximum 100-120 pages only in exceptional cases. When this threshold is deemed insufficient, it is suggested that the mandate should be reworked, split or eventually made more specific. A certain tendency to underuse annexes for technical details or repeat considerations already written elsewhere is also reported.

Background and Context. The vast majority of respondents are perfectly happy with the EFSA practice of copying and pasting the information they receive from the Commission as background information and do not see a real need for any further elaboration.

Box 2.1 The Complex and Poorly Harmonized Structure of EFSA Risk Assessments

Although there is general guidance on how scientific opinions should be structured in broad terms, EFSA current practice is still short of a harmonized and transparent standard to be used across the board. It was noted that the structure of some outputs varied greatly in their layout and tables of contents, although more homogeneity was reported on authorisation-related opinions whose structure is more consistent over time, and helps the reader. Moreover there is hardly any justification in the text about why a certain structure was selected. This peculiar feature of EFSA risk assessment outputs has hindered any attempt at measuring the usefulness of the various parts of the text from the beginning, as results would not be homogenous and comparable for analytical purposes. The table attached as appendix C reports the structure of the twelve case studies under consideration to highlight how deeply they differ in their structure and layout of contents. In some cases the structure of the text can be particularly puzzling and sections named "conclusions" are disseminated at different levels both as chapters and within chapters or as subparagraphs. In another case a section on "reply to the terms of reference" was added after the conclusions.

2.3 Summary of the Main Conclusions

- The section on **Conclusions and Recommendations and the Executive Summary** are confirmed to be generally perceived as the most useful sections of EFSA Scientific outputs and where risk managers' focus a large portion of their attention. However, while the first strictly correlates with the assessment of the overall usefulness the second does not necessarily do so. There is huge subjective variation among interviewees on the parts considered less useful, although information on background and context is generally deemed to be so.

- The **specific reasons for satisfaction or dissatisfaction also tend to consistently vary on a case-by-case basis** and few unanimous lessons can be learned from comparing the various cases. Also length of experience with EFSA appears to significantly influence findings. All in all the average assessment of the various parts appear fairly good. Well-drafted conclusions and a satisfactory analysis in terms of scope and significance significantly correlates with overall perception of usefulness.

- Other features that were fairly unanimously appreciated included **text that was concise and to the point**, that rarely exceeded a 100-120 page maximum, and use of rigorous highly specialised language. Reasons for dissatisfaction were related to quality features that lent themselves to **external challenges** first and foremost (because certain aspects were ignored in the analysis or methodologically unclear) and to lack of clarity in the way the text was structured and the lines of reasoning utilized.

- Since there was large variation in the reasons behind satisfaction and dissatisfaction with the various quality features there was even more **variation in suggested recommendations for improvement**. Some respondents deem certain proposals necessary, whereas others view them with scepticism. It is worth highlighting that some proposals would imply a major regulatory / organisational restructuring of the way EFSA operates and of resources needed, and would therefore face notable constraints in their implementation.

- For the time being substantial consensus was found on introducing procedures to ensure a **maximum length of text** was not exceeded or to redefining the mandate accordingly, as well as to introducing **terminological harmonisation** in the way the magnitude of risks are defined, a subject on which the EFSA Scientific Committee has reportedly already begun working on. There are also elements that suggest the need to strengthen enforcement of existing procedures about the **structure and transparency of documents and to improve cross-referencing** of key elements.

- The case studies provide little indication of how to improve timing and prioritisation of issues within the framework of the current EFSA regulation. Apart from obvious considerations on the availability of planning documents there appears to be a **substantial amount of informal information on future mandates** already shared well before the mandate is formally released.

CHAPTER THREE - COMPARISONS BETWEEN RISK MANAGERS AND EFSA STAFF

Introduction. This chapter compares risk managers' assessment with EFSA staff's own self-assessment. The purpose is twofold: (i) to have a first rough appreciation of the level to which EFSA performance indicators (i.e. the self-assessments and peer reviews carried out within the framework of the EFSA internal quality review system) can be used to complement information provided by the proposed impact indicator and represent reasonable proxies of risk managers' assessment criteria, and (ii) to provide quantitative indications on the need to prioritize efforts to redress areas that are perceived to need improvement. The chapter is structured in three parts. The first section analyses the degree to which EFSA staff agree with their counterparts' ranking of importance of the various parts of a scientific output. This is first done in average terms and then through a specific one-to-one comparison of the degree to which the subjective judgement of the staff of the various EFSA units specifically mirror the judgment criteria of their counterparts, given the extreme variability of the latter.

Then a more specific comparison will be made of the ex-post assessment made by both groups on the adequacy of effort devoted to the implementation of the twelve case studies in order to understand perceptions about the prioritisation of needs for improvement. Summary conclusions will finally be presented.

3.1 Compared Relative Importance of the Main Quality Features

Group Comparisons. The Table below (tab.3.1) summarises and compares the findings of the perceived relative importance of the various quality features in terms of ranking of importance between Commission interviewees and EFSA scientific unit staff. As can be seen there are some notable differences in the assessments made by the two groups. To EFSA staff the intrinsic quality features of the scientific assessment (e.g. data completeness and transparency, methodological transparency and appropriateness, and the scope and significance of the analysis) represent the most important parts, followed by the section on conclusions and recommendations and the executive summary. Their Commission counterparts rank importance in the opposite order. Then within the specific framework of the scientific assessment quality criteria, the scope and significance of the analysis appear to be least important to EFSA staff, while it is most important for their risk manager counterparts.

The two groups also notably diverge in the relative importance attributed to background and context. There is substantial coincidence of views on all other items with the possible exception of the interaction with MS and stakeholders, the importance of which tends to be underestimated by EFSA staff when compared to Commission risk managers.

Table 3.1 - EFSA Staff Self Assessment of the Overall Importance of Quality Features as Determinants of Usefulness as compared to Commission Risk Managers' Assessment

	Average Score	1	2	3	4	5	6	7	8	9	10
Executive summary EFSA	**8.72**							○	———	●	———
Executive summary EC	**8.83**						○	———	———	●	———
Background and context EFSA	**8.27**					○	———	———	●	———	———
Background and context EC	**5.00**	○	———	———	———	●	———	———	○		
Data transparency and completeness EFSA	**8.91**							○	———	●	———
Data transparency and completeness EC	**8.25**					○	———	———	●	———	———
Methodological transparency and appropriateness EFSA	**9.25**							○	———	———	●
Methodological transparency and appropriateness EC	**8.30**					○	———	———	●	———	———
Scope and significance of the analysis EFSA	**9.08**					○	———	———	———	———	●
Scope and significance of the analysis EC	**8.58**					○	———	———	———	●	———
Conclusions and recommendations EFSA	**9.00**							○	———	●	———
Conclusions and recommendations EC	**9.25**							○	———	———	●
Presentation aspects EFSA	**7.33**					○	———	●	———	———	○
Presentation aspects EC	**6.83**			○	———	———	———	●	———	———	
Interaction with Risk Managers EFSA	**8.17**				○	———	———	———	●	———	———
Interaction with Risk Managers EC	**7.18**					○	———	———	●	———	———
Interaction with Member States and Stakeholders EFSA	**6.67**			○	———	———	———	●	———		
Interaction with Member States and Stakeholders EC	**7.64**		○	———	———	———	———	———	●	———	———

Note: rank from 1 to 10 in increasing order of importance. Median value indicated as ●, outliers as ○.

As far as timing and resource issues are concerned, which are not reported in the table above, the two groups do not differ substantially in the importance attributed to timing aspects, that are ranjed mid-way by both, but EFSA staff are much more likely as a group to believe there was a shortage of human resources and expertise available in developing the opinions under consideration (some 40% of respondents as against none within the Commission) than their counterparts. They also maintain that more time should have been devoted to clarify sections of the content (30% of respondents). The last finding is compatible with a broadly similar proportion of risk managers who complained about EFSA's failure to cover the entire scope of the mandate due to missing data and, at least theoretically, were more than willing to trade-off a more extended deadline for a better coverage of all aspects.

One to One Comparisons. The table below (table 3.2) reports in simplified format the degree to which EFSA staff can be considered good predictors of the importance attributed to a given quality feature by their respective counterpart risk managers within the Commission. Perfect correspondence is defined as exactly the same score given, good correspondence as a variation in the range of +/- one point, limited correspondence corresponds to a range of +/- two points and poor correspondence is defined as a difference of three points or more.

Tab 3.2 Degree of One to One Correspondence between EFSA Staff and Risk Managers Assessments on the Relative Importance of the Quality Features

	Perfect Correspondence	Good Correspondence	Limited Correspondence	Poor Correspondence
Executive summary	●●	●●	●●	●
Background and context	●●	●	●	●●●
Data transparency and completeness	●	●●	●●	●●
Methodological transparency and appropriateness	●●	●●●	●●	●
Scope and significance of the analysis	●	●●	●●●	●●
Conclusions and recommendations	●●	●●	●●	●
Presentation aspects	●	●●	●	●●●
Interaction with Risk Managers	●	●●	●	●●
Interaction with Member States and Stakeholders	●●●	●	●●	●

Legend = ● from 0% to below 20%, ●● from 20 to below 40%, ●●● 40% and over

Background and context are quality features where approximation of views is more difficult to achieve, while the executive summary and the conclusions and recommendations parts are relatively easier to predict, but this depends also on more limited variation in responses. EFSA staff also seem to have a divergent perspective than their counterparts when it comes to scope and significance of analysis considerations and presentation aspects. Interestingly, they appear to share the same views as far as mutual interaction and interaction with stakeholders is concerned despite the fact that these are areas with notable underlying variations in assessment.

3.2 Satisfaction with the Level of Effort Devoted to the Various Parts

Main Comparative Findings. The table below (table 3.3) reports the different assessments made by Commission risk managers and EFSA staff on the adequacy of the level of effort devoted to various parts of the opinions included in the sample, when compared to their own quality

benchmarks. The major differences derive from the Commission's perception that too little effort was devoted to drafting the executive summary or to ensuring an adequate scope and significance to the analysis. Some other reservations were expressed in areas where the effort devoted appeared not to be justified by the needs as was the case with certain aspects of authorization-related situations that exceeded strict regulatory requirements, or with complex statistical calculations or other forms of modelling, as well as the use of unnecessary academic detail in the text.

Table 3.3 - Adequacy of Effort Devoted to Quality Features While Implementing the Specific Opinion under Consideration (rounded at closer 5 %)

	EFSA			EC		
	Too Limited Effort	Adequate Effort	Too much effort	Too Limited Effort	Adequate Effort	Too much effort
Executive summary	10%	90%	-	55%	45%	-
Background and context	25%	50%	25%	25%	65%	10%
Data transparency and completeness	-	90%	10%	20%	70%	10%
Methodological transparency and appropriateness	25%	75%	-	40%	40%	20%
Scope and significance of the analysis	10%	75%	15%	55%	20%	25%
Conclusions and recommendations	10%	75%	15%	35%	55%	10%
Presentation aspects	15%	60%	25%	20%	55%	25%
Interaction with Risk Managers	30%	60%	10%	25%	60%	15%
Interaction with Member States and Stakeholders	10%	80%	10%	30%	60%	10%

One to One Comparisons. Also in this case a one-to-one comparison was carried out to assess the level of similarity in views between the components of the two groups reported in table 3.4 below. Perfect correspondence was defined as perfect identity in the judgement, limited correspondence as a variation of +/- one point in a scale of five and poor correspondence as any difference exceeding two points. The results basically confirm the findings above. There is less agreement between the two on the effort devoted to background and to scope and significance of analysis. Yet the views of EFSA staff appear to be a reasonably good predictor of their counterparts' assessments in terms of the executive summary, conclusions and procedural aspects.

Tab. 3.4 - Degree of One to One Correspondence in the Assessments as far as Adequacy of Effort is Concerned

	Perfect Correspondence	Limited Correspondence	Poor Correspondence
Executive summary	●●●	●●	●
Background and context	●●	●●●	●
Data transparency and completeness	●●●	●●	●
Methodological transparency and appropriateness	●●	●●●	●
Scope and significance of the analysis	●	●●●	●●
Conclusions and recommendations	●●●	●●	●
Presentation aspects	●●	●●●	●
Interaction with Risk Managers	●●	●●●	●
Interaction with Member States and Stakeholders	●●●	●●	●

Legend = ● from 0% to below 20%, ●● from 20 to below 40%, ●●● 40% and over

3.3 Summary of Main Conclusions

- Quality criteria used by EFSA staff are generally more influenced by academic considerations than those of their counterparts within the Commission that appear more practically-oriented.

- Both self-assessment and peer review can be considered good instruments for internal quality control to complement the findings of the impact, but both share the same weaknesses in grasping risk managers' feedback as far as certain quality aspects are concerned. Complementary use of external review can help reduce these self-assessment biases, as well as provide a more detailed feedback exercise on a multi-annual basis.

- There are areas where room for improvement is deemed possible with existing resources though this would require compliance with stricter procedures. There are also a limited number of areas where further cost savings are deemed possible, as the level of effort is too high to meet risk managers' expectations.

APPENDIXES

APPENDIX A – THE INTERVIEW PROGRAMMES

A.1 EFSA Staff

Date	Interviewee	Subject
March 10th	Luc Mohimont (Acting Head of Unit)	PPR - Updating the opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Toxicological and metabolism studies
March 10th	Claudia Heppner	CONTAM - Review of the criteria for acceptable previous cargoes for edible fats and oils
March 10th	Franck Berthe, Per Have, Oriol Ribò Arboledas	AHAW - Opinion of the Scientific Panel on Animal Health and Welfare (AHAW) related with the vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds
March 10th	Claudia Roncancio Pena	FEEDAP - Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the Maximum Residue Limits for Clinacox 0.5 % (diclazuril) for turkeys for fattening, chickens for fattening and chickens reared for laying
Date	**Interviewee**	**Subject**
March 11th	Juliane Kleiner	NDA Plant Stanols and Plant Sterols and Blood LDL-Cholesterol - Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission and a similar request from France in relation to the authorization procedure for health claims on plant stanols and plant sterols and lowering/reducing blood LDL-cholesterol pursuant to Article 14 of Regulation (EC) No 1924/2006
March 11th	Alexandre Feigenbaum, Anna Federica Castaldi	CEF - "Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A"
March 11th	Djien Liem	Scientific Committee. Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals including the two updates in 2008 and 2009
Date	**Interviewee**	**Subject**
March 14th	Elzbieta Ceglarska	PLH Evaluation of a pest risk analysis on Thaumetopoea processionea L., the oak processionary moth, prepared by the UK and extension of its scope to the EU territory
Date	**Interviewee**	**Subject**
March 15th	Marta Hugas, Fulvio Barizzone	BIOHAZ Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE
Date	**Interviewee**	**Subject**
March 21st	Per Bergman	GMO Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and

		feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto
March 21st	Herman Fontier, Hermine Reich	PRAPeR. "Potential risks for public health due to the presence of nicotine in wild mushrooms".
March 21st	Hugues Kenigswald	ANS. Chromium picolinate, zinc picolinate and zinc picolinate dihydrate added for nutritional purposes in food supplements

A.2 European Commission Staff

Panel/ Unit	Case Study	Interviewee	Date
AHAW	Opinion of the Scientific Panel on Animal Health and Welfare (AHAW) related with the vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds	Alberto Laddomada Maria Pittman	31 March 2011
ANS	Chromium picolinate, zinc picolinate and zinc picolinate dihydrate added for nutritional purposes in food supplements	Agnwska Kordasiewicz	5 April 2011
BIOHAZ	Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE	Koen van Dyck	6 April 2011
CEF	Opinion on Bisphenol A: evaluation of a study investigating its neurodevelopmental toxicity, review of recent scientific literature on its toxicity and advice on the Danish risk assessment of Bisphenol A	Chantal Bruetschy Annette Schaeffer	5 April 2011
CONTAM	Review of the criteria for acceptable previous cargoes for edible fats and oils	Frank Swartenbroux	6 April 2011
FEEDAP	Opinion of the Scientific Panel on additives and products or substances used in animal feed (FEEDAP) on the Maximum Residue Limits for Clinacox 0.5 % (diclazuril) for turkeys for fattening, chickens for fattening and chickens reared for laying (02.07.2007)	Willem Penning	1 April 2011
GMO	Applications (EFSA-GMO-RX-MON810) for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto	Dorothée Andre	5 April 2011
NDA	Plant Stanols and Plant Sterols and Blood LDL-Cholesterol - Scientific Opinion of the Panel on Dietetic Products Nutrition and Allergies on a request from the European Commission and a similar request from France in relation to the authorization procedure for health claims on plant stanols and plant sterols and lowering/reducing blood LDL-cholesterol pursuant to Article 14 of Regulation (EC) No 1924/2006	Christina Antoniou	5 April 2011
PLH	Evaluation of a pest risk analysis on Thaumetopoea processionea L., the oak processionary moth, prepared by the UK and extension of its scope to the EU territory	Dana Irina Simion Harry Arus	31 March 2011
PPR	Updating the opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market –	Francesca Arena	30 March 2011

Panel/ Unit	Case Study	Interviewee	Date
	Toxicological and metabolism studies		
PRAPER	Potential risks for public health due to the presence of nicotine in wild mushrooms	Francesca Arena	30 March 2011
SC&AF	Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals including the two updates in 2008 and 2009	Chantal Bruetschy José Luis De Felipe Gardon Andreas Kleptsch	5 April 2011

A.3 Member States and Stakeholders' Groups

#	Name	Affiliation	Position	Date of the Interview
1	Andrew WADGE	Food Standards Agency (UK)	Director	May 03rd
2	Ruth VEALE	BEUC (European Consumers Organisation)	Head of Food Policy Department	May 06th
3	Christophe DERRIEN	Copa - Cogeca (European farmers and agri-cooperatives)	Policy Advisor	May 06th
4	Liviu RUSU	National Sanitary Veterinary and Food Safety Authority (RO)	General Director	May 06th
5	Beate KETTLITZ	CIAA (confederation of the food and drink industries)	Director Food Policy, Science and R&D	May 13th

APPENDIX B – THE SEMISTRUCTURED INTERVIEW TO COMMISSION RISK MANAGERS

1. Opinion Contents

1.1 Executive Summary

Questions	Type of Answer
To what extent is the executive summary informative for your decision making needs ? Are all relevant issues highlighted ?	Qualitative answer
Does the executive summary adequately reflect the background, the mandate received and the conclusions /recommendations formulated by the Panel/SC?	Qualitative answer
All in all, how do you rate the quality of the executive summary?	Rank from 1=poor to 5=excellent.

1.2 Background and Context

Questions	Type of Answer
Is the background info clearly exposed to put the opinion into context?	Qualitative answer
Are the terms of reference of the mandate clearly described?	Qualitative answer
All in all, how do you rate the quality of the background and context description?	Rank from 1=poor to 5=excellent.

1.3 Scientific Assessment – Data Transparency and Completeness

Questions	Type of Answer
Are data on which the opinion is based clearly described? Are possible limitations of these data adequately described in the opinion? Are sources adequately referenced at the end of the document?	Qualitative answer
Does the opinion use all relevant data sources? Are there missing info?	Qualitative answer
In the event some data were excluded, is the rationale and criteria adequately justified?	Qualitative answer

All in all, how do you rate the transparency of the data and the completeness of the data-gathering work done?	Rank from 1=poor to 5=excellent.

1.4 Scientific Assessment – Methodological Transparency and Appropriateness

Questions	**Type of Answer**
Is the methodology followed adequately described? Are the assumptions, lines of reasoning and (if applicable) calculation and mathematical models clearly justified? Or do they remain somehow implicit ?	Qualitative answer
Does the opinion follow internationally recognised methods? And, more generally, is the opinion based on the best available science?	Qualitative answer
All in all, how do you rate the transparency and appropriateness of the methodology used?	Rank from 1=poor to 5=excellent.

1.5 Scientific Assessment – Scope and Significance of the Analysis

Questions	**Type of Answer**
Have all the relevant issues for decision makers been identified? Is the analysis of these issues sufficiently exhaustive for your needs ?	Qualitative answer
Are these issues duly prioritised ? Is there any presentation by order of importance ? Is the reader facilitated to understand what matters?	Qualitative answer
Are possible alternative counterarguments clearly described and adequately confuted ?	Qualitative answer
All in all, how do you rate the scope and significance of the analysis?	Rank from 1=poor to 5=excellent.

1.6 Conclusions and recommendations.

Questions	**Type of Answer**
Are conclusions (and – where applicable – recommendations) sufficiently clear, succinct and operational-oriented?	Qualitative answer
Are conclusions (and – where applicable – recommendations) sufficiently justified by the underlying	Qualitative answer

analysis ?	
Are possible reservations (e.g. methodological weaknesses / uncertainties and data 'gaps') on the validity of conclusions clearly described?	Qualitative answer
All in all, how do you rate the quality of conclusions and recommendations?	Rank from 1=poor to 5=excellent.

2. Presentation and Operational Aspects.

2.1 Presentation

Questions	**Type of Answer**
Are you satisfied with the length of the text? Or could it have been made shorter / longer ?	Qualitative answer
Is the opinion written in a language reasonably accessible also to the non specialist reader ?	Qualitative answer
Is the opinion using internationally accepted terminology ?	Is the opinion using internationally accepted terminology?
All in all, how do you rate the quality of the overall presentation ?	Rank from 1=poor to 5=excellent.

2.2 Timing of the Process

Question	**Type of Answer**
Was the opinion delivered reasonably in line with the agreed timetable? If not, what are in your opinion the main causes ?	Qualitative answer
All things considered and irrespective of agreed deadlines has the opinion arrived on time to be taken in consideration in the decision making process?	Qualitative answer
If you had been given the possibility would you have traded off a speedier delivery with less in-depth contents or *vice-versa* you would have preferred giving EFSA more time to analyse certain aspects ? If so, please elaborate.	Qualitative answer
All in all, how do you rate the timing of the process ?	Rank from 1=poor to 5=excellent.

2.3 Interaction with EFSA

Question	**Type of Answer**
Are you satisfied with the interactions you could have with EFSA to clarify developing information, or ensure that your main concerns as risk manager were being addressed? If not, why?	Qualitative answer
In case, have you adequately warned in advance of possible operational problems (e.g. delays in finalisation, missing key data, likely inconclusive findings, etc.)? Or were you caught by surprise ?	Qualitative answer
All in all, how do you rate the interaction with EFSA during the development of the opinion?	Rank from 1=poor to 5=excellent.

2.4 Interaction with Stakeholders and Member States

Question	**Type of Answer**
Are you satisfied with the arrangements made to gather and analyse the points of view of national counterparts and stakeholder groups ? Has the process been inclusive enough ?	Qualitative answer
All in all, how do you rate the interaction with stakeholder groups and Member States?	Rank from 1=poor to 5=excellent.

3. Summary Judgment

3.1 Overall Usefulness of Output and Responsiveness to Risk Management Needs.

Question	**Type of Answer**
All in all, was the opinion useful to you as risk managers? Did the opinion provide clarity and surety to the decision making process? Could you have proceeded without it?	Qualitative answer
Did the opinion fully address the scope and meaning of the mandate?	Qualitative answer
With the benefit of hindsight would you have drafted the mandate differently ? If so, how? Do you think that EFSA procedures (e.g. the Committee of Panel) were flexible	Qualitative answer

enough to ensure responsiveness to your needs?	
All in all to what extent do you think the opinion was fit for purpose?	Rank from 1=poor to 5=excellent.

3.2 Broader Policymaking Support.

Questions	**Type of Answer**
Did the opinion otherwise raise issues of concern for the policy agenda ? In case, was this useful at that time (e.g. in developing your risk management activities, or in developing further the policy orientation in the areas of the mandate)?	Qualitative answer
All in all how do you rate the contribution of the opinion to broader policymaking support?	Rank from 1=poor to 5=excellent.

3.3 Comparative Importance of Different Parts and Appropriateness of Related Effort

Question	**Type of Answer**
Have the efforts devoted to the following elements of the opinion drafting been in line with your expectations?	Rank from 1 too little effort to 3 right level of effort to 5 too much effort
Generally speaking, what is the importance you attach to these elements?	Rank from 1 very negative importance to 10 very important

	Assessment of efforts						***Assessment of overall importance***
	1	2	3	4	5		(1 to 10)
effort devoted to drafting the **executive summary**							
effort devoted to **clarifying background and context**							
effort devoted to ensure **data transparency and completeness**							
effort devoted to ensure the **methodological transparency and appropriateness**							
effort devoted to ensure the quality of the overall **analysis**							

effort devoted to write **conclusions and recommendations**							
effort devoted to overall **presentation aspects**							
effort devoted to **timely** process the opinion							
effort devoted to **interaction with risk managers**							
effort devoted to **interaction with national counterparts and stakeholders**							

3.4 Value-for-money

Question	**Type of Answer**
Based on the usefulness the opinion had for your risk managing purposes and your overall satisfaction with qualitative features how would you assess the following aspects: - human resources and expertise - time invested	Based on the options below and qualitative assessment
All in all how do you rate the value-for-money of the opinion?	Rank from 1=poor to 5=excellent.

There was a severe shortage of human resources and expertise	*There was some shortage of human resources and expertise*	*All in all fair*	*Maybe a bit too much was invested for the results achieved*	*Definitely too much was invested to justify the results*
Much more time should be invested to further explore issues	*A bit more time should have spent to clarify a few more things*	*All in all fair*	*It lasted a bit too long for the output we have received*	*It lasted definitely too long for the output we have received*

3.5 Comparative assessment

Question	**Type of Answer**
All in all, how do this opinion compare to similar opinions from the same panel ? Is it above average in line with average or below average?	Qualitative answer with quantitative classification: below average, average, above average.
If above or below average, what is the main reason why ?	Qualitative answer

APPENDIX C – THE TABLE OF CONTENTS OF THE CASE STUDIES

First Level Structure	Second Level Structure
Avian Influenza Vaccines 1. Background 2. Terms of reference 2.1. Clarification of the Terms of Reference I. Update on the most recent development on vaccines against avian influenza of H5 and H7 subtypes, both for domestic poultry and other captive birds, including experiences with their use under laboratory conditions and in the field, as well as future perspectives II. Evaluation of laboratory testing methods for surveillance of vaccinated flocks in particular discriminatory tests used in the context of a DIVA (Differentiating Infected from Vaccinated Animals) strategy 3.Conclusions and recommendations 4.Working Group Members 5. Acknowledgements 6. AHAW Scientific Panel Members 7. References 8. Annexes	I.2. Risk and benefits of AI vaccination of poultry and other captive birds I.3. Public health implications of vaccination I.4. International experience in the field of vaccine effectiveness in domestic fowl I.5. Current regulatory status of H5/H7 AI vaccines in the EU I.6. Animal welfare considerations in the development and testing of Vaccines II.1. Strategies to discriminate AI H5/H7-infected from non-infected vaccinated flocks: DIVA II.1.1. Background II.1.2. Surveillance II.1.3. Inactivated conventional vaccines and accompanying diagnostic tests or systems to reveal field exposure II.1.4. Engineered vaccines and accompanying tests II.1.5. General characteristics that need to meet the diagnostic serology and virology tests 3.1. Update on the most recent development on vaccines against AI of H5 and H7 subtypes 3.1.1. Conclusions 3.1.2. Recommendations 3.2. Evaluation of laboratory testing methods for surveillance of vaccinated flocks in particular DIVA 3.2.1. Conclusions 3.2.2. Recommendations
Picolinates as Supplements - Panel Members - Summary - Table of Contents - Background as provided by the European Commission - Terms of reference as provided by the European Commission - Acknowledgements - Assessment: 1. Introduction 2. Technical Data 3.Biological and Toxicological Data 4. Discussion - Conclusions - Documentation provided to EFSA - References - Glossary / Abbreviations	2.1. Chemistry 2.2. Specifications 2.3. Manufacturing process 2.4. Methods of analysis in food 2.5. Reaction and fate in foods to which the source is added 2.6. Case of need and proposed uses 2.7. Existing authorisations and evaluations 2.8. Exposure 3.1. Bioavailability, absorption, distribution, metabolism and excretion 3.2. Toxicological data 3.3. Reproductive and developmental toxicity 3.4. Chronic toxicity and carcinogenicity 3.5. Genotoxicity 3.6. Human data

Fishmeal as Feed for Ruminants 1. Introduction 2. Terms of Reference 3. Background to the Mandate 4. Risk Assessment 5. Conclusions 6. Reply to the Terms of Reference 7. Recommendations 8. Documentation provided to EFSA 9. References 10. Annex I:Background on fish meal production and use for feeding	3.1. Scientific knowledge and former SSC opinions 3.2. Justification of the request for a scientific opinion 4.1. Preamble 4.2. Introduction 4.3. Analysis of new scientific information 4.3.1. Update on recent research on Prion Proteins in fish 4.3.2. Analysis of the research on the evaluation of different discriminatory tests 5.1. Conclusions on the TSE risks including public health of feeding of ruminants with fishmeal 5.2. Conclusions on detection methods
Bisphenol A - Abstract - Summary - Table of contents - Background as provided by the European Commission - Terms of reference as provided by the European Commission - Interpretation of the terms of reference by the EFSA Part I – Evaluation of the dietary developmental neurotoxicity study of Bisphenol A in rats by Stump (2009) Part I – Assessment 1. Introduction. 2. Assessment of a newly available developmental neurotoxicity study in rats Part I – Conclusions Part I - Documentation provided to EFSA Part I – References Part I – Abbreviations Part I – Appendices Part II - Review of recent scientific literature on the toxicity of Bisphenol A Part II – Assessment 3. Introduction 4. Toxicokinetics 5. Toxicity Part II – Conclusions Part II – References Part II – Abbreviations Part III - Advice on the Danish risk assessment of Bisphenol A Part III – Assessment 6. Introduction 7. Conclusions of the Danish risk assessment 8. Discussion of the Panel on the Danish risk assessment Part III – Conclusions Part III – References Part III – Abbreviations Part IV - Overall Panel conclusions 9. Background 10. Conclusions from PART I: Evaluation of the dietary developmental neurotoxicity study of Bisphenol A in rats	2.1. Summary of the study as reported by Stump (2009) 2.2. The Panel's comments to the study design and results 2.3. Discussion of the study outcome 4.1. New pharmacokinetic studies in rats and monkeys (Doerge et al. 2010a, 2010b) 4.2. The enzymes involved in BPA biotransformation 4.3. In utero exposure and kinetics 4.4. Neonatal exposure and kinetics 4.5. Human physiologically based pharmacokinetic (PBPK) modelling 4.6. BPA repeated exposure 4.7. Summary and conclusions on toxicokinetics 5.1. Human studies 5.2. Animal toxicity studies 5.3. Other information on the endocrine-mediated action of BPA 5.4. Conclusions on toxicokinetics 5.5. Conclusions on human studies 5.6. Conclusions on studies in animals 5.7. Conclusions on endocrine-mediated action of BPA 11.1. Conclusions on toxicokinetics 11.2. Conclusions on human studies 11.3. Conclusions on studies in animals

11. Conclusions from PART II: Review of recent scientific literature on the toxicity of Bisphenol A 12. Conclusions from PART III: Advice on the Danish risk assessment of Bisphenol A 13. Overall conclusion Part IV – References Part IV – Abbreviations	
Edible Fats and Oils - Panel Members - Summary - Table of Contents - Background as provided by the European Commission -Terms of reference as provided by the European Commission - Acknowledgements - Assessment 1. Introduction 2. Previous assessments of the criteria for acceptable previous cargoes 3. Assessment of the SCF criteria and the CCFO criteria - Conclusions and Recommendations - References - Abbreviations	2.1. Scientific Committee on Food Opinion (SCF Criteria) 2.2. Joint FAO/WHO Technical Meeting (FAO/WHO Criteria) 2.3. 21st session of the Codex Committee for Fats and Oils (CCFO Criteria)
Clinacox - Summary - Background - Terms of Reference - Assessment 1. Introduction - Conclusions - Documentation provided to EFSA - References - Scientific Panel Members	1.1 Acceptable daily intake (ADI)
Maize Mon 810 - Panel Members - Summary - Table of Contents - Background - Terms of Reference - Acknowledgements - Assessment 1. Introduction 2. Issues raised by Member States 3. Molecular characterisation 4. Comparative analysis 5. Food/Feed safety assessment 6. Environmental risk assessment and monitoring Overall Conclusions and Recommendations - Documentation provided to EFSA - References	3.1. Evaluation of relevant scientific data 3.2. Conclusion 4.1. Evaluation of relevant scientific data 4.2. Conclusion 5.1. Evaluation of relevant scientific data 5.2. Conclusion 6.1. Evaluation of relevant scientific data 6.1.6.4. Conclusion 6.1.8. Conclusion 6.2. Post-market environmental monitoring 6.2.6. Conclusion
Plant Sterols and Stenols - Panel Members - Summary - Table of Contents - Background as provided by the European Commission - Terms of Reference as provided by European Commission - Acknowledgements - Assessment 1. Introduction 2. The range of daily intake of plant sterols and plant stanols and the	

corresponding biologically significant LDL-cholesterol lowering effect expressed in percentage which can be reasonably expected. 3. Reference to the time needed to obtain the claimed effect expressed in weeks and to the sustainablility of the claimed effect 4. The food matrix to which plant sterols/plant stanols are added and other food characteristics that possibly determine the size of effect - Conclusions - References	
The Oak Processionary Moth - Panel Members - Summary - Table of Contents - Background as provided by the European Commission -Terms of reference as provided by the European Commission - Acknowledgements - Assessment 1. Introduction 2. Evaluation of the UK pest risk analysis and extension to the whole EU area - Conclusions and Recommendations - Documentation provided to EFSA - References - Appendix A - Appendix B - Appendix C	1.1. General introduction to Thaumetopoea processionea L. 1.2. The document under scrutiny 1.3. Evaluation procedure 2.1. Pest categorization 2.2. Assessment of the probability of introduction and spread 2.3. Assessment of potential consequences 2.4. Comments on the conclusion of the pest risk assessment 2.5. Degree of uncertainty 2.6. Evaluation of pest risk management options 2.6.5. Conclusions
Toxicological and Metabolism Studies - Panel Members - Summary - Table of Contents - Background as provided by EFSA - Terms of Reference as provided by EFSA - Acknowledgements - Evaluation 1. Introduction 2. Opinion - References	
Nicotine in Mushrooms - Background to this request as provided by the European Commission - Terms of Reference - Clarification of the terms of Reference - Evaluation 1. Introduction 2. Legislative background 3. Hazard identification and characterisation 4. Assessment of exposure 5. Exposure estimates compared to the health based guidance values set by EFSA 6. Assessment of the MRL proposal - Conclusions and Recommendations - References - Appendix A: Short term dietary intake calculations - Appendix B: Trade data of mushrooms. Source: EUROSTAT Comext database - Glossary / Abbreviations	3.1. Absorption, distribution, excretion, metabolism 3.2. Acute Toxicity 3.3. Short term toxicity 3.4. Genotoxicity 3.5. Chronic toxicity and carcinogenicity 3.6. Reproductive and developmental toxicity 3.7. Neurotoxicity3.8. Health-based guidance values 4.1. Occurrence of nicotine in wild mushrooms 4.2. Mushroom consumption 4.3. Exposure estimates based on available occurrence data 5.1. Long term health effects: 5.2 Acute health effects 6.1. Methodology of long-term and short-term consumer exposure in the framework of setting MRLs 6.2. Food consumption data used in the

	pesticide risk assessment 6.3. Calculation of consumer exposure
Animal Cloning - Scientific Committee Members - Summary - Table of Contents - Background as provided by the European Commission - Terms of Reference as provided by the European Commission - Acknowledgements - Assessment 1. Introduction to the opinion 2. Animal breeding and reproductive techniques 3. Epigenetic and genetic aspects of SCNT 4. Animal health and welfare implications of SCNT 5. Safety of meat and milk derived from clones (F0) and their progeny (F1) 6. Impact on the genetic diversity, biodiversity and environment - Overall Conclusions and Recommendations - Conclusions - Recommendations - Information made available to EFSA - Glossary and abbreviations used in the opinion	1.1. Matters not addressed in the opinion 1.2. Terms used in the opinion 2.1. Introduction to Somatic Cell Nucleus Transfer (SCNT 2.2. Cloned species and cloning efficiency 2.3. Data on clones and their life span 2.4. Possible use of cloning 3.1. Epigenetic aspects: Reprogramming in clones 3.2. Genetic aspects. 3.3. Other aspects 3.4. Conclusions of epigenetic and genetic aspects of SCNT 4.1. Animal health 4.1.5. Conclusions on animal health 4.2. Animal welfare aspects 4.2.5. Conclusions on animal welfare 5.1. Molecular, biological and chemical aspects considered for safety 5.2. Conclusions on food safety 6.1. Genetic diversity 6.2. Biodiversity 6.3. Environmental impacts 6.4. Conclusions on Impact on the Environment and Genetic diversity

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