Dr Bernhard Url, EFSA Acting Executive Director
EFSA Management Board
EFSA
Parma, Italy

By email only

Brussels, 17 February 2014

Subject: Operational, procedural and scientific challenges for industries impacted by EFSA

Dear Dr Url, dear EFSA Management Board members,

This letter is sent on behalf of 11 federations representing tens of thousands of companies whose businesses are directly and indirectly impacted by EFSA processes and outputs. We have recently compared experiences regarding developments at, and interactions with, EFSA.

We are strong supporters of a credible and efficient EFSA, but we have shared and growing concerns about operational and scientific challenges at EFSA. These concerns relate especially to communications between EFSA and individual applicants, to the setting of mandates and transparency. We have described these in the annex and have drawn lessons from comparable EU regulatory bodies.

To address these challenges, and drawing lessons from practices at other EU regulatory bodies, we make 14 specific proposals for consideration. We call particular attention to three:

1. A proposed meeting between EFSA management and the undersigned, similar to the EFSA meeting with NGOs, where these issues, as well as others can be discussed (proposal 1),

2. A proposal for an EFSA pilot project on pre-submission meetings (proposal 4),

3. A proposal for an EFSA pilot project to consider more detailed mandates with a consultation of stakeholders and risk managers (proposal 14).

With this communication we would hope to engage with EFSA on these issues in a positive spirit, with the aim of improving the quality, efficiency and timeliness of processes and outputs, and to produce high quality science in a high quality regulatory system. We hope that any progress achieved on regulated products and mandates will help achieve general principles for efficient interaction with industry that may benefit other EFSA activity.

Best wishes,

Signed overleaf by the leaders of 11 European federations

CC:

Paola Testori Coggi (DG SANCO), Per Bergman (EFSA Director of Scientific Evaluation of Regulated Products), Anthony Hardy (Chair of EFSA Scientific Committee)

Correspondence contact:

FEFANA, Secretary-General Didier Jans (dja@fefana.org)

11 associations representing tens of thousands of companies affected by EFSA processes.			
 Didier Jans, Secretary-General		The **EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA)** is the independent spokesman of the specialty feed ingredients industry.	100+companies
 Dr Hubertus Cranz, Director-General		The **Association of the European Self–Medication Industry (AESGP)** represents manufacturers of non-prescription medicines, food supplements and self-care medical devices.	21 companies, 25 national associations
 Marc Vermeulen, Director Foodchain		The **European Chemical Industry Council (CEFIC)** is the forum and the voice of the chemical industry in Europe.	640 members
 Christina Kaul, Secretary-General		**Energy Drinks Europe (EDE)** represents the interests of energy drinks companies across Europe.	5 companies
 Nathalie Moll, Secretary-General		The **European Association for Bio-industries (EuropaBio)** represents the biotechnology industry in agriculture (seeds), pharmaceuticals and industrial biotech.	1800 companies
 Jean-Charles Bocquet, Director-General		The **European Crop Protection Association (ECPA)** represents the crop protection industry in Europe.	19 companies
 Alexander Döring, Secretary-General		The **European Feed Manufacturers' Federation (FEFAC)** is the voice of the European feed industry.	4000 companies
 Garlich von Essen, Secretary-General		The **European Seed Association (ESA)** is the voice of the European seed industry, representing those active in research, breeding, production and marketing of seeds.	7000 companies
 Maryse Hervé, Secretary-General		The **Federation of European Specialty Food Ingredients Industries (ELC)** represents a united voice for the specialty food ingredients industry on scientific, technical and regulatory topics.	200+ companies
 Mella Frewen, Director-General		**FoodDrinkEurope** represents the European food and drink industry, the largest manufacturing sector in the EU in terms of turnover and employment.	Tens of thousands of companies
 Declan O'Brien, Managing Director		The **International Federation for Animal Health - Europe (IFAH-Europe)** represents manufacturers of veterinary medicines, vaccines and other animal health products.	13 companies, 19 national associations

Achieving greater efficiencies in the evaluation procedures

A paper prepared by the industries impacted by EFSA work

Introduction

This paper sets out a series of challenges and solutions related to communication between EFSA and applicants from regulated industries whose products are assessed by EFSA (p 4). It also addresses issues related to the development of mandates for providing opinions and guidance to support the risk assessment and the risk management procedures in specific legislation (p 8).

This paper reflects the collective views of the following groups:

1. EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA)
2. Association of the European Self-Medication Industry (AESGP)
3. European Chemical Industry Council (CEFIC)
4. Energy Drinks Europe (EDE)
5. European Association for Bio-industries (EuropaBio)
6. European Crop Protection Association (ECPA)
7. European Feed Manufacturers' Federation (FEFAC)
8. European Seed Association (ESA)
9. Federation of European Specialty Food Ingredients Industries (ELC)
10. Food Drink Europe
11. International Federation for Animal Health - Europe (IFAH-Europe)

We share a strong belief that dialogue between applicants/affected industries and EFSA helps to:

- avoid misunderstandings,
- enables better dossier content,
- increases the quality of opinions,
- leads to more efficient work processes,
- shortens the time from request to delivery,
- enables a better use of public and private resources.

The group has taken note of Ernst & Young's 2012 report assessing EFSA. The report was generally positive about most of EFSA's processes. Nonetheless, it made a number of observations and recommendations. It noted that "…*the capacity to meet the industry's needs should be improved, balancing the need to respond effectively to industry needs with its independence and taking into account that applications cover more than 60% of EFSA's output."*[i]

The EFSA Management Board took the Ernst & Young report recommendations and included many of them in the EFSA Multiannual Plan 2014-2016[ii]. It stated that EFSA *"…aims to provide food and feed operators with a more predictable regulatory environment and enhanced interaction….and to review its efficiency in handling applications within the context of existing legal frameworks and good administrative practice as well as streamlining its working processes."*

This paper put forward a number of proposals and suggestions for improvements in the processes in order to help achieve these goals. These proposals are made in two sections:

- EFSA and applicants: Achieving efficiencies through better communications
- The development of mandates and their impact on EFSA opinions

EFSA and applicants: Achieving efficiencies through better communications

Introduction: The common challenges

The associations feel that there is a growing challenge related to "*communication between applicants and EFSA on specific applications".* They note with concern that dialogue with EFSA has become more difficult. It is felt that this is largely the result of undue pressure on EFSA over supposed influence from applicants. Despite widespread speculation by some groups, there are no examples and no evidence that there has been such undue influence. In order to shield it from such accusations, it is felt that EFSA has structured communications with individual applicants in a minimalistic manner. This has resulted in a lack of dialogue which has had a negative impact on efficiency. Specific challenges are:

1. **Communications related to risk assessment/ EFSA guidance.** Most sectors have EFSA technical guidance documents pertaining to the submission of their dossiers, but often there are questions on how to interpret details, how to apply the requirements due to inconsistencies with good scientific practices and how to manage inconsistencies between the guidance's and regulatory requirements and the freedom left by the regulator to the applicant, and what would be acceptable to EFSA. With ever-changing regulatory data requirements, this issue is even more relevant**.** Yet it is felt that often the clarifications requested by applicants are not provided, that timeframes for comment are too short and some panels tend to consider the guidance documents as a list of fixed requirements rather than as an orientation support to applicants.

2. **Communication between EFSA and applicants prior to submission of a new dossier.** Pre-submission meetings are not conducted by EFSA. Should product specific pre-submission meetings between the notifiers and the evaluating group be undertaken, it is felt the quality of dossiers would improve, especially for dossiers concerning innovative products. Other regulatory agencies, like EMA, building on their positive experiences in the improvement of dossier quality, now actively encourage applicants to ask for pre-submission meetings. "*The EMA emphasises the importance of scientific advice or protocol assistance pre-submission meetings with companies*".[iii]

3. **Communication with applicants during the risk assessment process**. Often EFSA requires applicants to provide additional data, yet interaction (beyond the question) as to the appropriateness of additional data submitted is not possible. This leads in some cases to misunderstandings or misinterpretations, as the background of the question is usually absent, thus there are cases where additional regulatory data, provided at EFSA request, was not sufficient or appropriate. In these cases EFSA sometimes does not inform the applicant or provide feedback whether the data submitted is acceptable or not - and risk assessment opinions are finalised with negative or non-conclusive statements. In addition, there is often poor coordination on timing between panels. Specific industries have different experiences – some positive, some less so - but overall it is felt that the process used to request additional data from applicants lacks clarity and this leads to situations where notifiers unknowingly provide inadequate or superfluous responses.

4. **Communication after risk assessment process**. Publication of negative opinions on products already on the market before the Commission has made a final decision has a devastating effect on the public confidence in the functioning of the Commission and the future of the product. EFSA opinions in relation to products already on the market (in the frame of a renewal procedure) should be kept confidential until a final decision is taken by the Commission and Member States.

Measures taken by EFSA for more effective communication - publication of minutes, application lead, as well certain opportunities for comment are helpful in some respects, but because the information shared is general, it does not allow any scope to address specific application questions. The APDESK, which by nature is limited to generalities, is also perceived as a further stumbling block in communication rather than a help. Some industry groups have annual industry/association meetings with EFSA but for commercial reasons, the status of individual applications cannot be discussed during these general meetings. Other means of dialogue are therefore needed to ensure efficiency in the evaluation of individual applications.

The effect of these challenges

The overall effect of the growing deficiency of applicant-EFSA communications includes:

1. A growing lack of predictability regarding the timings and data requirements of processes.

2. Growing conservatism in the evaluation work where the assessments are irrelevant to actual conditions of use and therefore a poor basis for regulatory decisions.

3. A growing challenge for applicants to understand the precise requirements of guidance documents, leading to inconclusive or negative opinions.

4. Higher regulatory costs due to the need to redo or redesign studies in applications.

5. A higher workload within EFSA, due to missed efficiencies, leading ultimately to lower number of products assessed and an unnecessarily high failure rate due to a lack of clarity of the requirements.

6. A challenge of trust and credibility for EFSA which might be perceived by applicants and experts watching the result of their work as taking unfounded positions.

Observations about EMA

The EMA has recently been rated as a world leader in the standard of service and efficiency in the regulation of veterinary medicinal products.[iv] This success is largely driven by the culture of open and comprehensive consultation with stakeholders to ensure the guidance and processes are fit for purpose and with applicants to ensure that data dossiers are of appropriate quality.

On the assessment process: opportunities for dialogue between the scientific committee, or the rapporteur and co-rapporteur, always with a member of the agency staff present, are provided as follows: pre-submission meeting; scientific advice (and opportunity for follow-up questions of clarification); oral hearing during the assessment; oral hearing during an appeal.

On general communications: publication of procedural documents and procedural advice (including a comprehensive “Notice to Applicants”), reflection papers and discussion documents from the scientific committee. Organisation of an annual “Information day” where the latest scientific topics and procedural changes are presented and discussed. Organisation of an annual “Interested Parties” meeting between the scientific committee and stakeholders. Regular bilateral meetings between agency management and industry association management.

In conclusion, the EMA and industry work together to get the guidance and procedures fit for purpose, so that only “approvable” applications are received by the agency. A negative outcome is regarded as a failure of the system by the EMA.

Examples
To make these effects clearer, some real examples from different applicants are provided here:

Food additives. The revaluation of food additives currently on the European market is an important but extremely complex exercise. Seven years after its initiation in 2006 around 10% of food additives have been revaluated. One of the specific problems faced is that additives are generic and produced and used by multiple companies. The relevant information required by risk assessors in order to undertake a comprehensive evaluation is therefore typically spread across numerous actors. Coordination of information and adequate dialogue is essential to the successful completion of the evaluation. However, beyond the public calls for data, communication/requests for information are currently based on one-to-one contacts between EFSA Secretariat and data providers. This has, in some cases, led to miscommunication and incomplete understanding of what is required. An improvement in the efficiency and thus cost-effectiveness of this revaluation process requires an opportunity for petitioners with an interest in a particular additive to meet with EFSA and appointed experts to understand what data is required, to clarify concerns which necessitated additional data requests, and to ensure that all petitioners are aware of relevant data gaps to avoid data requests being misdirected. Organised in the right way, this process will ultimately save EFSA resources and can fully address any concerns about transparency.

Novel foods. The scope and extent of food innovation in Europe is shaped in large part by the novel foods authorisation procedure. An analysis of the timeframe of authorisation procedures in different regions across the world shows that the EU process is inordinately lengthy compared to other countries such as Switzerland, Australia, Japan or the USA. While EFSA's contribution, through risk assessment, is only one step in this process, insufficient and outdated guidance to applicants combined with limited opportunity to discuss applications inhibits industry's use of research and contributes to delays in bringing new products to market.

Feed additives. In the case of feed additives and the related technical guidance for zootechnical feed additives - there is large uncertainty about the application of the guidance for animal feeding trials for the proof of a feed additive`s efficacy in the target species. The EFSA guidance are partly not applicable to good scientific practices and do not reflect good scientific practices regarding trial set up and required endpoints.

GM products. In the case of GMOs, changes of regulatory requirements or the interpretation thereof were not consistently communicated to applicants. Only when the question was asked on several subsequent applications, it became clear to applicants that a new interpretation of the requirement was in place. There are cases where several years after submission of the dossier, questions were posed to applicants that could have been anticipated during the completeness check or at very early stages of risk assessment.

Health claims. In case of health claims it can be noted that only a limited number of the scientific dossiers evaluated so far received a positive opinion by EFSA and that a number of applicants withdrew their dossiers at an advanced stage of the evaluation process. While guidance documents provided by EFSA are certainly helpful, they remain general and cannot answer all specific issues faced by the applicants, as EFSA assesses dossiers on a case-by-case basis. It is felt that many of the difficulties currently encountered in this process could be overcome by providing to the applicant a possibility to discuss with EFSA all relevant scientific aspects of a dossier prior to its submission. This would reduce both the number of applications withdrawn at the very last minute and the valuable resources spent by EFSA on the assessment of insufficient dossiers.

Plant protection products. In the case of plant protection products, the notifier has a close dialogue with a rapporteur Member State (RMS) who carries out an initial evaluation of active substances. However, once the evaluation of the RMS has been completed, there is limited communication with industry. Changes in EFSA's interpretation of issues have been noted but there is no clear communication to industry (nor to the RMS) about interpretation changes. In the past, EFSA did collate 'manuals' which set out information about interpretations of EFSA in different situations. These manuals were however internal documents and were not communicated directly to industry, who were therefore unable to adapt to any new interpretations. Today, EFSA no longer collates such manuals, and this has further increased uncertainty– as the RMS no longer has a full overview of EFSA interpretations and industry does not have the opportunity to dialogue directly.

There is also genuine concern at the use of unrealistic exposure and risk scenarios which leads to unwarranted scientific conservatism. The combination of inputs that are systematically selected to be conservative leads to exposure scenarios and risk assessments that are unrealistic and irrelevant to actual conditions of use – and are therefore a poor basis for regulatory decisions. That trend is observed in the adoption of recent scientific guidance and in EFSA evaluations (active substances and MRLs). Examples include the use of large factors of uncertainty or extrapolation, ignoring the weight of evidence and discarding relevant evidence based on realistic conditions of use. Better dialogue with notifiers and national evaluators would help to ensure the use of more realistic conditions in the evaluation.

Recommended solutions

As noted earlier, the EFSA Multiannual Plan 2014-2016 wrote of *"…enhanced interaction."* In order to help achieve this, the following eight proposals for EFSA-applicant communications are given:

General communications

Proposal 1: Meeting. Establish a common understanding that better dialogue can improve the quality of applications, shorten review timelines and ultimately increase EFSA efficiency. To that end it is proposed to have a meeting between the undersigning federations and EFSA management, similar to the annual meeting with NGOs, where these and other issues can be addressed.

Proposal 2: Communication procedure. Establish a standard procedure for clear and timely communication to applicants when new regulatory requirements occur, including reasonable transition periods. Any changed interpretations of the EFSA guidance documents should be communicated and the scientific rationale explained to all applicants, including the date as of which these changes enter into effect. EFSA guidance should not be applied retroactively.

Proposal 3: Focus groups for guidelines. Systematically initiate focus group meetings with applicants as part of the design of the guidelines.

Product specific communication

Proposal 4: Pilot pre-submission project. Foresee pre-submission meetings, with individual units, where applicants can seek and get advice from EFSA on appropriateness of regulatory data or interpretation of guidance documents. Some companies have had very positive experiences with the EMA under the Scientific Advice and Protocol Assistance[v], where scientific advice and protocol assistance is given to applicants either during the development of a product or later on.[vi] It is felt that many of the difficulties currently encountered by applicants could be overcome by establishing such meetings. The E&Y Report and the Multiannual Plan consider these as an option, and the 2013 ICF GHK review of the EFSA Application Desk regarding stakeholder needs identified meetings as a priority.[vii] The suggestion is for EFSA to institute a pilot pre-submission meeting project. This could involve 1- 2 pre-submission meetings with applicants in 3-4 sectors over a period of half a year, all under conditions aimed at guarding efficiency and transparency. These meetings would then be evaluated and a report produced recommending continuing these or not.

Proposal 5: Opportunity for clarification. Give opportunities for clarification on exactly what data is required in case of requests by EFSA for additional data. EFSA should grant the opportunity to allow for a follow-up question from applicant if additional data is requested. When additional data is submitted, EFSA should indicate to applicants when it will be considered by WG or Panel, and whether that data is not appropriate or not complete. If not acceptable, applicants could then provide further clarification and/or additional data.

Proposal 6: Process for stop-the-clock. Establish a clear understanding on EFSA's application of the stop-the-clock mechanism where it exists in specific legislation (timelines, communication, etc.).

Proposal 7: Procedure for interaction. Establish a procedure whereby individual applicants can discuss technical/ scientific challenges related to an application on a case-by-case basis.

Right to appeal

Proposal 8: Hearing and appeal process. At the EMA an applicant can also appeal a scientific opinion in cases where the notifier is not satisfied with the evaluation. There should be an opportunity for a hearing with the panel and an appeal process. As an additional element, or alternative, one might have to consider the need for a systematic quality control process of the opinions including scientific peer review of the opinions, and review by a risk assessor.

The development of mandates and their impact on EFSA opinions

Introduction – The common challenges

Many mandates are given to EFSA with the aim of providing opinions and guidance that are to be used to support risk management decision making. However, there are concerns that some of the output (and input) is not particularly helpful in supporting the final decision making process.

Our observations and concerns in particular relate to:

- mandates that have a general impact on applications within a specific regulatory framework. This relates in particular to opinions and guidance documents that are developed with the aim of supporting predictable and consistent regulatory procedures, and
- mandates that ask for opinions on specific risk-related issues required for risk management decisions within the regulatory framework of EU food law .

We would note that many mandates to EFSA are set out within a particular regulatory framework for the evaluation of specific dossiers. These application-specific mandates are not considered here; the focus of this section is on mandates that have a general impact on applications and product composition and labelling within a specific regulatory framework.

In the development of opinions and guidance documents in particular, there is a need to ensure that the work of the Panels does indeed provide actual guidance that will give greater clarity for applicants, evaluators and risk managers - to support and ensure a transparent and efficient decision making process.

The role of the mandates

While the output of EFSA in these cases is not always helpful to improve the efficiency of the regulatory procedures, it has to be acknowledged the mandates provided have often lacked clarity in setting out what is actually required. This is an issue that must also be addressed in the Commission.

It is clear that the relevant EFSA experts or Panel can only answer the question that has been put to them. Greater clarity in the mandates would therefore be helpful in order to provide parameters for EFSA's work, and to ensure that the final output is focussed and provides a suitable framework to support a more efficient risk assessment, and providing clearer advice for the risk managers.

In some cases, regulatory guidelines established by the risk manager (in consultation with the risk assessor) are defining the borderlines of the risk assessment and can be seen as a standing mandate. It is important in these cases that the EFSA avoid excessive interpretation of these requirements and seek risk manager guidance in case of doubt.

The Commission has a key role in the setting of clear and focussed mandates – allowing EFSA to provide clear and helpful input to ensure a well-informed decision making by the risk managers.

Observations about EMA: Mandates and guidelines

Within EMA, a comprehensive system of consultation to ensure a Guidance meets the right balance between being achievable and delivering the necessary data for the benefit/risk assessment of a medicinal product. This includes a concept paper consultation of 3 months and a draft guideline public consultation period of 6 months; if disparate views emerge on the science or feasibility then a focus group meeting between the agency experts and the industry experts may be organised to explore the issue in depth. The concept paper is in many ways similar to the EFSA mandate but is much more comprehensive, setting out the issue in 9 sections that include the problem statement, along with a proposed timetable and resource requirements, an impact statement as well as a listing of interested parties and references to relevant literature and guidelines.

Quality and transparency of the mandates

Many, though not all industries feel that there is a high level of transparency in the EFSA work once the mandate has been agreed, but/however the level of transparency is considered to be limited during the development of the mandates. This is true for industry and national regulators and we believe that greater transparency could provide an improved focus in the mandates given.

Recommended solutions

In order to improve mandates, we would suggest six ideas:

Proposal 9: More detailed aims. The aims and needs set out in the mandate are often set out in general terms. We believe that further clarity should be provided, which would require greater cooperation between EFSA and the Commission. We would in particular highlight the process in the EMA where concept papers are developed which set out in detail what is actually needed in the guidance.

Proposal 10: Co-ordination with risk manager leadership in setting protection goals. Clear and practicable protection goals need to be set out by risk managers and these protection goals should be set out within the initial detailed mandate.

Proposal 11: Internal quality control. To ensure consistency in the mandates provided to EFSA, a quality control mechanism would be useful. Such a mechanism would be helpful within the Commission, to ensure that their mandates provide clear parameters for the opinions requested, as this would ensure quality control and consistency.

Proposal 12: Notification period. In order to improve transparency, we would suggest that there should be always be a public notification period, which would allow stakeholders and authorities to comment on a concept paper and the draft mandate. For example, this was done with the acrylamide assessment, where EFSA consulted stakeholders prior to starting with the opinion mandate.

Proposal 13: Transparency and consultation. In some cases, we appreciate that there is a need for consultation between EFSA and the risk managers after the actual work has taken place. There is however a need for further transparency in this dialogue, also allowing input from stakeholders, and communication regarding which comments have not been considered and for what reasons.

Proposal 14: Pilot project. We propose an EFSA pilot project built on the reflections above to consider more detailed mandates with a consultation of stakeholders and risk managers.

ANNEX I

Learning from other regulatory bodies

Regarding communications between EFSA and applicants, we have compared the situations in the two other agencies that assess regulated products - EMA and ECHA. This comparison highlights the striking difference between opportunities to interact between EFSA on the one hand, and EMA and ECHA on the other.

	EFSA	**EMA***	**ECHA (REACH related and more focused on authorisation process)**	**ECHA** (Biocides)
Communications related to guidance documents.				
• During guidance development, the concept paper and draft guideline open for consultation; all comments published.	Yes	Yes	Yes	Yes
• Focus group meetings between industry and agency experts.	No	Yes	Yes	TBD
General communications (non-application specific).				
• Annual meetings between agency and association (4 for EMA).	Yes	Yes	Yes	Yes
• Information days (not the same as scientific hearings)	No	Yes	Yes	Yes
Product specific communication - agency with applicant.				
• Pre-submission meeting to discuss plans and development.	No	Yes	Yes	TBD
• Scientific advice (access to advice via national agency).	No	Yes	No	TBD
• Opportunity for follow-up question from applicant.	No	Yes	Yes	TBD
• Access to agency secretariat and project managers.	No	Yes	Yes	Yes
Timing.				
• Upon application, a timetable indicating each phase (and the pre-set) days each phase takes is indicated.**	No	Yes	Yes, partially	Yes
• Timing generally keeps to predictable timeline.	No	Yes	TBD	TBD
Applicant rights to appeal				
• Opportunity for oral hearing with the scientific committee.	No	Yes	No	?
• Opportunity for appeals (and another oral hearing).	No	Yes	No (only final decision by COM can be appealed)	Yes

*Please note that for EMA, there are slight variations per industry sector.
**In the new novel food legislation such timelines will be foreseen.

[ii] http://www.efsa.europa.eu/en/press/news/120905.htm
[i] http://www.efsa.europa.eu/en/corporate/doc/amp1416.pdf
[iii] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000065.jsp&mid=
[iv] IFAH Global Benchmarking Survey 2011 - http://www.ifahsec.org/media/publications/
[v] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000049.jsp&mid=WC0b01ac05800229b9
[v] During meetings, the applicant has the opportunity to propose a development programme to ensure that the appropriate studies are performed or can obtain advice at any stage of the procedure to limit the risk of a negative outcome. This practice is appreciated by applicants as the expectations of the Agency can be better understood and dossiers can be processed faster.
[vi] www.efsa.europa.eu/en/supporting/doc/482e.pdf