

TECHNICAL REPORT OF EFSA

Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims¹

European Food Safety Authority (EFSA), Parma, Italy

INTRODUCTION

In July 2008, the European Commission requested EFSA to give a scientific opinion on the Community list of permitted health claims pursuant to Article 13.1 of Regulation 1924/2006 on nutrition and health claims made on foods². To this end EFSA received from the European Commission the terms of reference and a consolidated list of claims submitted by Member States containing over 4000 main entry health claims with corresponding conditions of use and references for about 10,000 similar claims. The list is the result of a consolidation process carried out by the Commission after examining over 44,000 claims supplied by Member States (documents are available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>).

The consolidated list has been screened by EFSA and those main entry health claims for which EFSA considered that insufficient information had been provided on the list (over 2000) were referred back to the European Commission/Member States for further information or clarification. For the remaining claims, EFSA started the assessment. In this context, the first series of opinions covering over 500 health claims was adopted by the NDA Panel on 2 July 2009 and published on 1 October 2009.

In addition, a number of claims were referred back to the Commission in June 2009 for consideration of their eligibility (approximately 220 so-called product specific claims and approximately 90 comparative claims).

In the light of the experience gained to date, EFSA has prepared this briefing document to update Member States and the European Commission on the evaluation of Article 13.1 health claims. The briefing document will be updated as appropriate as additional issues are addressed.

¹ On request from EFSA, Question No EFSA-Q-2009-00902 finalized on 11 November 2009.

² Art. 13 health claims, often referred to as general function claims, are health claims other than those referring to the reduction of disease risk and to children development and health. Article 13 claims describe or refer to the role of a nutrient or other substance in the functions of the body, or to the psychological and behavioural functions, or to slimming or weight control or to a reduction in the sense of hunger or to an increase in the sense of satiety or to the reduction of the available energy from the diet.

The following topics are addressed in this briefing document:

- 1. Overview of main issues addressed by the NDA Panel in evaluation of Art 13.1 claims**
- 2. How does the NDA Panel decide whether a claim is substantiated?**
- 3. What is the totality of the available scientific data?**
- 4. What are pertinent studies for substantiation of a claim?**
- 5. On what basis does EFSA propose wordings of claims?**
- 6. To what extent should a food/constituent be characterised?**
- 7. How should the claimed effect be shown to be beneficial?**
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1. Overview of main issues addressed by the NDA Panel in evaluation of Art 13.1 claims

The Terms of Reference (TOR) provided to EFSA for the Article 13(1) health claims list are consistent with the approach adopted by EFSA in evaluation of claims under Articles 13.5 and 14 of the Regulation. Thus, EFSA has adopted a similar approach to evaluation of Article 13(1) health claims, with some differences noted in appropriate sections following.

Each relationship between a food/constituent and a claimed effect is assessed separately; however, individual assessments are combined, as appropriate, to form coherent opinions.

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

- the food/constituent is defined and characterised ;
- the claimed effect is defined and is a beneficial nutritional or physiological effect (“beneficial to human health”);
- a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use) ;

and, if a cause and effect relationship is considered to be established, whether:

- the quantity of food/pattern of consumption required to obtain the claimed effect can reasonably be consumed within a balanced diet ;
- the proposed wording reflects the scientific evidence ;
- the proposed wording complies with the criteria for the use of claims specified in the Regulation ;
- the proposed conditions/restrictions of use are appropriate.

Because health claims are assessed on a case by case basis, the detailed application of these steps may vary.

Substantiation of the claim is dependent on a favourable outcome of the assessment of both (1) whether the food/constituent is sufficiently defined and characterised and (2) whether the claimed effect of the food/constituent in the identified function is sufficiently defined and is beneficial. Thus, a cause and effect relationship is considered not to be established if the outcome of either of these assessments is unfavourable.

2. How does the NDA Panel decide whether a claim is substantiated?

The TOR specify that EFSA should consider, and provide advice on whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria. In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed ;
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

In assessing each specific food/health relationship that forms the basis of a claim the NDA Panel makes a scientific judgement on the extent to which a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the

proposed conditions of use). All the evidence from the pertinent studies (i.e. studies from which scientific conclusions can be drawn for substantiation of the claim) is weighed with respect to its overall strength, consistency and biological plausibility, taking into account the quality of individual studies and with particular regard to the population group for which the claim is intended and the conditions of use proposed for the claimed effect. A grade is not assigned to the evidence. While studies in animals or in vitro may provide supportive evidence, human data are central for the substantiation of the claim. This procedure is in agreement with the hierarchy of evidence as described in the EFSA guidance (document is available on: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm).

Each relationship between a food/constituent and a claimed effect is assessed separately. There is no pre-established formula as to how many or what type of studies are needed to substantiate a claim. However, the NDA panel considers what the accepted norms are in the relevant research fields and EFSA consults experts from various disciplines, as appropriate.

The outcome of each assessment is one of three possible conclusions:

1. *A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect.*

This statement represents the best judgement of the NDA panel on whether a cause and effect relationship is established between consumption of the food/constituent and the claimed effect by the evidence provided (i.e. that the claim is substantiated by generally accepted scientific evidence).

2. *The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect.*

This statement represents the best judgement of the NDA panel that although there is scientific evidence supporting a cause and effect relationship, the evidence is not conclusive (i.e. that the claim is not substantiated by 'generally accepted scientific evidence').

3. *A cause and effect relationship is not established between the consumption of the food/constituent and the claimed effect.*

The NDA panel considers that there is, at most, limited scientific evidence supporting a cause and effect relationship and the claim is not substantiated by 'generally accepted scientific evidence'.

There are several possible reasons for reaching a conclusion that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect. For example, it could be owing to emerging evidence, conflicting evidence, etc. The reasons for such a conclusion are provided in the respective opinions.

3. What is the totality of the available scientific data?

The totality of data refers to all studies available to EFSA that are considered pertinent (i.e. the studies from which scientific conclusions can be drawn for substantiation of the claim), including those that support the relationship as well as studies showing no effect and/or opposing effects.

EFSA uses the references received from the Member States and references received directly from stakeholders. In the assessment the Panel may use data which are not included in the references provided if they are considered pertinent to the claim. However, EFSA is not required to search for additional references.

There are several limitations (including inaccurate or incomplete references, references to documents which are not readily accessible (e.g. published in journals not readily available), and references to documents in languages other than English) regarding the availability of documents cited in the references provided.

EFSA carries out the evaluation of claims with the data available to it, taking into account the availability of the documents cited in the references provided. EFSA notes that it has no assurance that the references provided represent all data pertinent to the claim, i.e. that they include evidence of no

effect and/or opposing effects as well as evidence that supports the relationship.

For claims for which there is well established consensus among scientific experts as to their substantiation by generally accepted scientific evidence, e.g. many of the functions of the essential nutrients, EFSA may rely on such consensus as indicated by authoritative scientific sources. In such cases it may not be necessary to review the primary scientific studies on the claimed effect of the food/constituent on the function. For claims for which there is no established consensus, as indicated by authoritative scientific sources, it is necessary to review the primary studies in order to assess whether such claims are substantiated.

4. What are pertinent studies for substantiation of a claim?

In considering whether the studies identified by the references provided are pertinent (i.e. studies from which scientific conclusions can be drawn for the substantiation of the claim), the NDA Panel addresses the following questions:

- Have the studies been carried out with the food/constituent for which the claim is made? This requires that there should be sufficient definition of the food/constituent for which the claim is made and the food/constituent that is the subject of the studies provided for substantiation of the claim.
- Have the human studies used an appropriate outcome measure(s) of the claimed effect?
- How do the conditions under which the human studies were performed relate to the conditions of use (e.g. food/constituent quantity and pattern of consumption) proposed for the claim?
- Have the human studies been carried out in a study group representative of the population group for which the claim is intended? Can the results obtained in the studied population be extrapolated to the target population?
- To what extent can evidence derived from studies in animals/*in vitro* support the claimed effect in humans?

As human data are central for the substantiation of a claim, particular attention is given to whether the human studies provided are pertinent to the claim.

For studies in groups (e.g. subjects with a disease) other than the target group (e.g. general population) for a claim EFSA considers whether scientific conclusions can be drawn for the substantiation of the claim on a case by case basis. For example, for claims on reducing gastro-intestinal discomfort (in the general population) evidence in patients with irritable bowel syndrome may be accepted. However, for claims on maintenance of normal joints (in the general population), evidence in osteoarthritis patients is not accepted as osteoarthritis patients are not considered to be representative of the general population with regard to the status of the joint tissues. In its evaluation, EFSA considers that where a health claim relates to a function that may be associated with a disease, subjects with the disease are not the target for the claim.

5. On what basis does EFSA propose wordings of claims?

In the TOR, EFSA is requested to consider the claimed effect on the function, and provide advice on the extent to which the wording used to express the claim reflects the scientific evidence and complies with the criteria laid down in the Regulation.

For claims for which a cause and effect relationship has been established, EFSA considers whether the proposed wording reflects the scientific evidence and complies with the criteria laid down in the Regulation (e.g. it should not refer only to general, non-specific health benefits of the food/constituent); if not, EFSA may propose an appropriate wording.

It should be noted that the wording adopted by the Commission during authorisation may need to take into account aspects other than agreement with the scientific evidence, e.g. understanding by consumers.

6. To what extent should a food/constituent be characterised?

The TOR specifies that EFSA should consider, and provide advice on, whether adequate information is provided on the characteristics of the food which may influence the specific physiological effect that is the basis of the claim.

Health claims can be made on a food category, a food or a food constituent (e.g. a nutrient, or other substance, or a combination of nutrients/other substances) and these are covered under the term “food/constituent”.

EFSA considers whether the specific food/constituent as provided in the consolidated list is sufficiently defined and characterised to establish that the studies provided for substantiation of the claim were performed with the food/constituent in respect of which the claim is made. (There should also be sufficient definition of the food/constituent used in the studies provided for substantiation of the claim.) Characterisation should be also sufficient to allow appropriate conditions of use to be defined. Although not required for substantiation of a claim, characterisation should also be sufficient to allow control authorities to verify that the food/constituent which bears a claim is the same one that was the subject of a community authorisation.

EFSA considers whether the information provided includes those characteristics considered pertinent to the claimed effect, i.e. those that may influence the specific physiological effect that is the basis of the claim.

It may be necessary to distinguish between a specific formulation, a specific constituent or combination of constituents. If the claim is for an individual constituent, then substantiation of the claim is based on studies performed with this constituent. However, if the claim is for a specific formulation or fixed combination of constituents, then studies are needed on this specific formulation or combination. In the latter case, EFSA considers whether sufficient information is provided to identify the role of each constituent proposed to contribute to the claimed effect.

For a food category (e.g. “wholegrain”, “dairy”), EFSA considers whether the information provided sufficiently addresses the variability between individual foods for those characteristics considered pertinent to the claimed effect. For plant products, EFSA considers whether the information provided includes the scientific name, the part used and the preparation procedure. The panel also considers whether the food/constituent has been sufficiently characterised with respect to the claimed effect and the proposed conditions of use, taking into account information extracted from standard reference textbooks.

For microorganisms (e.g. bacteria, yeast), EFSA considers whether, in addition to species identification, sufficient information is provided for the characterisation (genetic typing) at strain level by internationally accepted molecular methods and naming of strains according to the International Code of Nomenclature. (There should also be sufficient definition of the strain of the microorganism(s) used in the studies provided for substantiation of the claim.). Although not required for substantiation of a claim, it is also desirable that strains are deposited in an internationally recognized culture collection (with access number) for control purposes. In case of combination of two or more microorganisms, the Panel considers that if one microorganism used in the combination is not sufficiently characterised, the combination proposed is not sufficiently characterised.

The characterisation of food constituents that are microorganisms is based on evaluation of available references up to end December 2008, including the following:

- The information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders ;
- Generally available data obtained by searching Pubmed and Web of Science databases by using the strain name as search term.

During the scientific evaluation of the claims, the NDA Panel considered that the information

provided was not sufficient to characterise a number of foods/constituents with respect to the claimed effects (including some, but not all, 'probiotic' bacteria) and that the foods/constituents did not comply with a key criterion in the TOR for evaluation of claims. In these cases, the claims could not be substantiated because the food/constituent was not sufficiently characterised and it could not be established that the scientific studies that were submitted in support of the claim were performed with the same food/constituent as was proposed for the claim.

In the list, some foods/constituents are classified only on the basis of the claimed effect, i.e. the name of the food/constituent contains a description or indication of a beneficial effect on a function (e.g. non-cariogenic, low GI, antioxidants). Claims on such foods/constituents cannot be substantiated because these foods/constituents cannot be sufficiently characterised without substantiation of the claim.

7. How should the claimed effect be shown to be beneficial?

According to Regulation EC (No) 1924/2006, the use of nutrition and health claims shall only be permitted if the food/constituent, in respect of which the claim is made, has been shown to have a beneficial nutritional or physiological effect.

In the TOR, EFSA is requested to consider the claimed effect on the function, and provide advice on the extent to which the claimed effect in the identified function is beneficial.

In assessing each claim, the NDA Panel makes a scientific judgement on whether the claimed effect is considered to be a beneficial nutritional or physiological effect in the context of the specific claim as described in the information provided. For function claims, a beneficial effect may relate to maintenance or improvement of a function.

EFSA considers whether the claimed effect as provided in the consolidated list is sufficiently defined to establish that the studies identified for substantiation of the claim were performed with an appropriate outcome measure(s) of that claimed effect. Thus, it may be necessary to distinguish between different possible effects or interpretations.

The Panel considers whether the claimed effect refers to a specific health claim (and is not general and non-specific) as required by Regulation (EC) No 1924/2006. The claimed effect needs to be specific enough to be testable and measurable by generally accepted methods. For example, "gut health" is too general (unclear what measure can be used) but "transit time" is specific (measurable by generally accepted methods).

For claims for which the information on the list is unclear as to the definition of the claimed effect, EFSA will use its best judgement to identify the claimed effect, e.g. by reference to the proposed wordings as well as the health relationship. EFSA will also use its best judgement to identify the appropriate target group for the claim where this information is not provided. In its evaluation, EFSA considers that where a health claim relates to a function that may be associated with a disease, subjects with the disease are not the target for the claim.

8. Procedural aspects

The list of claims

EFSA has received in July 2008 from the European Commission nine Access databases with a consolidated list of 4,185 main entry health claims with around 10,000 similar health claims. The similar health claims were accompanied by the conditions of use and scientific references. Subsequently, EFSA combined the databases into one master database which has been published on the EFSA website in January 2009. (<http://www.efsa.europa.eu/panels/nda/claims/article13.htm>). Since the publication of the list, a number of changes have been made to the list (reallocating of similar health claims which had been accidentally placed under a wrong main entry health claim, adding missing similar claims) upon request of the Commission and Member States. An updated access database taking into account these changes will be published on the EFSA website this

year.

Screening of claims

The consolidated list of Article 13 health claims published on the EFSA website contains 4185 health claims (main entries) with corresponding conditions of use and literature for about 10000 similar claims/health relationships.

EFSA has screened all health claims on the consolidated list using six criteria³ established by the NDA Panel to identify claims for which EFSA considers insufficient information had been provided (approximately 2000 main entry health claims). These claims were referred back to the European Commission/Member States for further information or clarification. The outcome of this screening is indicated for each claim (main entry) on the list. The European Commission had agreed to coordinate with Member States the provision of the information or clarification needed by EFSA in order to carry out the evaluation of these claims. For the remaining claims, EFSA proceeded with the evaluation.

This screening was based on the information provided on the list, i.e. the name of the food, the proposed health relationship, the proposed conditions of use and examples of wordings. Screening was applied to all claims in the same way. For example, 94 claims (main entries) were considered to require more information or clarification with respect to criterion 4 'foods which are not sufficiently characterised or conditions of use are not sufficiently specified'. This procedure was undertaken because the screening step showed that the information provided on the list (the name of the food and the proposed conditions of use) for the food/constituent was not properly identified for the assessment purposes (e.g. 'dairy products' or 'soups'). Therefore scientific evaluation of the claim was not started and the claim was referred back to the Commission for more information or clarification with regard to criterion 4.

During the scientific evaluation of the claims, the NDA Panel considered that the information provided was not sufficient to characterise a number of foods/constituents with respect to the claimed effects (including some, but not all, 'probiotic' bacteria) and that the foods/constituents did not comply with a key criterion in the TOR for evaluation of claims. In these cases, the claims could not be substantiated because the food/constituent was not sufficiently characterised and it could not be established that the scientific studies that were submitted in support of the claim were performed with the same food/constituent as was proposed for the claim.

Many claims (main entries) were considered to require more information or clarification with respect to criterion 2 'general well-being claims where the health relationship is not clear' and 3 'claims which are too vague (claimed effect not specified/measurable)'. Based on screening the information provided on the list (the proposed health relationship and examples of wordings), a specific claim could not be identified owing to lack of definition of the claim or that the only claims defined were of a general, non-specific nature (e.g. 'sustain vitality while ageing'). Therefore, evaluation of the claim was not started and the claim was referred back to the Commission for more information or clarification with regard to criterion 2 or 3. Claims were not referred back to the Commission under criterion 2 or 3 if any specific claim could be identified from either the health relationship or the proposed wordings.

³ **Screening criteria**

1. Claims where clarification on legal scope is needed (e.g. claims referring to risk reduction or referring to children's development and health, or medicinal claims)
2. General well-being claims where the health relationship is not clear, e.g. "Compound X supplementation to sustain vitality while aging"
3. Claims which are too vague (claimed effect not specified/measurable), e.g. Compound X and "energy and vitality". Proposed wording: Compound X is "necessary to maintain energy and general vitality"
4. Foods which are not sufficiently characterised or conditions of use are not sufficiently specified
5. Combination constituents that are not sufficiently defined
6. Claims in languages other than English (to be returned for translation). If EFSA is asked to carry out the translations, EFSA will send translated claims back to Member States for validation of the translation.

References

The references provided by Member States were either included in the access database or were provided in separate files. In addition, full-text copies of references were provided directly to EFSA from some stakeholders. The deadline for submission of full-text copies of references was at the end of 2008. In some instances, references provided to EFSA referred to papers which were submitted for publication. In the case of subsequent publication in the public domain, EFSA has endeavoured to include the correct citation in the list of references and this inclusion may result in some references carrying a 2009 publication date.

For those claims which EFSA has proceeded to evaluate after the screening of the consolidated list of claims, a full list of the references to be used for evaluation, identifying the references associated with each health claim (main entry), has been published on the EFSA website in September 2009 (<http://www.efsa.europa.eu/panels/nda/claims/article13.htm>).

Some issues related to the references provided are covered in section 3.

EFSA's contact point for further clarification on claims

Based on the Regulation 1924/2006, the list of claims has been submitted to EFSA from MS via the European Commission. Therefore, the EFSA's contact point for any issues related to the Article 13 list is the European Commission/Member States.

9. Compliance/eligibility issues for health claims on the Art. 13 list

Compliance with the criteria laid down in the Regulation

In the TOR, EFSA is requested to consider the claimed effect on the function, and provide advice on the extent to which the wording used to express the claimed effect complies with the criteria laid down in the Regulation.

Such criteria include:

- General, non-specific claims - reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14. (Article 10.3).
- Claims that encourage excess consumption of a food – the use of health claims shall not encourage or condone excess consumption of a food (Article 3c and Recital 18).
- The claimed effect must be beneficial - the use of health claims shall only be permitted if the food/constituent in respect of which the claim is made has been shown to have a beneficial physiological effect (Article 5.1(a)).
- Claims on foods/constituents with no independent role in the claimed effect - the use of health claims shall only be permitted if the presence, absence or reduced content in a food or category of food of a nutrient or other substance, in respect of which the claim is made, has been shown to have a beneficial physiological effect (Article 5.1(a)). EFSA considers whether the food/constituent has an independent role in the claimed effect or whether its role is based on the inclusion or replacement (i.e., substitution) of other substances.

Borderline issues

In the Article 13 list, there are some claims that refer to the maintenance of a function but the scientific evidence is based on a reduction of a (well established) risk factor for disease (e.g. maintenance of normal blood cholesterol level, based on evidence of LDL cholesterol reduction). EFSA notes the Commission guidance on the implementation of regulation EC 1924/2006, of December 2007 (http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm): 'when the claim mentions a disease risk factor generally recognised by scientific evidence, it should be

considered as an Article 14 claim only when a reduction of this risk factor is stated, suggested or implied' and 'when a claim refers to a risk factor of a disease, without stating, suggesting or implying its reduction it is considered an Article 13 claim'.

EFSA has evaluated claims for the maintenance of normal blood cholesterol concentrations under Article 13 even when the evidence for substantiation of the claimed effect is based on studies showing a reduction of blood cholesterol. Such evaluations have also been done for claims related to the maintenance of normal blood pressure.

In accordance with the Commission guidance on the Implementation of Regulation EC 1924/2006, of December 2007, claims which EFSA considers would only be scientifically justified for children are considered as Article 14 and are not evaluated.

Comparative claims – the Article 13 list contains a number of claims based on effects of a food/constituent when used in substitution of another food/constituent, e.g. effects of monounsaturated fats when replacing saturated fats, claims on low-fermentable carbohydrates and dental health or 'non-cariogenic' (all compared to a reference carbohydrate), some claims on satiety (improved compared to a reference food). The Commission guidance addressed comparative nutrition claims but did not consider comparative health claims. EFSA referred back to the Commission/Member States in June 2009 around 90 comparative claims for consideration of their eligibility. The Commission has indicated in its letter of 10 November 2009 that such health claims should remain on the consolidated list. EFSA will proceed with evaluation of these claims.

Some foods/constituents are classified only on the basis of the claimed effect, i.e. when the name of the food/constituent contains a description or indication of an effect on a function (e.g. antioxidants). Claims on such foods/constituents cannot be substantiated because these foods/constituents cannot be sufficiently characterised without substantiation of the claim.

EFSA has referred back to the Commission/Member States in June 2009 a number of product specific claims (223) for consideration of their eligibility. In its letter of 10 November 2009 the Commission requested EFSA not to proceed with assessment of these claims, as well as a further 37 claims identified by the Commission, pending further discussions with Member States.

10. Status of Article 13.1 claims evaluation

On 10 November 2009, EFSA received clarification on the status of those health claims in the consolidated list which have been sent back in January 2009 to the Commission/Member States (2145 main entry health claims) for further clarification (see section 11) and those which have been referred back to the Commission/Member States in June 2009 for clarification on the eligibility of so-called product specific claims and comparative claims (see section 9). EFSA is asked by the Commission to evaluate those claims, except the product specific claims, which are on hold for further discussion with Member States and those which have been withdrawn. The Commission has indicated that an addendum to the list (300-500 claims) will be submitted to EFSA.

Schedule of adoption and publication of opinions

EFSA will continue to assess the claims on the list taking into account the clarifications provided by the MS or the European Commission in November 2009. In order to comply with requirements for transparency⁴ and to keep the workload manageable, EFSA will publish claims opinions in series as they are adopted at Plenary meetings of the NDA Panel. Assessments of individual claims will be combined, as appropriate, to form coherent opinions. The first series of claims opinions (94 Opinions covering over 520 claims) was published on the EFSA website on 1st October, 2009 and the next publication is planned to take place early 2010.

⁴ Regulation (EC) No 178/2002 requires EFSA to make public without delay the opinions of the Scientific Panels