

NOVEL FOODS REGULATION PROPOSAL

BEUC Position

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Summary

On 14 January 2008 the European Commission published a proposal¹ for a Regulation laying down harmonised rules for the placing of Novel Foods² on the market in the Community. It will replace Regulation (EC) No 258/97.

Novel foods such as sterols (e.g. used in yellow fat spreads) to lower blood cholesterol levels, lycopene (e.g. used in soups), for which it is claimed that it may help prevent certain cancers, and salatrims used in reduced fat bakery products and confectionary must be safe and offer benefits to consumers to be allowed on the market. There should be no danger to consumers' health should consumers ingest combinations of novel foods. Finally, novel foods should be clearly labelled, so that consumers can make well-informed choices.

The current proposal needs to be improved. We call for the following:

- the definition of what is meant by novel foods should be clarified and elaborated;
- all novel foods should be subject to long-term monitoring;
- a transparent appraisal procedure for foods with no history of safe use in the EU should be applied;
- consumers should be enabled to make informed choices regarding the use of novel foods and not be misled as to their properties.

¹ Proposal for a Regulation on Novel Foods and amending Regulation (EC) No XXX/XXXX [common procedure]. The proposal lays down harmonised rules for the placing of novel foods on the market in the Community. It will replace Regulation (EC) No 258/97.

² Food means any substance or product intended to be, or reasonably expected to be ingested by humans. (General Food Law Regulation (EC) No 178/2002)

Definition

Article 3.2. (a) designates the definition of what “novel food” means. We believe that the definition in the text of the regulation should be clarified and indicate which categories of products are covered in all circumstances by the novel food regulation. In particular, products belonging to the following categories of foods which have not until now been used for human consumption to a significant degree within the Community should be defined as novel foods in all circumstances:

- a) Foods with a new or intentionally modified primary molecular structure, such as sterols which may be added to yellow spreads and other food products in order lower the blood cholesterol level;
- b) Foods consisting of, or isolated from, micro-organisms, fungi or algae such as the substance lycopene that is extracted from the micro-organism *Blakeslea trispora* and that may be used in several food groups. Lycopene is a carotenoid which is claimed may help prevent prostate cancer and some other forms of cancer;
- c) Foods produced using nanotechnology and nanoscience;
- d) Food products from cloned animals, from the offspring of clones and their descendants³;
- e) New strains of micro-organism with no history of food use such as new bacterial strains that are applied to produce new yoghurts;
- f) Novel foods that were approved under the so-called ‘fast track procedure’ of Regulation (EC) no 258/97 concerning novel foods and novel food ingredients. According to Article 5 of Regulation 258/97 the placing on the market of products belonging to the categories b) and g) had to be notified to the Commission but a complete safety assessment at EU level was not required;
- g) Concentrates of substances that naturally occur in plants such as ‘rapeseed oil high in unsaponifiable matter’. This product is used as a source of Vitamin E.
- h) Food supplements other than vitamins and minerals falling within the scope of Directive 89/398/EEC⁴, Directive 2002/46/EC⁵ or Regulation (EC) No 1925/2003⁶.

³ In order to address current legal vacuum, BEUC calls for the inclusion of clones, their offspring and descendants, and derivatives under the scope of the Novel Foods Regulation as a transitory measure, until the Commission comes up with a specific regulation which would regulate all aspects of cloning and introduce a complete ban on the use of those techniques for food production purposes.

⁴ Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (89/398/EEC).

⁵ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

⁶ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

Authorisation process

We welcome the fact that the safety assessment of novel foods shall be centralised within EFSA. We believe that the data from the safety assessment should be publicly available.

Benefits for the consumer of the introduction of a novel food should be considered as part of the authorisation process.

Dietary exposure should be thoroughly considered as part of the authorisation process, in particular concerning the combined consumption of different novel foods with similar characteristics. Some consumers may be eating several types of novel foods and in such cases there should be no risks. The intake of a novel food can be bound to a maximum for reasons of health protection. If this is the case, the maximum permitted levels of such a novel food in different foodstuffs or categories of foodstuff should be specifically stipulated in the decision to authorise the novel food.

The safety assessment should not only be based on checking whether or not the food is as safe as food from a comparable food category already on the market or as the food that the novel food is intended to replace. The assessment should also take into account the impact of any novel characteristic of a food on an individual basis.

In addition to the safety assessment, other legitimate factors, including environmental and ethical criteria, should be taken into account as part of the risk management decision. The precautionary principle should be applied, if there is insufficient scientific certainty or lack of data. In case of doubt in relation to the safety of its use, a novel food should not be placed on the market.

The proposed Regulation makes reference to the possibility of consulting the European Group on Ethics in Science and New Technologies, but it is not clear within the provisions of the proposal how any issues raised could be taken into account as part of the approval process. Therefore further clarification is required on this point.

Post market monitoring

There should be a requirement for long-term monitoring of all novel foods introduced onto the European market. This monitoring should include food safety aspects, the environmental impact and animal health and welfare aspects.

All novel foods which have been allowed on the market should be reviewed regularly (every 5 years) and when relevant scientific evidence becomes available.

Traditional foods from third countries

The draft Regulation proposes a different approach for the safety assessment and management of traditional foods from third countries, based on their history of safe use in the third country of origin. Clear criteria on which manner a 'history of safe use' should be defined should be included in the proposal. The absence of any reporting of adverse effects from new products from third countries does not necessarily mean that a product is safe. Therefore, the section in the proposal on traditional foods from third countries should be revised and strengthened.

In order to assess the safety of traditional foods from third countries, various investigations⁷ should be carried out, such as:

- considering different populations that consume different quantities of a product;
- collecting medical case studies that may be relevant;
- carrying out population observational studies;
- establishing relationships between consumption pattern and health status;
- conducting biomarker-based epidemiological studies to find the effect of the consumption on the biomarker, if a biomarker is available;
- if relevant, performing in-vitro or in-vivo toxicity testing to find out the mechanism of toxicity.

There should be an appraisal procedure in which EFSA is involved. EFSA should prepare guidelines that describe the information which must be provided by the operator responsible for putting the product onto the market.

Labelling

Consumers should be enabled to make informed choices regarding the use of novel foods and should not be misled as to their properties. Specific labelling requirements should apply to novel foods if any characteristic or food property such as: composition, nutrition value and intended use of the food, makes the novel food no longer equivalent to a conventional food.

Central role for EFSA

The safety assessments of novel foods should be centralised within EFSA, and the toxicological data of the safety assessments should be made publicly available.

Distinction with medicines

The distinction between foods and medicines is becoming narrower. It is essential that a clear distinction between medicines and foods is maintained. If a novel food may have effects comparable to a medicine, EMEA (European Medicines Agency) should determine whether or not it is a medicine. If EMEA believes it is a medicine, then a full application to EMEA is required.

⁷ Essers, A.J. Alexander et al., 1998 Food plant toxicants and safety Risk assessment and regulations of inherent toxicants in plant foods. *Environmental Toxicology and Pharmacology* 5 (1998) 155-172.

SPECIFIC COMMENTS

Chapter I

Introductory provisions

Article 1: Subject matter

Animal health and welfare, as well as the protection of the environment should be included in the subject matter.

The inclusion of animal health and welfare would mean that the health and welfare aspects in relation to non-traditional breeding techniques, including cloning, are a mandatory element of the authorisation process. Including the protection of the environment would for example allow taking account of the environmental impact of substances that are not digested and that are persistent and accumulative in the environment.

Article 2: Scope

If a novel food may have effects comparable to a medicine, EMEA should determine whether or not it is a medicine. If EMEA believes it is a medicine, then an application as a medicine is required.

Art 2.2: Novel foods which also have the impact of an additive or flavouring in the final product should be covered by both the novel food regulation and the food additives legislation or the food flavourings legislation. For example lycopene has been approved as a novel food, but lycopene (additive E160d) also needed to be authorised as a permitted colour.

We welcome the provision of Article 2.2(a) (v) which means that food supplements other than vitamins and minerals⁸ falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2003 are covered by the proposed regulation.

Article 3: Definitions

Article 3.2. (a) indicates that "novel food" means:

- (i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;
- (ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique not used before 15 May 1997; and
- (iii) food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affects its nutritional value, metabolism or level of undesirable substances.

⁸ Falling within the scope of Directive 89/398/EEC, Directive 2002/46/EC or Regulation (EC) No 1925/2003.

In order to make clearer what is meant by “novel food”, the definition of “novel food” should indicate that in all circumstances the following categories of foods fall under the definition of “novel food”.

- a) Foods with a new or intentionally modified primary molecular structure;
This category was included in the 1997 Novel Foods Regulation and various authorisations concerned products from this category. For example a Commission Decision⁹ authorised the placing on the market of yellow fats spreads with added phytosterol esters. The product is aimed at people who try to lower their blood cholesterol levels. Another example is the Commission Decision¹⁰ which authorised the placing on the market of salatrims as a novel food ingredient. Salatrims are a group of reduced calorie fat-like substances developed for use as alternative fats.

The Novel Foods Regulation should unambiguously indicate that substances with a new or intentionally modified primary molecular structure, such as phytosterols and salatrims, should fall under the definition of “novel food”.

- b) Foods consisting of or isolated from micro-organisms, fungi or algae;
This category was also included in the 1997 Regulation. For example a Commission Decision¹¹ authorised the placing on the market of trehalose¹². Trehalose is extracted from yeast (a micro-organism) and was considered as novel because significant amounts of trehalose had not been marketed. Trehalose is a sugar. Trehalose exhibits the same technological properties as ‘normal’ sugar with a relative sweetness of 40-45% of that of sucrose. Because it originates from yeast the possible presence of allergy causing proteins must be taken into account.
- c) Foods produced using nanotechnology and nanoscience;
If nanotechnology and nanoscience is used, the resulting food products should be considered as novel foods. We believe that the sub-paragraph of Article 3 does not adequately reflect this. It only classifies products produced as being novel where there is a ‘significant change in the composition or structure of the food’. We believe that there should be an appropriate risk assessment procedure put in place to determine the safety of foods produced through nanotechnology before they are placed on the European market.

⁹ Commission Decision of 24 July 2000 on authorising the placing on the market of ‘yellow fat spreads with added phytosterol esters’ as a novel food or novel food ingredient under Regulation No 258/97 of the European Parliament and of the Council. (OJ L 2000 8.8.2000, p59).

¹⁰ Commission Decision of 1 December 2003 authorising the placing on the market of salatrims as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. (OJ L 326, 13.12.2003, p. 32.).

¹¹ Commission Decision of 25 September 2001 authorising the placing on the market of trehalose as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. (OJ L 296, 26.10.2006, p. 13).

¹² A non-reducing disaccharide that consists of two glucose moieties links by a α -1,1-glucoside bond. It is obtained from liquefied starch by a multistep enzymatic process. The commercial product is the dehydrate.

The lack of specific legal rules for foods produced using nanotechnology and nanoscience and the uncertainty associated with the assessment of their possible risks imply that the precautionary principle must be applied in order to protect consumers and the environment. In its opinion on Nanoscience and Nanotechnologies in Food and Feed Safety¹³, the EFSA Scientific Committee stressed the potential health and environmental risks associated with the specific characteristics (e.g. small size, high surface-to-mass ratio) and properties (e.g. surface reactivity) of nanomaterials. The Committee highlighted vast gaps in current knowledge, in particular with regards to the characterisation, toxicity and exposure assessment of nanomaterials, as well as high degrees of uncertainty in relation to current risk assessments.

- d) Food products resulting from cloned animals, their offspring and descendants; BEUC believes that animal cloning should not be allowed for food production purposes. Recent opinion surveys, including an EU-wide Eurobarometer survey, have clearly highlighted a high level of consumer concern and showed that the majority of Europeans do not want foods derived from cloned animals in the food chain^{14,15}. Therefore, BEUC urges the Commission to propose a specific regulation on cloning without further delay.

In view of international developments, BEUC is very concerned that such products will appear on the EU market in the near future. The current situation where European consumers have no information about or control over whether products derived from cloned animals or their offspring are in their food is unacceptable. Therefore, intermediary measures must be adopted as a matter of urgency, in particular with regard to the labelling and traceability of clones, their offspring, descendants and derivatives. In order to address the current legal vacuum which exists, BEUC calls for the inclusion of clones, their offspring and descendants, and derivatives under the scope of the Novel Foods Regulation as a transitory measure, while the Commission draws up a specific regulation which would regulate all aspects of cloning. This inclusion must be accompanied by strict labelling and traceability rules, which would apply to clones, their offspring and descendants, and derived foods. A strict timeline should also be set in order for the new Commission to come forward with a separate legislative proposal on cloning as a matter of urgency. Such a proposal must address all aspects and applications of cloning techniques in a comprehensive manner. In particular, as technology and research are advancing at a rapid pace, it should provide a suitable regulatory framework for the governance of future scientific developments in this area, such as the cloning of GM animals.

¹³ EFSA Scientific Opinion of 10 February 2010, The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety.

¹⁴ Flash Eurobarometer, October 2008, Europeans' attitudes towards animal cloning, Analytical Report.

¹⁵ COI, on behalf of the UK Food Standards Agency, May 2008, Animal Cloning and Implications for the Food Chain, Findings of Research Among the General Public.

- e) New strains of micro-organisms (i.e. bacteria, yeasts, moulds);
 New strains of micro-organisms should be considered as a “novel food”. New strains are, for example, developed for use as probiotic bacteria in dairy products (e.g. in yoghurts which are claimed to be good for the intestines). We believe that such new bacterial strains should be subject to an authorisation procedure, including a safety assessment by EFSA. Currently specific legislation exists for genetically modified micro-organisms and for bacterial cultures for infant and follow-on formulae. However, there are no legal provisions on the use of new strains of micro-organisms in food. In particular, new strains of micro-organism with no history of food use should undergo a robust safety assessment. The safety assessment should be carried out at strain level, because it is at the strain level where specific characteristics are found.
- f) Novel foods that were approved under the ‘so-called’ fast track procedure;
 Article 5 of the 1997 Novel Foods Regulation provides for a ‘light’ fast track notification procedure for placing on the market of novel foods. The authorisation of these products should be limited to e.g. 3 years. During this period they should be monitored, and then be re-evaluated for a full novel food approval.
- g) Concentrates of naturally occurring substances;
 We would welcome the explicit mentioning of concentrates of naturally occurring substances, i.e. substances that are naturally present in plants or animals. After naturally occurring substances have been isolated from the plant or the animal they can be concentrated into so-called “food supplements”. The amounts of these substances in food supplements can be far higher than the amounts in plants. However, for various natural occurring substances there is a relatively small margin between normal consumption and adverse effects. Examples of naturally occurring substances for which there is a small margin between normal consumption and adverse effects are phyto-estrogens (present in soybeans), quercetin (present in onions) and carotenoids (present in carrots). Positive health effects are attributed to low intakes of phyto-estrogens. However, the high exposure of infants to phyto-estrogens from soy-based infant formula is likely to exert biological effects.¹⁶ In female rats neonatal exposure to phyto-estrogens altered the uterus weight, as well as the neuro-endocrine development in both male and female rats.¹⁷ Quercetin has been shown to have carcinogenic effects in experimental studies¹⁸ while epidemiological studies¹⁹ indicate protection against diseases.

Article 3.2. (a) (i) of the proposed novel food Regulation points to “food that has been used for human consumption to a significant degree ...”. Clarified is needed as to what is meant by ‘human consumption to a significant degree’.

Art 3.2(a) (ii): Further elaboration of this section would be welcomed. We assume that animal cloning is meant to be a non-traditional breeding technique. In order to know whether a breeding technique is non-traditional, breeding techniques which are considered traditional should be listed.

¹⁶ Setchell, K.D.R., 1997. Exposure of infants to phyto-estrogens from soy-based infant formula. *Lancet* 350 (July 5), 23-27.

¹⁷ Essers, A.J. Alexander et al., 1998 Food plant toxicants and safety Risk assessment and regulations of inherent toxicants in plant foods. *Environmental Toxicology and Pharmacology* 5 (1998) 155-172.

¹⁸ Zhu, B.T., Liehr, J.G., 1994. Quercetin increases the severity of estradiol-induced tumorigenesis in hamster kidney. *Toxicol. Appl. Pharmacol.* 125 (1), 149-158.

¹⁹ Hertog, M.G.L., 1994. Flavonols and Flavones in Foods and their Relation with Cancer and Coronary Heart Disease Risk. PhD Thesis, Landbouwhogeschool, Wageningen, The Netherlands, p151.

Art 3.2(a) (iii): The phrasing “Food to which is applied a new production process, not used before 15 May 1997, where that production process gives rise to significant changes in the composition or structure of the food which affect its nutrition value, metabolism or level of undesirable substances” is too vague. It should be indicated when changes are considered significant.

We agree with **Recital 6** where it states: “It should also be clarified that a food should be considered as novel when it is applied a production technology which was not previously used.” We propose that this phrase also be included in **Art 3.1(a) (iii)** in order to ensure that real new production technologies are included.

Article 4: Collection of information regarding the use of a food for human consumption

Art 4.1: The wording of this paragraph is not concrete enough. The business operator should be obliged to transfer information on the extent a food has been used for human consumption before 15 May 1997. In addition this information should be confirmed by the Competent Authority of the Member State and should be publicly available.

Chapter II

Community list of approved novel foods

Article 5: Community list of approved novel foods

We welcome that only novel foods that are included in the Community list may be placed on the market.

Article 6: Conditions for inclusion in the Community list

Art 6: The behaviour in the environment of substances that are not digested in the human body and that are persistent and accumulative in the environment should be assessed.

Special attention should be paid to products that may have adverse effects for particular groups. If needed specific provisions (e.g. labelling /information/ education, etc) should be adopted to accommodate the needs of particular groups.

There should also be a public list of foods/food ingredients that applied for novel food status and did not pass the risk assessment or were withdrawn for other reasons. For NGOs such a list would be a useful reference document, for example when comparing risk assessments between EU and third countries.

We propose to add the following additional conditions for a novel food to be included in the Community list:

- (d) As an element of the authorisation process the risk managers should assess whether a novel food offers benefits to the consumer;

- (e) The risk managers should also take account of other legitimate factors, such as environmental and ethical criteria, including for example, any relevant opinions from the European Group on Ethics in Science and New Technologies, an EU Advisory Body.

Article 7: Content of the Community list

Art 7.2: Labelling requirements should also apply to traditional foods from a third country.

Specific labelling requirements should apply to novel foods in order to ensure that the final consumer is informed of any characteristic or food property such as: composition, nutrition value and intended use of the food which renders a novel food no longer equivalent to an existing food. The consumer must also be informed if in the novel food material is present which is not present in an existing equivalent foodstuff.

We believe that post-market monitoring should be required for all novel foods introduced onto the European market. Novel foods which have been allowed onto the market should be reviewed regularly (e.g. every 5 years) and when more scientific evidence becomes available. In the monitoring, special attention should be paid to the categories of the population with the highest dietary intakes.

The information given in the Community list should include:

- (a) Name and address of the applicant;
- (b) Description allowing the identification of the food or food ingredient;
- (c) Intended use of the food or food ingredient;
- (d) Summary of the dossier, except for those parts for which the confidential character has been determined in accordance with Article 1(3);
- (e) Date of receipt of a complete request.

In case a novel food is an ingredient with a risk linked with consuming too much of it, it should get approval for use with maximum level in certain foods or food categories in order to prevent the risk of over-dosing and consumers should be informed of this through clear labels.

Article 7.3: Novel foods which are traditional foods from third countries should also be included in the Community list.

Article 8: Traditional food from a third country

The provisions dealing with the authorisation of 'traditional foods from third countries' fall short in providing sufficient safety guarantees for consumers. An appraisal procedure, in which EFSA is involved, should be set up and guidelines laying down what information should be provided by the applicant should be adopted.

Many traditional foods may have a history of safe use, but this cannot be assumed in all cases. Merely the fact that a product has been consumed for many years in a country does not necessarily mean that it is safe. It may be that there has not been any monitoring carried out that would determine whether there have been any adverse effects. There is also always the possibility of mild adverse effects occurring after a long time.

Art 8.3: Since there are no guidelines that indicate what information the food business operator must provide in the notification including the demonstration of the history of safe use of a traditional food from a third country, it may be difficult, if not impossible in particular cases, for the Commission, Member States and the EFSA to carry out an appropriate assessment of the safety of the traditional food concerned.

On traditional foods from third countries, we propose the following amendments:

Article 8(1) 2nd paragraph:

'The notification shall be accompanied by documented data demonstrating the history of safe food use in the third country based on guideline criteria established by the EU in consultation with the European Food Safety Authority.'

Article 8(4):

'If no reasoned safety objections, based on scientific evidence, have been raised and no information thereof has been communicated to the food business operator concerned in accordance with paragraph 3, and the considerations specified in Articles 6 and 7 have been addressed, the traditional food may be placed on the market in the Community after five months from the date of the notification in accordance with paragraph 1.

In order to assess the safety of traditional foods from third countries, various investigations²⁰ should be carried out, such as:

- considering different populations that consume different quantities of a product;
- collecting medical case studies that may be relevant;
- carrying out population observational studies;
- establishing relationships between consumption pattern and health status;
- conducting biomarker-based epidemiological studies to find the effect of the consumption on the biomarker (to be carried out only if a biomarker is available);
- if relevant, performing in-vitro or in-vivo toxicity testing to find out mechanism of toxicity.

Article 9: Technical guidelines

We would welcome that technical guidance and tools to assist in particular SMEs will be prepared.

²⁰ Essers, A.J. Alexander et al., 1998 Food plant toxicants and safety Risk assessment and regulations of inherent toxicants in plant foods. *Environmental Toxicology and Pharmacology* 5 (1998) 155-172.

Article 10: Opinion of the Authority

As to assessing the safety of novel foods we support a centralised approach with a main role for EFSA. Such an approach contributes to capacity building within EFSA and eases assessments of comparable novel products.

In addition, it should be clarified what information would be used by EFSA to express a positive or negative opinion.

We believe that the assessment of a novel food is too limited if it is based on assessing whether the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace. Foods produced using nanotechnologies, for example, may have novel characteristics that cannot be adequately assessed merely by comparing them to existing products already on the market. We therefore suggest that this is amended as follows:

'Compare, to the extent that it is possible, if the food is as safe as food from a comparable food category already existing on the market in the Community or as the food that the novel food is intended to replace while also taking into account the implications of any novel characteristics.'

Moreover, the Authority should assess the nutritional value of the novel food in order to ensure that its normal consumption is not disadvantageous for the consumer.

Article 10 (b): Since there is no guidance on the requirements for the data aimed at demonstrating the history of safe use for traditional food from a third country, it will not always be possible to draw reliable conclusions on the history of such products.

Article 11: Obligations on the food business operators

Article 11.1: Post-marketing monitoring should be mandatory for all novel foods. This monitoring should take into account food safety aspects, the environmental impact and animal health and welfare. In addition, novel foods which have been allowed onto the market should be reviewed regularly (every 5 years).

Art 11.2: We welcome the provision that the producer shall forthwith inform the Commission of:

- any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;
- any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.

We believe however that this general provision cannot replace the requirement for systematic monitoring indicated in article 11.1.

Chapter III

General Provisions

Article 12: Data protection

If EFSA is made aware of any food safety issues from one application that has relevance to another, it should be able to take them into account. It would be failing in its responsibility to protect public health if it did otherwise. We therefore suggest that this Article is amended as follows:

'On request by the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and proprietary scientific data provided to support the applications, may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Community list without the agreement of the applicant unless there is a public health protection justification for doing so'.

Article 13: Penalties

In order to create a level playing field in the European Union, initiatives aimed at harmonising oversight procedures and penalties by national authorities would be welcomed.

END