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AMENDMENTS
13 - 41

Draft opinion
Vincenzo Lavarra
(PE405.878v01-00)

Novel foods

Proposal for a regulation
(COM(2007)0872 – C6-0027/2008 – 2008/0002(COD))

AM_Com_LegOpinion

Amendment 13
Niels Busk

Proposal for a regulation – amending act
Recital 5

Text proposed by the Commission	*Amendment*
(5) The existing definition of novel food should be clarified and updated by replacing the existing categories, with a reference to the general definition of food in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.	(5) The existing definition of novel food should be clarified, ***with an explanation of the criteria for novelty,*** and updated by replacing the existing categories, with a reference to the general definition of food in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Or. en

Justification

In order to make the legislation clear, there should be some explanation of the criteria for novelty of a food in the text itself or in the recitals.

Amendment 14
Niels Busk

Proposal for a regulation – amending act
Recital 6

Text proposed by the Commission	*Amendment*
(6) 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. In particular, emerging technologies in breeding and food production processes, which have an	(6) ***The scope of this Regulation should include all foods which have not been used for human consumption to a significant degree within the Community before 15 May 1997. The criteria for novelty in relation to food should include***

impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from plants and animals, produced by non-traditional breeding techniques, and foods modified by new production processes, such as nanotechnology and nanoscience which might have an impact on food. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.	***the use of new species of organisms such as plants, animals, microorganisms, fungi or algae. Also the use of new parts of existing organisms and substances with a new molecular structure should be regarded as novel foods. An existing food should be considered novel if it has been modified in a way that changes its chemical composition, molecular structure, particle size or other elements, in a way that is likely to have an impact on food safety.*** 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. In particular, emerging technologies in breeding and food production processes, which have an impact on food and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from plants and animals, produced by non-traditional breeding techniques, and foods modified by new production processes, such as nanotechnology and nanoscience which might have an impact on food ***safety***. Food derived from new plant varieties, or animal breeds produced by traditional breeding techniques, should not be considered as novel foods.

Or. en

Justification

In order to make the legislation clear, there should be some explanation of the criteria for novelty of a food preferably in the text itself or in the recitals. The proposed text aims at describing the way the novel food legislation is working at present. The word "safety" is missing in the second last sentence.

Amendment 15
Janusz Wojciechowski

Proposal for a regulation – amending act
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) The European Group on Ethics in Science and New Technologies (EGE) stated in its opinion nr. 23 on ethical aspects of animal cloning for food supply of 16 January 2008 "considering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified". The EGE added that it "does not see convincing arguments to justify the production of food from clones and their offspring". In light of the conclusions of the EGE and the provisions of Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes[1], food from cloned animals or their offspring should not be placed on the market in the Community.

Or. en

Justification

A wide range of scientific research and the Opinion of the European Group on Ethics show that cloning leads to serious health and welfare problems for both the cloned animals and their surrogate mothers. Cloned foetuses are often larger than normal; this leads to difficult births and to many deliveries being by caesarean section. Many clones die during pregnancy or in the early weeks of life from immune deficiencies, cardiovascular failure, respiratory problems and kidney abnormalities. Additionally, it is important cloned animals and their offspring are included in this Regulation to ensure proper control.

Amendment 16
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) However, foods derived from cloned animals and their descendants should be excluded from the scope of this Regulation. They should be dealt with in a specific regulation, adopted under the codecision procedure, and not be covered by the uniform authorisation procedure laid down in Regulation (EC) No ... [common procedure]. Pending the entry into force of this Regulation, the Commission should put forward a corresponding legislative proposal. Pending the entry into force of a regulation on cloned animals, a moratorium should be imposed on the placing on the market of foods manufactured from cloned animals and their descendants.

Or. de

Amendment 17
Janusz Wojciechowski

Proposal for a regulation – amending act
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) The cloning of animals is incompatible with paragraphs 20 and 21 of the Annex to Council Directive 98/58/EC. Paragraph 20 prohibits natural or artificial breeding or breeding procedures which cause or are likely to cause suffering or injury to any of the animals concerned. Paragraph 21 prohibits the keeping of animals for

farming purposes unless it can reasonably be expected that, on the basis of their genotype or phenotype, they can be kept without detrimental effect on their health or welfare.

[1] OJ L 221, 8.8.1998, p. 23.

Or. en

Justification

The animal health and welfare problems caused by cloning mean that this process is incompatible with certain provisions of Council Directive 98/58/EC.

Amendment 18
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Recital 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) Little is known at present about the health implications of foods containing nanoparticles manufactured by means of nanotechnological procedures. In keeping with the precautionary principle, the use of nanoparticles in the manufacturing of foods should be suspended until scientific findings concerning the implications of their use are available.

Or. de

Amendment 19
Niels Busk

Proposal for a regulation – amending act
Recital 7

Text proposed by the Commission	*Amendment*
(7) ***If necessary,*** implementing measures should be adopted to provide for criteria in order to facilitate the assessment of whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior that date, it can be placed on the market after that date for the same use without being considered as a novel food. However, that use as or in a food supplement should not be taken into account for the assessment whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.	(7) Implementing measures should be adopted to provide for ***further*** criteria in order to facilitate the assessment of whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997. If a food has been used exclusively as or in a food supplement, as defined in Directive 2002/46/EC, prior that date, it can be placed on the market after that date for the same use without being considered as a novel food. However, that use as or in a food supplement should not be taken into account for the assessment whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. Therefore, other uses of the food concerned, e.g. other than food supplement uses, have to be authorised in accordance with this Regulation.

Or. en

Justification

It is necessary that implementing measures are adopted in order to further describe the criteria for novelty. The word further should be added as some explanation is already given with the amendments to recital 6.

Amendment 20
Niels Busk

Proposal for a regulation – amending act
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) The provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use[1] should apply where, taking into account all its characteristics, a product may fall within the definition of "medicinal product" and within the definition of a product covered by other Community legislation. In this respect, a Member State may, if it establishes in accordance with Directive 2001/83/EC that a substance is a medicinal product, restrict the placing on the market of such product in accordance with Community law.
	[1] OJ L 311, 28.11.2001, p. 67.

Or. en

Justification

As many borderline issues arise when dealing with novel foods, it is important to stress this general principle in the recital. This provides more clarity for industry and consumers about the functioning of the market in relation to borderline products (medicine/food).

Amendment 21
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) Foods of animal origin manufactured by feeding animals with

genetically modified products are not at present labelled as such. In order to create transparency for consumers and to prevent distortions of competition on the market for feedingstuffs and animal products, this Regulation should lay down provisions governing the labelling of these products.

Or. de

Justification

Regulation (EC) No 1829/2003 has thus far been interpreted to mean that foods of animal origin manufactured by feeding animals with genetically modified products fall outside the scope of the labelling rules. As a result of this loophole, European producers are being exposed to distortions of competition, since the use of genetically modified feedingstuffs, in particular in the case of imports from third countries, is not obvious from the final product.

Amendment 22
Jan Mulder

Proposal for a regulation – amending act
Recital 20

Text proposed by the Commission	*Amendment*
(20) Under specific circumstances in order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Community list should not be used to the benefit of another applicant during a limited *period* of time, without the agreement of the first applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Community list of novel foods on the basis of their own scientific data.	(20) Under specific circumstances in order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Community list should not be used to the benefit of another applicant during a limited period of time, without the agreement of the first applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Community list of novel foods on the basis of their own scientific data. ***In addition, the protection of scientific data shall not prevent transparency and access to information with regard to the data used in the safety***

assessment of novel foods. Intellectual property rights should, however, be respected.

Or. en

Justification

In line with Amendment 5 of the draft opinion, but aims to guarantee the protection of producers´ intellectual property rights.

Amendment 23
Niels Busk

Proposal for a regulation – amending act
Recital 21

Text proposed by the Commission	*Amendment*
(21) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use. Therefore, the inclusion of a novel food in the Community list may impose specific conditions of use or labelling obligations.	(21) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source, or its conditions of use***, which may include information relating to ethical considerations***. Therefore, the inclusion of a novel food in the Community list may impose specific conditions of use or labelling obligations.

Or. en

Justification

The criteria for additional labelling should also include ethical considerations such as cloning. Thus, it should be possible to require labelling of foods produced from cloned animals.

Amendment 24
Jan Mulder

Proposal for a regulation – amending act
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) The introduction of a European quality label will allow consumers to identify products that are produced in accordance with EU´s strict environmental, animal-welfare and food-safety standards and will form another essential part, in addition to this regulation, of the EU´s general policy of informing its citizens about the characteristics of products and the circumstances under which they were produced.

Or. en

Amendment 25
Elisabeth Jeggle

Proposal for a regulation – amending act
Recital 24

Text proposed by the Commission	*Amendment*
(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***may*** be consulted***, where appropriate,*** with a view to obtaining advice on ethical issues regarding the placing on the market of novel foods.	(24) The European Group on Ethics in Science and New Technologies established by Commission Decision of 16 December 1997 ***should*** be consulted ***in connection with ethical issues*** with a view to obtaining advice on ethical issues regarding ***the use of new technologies and*** the placing on the market of novel foods.

Or. de

Justification

Consultation of the European Group on Ethics in connection with every application for authorisation of a novel food, as proposed by the rapporteur, would not seem to be justified. However, it would be appropriate if ethical issues are involved. On that basis, the amendment proposed by the rapporteur is perhaps too restrictive and would run counter to the aim of the regulation, i.e. to improve and speed up the authorisation procedure.

Amendment 26
Elisabeth Jeggle

Proposal for a regulation – amending act
Article 2 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Notwithstanding paragraph 2, this Regulation shall apply to food additives, food enzymes, minerals and flavourings and certain food ingredients with flavouring properties to which are applied a new production process not used before 15 May 1997 which gives rise to significant changes in the composition or structure of the food which affects its nutritional value, metabolism or level of undesirable substances.

Or. de

Justification

A food ingredient or additive manufactured using a production technology which has not previously been employed, such as nanotechnology and nanoscience, should be covered by the regulation on novel foods. These substances may have completely new properties. On precautionary consumer protection grounds, a separate assessment is needed which takes no account of the previous standard use of the substance or of its authorisation.

Amendment 27
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Article 2 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Notwithstanding paragraph 2(b) this Regulation shall lay down labelling rules for foods manufactured from animals fed with genetically modified feedingstuffs.

Or. de

Justification

Recital 16 of Regulation 1829/2003 is interpreted to mean that foods manufactured from GMO-fed animals are not covered by the scope of the regulation. Since Regulation 1829/2003 contains no provisions on labelling, corresponding rules should be laid down in this regulation.

Amendment 28
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where necessary, it may be determined in accordance with the procedure referred to in ***Article 14(2)*** whether a type of food falls within the scope of this Regulation.	Where necessary, it may be determined in accordance with the procedure referred to in ***Article 14(3)*** whether a type of food falls within the scope of this Regulation.

Or. de

Amendment 29
Niels Busk

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a)"novel food" means:	(a) "novel food" means ***food that has not been used for human consumption to a significant degree within the Community before 15 May 1997, including***
(i) food that has not been used for human consumption to a significant degree within the Community before 15 May 1997;	***(i) food of plant or animal origin when a non-traditional breeding technique not used before 15 May 1997 is applied to the plant or animal; and***
The use of a food exclusively as or in a food supplement shall not be sufficient to show whether it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as or in a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered as novel food. Further criteria for assessing if a food has been used for human consumption to a significant degree within the Community before 15 May 1997, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, <u>may</u> be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	***(ii) 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 nutritional value, metabolism or level of undesirable substances.***
(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	***The use of a food exclusively as, or in, a food supplement shall not be sufficient to show that it has been used for human consumption to a significant degree within the Community before 15 May 1997. However, if a food has been used exclusively as, or in, a food supplement prior that date, it can be placed on the Community market after that date for the same use without being considered novel food. <u>Before the date of application of this</u>***

	Regulation, further criteria for assessing whether a food has been used for human consumption to a significant degree within the Community before 15 May 1997, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).
(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 affect its nutritional value, metabolism or level of undesirable substances.	

Or. en

Justification

The overall definition of a novel food is given in Article 3.2 a(i). The following two categories (ii) and (iii) are sub-groups under this overall definition. On the other hand, subparagraph 2 in point a (i) relates to all categories mentioned in Article 3, paragraph 2, point a. The implementing measures should be adopted before the application of the Regulation.

Amendment 30
Alyn Smith, Friedrich-Wilhelm Graefe zu Baringdorf

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point a – point ii

Text proposed by the Commission	*Amendment*
(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	(ii) food of plant or animal origin when to the plant and animal is applied a non-traditional breeding technique ***- not including cloning -*** not ***commercially*** used before 15 May 1997; and

Or. de

Amendment 31
Elisabeth Jeggle

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least ***one generation*** in a large part of the population of the country;	(b) "traditional food from a third country" means novel food with a history of food use in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least ***25 years*** in a large part of the population of the country;

Or. de

Justification

The aim of laying down much more precise rules governing traditional food from third countries is a reasonable one. However, the period proposed by the rapporteur (50 years) seems too long, particularly as in other food-related provisions a generation is traditionally seen as amounting to 25 years (see Article 2(1)(b) of Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed).

Amendment 32
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Article 3 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) 'produced from animals fed with genetically modified feedingstuffs' means that feedingstuffs containing genetically modified organisms were used to feed the animals from which the food in question originates.

Or. de

Amendment 33
Niels Busk

Proposal for a regulation – amending act
Article 6 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) it is considered to be produced under ethically acceptable conditions.

Or. en

Justification

It should be possible to take into account ethical aspects when considering authorisation of a novel food. Without mentioning ethical aspects as a criterion in Article 6, it is not clear whether ethical aspects can legally be used in relation to authorisation of a novel food.

Amendment 34
Janusz Wojciechowski

Proposal for a regulation – amending act
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article 6a
	Food from cloned animals
	6a. Food from cloned animals or their offspring shall not be placed on the market in the Community.

Or. en

Justification

As cloning leads to serious health and welfare problems for cloned animals and their surrogate mothers, animals should not be cloned either to be used for breeding or the supply of meat or dairy products.

Amendment 35
Elisabeth Jeggle

Proposal for a regulation – amending act
Article 7 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. In the cases referred to in Article 2(2a) the common procedure shall be employed irrespective of the previous use or authorisation of the substance to which a standard production process was applied.

Or. de

JustificationA food ingredient or additive manufactured using a production technology which has not previously been employed, such as nanotechnology and nanoscience, should be covered by the regulation on novel foods. These substances may have completely new properties. On precautionary consumer protection grounds, a separate assessment is needed which takes no account of the previous standard use of the substance or of its authorisation.

Amendment 36
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure referred to in ***Article 14(2)*** in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.	By way of derogation from the third paragraph of Article 7 of Regulation (EC) No [common procedure], the updating of the Community list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure ***with scrutiny,*** referred to in ***Article 14(3),*** in cases where newly developed scientific evidence and proprietary data are protected in accordance with Article 12.

Amendment 37
Niels Busk

Proposal for a regulation – amending act
Article 8

Text proposed by the Commission	*Amendment*
Article 8	***deleted***
Traditional food from a third country	
1. A food business operator intending to place a traditional food from a third country on the market in the Community shall notify it to the Commission, indicating the name of the food, its composition and country of origin.	
The notification shall be accompanied by documented data demonstrating the history of safe food use in the third country.	
2. The Commission shall forward the notification including the demonstration of history of safe food use referred to in paragraph 1 without delay to the Member States and the Authority.	
3. Within four months from the date on which the notification provided for in paragraph 2 is forwarded by the Commission, a Member State and the Authority may inform the Commission that they have reasoned, safety objections, based on scientific evidence, to the placing on the market of the traditional food concerned.	
In that case, the food shall not be placed on the market in the Community and Articles 5 to 7 shall apply. The notification as referred to in paragraph 1 shall be considered as an application referred to in Article 3(1) of the Regulation XX/XXX [common	

procedure].

The Commission shall inform the food business operator concerned of the safety objections invoked accordingly within five months from the date of the notification in accordance with paragraph 1.

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, 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.

5. The Commission shall publish a list of traditional foods from third countries. that may be placed on the market in the Community in accordance with paragraph 4, after five months from the date of the notification in accordance with paragraph 1.

6. Detailed rules for the implementation of this Article, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Or. en

Justification

Traditional foods from a third country, which are novel foods in the EU should be handled under the same authorisation procedure as other novel foods, but with an adjusted safety assessment.

Amendment 38
Elisabeth Jeggle

Proposal for a regulation – amending act
Article 8 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Detailed rules for the implementation of this Article, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***may*** be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).	6. Detailed rules for the implementation of this Article, which are designed to amend non-essential elements of this Regulation, inter alia by supplementing it, ***shall*** be adopted ***at the latest six months following publication of this Regulation*** in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

Or. de

Justification

In order to guarantee comprehensive consumer protection, the detailed rules for the implementation of the simplified authorisation procedure for traditional foods from third countries must be laid down as soon as possible after the entry into force of the regulation.

Amendment 39
Niels Busk

Proposal for a regulation – amending act
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	Opinion of the European Group on Ethics in Science and New Technologies
	Where appropriate, on ethical questions relating to science and new technologies of major ethical importance, the Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics and new Technologies with a view to obtaining its opinion on ethical issues.

The Commission shall make this opinion publicly available, including by publishing it on a dedicated page of its website.

Or. en

Justification

In justified cases (such as the use of nanotechnologies or cloning techniques)) it is appropriate that ethical issues should have to be referred to the European Group on Ethics in Science and New Technologies for consultation. This consultation process can be launched by the Commission itself or by the Member State. In the interest of transparency and involvement of experts as well as the general public the opinion must be published on the Internet.

Amendment 40
Friedrich-Wilhelm Graefe zu Baringdorf, Alyn Smith

Proposal for a regulation – amending act
Article 11 a (new)

Text proposed by the Commission	*Amendment*
	CHAPTER IIa
	SPECIFIC LABELLING RULES
	Article 11a
	Labelling of foods of animal origin manufactured using genetically modified organisms
	If a product was manufactured from animals fed with genetically modified feedingstuffs, the words 'manufactured from animals fed with genetically modified feedingstuffs' shall appear on the packaging, alongside the relevant ingredient, in the list of ingredients provided for in Article 6 of Directive 2000/13/EC; in the case of non-prepackaged products, these words shall appear on or be displayed next to the product.

Or. de

Justification

Recital 16 of Regulation 1829/2003 is interpreted to mean that foods manufactured from GMO-fed animals are not covered by the scope of the regulation. Since Regulation 1829/2003 contains no provisions on labelling, corresponding rules should be laid down in this regulation.

Amendment 41
Janusz Wojciechowski

Proposal for a regulation – amending act
Article 19 a (new)
Directive 98/58/EC
Annex – paragraph 20

Text proposed by the Commission	*Amendment*
	Article 19a
	Amendment to Council Directive 98/58/EC
	In the Annex to Council Directive 98/58/EC paragraph 20 shall be amended as follows:
	20. Natural or artificial breeding or breeding procedures which case or are likely to cause suffering or injury to any of the animals concerned must not be practised.
	This provision shall not preclude the use of certain procedures likely to cause minimal or momentary suffering or injury, or which might necessitate interventions which would not cause lasting injury, where these are allowed by national provisions. Animals shall not be cloned for the purpose of breeding or the production of food.

Or. en

Justification

As cloning leads to serious health and welfare problems for cloned animals and their surrogate mothers, animals should not be cloned either to be used for breeding or the supply of meat or dairy products.