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Committee on Agriculture and Rural Development

2013/0435(COD)

25.9.2014

DRAFT OPINION

of the Committee on Agriculture and Rural Development

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council
on novel foods
(COM(2013)0894 – C7-0487/2013 – 2013/0435(COD))

Rapporteur: Daciana Octavia Sârbu

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SHORT JUSTIFICATION

In January 2008, the Commission proposed a revision of EU legislation on novel foods (2008/0002 (COD)). However, the legislative procedure failed at the conciliation phase mainly because of disagreements over the inclusion of food from cloned animals within the scope of the regulation. In December 2013, the Commission adopted a revised package of measures on animal cloning and novel food.

The proposed novel food regulation no longer covers food from cloned animals, as this is covered by a separate proposal in the package. The rapporteur welcomes the exclusion of food from animal clones from the scope of this regulation and its inclusion in a specific proposal, as this had been requested by the Committee on Agriculture and Rural Affairs previously. The proposal does also not apply to genetically modified foods falling within the scope of Regulation (EC) No 1829/2003¹.

The novel food proposal aims to revise the current novel food legislation (Regulation (EC) No 258/97² and Regulation (EC) No 1852/2001³) in order to update and simplify the current authorisation procedures and to take account of recent developments in Union law. With the proposed Regulation, the Commission intends to create a centralised authorisation system, which should create more certainty for applicants seeking authorisation for a novel food and should simplify and speed up the authorisation process. The rapporteur agrees with the need to simplify the current authorisation procedure, but maintains that priority should be given to safeguarding food safety and the health of consumers, at all stages of the authorisation procedure for novel foods. In addition, in accordance with the precautionary principle, the Union should provide its citizens with a full range of safeguards concerning the safety of foods placed on the market in the Union.

In the case of traditional foods from third countries, in order to remove any barriers to trade caused by the current lengthy authorisation process, the proposal also introduces a simplified authorisation process. If a history of safe use in the third country can be demonstrated and if there are no safety objections from the Member States or EFSA, then the food will be allowed to be placed on the EU market. The rapporteur considers that foods from third countries should also be required to meet equivalent standards to those required from EU foods.

The rapporteur also believes that Member States should have the possibility to consult the Commission and other Member States when they have difficulties establishing whether a food falls within the scope of this Regulation, after considering all the necessary information provided

¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).

² Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

³ Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17).

by the food business operators.

At the same time, when assessing the safety of a novel food which is intended to replace a similar food, EFSA needs to ensure that the novel food does not result in a nutritional disadvantage for the consumer when compared to the food it is intended to replace.

The Commission proposes drawing up the initial Union list of authorised novel foods and traditional food from a third country by means of an implementing act. However, the list of novel foods is an essential element which should be incorporated into the basic act (in an annex). Furthermore, the possibility should be provided to update the list of novel foods, without the procedure being as lengthy as for a basic legal act, hence the use of delegated acts.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation

Recital 2

Text proposed by the Commission

(2) A high level of protection of human health and of consumers' interests **and the effective functioning of the internal market** should be assured in the pursuit of Union food policies, whilst ensuring transparency.

Amendment

(2) A high level of protection of human health and of consumers' interests should be assured in the pursuit of Union food policies, **and should be given priority over the effective functioning of the internal market**, whilst ensuring transparency **and stimulating innovation within the agri-food industry**.

Or. en

Justification

The first part of the amendment giving priority to health and consumers' interests was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)). The second part of the amendment reflects amendment 9 on Article 1.

Amendment 2

Proposal for a regulation Recital 2 a (new)

Text proposed by the Commission

Amendment

(2 a) The standards laid down in Union legislation should be applied to all foods placed on the market within the Union, including foods imported from third countries.

Or. en

Justification

This amendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate that Union standards should also apply to imported food.

Amendment 3

Proposal for a regulation Recital 17

Text proposed by the Commission

Amendment

(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

(17) Novel foods should be authorised and used only if they fulfil the criteria laid down in this Regulation. Novel foods should be safe and their ***safety assessment should be based on the precautionary principle as laid down in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council^{1 a}***. ***In addition, their*** use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

^{1 a} 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 (OJ L 31, 1.2.2002, p. 1).

Or. en

Justification

This amendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate here that the precautionary principle should be applied.

Amendment 4

Proposal for a regulation

Recital 18

Text proposed by the Commission

(18) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish, ***by means of an implementing act***, a Union list of novel foods by entering novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions. ***As those novel foods have already been evaluated for their safety, have been legally produced and marketed in the Union and have not given rise to health concerns in the past, the advisory procedure should be used for the initial establishment of the Union list.***

Amendment

(18) Novel foods should not be placed on the market or used in food for human consumption unless they are included in a Union list of novel foods authorised to be placed on the market within the Union ('the Union list'). Therefore, it is appropriate to establish a Union list of novel foods by entering novel foods already authorised or notified in accordance with Article 4, 5 or 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions.

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated

acts.

Amendment 5

Proposal for a regulation

Recital 19

Text proposed by the Commission

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. ***As the updating of the Union list implies the application of criteria laid down in this Regulation, implementing powers should be conferred on the Commission in that respect.***

Amendment

(19) It is appropriate to authorise a novel food by updating the Union list subject to the criteria and the procedures laid down in this Regulation. A procedure that is efficient, time-limited and transparent should be put in place. As regards traditional foods from third countries having a history of safe use it is appropriate to provide for a faster and simplified procedure to update the Union list if no reasoned safety objections are expressed. ***The power to adopt acts in accordance with Article 290 TFEU should therefore be delegated to the Commission, in order to update the Union list.***

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 6

Proposal for a regulation

Recital 27

Text proposed by the Commission

(27) In order to ensure uniform conditions for the implementation of this Regulation with regard to updating the Union list concerning the adding of a traditional food from a third country where no reasoned safety objections have

Amendment

deleted

been expressed, implementing powers should be conferred on the Commission.

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 7

Proposal for a regulation

Recital 28

Text proposed by the Commission

(28) The implementing powers relating to the ***definition of ‘novel food’, the consultation process for determination of novel food status, other updates of the Union list, the drafting and presentation of applications or notifications for the inclusion of foods in the Union list, the arrangements for checking the validity of applications or notifications, confidentiality treatment and transitional provisions, should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²²*** .

²² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment

(28) The implementing powers relating to the consultation process for determination of novel food status, the drafting and presentation of applications or notifications for the inclusion of foods in the Union list, the arrangements for checking the validity of applications or notifications, ***and confidentiality treatment provisions, should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council²²*** .

²² Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

Justification

Amendment is consistent with the changes made in the Articles concerning the use of implementing or delegated powers.

Amendment 8

Proposal for a regulation

Recital 28 a (new)

Text proposed by the Commission

Amendment

(28 a) In order to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the definition of 'novel food', of the authorisation of a novel food and of a traditional food from a third country, of updating the Union list, and of adopting transitional measures. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Or. en

Justification

Amendment is consistent with the changes made in the Articles concerning the use of implementing or delegated powers.

Amendment 9

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests.

Amendment

1. This Regulation lays down rules for the placing of novel foods on the market within the Union in order to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumer interests, ***ensuring transparency and stimulating innovation within the agri-food industry.***

Or. en

Justification

This amendment was included in Parliament's second reading position on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-include it in this proposal.

Amendment 10

Proposal for a regulation

Article 3 – title

Text proposed by the Commission

Implementing power concerning the definition of novel food in Article 2(2)(a)

Amendment

Delegated power concerning the definition of novel food in Article 2(2)(a)

Or. en

Amendment 11

Proposal for a regulation

Article 3 – paragraph 1

Text proposed by the Commission

In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts, whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).

Amendment

The Commission shall be empowered to adopt delegated acts, in accordance with Article 26 a, to decide whether or not a particular food falls within the definition of novel food, as laid down in Article 2(2)(a).

Justification

It is more appropriate to use delegated powers for a decision of such general application as the definition of novel food, which also determines the scope of this regulation.

Amendment 12**Proposal for a regulation****Article 3 – paragraph 2**

Text proposed by the Commission

Amendment

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3). ***deleted***

Amendment 13**Proposal for a regulation****Article 4 – paragraph 2**

Text proposed by the Commission

Amendment

2. Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation. In that case, food business operators shall provide the necessary information to the Member State ***on request*** to enable it to determine ***in particular the extent to which the food in question was used for human consumption*** within the ***Union before 15 May 1997***.

2. Food business operators shall consult a Member State where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation. In that case, food business operators shall provide ***all*** the necessary information to the Member State to enable it to determine ***whether or not a food falls*** within the ***scope of this Regulation***.

Justification

Food business operators need to make available all relevant information related to the new product that they intend to place on a market in order to establish whether it is a novel food.

Amendment 14

Proposal for a regulation

Article 4 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In order to establish whether a food falls within the scope of this Regulation, Member States may consult the Commission and the other Member States.

Or. en

Justification

In cases where the Member States have doubts related to inclusion of a food in the scope of this Regulation, they shall have the possibility to consult the Commission and/or the Member States

Amendment 15

Proposal for a regulation

Article 5 – paragraph 1

Text proposed by the Commission

Amendment

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ('the Union list').

1. A Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 6, 7 and 8 ('the Union list') ***is set out in the Annex.***

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 16

Proposal for a regulation Article 5 – paragraph 2

Text proposed by the Commission

2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such and used ***in or on foods under*** the conditions of use specified therein.

Amendment

2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such and used ***according to*** the conditions of use ***and the labelling requirements*** specified therein.

Or. en

Justification

Novel foods are subject to labelling requirements under Regulation (EU) No 1169/2011.

Amendment 17

Proposal for a regulation Article 6 – paragraph 1 – point a

Text proposed by the Commission

(a) it does not, on the basis of the scientific evidence available, pose a safety risk to human health;

Amendment

(a) it does not, on the basis of the scientific evidence available, ***and after application of the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002,*** pose a safety risk to human health;

Or. en

Justification

This amendment was adopted by the Agriculture and Rural Development in its first reading opinion on the 2008 proposal (2008/0002 (COD)) and it seems appropriate to re-iterate here that the precautionary principle should be applied.

Amendment 18

Proposal for a regulation Article 7

Text proposed by the Commission

Amendment

Article 7

deleted

Initial establishment of the Union list

No later than ...²³ the Commission shall, by means of an implementing act, establish the Union list by entering novel foods authorised or notified under Articles 4, 5 or 7 of Regulation (EC) N° 258/97 in the Union list, including any existing authorisation conditions.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 27(2).

²³ Publications Office: please insert date: 24 months after the entry into force of this Regulation.

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 19

**Proposal for a regulation
Article 9 – paragraph 3**

Text proposed by the Commission

Amendment

3. The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 8 shall end with the adoption of an implementing act in accordance with Article 11.

3. The Commission shall be empowered to adopt delegated acts, in accordance with Article 26 a, concerning the authorisation of the placing on the market within the Union of a novel food and the updating of the Union list laid down in the Annex.

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 20

Proposal for a regulation

Article 10 – paragraph 1 – subparagraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) whether the novel food meant to replace another food does not have different properties that result in nutritional disadvantages for the consumer.

Or. en

Justification

When assessing the safety of novel foods, EFSA needs to make sure that a novel food that replaces another similar food does not have different properties to the food it replaces which could result in a nutritional disadvantage for the consumer.

Amendment 21

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

Within nine months from the date of publication of EFSA's opinion, the Commission shall submit to the committee referred to in Article 27(1) a draft implementing act updating the Union list
taking account of:

The Commission shall be empowered to adopt a delegated act in accordance with Article 26 a, in order to update the Union list referred to in Article 5, within nine months from the date of publication of EFSA's opinion referred to in Article 10,
taking account of:

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country

should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 22

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission

Amendment

(c) the EFSA's opinion;

deleted

Or. en

Justification

The reference to EFSA in point (c) should be removed as there is already a reference to EFSA in the introductory part of the paragraph.

Amendment 23

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

That implementing act shall be adopted in accordance with the examination procedure referred to in Article 27(3).

deleted

Or. en

Amendment 24

Proposal for a regulation

Article 14 – title

Text proposed by the Commission

Amendment

Procedure for traditional foods from third countries

Notification procedure for traditional foods from third countries

Or. en

Justification

It should be specified that the following paragraphs refer to the notification procedure for traditional foods from third countries.

Amendment 25

Proposal for a regulation

Article 17 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission

Amendment

Within three months of the date of publication of EFSA's opinion, the Commission shall submit to the Committee referred to in Article 27(1) a draft implementing act to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:

The Commission shall be empowered to adopt delegated acts in accordance with Article 26 a, within three months of the date of publication of EFSA's opinion, to authorise the placing on the market within the Union of the traditional food from a third country and to update the Union list, taking into account the following:

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.

Amendment 26

Proposal for a regulation

Chapter 6 – title

Text proposed by the Commission

Amendment

Penalties and ***committee procedure***

Penalties and ***general provisions***

Or. en

Amendment 27

Proposal for a regulation

Article 26 a (new)

Article 26 a

Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.**
- 2. The delegation of power referred to in Articles 3, 9(3), 11(1), 17(1) and 29(3) shall be conferred on the Commission for a period of seven years from ...*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the seven-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council oppose such extension no later than three months before the end of each period.**
- 3. The delegation of power referred to in in Articles 3, 9(3), 11(1), 17(1) and 29(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.**
- 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.**
- 5. A delegated act adopted pursuant to Articles 3, 9(3), 11(1), 17(1) and 29(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months from the notification of that act to the European Parliament and the Council or if, before**

the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

**OJ: please insert the date of entry into force of this Regulation.*

Or. en

Amendment 28

Proposal for a regulation Article 27 b (new)

Text proposed by the Commission

Amendment

Article 27 b

Review

*By ... *, and in the light of experience gained, the Commission shall submit to the European Parliament and to the Council a report on the implementation of this Regulation accompanied, where appropriate, by any legislative proposals.*

**OJ: please insert the date 5 years after the entry into force of this Regulation.*

Or. en

Justification

Five years after entry into force, the Commission should report to the European Parliament and to the Council about the implementation of the new Regulation.

Amendment 29

Proposal for a regulation Article 29 – paragraph 3

Text proposed by the Commission

Amendment

3. The Commission **may, by means of implementing** acts, adopt transitional measures for the application of paragraphs 1 and 2. **Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(3).**

3. The Commission **shall be empowered to adopt delegated** acts, **in accordance with Article 26 a, to** adopt transitional measures for the application of paragraphs 1 and 2.

Or. en

Justification

Delegated acts should be used instead of implementing acts in order to adopt transitional measures.

Amendment 30

Proposal for a regulation Annex (new)

Text proposed by the Commission

Amendment

Annex

Union List of authorised novel foods and list of traditional foods from third countries

Or. en

Justification

The initial Union list of authorised novel foods and traditional food from a third country should be annexed to this Regulation and the list should be updated by means of delegated acts.