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AMENDMENTS 001-031

by the Committee on Industry, Research and Energy

Report

Ivo Belet

A7-0001/2011

Radioactive contamination of foodstuffs

Proposal for a regulation (COM(2010)0184 – C7-0137/2010 – 2010/0098(CNS))

Amendment 1

Proposal for a regulation

Citation 1

Text proposed by the Commission

Amendment

Having regard to the Treaty **establishing** the European **Atomic Energy Community**, and in particular Article **31** thereof,

Having regard to the Treaty **on the Functioning of the European Union**, and in particular Article **168(4) and Article 169(3)** thereof,

Justification

To ensure a high level of health protection for EU citizens in the event of radioactive contamination and to give democratic legitimacy to the adoption of this Regulation, the legal basis should be changed under the new Lisbon Treaty to give the European Parliament a decision-making role on a regulation potentially affecting public health. The proposal is to consider public health (Article 168) and consumer protection (Article 169(1)).

Amendment 2

Proposal for a regulation

Recital 2

Text proposed by the Commission

Amendment

(2) Article 2(b) of the Treaty requires that the Council establish uniform safety

deleted

standards to protect the health of workers and of the general public and ensure that they are applied, as further set out in Title Two, Chapter III, of the Treaty.

Justification

The reference to the Euratom article is unnecessary in view of the adoption of Directive 96/29/Euratom, which lays down these standards and which is mentioned in Recital 3. The reference to health protection and to the Lisbon Treaty replaces this recital.

Amendment 3

Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) In accordance with Article 168 of the Treaty on the Functioning of the European Union, a high level of human health protection should be ensured in the definition and implementation of all EU policies and activities.

Amendment 4

Proposal for a regulation

Recital 4

Text proposed by the Commission

Amendment

(4) Following the accident at the Chernobyl nuclear power-station on 26 April 1986, considerable quantities of radioactive materials were released into the atmosphere, contaminating foodstuffs and feedingstuffs in several European countries to levels significant from the health point of view.

(4) Following the accident at the Chernobyl nuclear power-station on 26 April 1986, considerable quantities of radioactive materials were released into the atmosphere, contaminating foodstuffs and feedingstuffs in several European countries to levels significant from the health point of view; ***the soil was also contaminated with radioactive fallout, which increased the radioactivity of forest and agricultural foodstuffs obtained from the affected areas.***

Justification

The effect of contamination with radioactive substances can be indirect and delayed (even by many years).

Amendment 5

Proposal for a regulation Recital 5 a (new)

Text proposed by the Commission

Amendment

(5a) A high level of human health protection is one of the objectives the Union shall achieve when defining and implementing its policies. Article 168(4)(b) of the Treaty on the Functioning of the European Union provides for the adoption of common measures in the veterinary field which have as a direct objective the protection of human health. Member States are responsible for monitoring compliance with the maximum permitted levels of radioactive contamination laid down in this Regulation, namely through the surveillance of the safety standards of foodstuffs and feedingstuffs.

Amendment 6

Proposal for a regulation Recital 6

Text proposed by the Commission

Amendment

(6) The need arises to set up a system allowing the European ***Atomic Energy Community***, following a nuclear accident or any other case of radiological emergency which is likely to lead or has led to a significant radioactive contamination of foodstuffs and feedingstuffs, to fix maximum permitted levels of radioactive contamination in order to ***protect the population***.

(6) The need arises to set up a system allowing the ***Union***, following a nuclear accident or any other case of radiological emergency which is likely to lead or has led to a significant radioactive contamination of foodstuffs and feedingstuffs, to fix maximum permitted levels of radioactive contamination in order to ***ensure a high level of public health protection***.

Amendment 7

Proposal for a regulation Recital 8

Text proposed by the Commission

Amendment

(8) The Commission should, ***if the***

(8) The Commission should immediately

circumstances so require, immediately adopt a Regulation rendering applicable pre-established maximum permitted levels.

apply the pre-established maximum permitted levels of radioactive contamination to a particular nuclear accident or radiological emergency.

Justification

Recital modified to be consistent with Article 2 as amended by the Rapporteur (Amendment 10).

Amendment 8

Proposal for a regulation

Recital 8 a (new)

Text proposed by the Commission

Amendment

(8a) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of the adaptation to technical progress of the maximum permitted levels of radioactive contamination of foodstuffs and feedingstuffs (Annexes I and III), and of the list of minor foodstuffs (Annex II). It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

Justification

Recital introduced to be consistent with Amendment 15 and the following ones by the Rapporteur, modifying the Article 5.

Amendment 9

Proposal for a regulation

Recital 9

Text proposed by the Commission

Amendment

(9) On the basis of current data available in the field of radiation protection, derived reference levels have been established and these levels may be used as a basis for the fixing of maximum permitted levels of radioactive contamination to be applied immediately following a nuclear accident or any other case of radiological emergency which is likely to lead or has

deleted

led to significant radioactive contamination of foodstuffs and feedingstuffs.

(If this amendment is adopted, the words "derived reference levels and the" in Amendment 10 shall be deleted.)

Justification

The Rapporteur is of the opinion that this Recital is vaguely drafted - what are "derived reference levels" - and does not correspond to the application of the maximum levels by the Commission as described both in the current Article 2 and in its amended version (Amendment 10 by the Rapporteur on Article 2 - paragraph 1).

Amendment 10

**Proposal for a regulation
Recital 10**

Text proposed by the Commission

(10) ***Such*** maximum permitted levels take due account of the latest scientific advice as presently available on an international scale ***whilst reflecting*** the need for reassuring the public and ***avoiding*** divergences in international regulatory practice.

Amendment

(10) ***The derived reference levels and the*** maximum permitted levels of radioactive contamination ***should be regularly revised to*** take due account of the latest scientific ***advances and*** advice as presently available on an international scale, ***to reflect*** the need for reassuring the public ***and to provide it with a high level of protection*** and ***avoid*** divergences in international regulatory practice.

Justification

The current values in the Regulation have not been updated since they were adopted. Since then, advances have been made in the assessment of exposure doses and health impacts. The US FDA revised the derived reference values and the maximum permitted levels in 1998, and recommended values much stricter than those in force in the EU, which must be brought into line with international advances in this field.

Amendment 11

**Proposal for a regulation
Recital 10 a (new)**

Text proposed by the Commission

Amendment

(10a) It must be acknowledged that the levels of radioactivity caused by contamination following a nuclear

accident or any other case of radiological emergency should be taken into account together with the natural levels of radioactivity already present which can sometimes be above the safety limits established.

Amendment 12

Proposal for a regulation Recital 10 b (new)

Text proposed by the Commission

Amendment

(10b) Annexes I, II and III should take into account the effect of the partial decay of radioactive isotopes during the shelf life of preserved foodstuffs. Depending on the type of contamination, e.g. with iodine isotopes, the radioactivity of these products should be constantly monitored.

Justification

Ionizing radioactivity diminishes over time.

Amendment 13

Proposal for a regulation Recital 11

Text proposed by the Commission

Amendment

(11) However, it is necessary to take due account of the particular conditions applying and, therefore, to establish a procedure allowing the rapid adaptation of these pre-established levels to maximum permitted levels appropriate to the circumstances of any particular nuclear accident or any other case of radiological emergency which is likely to lead or has led to significant radioactive contamination of foodstuffs and feedingstuffs.

deleted

Justification

The "procedure allowing the rapid adaptation of this pre-established levels" refers to the

procedure laid down in Article 3, which the Rapporteur proposes to delete (see, Amendment 21 by Rapporteur on Article 3).

Amendment 14

Proposal for a regulation

Recital 12

Text proposed by the Commission

Amendment

(12) A Regulation rendering applicable maximum permitted levels should also maintain the unity of the Internal Market and avoid deflections of trade within the Union . ***deleted***

Justification

In amending the Article 2, the Rapporteur intends to delete the "Regulation rendering applicable" which is not legally accurate (see, justification of amendment to Article 2 - paragraph 1).

In addition, by applying levels laid down in the basic regulation itself, the decision as such will have no effect on the unity of the internal market or distortions of trade.

Amendment 15

Proposal for a regulation

Recital 13

Text proposed by the Commission

Amendment

(13) In order to facilitate the adaptation of maximum permitted levels, procedures should be provided for allowing the consultation of experts including the Group of Experts referred to in Article 31 of the Treaty. ***deleted***

Justification

These procedures are now clearly described in the revised Article 5 and in the Articles 5a to 5c which provide for the consultation of experts of Article 31 of the Treaty. The corresponding Recital 8b (new) sufficiently covers the consultation of experts and refers to the appropriate legal procedure as regards "the adaptation of the levels".

Amendment 16

Proposal for a regulation

Recital 15

Text proposed by the Commission

Amendment

(15) It is appropriate for the Council to reserve the right to exercise directly the power to adopt a Regulation to timely endorse measures proposed by the Commission in the first month after a nuclear accident or a radiological emergency. The relevant proposal for the adaptation or confirmation of the provisions laid down in the Regulation adopted by the Commission, in particular the establishment of maximum permitted levels of radioactive contamination, should be based on Article 31 of the Treaty, in view of the health protection of the population. This is without prejudice to the possibility that in the long term after the accident or the radiological emergency other legal instruments or another legal basis may be used for the purpose of controlling foodstuffs or feedingstuffs being placed on the market.

deleted

Justification

For the Rapporteur, this Recital does not clearly motivate the need to reserve implementing powers to the Council in Article 3, as regards the context, the nature and the content of the basic act to be implemented. Furthermore, the Rapporteur is not convinced by the added-value of this two-level approach, where the Council can at the end validate or adapt decisions of the Commission which should be the only executive authority in the normal course of the events. (See also, justification to Amendment 13 introduced by the Rapporteur.) (Second and third sentence of the justification repeated (slightly modified) in the Explanatory Statement (ii) Assessment)

Amendment 17

Proposal for a regulation

Recital 16

Text proposed by the Commission

Amendment

(16) Compliance with the maximum

(16) *The general principles of food law as*

permitted levels should be the subject of appropriate checks,

laid down in Articles 5 to 21 of 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 safety¹

shall apply. Compliance with the maximum permitted levels of radioactive contamination should be the subject of appropriate checks *and official controls by Member States, as provided for in Article 17 of Regulation (EC) No 178/2002,*

¹ *OJ L 31, 1.2.2002, p. 1.*

Amendment 18

Proposal for a regulation Article 2 – paragraph 1

Text proposed by the Commission

1. In the event of the Commission receiving — in particular according to either the European Atomic Energy Community arrangements for the early exchange of information in case of a radiological emergency or under the IAEA Convention of 26 September 1986 on early notification of a nuclear accident — official information on accidents or on any other case of radiological emergency, substantiating that the maximum permitted levels for foodstuffs laid down in Annex I or the maximum permitted levels for feedingstuffs laid down in Annex III are likely to be reached or have been reached, it shall immediately adopt, *if the circumstances so require, a Regulation rendering applicable* those maximum permitted levels.

Amendment

1. In the event of the Commission receiving — in particular according to either the European Atomic Energy Community arrangements for the early exchange of information in case of a radiological emergency or under the IAEA Convention of 26 September 1986 on early notification of a nuclear accident — official information on accidents or on any other case of radiological emergency, substantiating that the maximum permitted levels of radioactive contamination for foodstuffs laid down in Annex I or such maximum permitted levels for feedingstuffs laid down in Annex III are likely to be reached or have been reached, it shall immediately adopt *a decision declaring a nuclear accident or radiological emergency and applying* those maximum permitted levels.

(If this amendment is adopted, the reference to "Regulation" in subparagraph 1 of Article 6 (1) shall be changed to "decision".)

Justification

The application of the maximum permitted levels of contamination to a specific situation is clearly an implementing power that should be conferred on the Commission, in accordance with Article 291 TFEU (applicable by reference of 106a Euratom Treaty).

Amendment 19

**Proposal for a regulation
Article 2 – paragraph 2**

Text proposed by the Commission

2. The period of validity of **any Regulation** *within the meaning of* paragraph 1 **shall be as short as possible and** shall not exceed three months, **subject to the provisions of Article 3(4).**

Amendment

2. The period of validity of the **decision referred to in** paragraph 1 shall not exceed three months.

Justification

See justification of Amendment 10.

Amendment 20

**Proposal for a regulation
Article 2 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. For the purpose of this Regulation, the Commission shall be assisted by a committee of independent scientific experts on public health and food safety. The members of the committee shall be selected according to scientific criteria. The Commission shall make public the composition of the committee of experts and its members' declaration of interests.

Amendment 21

**Proposal for a regulation
Article 3**

Text proposed by the Commission

Amendment

Article 3

deleted

1. After consultation with experts, which shall include the group of experts

referred to in Article 31 of the Treaty, hereinafter “group of experts”, the Commission shall submit to the Council a proposal for a Regulation to adapt or confirm the provisions of the Regulation referred to in Article 2(1) of this Regulation within one month of its adoption.

2. When submitting the proposal for a Regulation referred to in paragraph 1, the Commission shall take into account the basic standards laid down in accordance with Articles 30 and 31 of the Treaty, including the principle that all exposures shall be kept as low as reasonably achievable, taking the aspect of the protection of the health of the general public and economic and social factors into account.

3. The Council shall, acting by a qualified majority, take a decision on the proposal for a Regulation referred to in paragraphs 1 and 2 within the time limit set out in Article 2(2).

4. In the event that the Council does not decide within this time limit, the levels set out in Annexes I and III shall continue to apply until the Council does decide or until the Commission withdraws its proposal because the conditions set out in Article 2(1) no longer apply.

(If this amendment is adopted, the reference to Article 3 in subparagraph 1 of Article 6 (1) shall be deleted.)

Justification

The regime set out in Article 3, whereby the Council can adopt a regulation so as 'to adapt or confirm the provisions' of the 'ad hoc' regulation of the Commission seems unnecessary and a source of legal uncertainty. It seems that those Council measures can qualify as 'implementing acts' of the current regulation. However, according to Article 291 TFEU (applicable by reference of Article 106a Euratom), it is only in 'duly justified specific cases' that such a power can be conferred on the Council, the Commission being normally responsible for exercising that power. (Justification contains slightly modified text from Explanatory Statement (ii) Assessment)

Amendment 22

Proposal for a regulation

Article 4

Text proposed by the Commission

Amendment

Article 4

deleted

The period of validity of any Regulation within the meaning of Article 3 shall be limited. This period may be revised at the request of a Member State or on the initiative of the Commission in accordance with the procedure laid down in Article 3.

Justification

Deletion as a consequence of the deletion proposed for Article 3.

Amendment 23

Proposal for a regulation

Article 5

Text proposed by the Commission

Amendment

1. In order to ***ensure that the maximum permitted levels laid down in Annexes I and III take account of any new scientific data becoming available, the Commission shall, from time to time, seek the opinion of experts, which shall include the group of experts.***

In order to ***take account of any new scientific data becoming available, or if necessary after a nuclear accident or any other case of radiological emergency, the Commission shall adapt Annexes I, II and III by means of delegated acts in accordance with Article 5a and subject to the conditions of Articles 5b and 5c.***

2. ***At the request of a Member State or the Commission, the maximum permitted levels laid down in Annexes I and III may be revised or supplemented, upon the submission of a proposal from the Commission to the Council in accordance with the procedure laid down in Article 31 of the Treaty.***

Amendment 24

Proposal for a regulation Article 5 a (new)

Text proposed by the Commission

Amendment

Article 5a

Exercise of delegation

*1. The power to adopt the delegated acts referred to in Article 5 shall be conferred on the Commission for a period of five years from ... * . The Commission shall draw up a report in respect of the delegated power not later than six months before the end of the five-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 5b.*

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 5b and 5c.

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

Justification

The wording of Articles 5a, 5b and 5c is identical to that of legal acts (ex. pets regulation; energy labelling of the consumption of energy by energy-related products) recently adopted and which provide for delegated acts.

Amendment 25

Proposal for a regulation Article 5 b (new)

Text proposed by the Commission

Amendment

Article 5b

Revocation of the delegation

1. The delegation of power referred to in Article 5 may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Justification

See justification of Amendment 16 introduced by the Rapporteur.

Amendment 26

**Proposal for a regulation
Article 5 c (new)**

Text proposed by the Commission

Amendment

Article 5c

Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.

At the initiative of the European Parliament or the Council that period shall be extended by two months.

2. If, on expiry of the period referred to in paragraph 1, neither the European Parliament nor the Council has objected to the delegated act it shall be published in the Official Journal of the European

Union and shall enter into force on the date stated therein.

The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period, if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If either the European Parliament or the Council objects to the delegated act within the period referred to in paragraph 1, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

Justification

See justification of Amendment 16 introduced by the Rapporteur.

Amendment 27

Proposal for a regulation

Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission

*For the purposes of applying this Regulation, foodstuffs or feedingstuffs imported from third countries **shall be considered to be placed on the market if, on the customs territory of the Community, they undergo a customs procedure other than a transit procedure.***

Amendment

*This Regulation **shall also apply to** foodstuffs or feedingstuffs imported from third countries, **those in customs transit and those intended for export.***

Amendment 28

Proposal for a regulation

Article 6 – paragraph 2 a (new)

Text proposed by the Commission

2a. Member States shall monitor compliance with the maximum permitted levels of radioactive contamination. For that purpose Member States shall maintain a system of official controls of foodstuffs and feedingstuffs, and other activities as appropriate in the circumstances, including public

communication on food and feed safety and risks, in accordance with Article 17 of Regulation (EC) No 178/2002.

Amendment 29

Proposal for a regulation Article 8

Text proposed by the Commission

Amendment

Article 8

deleted

Rules for implementing this Regulation and adaptations to the list of minor foodstuffs, together with the maximum permitted levels of radioactive contamination to be applied thereto, as set out in Annex II, and to the maximum permitted levels for feedingstuffs set out in Annex III shall be adopted in accordance with the procedure referred to in Article 195(2) of Council Regulation (EC) No 1234/2007, which shall apply by analogy. To this end the Commission shall be assisted by an ad hoc Committee.

Justification

Article 8 was merged with Article 5, since both refer to revision of maximum levels (Annexes I and III) and/or adaptation of the list of Annex II, which can be treated jointly through a delegation of powers (delegated acts) to the Commission.

Amendment 30

Proposal for a regulation Article 8 a (new)

Text proposed by the Commission

Amendment

Article 8a

1. The Commission shall submit, by March 2012, a report to the European Parliament and the Council on the appropriateness of the maximum permitted levels of radioactive contamination laid down in Annexes I and III, and on the appropriateness of maintaining a list of minor foodstuffs as

laid down in Annex II.

2. That report shall in particular examine the compliance of the maximum permitted levels of radioactive contamination with the effective dose limit of 1 mSv/y for members of the public under the conditions laid down in Directive 96/29/Euratom and shall consider the possible inclusion of additional relevant radionuclides in Annex I and III. In assessing the levels, the report shall focus on the protection of the most vulnerable population groups, in particular children, and examine whether it would be appropriate to set maximum permitted levels for all categories of the population on that basis.

Amendment 31

Proposal for a regulation Annex I – footnote 19

Text proposed by the Commission

19 Infant food is defined as *those* foodstuffs intended for *the feeding of* infants *during the first four to six months of life*, which meet, in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages which are clearly identified and labelled "food preparation for infants";

Amendment

19 Infant food is defined as *infant formulae, including formula milk, follow-on formulae and equivalent* foodstuffs, intended for infants *under the age of twelve months*, which meet in themselves, the nutritional requirements of this category of person and are put up for retail sale in packages which are clearly identified and labelled "food preparation for infants";