

**Comments of the Commission on the European Ombudsman's Own initiative inquiry**

**- Ref. OI/5/2011/BEH**

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**I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY**

Following the events at the Fukushima nuclear power station since 11 March 2011, the Commission was informed by the Japanese authorities that radionuclide levels (iodine-131, caesium 134 and caesium-137) in certain food products originating in Japan, such as milk and spinach, exceeded the maximum permitted levels of radioactive contamination in food applicable in Japan.

**EU emergency measures and legal instruments**

**Recommendation to control via the Rapid Alert System for Food and Feed (RASFF)**

On 15 March 2011, DG Health and Consumers (SANCO) recommended in a Rapid Alert System for Food and Feed (RASFF) information notification addressed to its contact points in all Member States to carry out analysis on the levels of radioactivity in feed and food imported from Japan. As regards the acceptability of placing on the market of feed and food, the Commission services recommended to use the EURATOM pre-established maximum permitted levels laid down for:

- foodstuffs, in Council Regulation (EURATOM) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency<sup>1</sup>, and the following related acts:
- for feedingstuffs, in Commission Regulation (EURATOM) No 770/90 of 29 March 1990 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency<sup>2</sup>;
- for minor foodstuffs, Commission Regulation (EURATOM) No 944/89 of 12 April 1989 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency<sup>3</sup>. Reference to these three EURATOM Regulations will be hereafter made as "Regulation (EURATOM) 3954/87"

As stated above, SANCO recommended use of the abovementioned maximum permitted levels of radioactive contamination of food and feed to be applied following a nuclear accident or any other case of radiological emergency as laid down in Regulation (EURATOM) 3954/87.

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<sup>1</sup> OJ L371, 30.12.1987, p. 11

<sup>2</sup> OJ L 83, 30.03.1990, p. 78

<sup>3</sup> OJ L101, 13.04.1989, p. 17

Council Regulation (EC) No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station<sup>4</sup>, lays down maximum permitted radioactive contamination levels for the sum of caesium-134 and caesium-137 only in agricultural products from third countries intended to be placed on the EU market. These maximum levels were not recommended following the events at Fukushima, as they were established following the accident at the Chernobyl nuclear power station and it is evident that possible contamination of feed and food originating from Japan would certainly not be the consequence of the accident at the Chernobyl nuclear power station, but rather the consequence of the accident at the Fukushima nuclear power station. Furthermore, following the accident in Fukushima, high levels of iodine were also found in food and it was therefore necessary for the protection of public health to foresee also controls on iodine, whereas Regulation (EC) No 733/2008 provides only for maximum levels for radioactive caesium and not for radioactive iodine.

In the immediate aftermath of the accident, Japan enforced action levels for iodine, caesium, uranium and plutonium. Foodstuffs which do not comply with the action levels cannot be placed on the market in Japan and cannot be exported. The action levels set by Japan are lower than the maximum levels established in Regulation (EURATOM) 3954/87 (with one exception for iodine in "other foodstuffs"). The reason for this is that, in the current situation in Japan, a much higher percentage (than the 10 % on which the EU levels are based upon) of the population's daily diet could be contaminated with significant levels of radio-nuclides.

At the Chief Veterinary Officers (CVO) meeting on 22 March 2011, several delegations urged the European Commission to adopt urgently harmonised control measures at EU level as regards the import of feed and food from Japan. This request was re-iterated at the meeting of the Council Working group "Atomic Questions" on 23 March 2011. As there is no legal basis within the EURATOM legislation on radioactivity to adopt such control measures within a short notice, it was decided that such urgent harmonised control measures should be taken on the basis of Article 53 "Emergency measures for food and feed of Community origin or imported from a third country" 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 safety<sup>5</sup>. It was agreed that SANCO takes the lead within the Commission for these measures.

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<sup>4</sup> OJ L 201, 30.7.2008, p. 1

<sup>5</sup> OJ L 31, 1.2.2002, p. 1

## **Commission Implementing Regulation (EU) N° 297/2011**

On 25 March 2011, the Commission adopted, as a precautionary measure, Implementing Regulation (EU) N° 297/2011<sup>6</sup> imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station, based on Article 53 of Regulation (EC) 178/2002. This Regulation provided for the requirement of a pre-export check carried out by Japanese authorities on all exported feed and food from the affected zone (as defined in Regulation 297/2011), combined with random controls at the point of entry into the EU to confirm the compliance with the levels set out in Council Regulation (EURATOM) No 3954/87. The justification for the reference to these maximum levels is given above.

The Implementing Regulation entered into force on 27 March 2011.

## **Commission Implementing Regulation (EU) N° 351/2011, first amendment to Regulation (EU) 297/2011**

The reference to the maximum permitted levels established by Regulation (EURATOM) No 3954/87 of 22 December 1987 in Regulation (EU) 297/2011 became a point of discussion in the week following the entry into force of that Regulation. It was perceived that these maximum levels were not sufficiently health protective and were higher than the action levels currently applied in Japan, as well as higher than the maximum levels of caesium established in Regulation (EC) 733/2008 following the accident at the Chernobyl nuclear power station.

In order to ensure consistency between the pre-export checks performed by the Japanese authorities and the controls at import into the EU, the Commission adopted, on 11 April 2011, Implementing Regulation (EU) N° 351/2011<sup>7</sup>, amending Regulation (EU) No 297/2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station aligning, on a provisional basis, the applicable maximum levels on feed and food imported from Japan to the action levels in Japan.

This implementing Regulation entered into force on 13 April 2011.

## **II. THE OWN-INITIATIVE INQUIRY**

According to the European Ombudsman and based on complaints submitted to him, it appears that a number of Union citizens perceive a lack of precise and reliable information as regards the changes made to the maximum permitted levels in the aftermath of the Fukushima accident. He considers that no comparative information on the maximum permitted levels before and after the Fukushima accident has apparently been made available.

Therefore, the Ombudsman decided to open an own-initiative inquiry into the subject of the maximum permitted levels before and after the Fukushima accident in order to establish reliable information on the maximum permitted levels in force before the Fukushima accident and after that accident.

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<sup>6</sup> OJ L 80, 26.3.2011, p. 5.

<sup>7</sup> OJ L 97, 12.4.2011, p. 20

### III. THE COMMISSION'S OPINION ON THE OWN-INITIATIVE INQUIRY

#### **A) Before the Fukushima accident**

Before the Fukushima accident, only the maximum permitted levels established by Council Regulation (EC) No 733/2008 were applicable at EU level on imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station. This Regulation establishes levels for caesium-134 and 137 only, which are applicable since 1987.

Table 1: Maximum level (Bq/kg) for imports of agricultural products from third countries following the accident at the Chernobyl nuclear power station (\*)

	Milk and Infant food (**)	Other food and feed
Sum of caesium-134 and caesium -137	370	600

(\*) The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption.

(\*\*) 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."

#### **B) After the Fukushima accident**

##### **a) Maximum level for imports of agricultural products from third countries following the accident at the Chernobyl nuclear power station**

The maximum level for the sum of caesium-134 (meanwhile decayed) and caesium -137 established by Council Regulation (EC) No 733/2008 (see Table 1) remains applicable at EU level on imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station.

**b) Maximum permitted levels for imports of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station**

- Period 15 March 2011 – 27 March 2011 – Recommendation via RASFF

- Period 28 March 2011 – 12 April 2011 – Regulation (EU) N° 297/2011

In the Recommendation via the RASFF and Regulation (EU) N°297/2011, reference is made to the pre-established maximum levels in Regulation (EURATOM) 3954/87 (see Tables 2 and 3) to be applied for evaluating the acceptability of consignments of feed and food from Japan (for justification see above).

Table 2: Pre-established maximum levels (Bq/kg) for food in Regulation (EURATOM) 3954/87

	Foodstuffs(*)			
	Infant food (**)	Dairy produce	Other foodstuffs except minor foodstuffs (***)	Liquid foodstuffs
Sum of isotopes of strontium, notably Sr-90	75	125	750	125
Sum of isotopes of iodine, notably I- 131	150	500	2 000	500
Sum of Alpha-emitting isotopes of plutonium and transplutonium elements, notably Pu-239, Am-241	1	20	80	20
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134, Cs-137 (****)	400	1 000	1 250	1 000

(\*)The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption.

(\*\*)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”.

(\*\*\*) For the minor foodstuffs, listed in Regulation No 944/89 the maximum permitted levels to be applied are 10 times those applicable to "other foodstuffs except minor foodstuffs"

(\*\*\*\*) Carbon 14, tritium and potassium 40 are not included in this group

Table 3: Pre-established maximum levels (Bq/kg) for feedingstuffs in Regulation (EURATOM) 770/90

	Feed (*)		
	Pig	Poultry, lambs, calves	Other
Sum of caesium-134 and caesium-137	1 250	2 500	5 000

(\*) These levels apply to feed as ready for consumption

- Period since 13 April 2011: Regulation (EU) N° 351/2011 amending Regulation (EU) 297/2011

Maximum levels are established by Regulation (EU) N° 351/2011 aligning the applicable maximum levels on feed and food imported from Japan to the action levels applied in Japan.

Table 4: Maximum levels (Bq/kg) for foodstuffs (\*)

	Foods for infants and young children	Milk and dairy products	Other foodstuffs, except liquid foodstuffs	Liquid foodstuffs
Sum of Isotopes of strontium, notably Sr-90	75	125	750	125
Sum of Isotopes of iodine, notably I-131	100	300	2 000	300
Sum of Alpha-emitting isotopes of plutonium and trans-plutonium elements, notably Pu-239, Am-241	1	1	10	1
Sum of all other nuclides of half-life greater than 10 days, notably Cs-134 and Cs-137, except C-14 and H-3	200	200	500	200

(\*)The level applicable to concentrated or dried products is calculated on the basis of the reconstituted product as ready for consumption

Table 5: Maximum levels (Bq/kg) for feed (\*)

	Feed
Sum of Cs-134 and Cs-137	500
Sum of Isotopes of iodine, notably I-131	2000

(\*) Maximum level is relative to a feed with a moisture content of 12 %.

#### IV. CONCLUSIONS

The European Commission underlines that the EU measures related to the accident at the Fukushima nuclear power station as regards the import of feed and food from Japan invariably pursued the objective of ensuring a high level of human health protection.

A consultation of the Group of scientific experts, provided for in Article 31 of the Treaty establishing the European Atomic Energy Community has been held in June 2011 to provide further scientific analysis of the measures with regard to food and feed imported into the EU after the accident in Fukushima. The Opinion of the Group of experts is now available on the website of DG ENER under the following links:

[http://ec.europa.eu/energy/nuclear/radiation\\_protection/fukushima2](http://ec.europa.eu/energy/nuclear/radiation_protection/fukushima2)  
[http://ec.europa.eu/energy/nuclear/radiation\\_protection/article\\_31\\_en.htm](http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm).

The content of this Opinion should provide precise and reliable information for Union citizens as regards the changes made to the maximum permitted levels for food and feed in the aftermath of the Fukushima accident.

Based on the Opinion of the Euratom Article 31 Group of experts, the Commission takes the opportunity to inform the Ombudsman that it considers:

- that the maximum permitted levels pre-established for future accidents in Regulation 3954/87 are still valid and that there is neither a reason to revise their rationale nor to recalculate the maximum permitted levels; however, as soon as new dose coefficients will be published by the International Commission on Radiological Protection (ICRP), it should be checked whether there would be any significant impact on resulting doses of exposure to the population.
- that the small amount of food and feed imported from Japan into the EU does not necessitate, from the point of view of radiation protection, lower levels than those pre-established in Regulation 3954/87. This, together with the fact that Japan is committed to not exporting food and feed above the action levels (for food) applied in Japan, are good grounds to continue checking compliance with this commitment at the same levels (as laid down in Commission Implementing Regulation N° 351/2011), as long as such checks are considered to be necessary.
- that since 1987 there has been a difference between the levels applying to the sum of all radionuclides in the category which includes caesium-134 and caesium-137 in Regulation 3954/87 and those applying to the sum of caesium-134 (meanwhile decayed) and caesium-137 for the import from third countries affected by the Chernobyl accident. While the latter Regulation (733/2008/EC) has recently been extended, without modification, to 2020, the Commission considers that the fact that now also food from Japan is being controlled does not call for a revision of this Regulation.