Commission Regulation (EU) No 1258/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for nitrates in foodstuffs (Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[(2)] sets maximum levels for nitrates in certain leafy vegetables.

(2) In some cases, despite developments in good agricultural practice, the maximum levels are exceeded and therefore a temporary derogation was granted to certain Member States for the placing on the market of certain leafy vegetables, grown and intended for consumption in their territory with nitrate levels higher than the established maximum levels.

(3) Since the application of the maximum levels of nitrates in lettuce and spinach, many investigations have been performed on the factors involved in the presence of nitrates in lettuce and spinach and on the measures to be taken to reduce the presence of nitrates in lettuce and spinach as much as possible. Despite the progress achieved in the good agricultural practice to reduce the presence of nitrates in lettuce and spinach and a strict application of this good agricultural practice, it is not possible to achieve in a consistent way nitrate levels in lettuce and fresh spinach below the current maximum levels in certain regions of the Union. The reason is that the climate and in particular the light conditions are the main determinant factor in the presence of nitrates in lettuce and spinach. These climate conditions cannot be managed or changed by the producer.

(4) To provide an up-to-date scientific basis for the longer-term strategy for managing the risk arising from nitrates in vegetables, a scientific risk assessment by the European Food Safety Authority (EFSA), taking into account new information, was needed. Such assessment had to take into account any relevant considerations on risks and benefits, for example, weighing the possible negative impact of nitrate versus the possible positive effects of eating vegetables, such as antioxidant activities or other properties

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 1258/2011. (See end of Document for details)*

that might in some way counteract or provide a balance to the risks arising from nitrates and the resulting nitroso-compounds.

(5) On request of the Commission, the Panel on Contaminants in the Food Chain (the Panel) adopted on 10 April 2008 a Scientific opinion on nitrate in vegetables[3]. The Panel compared the risk and benefits of exposure to nitrate from vegetables. Overall, the estimated exposures to nitrate from vegetables are unlikely to result in appreciable health risks, therefore, the recognised beneficial effects of consumption of vegetables prevail. The Panel recognised that there are occasional circumstances (e.g. unfavourable local/home production conditions) for vegetables which constitute a large part of the diet, or individuals with a diet high in vegetables such as rucola which need to be assessed on a case-by-case basis.

(6) Following discussion on appropriate measures and concerns expressed as regards possible risks for infants and young children following acute dietary intake exposure, the Commission asked EFSA for a complementary scientific statement on nitrates in vegetables, whereby the possible risks for infants and young children related to the presence of nitrates in fresh vegetables are assessed in more detail, also considering the acute dietary intake, taking into account recent occurrence data on the presence of nitrates in vegetables, more detailed consumption data of vegetables by infants and young children and the possibility of the establishment of slightly higher than the current maximum levels for nitrates in leafy vegetables. The Panel adopted on 1 December 2010 a Statement on possible public health risks for infants and young children from the presence of nitrates in leafy vegetables[4].

(7) In that statement the Panel concluded that exposure to nitrate at the current or envisaged maximum levels in spinach cooked from fresh spinach is unlikely to be a health concern, although a risk for some infants eating more than one spinach meal per day cannot be excluded. EFSA noted that it did not take into account possible changes of the nitrate content due to processing of the food commodities, such as washing, peeling and/or cooking, as this could not be considered due to lack of representative data. The non-consideration of the quantitative impact of food processing on nitrate levels may consequently lead to an overestimation of the exposure. It was furthermore concluded that levels of nitrate in lettuce are not a health concern for children. Enforcing the current maximum levels for nitrate in lettuce and spinach, or envisaged maximum levels at 500 mg/kg higher than the current maximum levels, would have a minor impact.

(8) In order to provide legal security for the producer in all regions of the European Union which applies strictly the good agricultural practices to reduce the presence of nitrates in spinach and lettuce as much as possible, it is therefore appropriate to slightly increase the maximum level for nitrates in fresh spinach and lettuce without endangering public health.

(9) Given the sometimes very high levels of nitrates found in rucola, it is appropriate to set a maximum level for rucola. The maximum level for rucola should be reviewed in 2 years in view of a reduction of the levels after having identified the factors involved in the presence of nitrate in rucola and the full implementation of good agricultural practice in rucola to minimise the nitrate content.

(10) Given that EFSA has been mandated by the Commission to compile all occurrence data on contaminants, including nitrates, in food into one database, it is appropriate to communicate the results directly to EFSA.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1881/2006 is amended as follows:

(1) in Article 7, paragraphs 1, 2 and 3 are deleted;

(2) in Article 9, paragraph 1 is replaced by the following:

1. Member States shall monitor nitrate levels in vegetables which may contain significant levels, in particular green leaf vegetables, and communicate the result to EFSA on a regular basis.;

(3) in the Annex, Section 1: Nitrate is replaced by the Section in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from the date of its entry into force. However, the maximum levels for rucola provided for in point 1.5 of the Annex shall apply from 1 April 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 December 2011.

For the Commission

The President

José Manuel BARROSO