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Delegations will find attached document D063903/03/03.

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EUROPEAN
COMMISSION

Brussels, **XXX**
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[...](2019) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

**amending Regulation (EC) 1881/2006 as regards maximum levels of perchlorate in
certain foods**

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Regulation (EC) 1881/2006 as regards maximum levels of perchlorate in certain foods

(Text with EEA relevance)

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 food¹, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006² sets maximum levels for certain contaminants in foodstuffs.
- (2) On 30 September 2014, the Scientific Panel on Contaminants in the Food Chain ('the CONTAM Panel') of the European Food Safety Authority ('the Authority') adopted a scientific opinion on the risks to public health related to the presence of perchlorate in food³. The CONTAM Panel established a tolerable daily intake of 0.3 micrograms per kilogram of body weight per day, based on the inhibition of thyroid iodine uptake in healthy adults. The CONTAM Panel concluded that the current estimated chronic dietary exposure to perchlorate is of potential concern, in particular for the high consumers in the younger age groups of the population with mild to moderate iodine deficiency. Furthermore, it is possible that current estimated short-term exposure to perchlorate is of concern for breast-fed infants and small children with low iodine intake.
- (3) The CONTAM Panel recommended that Member States collect additional data on the occurrence of perchlorate in food in Europe, especially in relation to vegetables, infant formula, milk and dairy products, in order to further reduce the uncertainty in the risk assessment.
- (4) Commission Recommendation (EU) 2015/682⁴ was adopted on foot of the scientific report with the objective of monitoring the presence of perchlorate in food, in particular in food sampled after 1 September 2013, when mitigation measures were put in place.
- (5) The Authority carried out a human exposure assessment to perchlorate taking into account the occurrence data available in its database from samples taken after 1 September 2013 and

¹ OJ L 37, 13.2.1993, p. 1.

² Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

³ EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2014. Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables. EFSA Journal 2014;12(10):3869, 106 pp. doi:10.2903/j.efsa.2014.3869
<http://www.efsa.europa.eu/en/efsajournal/pub/3869>

⁴ Commission Recommendation (EU) 2015/682 of 29 April 2015 on the monitoring of the presence of perchlorate in food (OJ L 111, 30.4.2015, p. 32).

published a scientific report on the “Dietary exposure assessment to perchlorate in the European population”⁵ in 2017.

- (6) The CONTAM Panel considered the outcome of the report on perchlorate in food at its 87th plenary meeting in November 2017⁶ and noted a substantial alignment of the exposure levels estimated in this report with those estimated in the opinion of the CONTAM Panel in 2014. Given the previously established tolerable daily intake of 0.3 µg/kg bw per day, the CONTAM Panel confirmed the conclusion that the current chronic and short-term exposure to perchlorate may pose a possible concern for human health.
- (7) It is therefore appropriate to set maximum levels of perchlorate both in foodstuffs which contain significant levels of perchlorate and which contribute significantly to human exposure and in foodstuffs which are of relevance as regards the possible exposure of vulnerable groups of the population such as infants and young children.
- (8) Regulation (EC) No 1881/2006 should therefore be amended accordingly.
- (9) Food business operators should be allowed time to adapt to the new requirements set out in this Regulation. The date of application of the maximum levels of perchlorate for those foodstuffs should therefore be deferred.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Foodstuffs listed in the Annex to this Regulation that were lawfully placed on the market before 1 July 2020 may continue to be marketed until their date of minimum durability or use-by-date.

Article 3

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

It shall apply from 1 July 2020.

⁵ EFSA (European Food Safety Authority), Arcella D, Binaglia M and Vernazza F, 2017. Scientific Report on the Dietary exposure assessment to perchlorate in the European population. EFSA Journal 2017;15(10):5043, 24 pp. <https://doi.org/10.2903/j.efsa.2017.5043>

⁶ <http://www.efsa.europa.eu/sites/default/files/event/171121-m.pdf>

This Regulation shall be binding in its entirety and directly applicable in all Member States.
Done at Brussels,

The President

For the Commission