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Delegations will find attached document D066794/04.

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

of **XXX**

amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for titanium dioxide (E 171)

(Text with EEA relevance)

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

of **XXX**

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) Those specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (3) Titanium dioxide (E 171) is a substance authorised as a colour in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008.
- (4) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the European Food Safety Authority ('the Authority'). Commission Regulation (EU) No 257/2010⁴ provides that the re-evaluation of food colours was to be completed by 31 December 2015. On 14 September 2016, the Authority published a scientific opinion on the re-evaluation of the safety of titanium dioxide (E 171) as a food additive⁵. The Authority concluded that on the basis of the database available and the considerations on the absorption of titanium dioxide (E 171), the margins of safety, which were calculated considering the no observed adverse effect level (NOAEL) of 2 250 mg titanium dioxide/kg body weight per day identified in the toxicological data

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁴ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

⁵ EFSA Journal 2016;14(9):4545.

available and the exposure to titanium dioxide (E 171) obtained from the reported use/analytical levels, would not be of concern. In the opinion, the Authority recommended additional toxicological testing in order to enable the Authority to establish a health-based guidance value (acceptable daily intake - ADI) for the food additive titanium dioxide (E 171). The Authority also recommended that the Union specifications for titanium dioxide (E 171) should include a characterisation of particle size distribution and that the maximum limits for the impurities of arsenic, lead, mercury and cadmium should be revised in order to ensure that titanium dioxide (E 171) as a food additive will not be a significant source of exposure to those elements in foods.

- (5) On 30 January 2017, the Commission launched a public call for scientific and technological data on titanium dioxide (E 171)⁶, targeting the data needs identified in the scientific opinion on the re-evaluation of this substance as a food additive. Information on the actual use of alumina (aluminium oxide) for the coating of titanium dioxide (E 171) was also requested, to determine what would be the contribution of titanium dioxide (E 171) coated with alumina to the exposure to aluminium through food.
- (6) On 2 October 2017, business operators submitted information on the lowest achievable limits for the impurities of arsenic, lead, mercury and cadmium in titanium dioxide (E 171) as well as information on the actual use of alumina (aluminium oxide) for the coating of titanium dioxide (E 171). On 18 July 2019, business operators submitted analytical data on current levels of antimony, arsenic, lead, mercury and cadmium in the food additive titanium dioxide (E 171).
- (7) On 29 June 2018, business operators submitted data on particle size and particle size distribution for titanium dioxide (E 171), including a proposal for the specifications for E 171 with respect to particle size and particle size distribution. On 7 August 2018, the Commission requested the Authority to provide a scientific opinion on whether the analytical data provided by business operators adequately support the proposed amendment of the specifications for the food additive titanium dioxide (E 171), with respect to the inclusion of additional parameters related to its particle size.
- (8) As requested, on 12 July 2019, the Authority published a scientific opinion on the proposed amendment of the specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution⁷. It concluded that, on the basis of the available data and taking into account measurement uncertainty, a specification should be inserted setting out that the median minimum external dimension by number of the constituent particles measured by electron microscopy is higher than 100 nm, which is equivalent to less than 50% of constituent particles by number with a minimum external dimension below 100 nm.
- (9) The Authority also recommended that, in view of the additional information submitted by interested business operators, the definition of the food additive titanium dioxide (E 171) should be revised in the current Union specifications to indicate that, as a food additive, it may contain small quantities (< 0.5%) of constituent particle growth and crystal phase control agents (alumina, sodium or potassium in combination with phosphate), but it has no surface treatments or coatings. Furthermore, the Authority clarified that, in its view, potassium aluminium silicate-based pearlescent pigments are

⁶ http://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en.

⁷ EFSA Journal 2019;17(7):5760.

not covered by the definition of the food additive titanium dioxide (E 171) and therefore, that its assessment does not cover titanium dioxide used for the preparation of those pigments.

- (10) Pending the submission by business operators, and the evaluation by the Authority, of new toxicological data expected to enable the Authority to establish a health-based guidance value (ADI) for titanium dioxide (E 171), some amendments should be introduced already now to the specifications for titanium dioxide (E 171), as recommended by the Authority in the Scientific Opinion on the re-evaluation of the safety of titanium dioxide (E 171) as a food additive, published on 14 September 2016, and in the Scientific opinion on the proposed amendment of the EU specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution, published on 12 July 2019.
- (11) On the basis of the analytical data submitted by business operators in reply to the Commission's call for data, the Commission was able to derive new technically achievable limits for the impurities of antimony, lead, mercury and cadmium in titanium dioxide (E 171), which are lower than the current limits in the specifications for titanium dioxide (E 171).
- (12) The Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (13) Even if titanium dioxide complying with the current specifications but not complying with this Regulation should no longer be authorised for use as a food additive, there is no indication that it would pose a health concern which would require that, with immediate effect as of the date of entry into force of this Regulation, it is not at all placed on the market or remain on it. Therefore, in order to allow for a smooth transition to the amended specifications, it is appropriate to allow that during a transitional period titanium dioxide complying with either the old or the new specifications can legally be placed, and remain, on the market.
- (14) For the same reasons, it is also appropriate that foods containing titanium dioxide complying with the currently applicable specifications that have been lawfully placed on the market before or during that transitional period may continue to be marketed until the stocks are exhausted.
- (15) 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 (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

Article 2

1. Until xxxx (six months after date of entry into force of this Regulation), the food additive titanium dioxide (E 171) may continue to be placed on the market as such in accordance with the specifications applicable before xxxx (date of entry into force of this Regulation).
2. Until xxxx (six months after date of entry into force of this Regulation), foods containing titanium dioxide (E 171) complying with the specifications applicable

before xxxx (date of entry into force of this Regulation), may continue to be placed on the market. After that date, they may remain on the market until the exhaustion of stocks.

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*.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN