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Objection to an implementing act: Maximum levels of acrylamide in certain foodstuffs for infants and young children

European Parliament resolution of 8 October 2020 on the draft Commission regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of acrylamide in certain foodstuffs for infants and young children (D067815/03 — 2020/2735(RPS))

(2021/C 395/04)

The European Parliament,

— having regard to the draft Commission regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of acrylamide in certain foodstuffs for infants and young children (D067815/03,

— 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,

— having regard to Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food ([2]),

— having regard to the scientific opinion on acrylamide in food adopted by the Panel on Contaminants in the Food Chain (CONTAM Panel) of the European Food Safety Authority (EFSA) on 30 April 2015, and published on 4 June 2015 ([3]),

— having regard to Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([4]),

— having regard to Rule 112(2) and (3), and (4)(c) of its Rules of Procedure,

— having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

General

A. whereas acrylamide is a chemical compound present in food that is formed from the naturally present substances free asparagine and sugars during high temperature processing, such as frying, roasting and baking;

B. whereas consumers get exposed to acrylamide through industrially-produced food, such as crisps, bread, biscuits and coffee, but also from home cooking, e.g. when toasting bread or cooking fries;

C. whereas infants, toddlers and other children are the most exposed age group with a view to their lower body weight and are therefore specifically vulnerable; whereas it is known that children have a higher metabolism because of the larger liver/body weight ratio making it more likely that glycidamide (the metabolite of acrylamide, which forms through biotransformation) can be formed at a higher rate in children, enhancing the possibility of toxicity of acrylamide in children ([5]);

([1]) OJ L 37, 13.2.1993, p. 1.
([2]) OJ L 304, 21.11.2017, p. 24.
([3]) EFSA Journal 2015; 13(6):4104, http://www.efsa.europa.eu/en/efsajournal/pub/4104
([4]) OJ L 184, 17.7.1999, p. 23.
([5]) See Erkekoğlu, P., Baydar, T., 'Toxicity of acrylamide and evaluation of its exposure in baby foods', *Nutrition Research Reviews*, Volume 23, Issue 2, December 2010, pp. 323-333, https://doi.org/10.1017/S0954422410000211

Safety concerns

D. whereas, according to the harmonised classification and labelling (CLP00) approved by the Union, acrylamide is toxic if swallowed, may cause genetic defects, may cause cancer, causes damage to organs through prolonged or repeated exposure, is harmful in contact with skin, causes serious eye irritation, is harmful if inhaled, is suspected of damaging fertility, causes skin irritation and may cause an allergic skin reaction; whereas additionally, the classification provided by companies to the European Chemicals Agency (ECHA) in REACH registrations identifies that this substance is suspected of damaging fertility or the unborn child ([6]);

E. whereas beyond that, degeneration of the peripheral nerve and nerve terminals in some brain areas related to the memory, learning and cognitive functions, was observed ([7]);

F. whereas the CONTAM Panel's scientific opinion of 30 April 2015 on acrylamide in food ([8]) identified, from all data available, four possible critical endpoints for acrylamide toxicity, i.e. neurotoxicity, effects on male reproduction, developmental toxicity, and carcinogenicity; whereas the CONTAM Panel also noted that acrylamide is a germ cell mutagen and that there are at present no established procedures for risk assessment using this endpoint; whereas the CONTAM Panel more specifically confirmed previous evaluations that acrylamide in food potentially increases the risk of developing cancer for consumers in all age groups;

G. whereas the toxicity of acrylamide had already been recognised in 2002 in a joint FAO/WHO report ([9]); whereas acrylamide has been classified as a 'probable human carcinogen' by the International Agency for Research on Cancer (IARC) ([10]), as 'reasonably anticipated to be a human carcinogen' by the US National Toxicology Program (NTP) ([11]), and as 'likely to be carcinogenic to humans' by the US Environmental Protection Agency (EPA) ([12]);

H. whereas endocrine disrupting properties of acrylamide are discussed in several scientific studies ([13]) and urgently need examination;

([6]) ECHA Substance Infocard for Acrylamide, https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.067?_disssubsinfo_WAR_disssubsinfoportlet_backURL=https%3A%2F%2Fecha.europa.eu%2Fhome%3Fp_p_id%3Ddisssimplesearchhomepage_WAR_disssearchportlet%26p_p_lifecycle%3D0%26p_p_state%3Dnormal%26p_p_mode%3Dview%26p_p_col_id%3Dcolumn-1%26p_p_col_count%3D2%26_disssimplesearchhomepage_WAR_disssearchportlet_sessionCriteriaId%3D. See also ECHA Summary of Classification and Labelling, https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/104230: carcinogenic 1B (presumed), mutagenic 1B (presumed), toxic for reproduction 2 (suspected), skin sensitising 1, and STOT 1 (specific target organ toxicity — affecting the nervous system with repeated exposure).

([7]) Summary and conclusions of the sixty-fourth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), 8-17 February 2005, http://www.fao.org/3/a-at877e.pdf. See also Matoso, V., Bargi-Souza, P., Ivanski, F., Romano, M.A., Romano, R.M., 'Acrylamide: A review about its toxic effects in the light of Developmental Origin of Health and Disease (DOHaD) concept', *Food Chemistry*, 15 June 2019; 283:422-430, https://pubmed.ncbi.nlm.nih.gov/30722893/

([8]) *EFSA Journal 2015*;13(6):4104, http://www.efsa.europa.eu/en/efsajournal/pub/4104

([9]) Report of a Joint FAO/WHO Consultation, 'Health Implications of Acrylamide in Food', 25-27 June 2002 https://apps.who.int/iris/bitstream/handle/10665/42563/9241562188.pdf?sequence=1

([10]) https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Some-Industrial-Chemicals-1994, *'IARC Monographs on the Evaluation of Carcinogenic Risks to Humans'*, Some Industrial Chemicals, IARC, Lyon, France, 1994. See also Zhivagui, M., Ng, A.W.T., Ardin, M., et al., 'Experimental and pan-cancer genome analyses reveal widespread contribution of acrylamide exposure to carcinogenesis in humans', *Genome Research*, 2019; 29(4):521-531, https://www.iarc.fr/wp-content/uploads/2019/03/pr267_E.pdf

([11]) Report on Carcinogens, Acrylamide, National Toxicology Program, Department of Health and Human Services, Fourteenth Edition 2016, https://ntp.niehs.nih.gov/ntp/roc/content/profiles/acrylamide.pdf

([12]) Toxicological review of Acrylamide (CAS No. 79-06-1), March 2010, U.S. Environmental Protection Agency, Washington, DC, https://nepis.epa.gov/Exe/ZyPDF.cgi/P1006QL0.PDF?Dockey=P1006QL0.PDF

([13]) Matoso, V., Bargi-Souza, P., Ivanski, F., Roman, M.A., Romana, R.M., 'Acrylamide: A review about its toxic effects in the light of Developmental Origin of Health and Disease (DOHaD) concept', *Food Chemistry 283* (2019) 422-430, https://www2.unicentro.br/ppgvet/files/2019/11/3-Acrylamide-A-review-about-its-toxic-effects-in-the-light-of-Developmental-Origin-of-Health-and-Disease-DOHaD-concept.pdf?x26325, Kassotis, C.D., et al., 'Endocrine-Disrupting Activity of Hydraulic Fracturing Chemicals and Adverse Health Outcomes After Prenatal Exposure in Male Mice', *Endocrinology*, December 2015, 156(12):4458–4473, https://academic.oup.com/endo/article/156/12/4458/2422671, Hamdy, S.M., Bakeer, H.M., Eskander, E.F., Sayed, O.N., 'Effect of acrylamide on some hormones and endocrine tissues in male rats', *Human & Experimental Toxicology* 2012, 31(5):, 483-91, https://journals.sagepub.com/doi/10.1177/0960327111417267

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Precautionary principle

I. whereas Article 191(2) of the Treaty on the Functioning of the European Union (TFEU) sets out the precautionary principle as one of the fundamental principles of the Union;

J. whereas Article 168(1) TFEU states that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities';

Specific legal requirements

K. whereas Article 2(1) and (2) of Regulation (EEC) No 315/93 provide that food containing a contaminant in an amount which is unacceptable from the public health viewpoint and in particular at a toxicological level shall not be placed on the market, and that contaminant levels shall be kept as low as can reasonably be achieved by following good practices at all stages of food production;

L. whereas Regulation (EU) 2017/2158 requires food business operators to apply mitigation measures and carry out certain activities to reduce the levels of acrylamide in certain foodstuffs with a view to ensuring that the levels of acrylamide in their products remain below 'benchmark levels', which are used to verify the effectiveness of the mitigation measures through sampling and analysis;

M. whereas the benchmark levels laid down in Regulation (EU) 2017/2158 have applied since April 2018, and are to be reviewed by the Commission every three years and the first time within three years following the entry into application of that Regulation, with the aim to set lower levels ([14]);

N. whereas benchmark levels are missing for several product categories, such as vegetable crisps, croquettes, or rice crackers, some of which have been proven to contain high levels of acrylamide; whereas Commission Recommendation (EU) 2019/1888 ([15]) lays down a non-exhaustive list of food categories that should be monitored regularly for the presence of acrylamide;

O. whereas, in accordance with Article 2(3) of Regulation (EEC) No 315/93, the Commission may where necessary establish the maximum tolerances for specific contaminants, in order to protect public health; whereas no maximum levels for acrylamide in food have yet been set; whereas Recital 15 of Regulation (EU) 2017/2158 indicates that complementary to the mitigation measures, the setting of maximum levels for acrylamide in certain foods should be considered;

The draft Commission regulation

P. whereas the draft Commission regulation acknowledges the importance of levels of acrylamide in food being as low as reasonably achievable;

Q. whereas the draft Commission regulation proposes to set maximum levels for two very specific categories of food only, namely for 'biscuits and rusks for infants and young children' (150 μg/kg, which corresponds to the current benchmark level) and for 'baby foods, processed cereal based foods for infants and young children excluding biscuits and rusks' (50 μg/kg, which is even 10 μg/kg higher than the current benchmark level of 40 μg/kg);

R. whereas the occurrence data the Commission based its draft regulation upon stems from the period from 2015 to 2018; whereas, if Regulation (EU) 2017/2158 is to have an effect on acrylamide levels in foods, it can be reasonably expected that food manufacturers should have at least reached by now the benchmark value established three years ago;

Market situation and assessment of the draft Commission regulation

S. whereas research carried out in autumn 2018 by ten consumer organisations across Europe ([16]) has shown that a range of products which do not fall under the two categories regulated in the draft Commission regulation, such as biscuits and wafers, are often consumed by children below three years of age; and some of these products are obviously marketed to children (i.e. packaging design with cartoon characters that appeal to children); whereas a similar situation can be supposed for products such as crackers or breakfast cereals;

([14]) Article 5 and Recital 11 of Regulation (EU) 2017/2158.
([15]) Commission Recommendation (EU) 2019/1888 of 7 November 2019 on the monitoring of the presence of acrylamide in certain foods (OJ L 290, 11.11.2019, p. 31).
([16]) https://www.beuc.eu/publications/beuc-x-2019-010_more_efforts_needed_to_protect_consumers_from_acrylamide_in_food.pdf

T. whereas the benchmark level for 'biscuits and wafers' (350 µg/kg) and the benchmark level for 'biscuits and rusks for infants and young children' (150 µg/kg) differ significantly, without the parents being made aware of the difference in terms of the sought maximum acrylamide content;

U. whereas it was also found that for biscuits and wafers, a third of the products tested were at or above the benchmark level, and out of the biscuits and wafers identified as 'frequently consumed by children under three' close to two-thirds would not have passed the benchmark set for the category 'biscuits and rusks for infants and young children';

V. whereas it is undisputed that the occurrence of acrylamide in food can be minimised by applying appropriate mitigation measures ([17]); whereas, across all food categories, it has been proven possible to produce products with a low acrylamide content ([18]);

W. whereas, with regard to the draft Commission regulation, both data from consumer research ([19]) in 2018 and occurrence data stemming from the EFSA database from the period 2015 to 2018 show that lower levels than the proposed 150 µg/kg and 50 µg/kg have been easily achieved by a very big majority of producers in both food categories; whereas it can be assumed that almost all products can meet those levels today; whereas stricter levels are therefore necessary in order to set an incentive for further reduction;

X. whereas the setting of maximum levels clearly facilitates enforcement of rules regarding acrylamide by Member States; whereas maximum levels must still nevertheless be set in accordance with the ALARA ('As Low As Reasonably Achievable') principle as laid down in Article 2 of Regulation (EEC) No 315/93;

Y. whereas, in conclusion, the levels proposed in the draft Commission regulation are already easily met by most products on the market, and lower levels have been proven to be achievable without the need for big efforts;

Further considerations

Z. whereas more research could help to understand the reasons for the high variability of acrylamide levels within food categories and identify strategies aiming at minimising the formation of acrylamide;

AA. whereas monitoring of the effectiveness of the rules regarding acrylamide is crucial; whereas this implies that Member States carry out effective and frequent enough controls and collect data on acrylamide occurrence;

AB. whereas public information campaigns can help raise consumers' awareness of products with potentially higher acrylamide contents and inform them how to limit acrylamide exposure when cooking;

1. Opposes adoption of the draft Commission regulation;

2. Considers that the draft Commission regulation is not compatible with the aim and content of Regulation (EEC) No 315/93;

3. Considers that continuing to allow high levels of acrylamide in food may have adverse effects on the health of European consumers; therefore considers it of outermost importance to lower acrylamide levels in foods;

4. Considers that the proposed maximum level for acrylamide in the food category of 'baby foods, processed cereal based foods for infants and young children excluding biscuits and rusks' should be set below, and certainly not above, the current benchmark level of 40 µg/kg;

([17]) See Regulation (EU) 2017/2158.
([18]) https://www.beuc.eu/publications/beuc-x-2019-010_more_efforts_needed_to_protect_consumers_from_acrylamide_in_food.pdf
([19]) https://www.beuc.eu/publications/beuc-x-2019-010_more_efforts_needed_to_protect_consumers_from_acrylamide_in_food.pdf

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5. Considers that the proposed maximum level for acrylamide in the food category of 'biscuits and rusks for infants and young children' should be set clearly below the current benchmark level of 150 μg/kg;

6. Asks the Commission to set strict maximum levels not only for the two product categories proposed in the draft Commission regulation, but also for other product categories, and most urgently for biscuits and rusks that do not fall under the specific category of 'biscuits and rusks for infants and young children';

7. Is looking forward to the revision of benchmark levels by April 2021 with a view to lowering them; insists that benchmark levels must reflect the continuous reduction of the presence of acrylamide in food, and be oriented on the best performers, in order to incentivise additional efforts by manufacturers;

8. Welcomes Commission Recommendation (EU) 2019/1888 of 7 November 2019 on the monitoring of the presence of acrylamide in certain foods; insists that benchmark levels (possibly to be followed by maximum levels) need to be set quickly for product categories that turn out to contain high levels of acrylamide;

9. Asks the Commission and Member States to intensify research on the formation of acrylamide in foods with a view to identifying strategies aiming at minimising the formation of acrylamide; requests that the Commission and Member States stimulate research on possible endocrine disrupting properties of acrylamide and glycidamide;

10. Calls upon Member States to step up their food control capacities with a view to monitoring the effectiveness of the rules regarding acrylamide and collect, publish and pass data on acrylamide occurrence to EFSA;

11. Asks the Commission and Member States to inform the public about product categories with potentially higher acrylamide contents and about strategies on how to limit acrylamide exposure when cooking;

12. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee;

13. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.