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Bundesminister Cem Őzdemir Bundesministerium für Ernährung und Landwirtschaft Wilhelmstrasse 54 10117 Berlin

27 November 2023

Dear Minister Steffi Lemke and Minister Cem Őzdemir,

Open letter regarding the recent handling of bisphenols by German regulatory agencies

As scientists actively engaged in researching the health effects of chemical exposures, we are writing to express our concerns about the recent handling of bisphenol A and other bisphenols by German regulatory authorities.

Bisphenol A is one of the most extensively studied chemicals and its toxicity is well described. All the evidence required to restrict the use of these chemicals according to the European chemical regulation REACH is available, yet the German authorities have recently withdrawn their REACH restriction proposal.

Current human exposures to bisphenol A in the European Union (EU) are 100- to 1000-fold higher than the new bisphenol A health-based guidance value derived by the European Food Safety Authority (EFSA) (1, 2). On an EU-wide scale therefore, human exposures to bisphenol A cannot be regarded as safe. The same applies to wildlife exposures. Existing EU-wide and national measures to ensure safe use of bisphenol A and other bisphenols have failed. To protect humans and wildlife from these chemicals, EU-wide restrictions are now urgently required, yet Germany is backing away from measures that would achieve better protection of humans and wildlife in the EU.

Paradoxically, the recently withdrawn German REACH restriction proposal only considered hazards of bisphenols to wildlife but ignored adverse health effects in humans.

In addition, the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) has recently provoked a dispute with EFSA in which they refused to recognize immunotoxic effects of bisphenol A as the basis for risk assessment. This has culminated in the publication of an alternative "safe" bisphenol A regulatory threshold, 1000-times higher than the EFSA value, based on bisphenol A hazards to semen quality. Astonishingly, the BfR claims that their alternative value also protects against all other human health risks, including immunotoxicity (3). In our opinion, the scientific weight of evidence strongly supports EFSA's value (4).

The bisphenol A hazard assessment procedure adopted by BfR consistently erred on the side of disregarding evidence that could have supported lower regulatory values. Because of this strong bias, the BfR proposal for "safe" bisphenol A exposures comes close to doses shown to produce effects on semen quality in animal studies and in human studies (5). This procedure violates internationally accepted standards of hazard characterization.

Even if declines in semen quality were accepted as a basis for defining safe bisphenol A exposures, far lower values than proposed by BfR are required. To a large degree, the position adopted by the BfR in its dispute with EFSA therefore misses the point. Whether bisphenol A's immunotoxicity, or its

effects on semen quality are regarded as critical for deriving regulatory thresholds, is irrelevant. In both cases, current EU-wide human exposures are far in excess of levels that can be regarded as safe.

We are concerned that BfR's actions seriously undermine efforts to ensure the safety of humans and wildlife. Equally problematic is BfR's refusal to accept human biomonitoring as a valid method for establishing the extent of exposures to bisphenols. In this, and in the position taken in the hazard assessment of bisphenol A, the BfR is failing in its mandate to provide independent and sound scientific advice for the protection of citizens from chemical risks.

As the Ministers responsible for protecting humans and wildlife from chemical harm, we call on you to direct the German authorities to re-submit the REACH restriction proposal for bisphenols as a matter of urgency. The re-submission must be strengthened by also considering harms to human health. The over-arching aim must be to minimize bisphenol exposures to humans and the environment. A recent analysis has shown that restricting bisphenol exposures will reap disproportionately high rewards in protecting against risks to male reproductive health (6).

We also call on you to promote a fast European Commission decision on restricting bisphenols in food contact materials.

In the face of delays to regulatory action for bisphenols and other endocrine disrupting chemicals at the EU level, we regard the recent publication of the German Government's Five-Point-Plan for the protection against endocrine disruptors as a step in the right direction. We hope that the implementation of this Plan will match, or better, surpass similar efforts in France or Belgium. We have no doubt that this would give a positive signal for strengthening better health protection at the EU level.

Yours sincerely, on behalf of all 56 signatories

Andreas Kortulamp

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