toxicology and regulatory news

February 2025

An update regarding bisphenol A (BPA) in the EU

On 19th December 2024, the European Commission adopted a ban on the use of BPA in food-contact materials. This decision was at least partially based on the human health concerns outlined in the latest (2023) scientific assessment of BPA by the European Food Safety Authority (see our article on the BPA controversy). It is worth noting that the ban also covers other (current and future) bisphenols and bisphenol derivatives, including their salts, with harmonised classifications in the EU for hazards such as reproductive toxicity and endocrine disruption. For most products, there will be an 18-month phase out period. In exceptional cases, where no alternatives exist, industry will be allowed time to adapt to avoid disruption of the food chain.

European Commission (2024). Commission adopts ban of Bisphenol A in food contact materials.

See also the EFSA assessment of BPA alternatives (page 6).

Toxicology and Regulatory News

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International

ISO 10993-4 amendment

ISO has released a draft amendment to Part 4 of its 10993 series on the biological evaluation of medical devices. ISO 10993-4 specifies the requirements for evaluating the interactions of medical devices with blood. This amended version includes some minor updates and corrections.

International Organization for Standardization (2025). Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood — AMENDMENT 1. ISO 10993-4:2017/Amd 1:2025(en).

Europe

ECHA...

...evaluates occupational limit values for two substances

In draft evaluations of 1,2-dibromoethane and *N*-(hydroxymethyl)acrylamide, the assumed non-threshold carcinogenic nature of both compounds prevents ECHA from establishing Occupational Exposure Levels (OELs). In each case, an Exposure-Risk Relationship (ERR) was considered instead. For 1,2-dibromoethane, the critical effect was the formation of tumours in the nasal cavity of rats exposed at 78 mg/m^3 for 2 years. For *N*-(hydroxymethyl)acrylamide, the key effect was an increase in the incidence of lung adenomas and carcinomas (combined) in mice exposed orally at 50 mg/kg bw/day for 2 years.

European Chemicals Agency (2024-2025).
ECHA scientific report for evaluation of limit values for 1,2-dibromoethane (ethylene dibromide) at the workplace.
ECHA scientific report for evaluation of limit values for *N*-(hydroxymethyl)acrylamide (NMA) at the workplace.

...decision on (tetrapropenylsuccinimido)-caproic acid

(Tetrapropenylsuccinimido)-caproic acid, a synonym for 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, has been added to ECHA's Candidate List of Substances of Very High Concern (SVHC) for Authorisation, based on concerns for reproductive toxicity. A future decision will be made as to whether it will be subject to authorisation. ECHA reminds companies that they may have resultant legal obligations.

European Chemicals Agency (2025). Candidate List of substances of very high concern for Authorisation.

...calls for data on mammalian testing proposals for 16 REACH substances

ECHA has requested information from third parties, by 7th March 2025, on *in vivo* testing proposals for various REACH-registered substances, notably the following related to mammalian toxicity:

- 2,9,11,13,15,22,24,26,27,28-decaazatricyclo[21.3.1.1^(10,14)]octacosa-1(27),10,12,14(28),23,25-hexaene-12,25-diamine, *N*,*N*'-bis(1,1,3,3-tetramethylbutyl)-2,9,15,22-tetrakis(2,2,6,6-tetramethyl-4-piperidinyl)- (for genotoxicity)
- cobalt, borate neodecanoate complexes (for genotoxicity and developmental toxicity)
- dodecamethylpentasiloxane (for reproductive and developmental toxicity)
- *N*,*N*-dimethyldodec-9-enamide (for repeated-dose oral toxicity and developmental toxicity)
- neodecanoic acid, cobalt salt (for genotoxicity and developmental toxicity)
- piperonal (for reproductive toxicity)
- propyl (2*S*)-2-[(2-methylbutan-2-yl)oxy]propanoate (for repeated-dose oral toxicity and developmental toxicity)
- reaction mass of ethylbenzene and xylene, reaction mass of ethylbenzene and *m*-xylene, and reaction mass of ethylbenzene, *m*-xylene and *p*-xylene (for reproductive toxicity)
- resin acids and rosin acids, cobalt salts (for genotoxicity and for reproductive and developmental toxicity)
- stearic acid, cobalt salt (for genotoxicity and developmental toxicity)
- xylene, *m*-xylene, *o*-xylene and *p*-xylene (for reproductive toxicity)

European Chemicals Agency (2025). Testing proposals.

Biocidal Products Regulation...

...BPC opinions on five biocidal actives

On 25-27th November 2024, ECHA's Biocidal Products Committee (BPC) adopted opinions on the approval of the following active substances:

- 2,2-dibromo-2-cyanoacetamide for Product Type (PT) 11 (preservatives for liquid-cooling and processing systems)
- 2-methyl-2,3-dihydro-1,2-thiazol-3-one hydrochloride for PT 6 (preservatives for products during storage)
- 2-methyl-2H-isothiazol-3-one for PT 6

- epsilon-metofluthrin for PTs 18 (insecticides, acaricides and products to control other arthropods) and 19 (repellents and attractants)
- peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and hydrogen peroxide for PT 2 (disinfectants and algaecides not intended for direct application to humans or animals)

European Chemicals Agency (2024). Biocidal Products Committee opinions on active substance approval.

Classification and labelling...

...proposals for the CLH of nine REACH substances

Under the EU Classification, Labelling and Packaging (CLP) regulation, there is a legal obligation for suppliers to evaluate the hazards of chemicals (substances and mixtures) that are to be placed on the market, and to classify and label them appropriately. An option also exists for Member State Competent Authorities or industry to propose the Harmonised Classification and Labelling (CLH) of a substance across Europe. Following the submission of a CLH proposal, ECHA organises a public consultation period of 60 days. Under this scheme, CLH reports have been submitted by the Austrian, French, German, Hungarian and Swedish authorities to standardise the classification and labelling for various REACH-registered substances, notably the following associated with mammalian toxicity:

- (2-hydroxy-1,1-dimethylethyl)ammonium chloride and reaction mass of 2-amino-2-methylpropanol and (2-hydroxy-1,1-dimethylethyl)ammonium chloride (for several human health hazards)
- (*tert*-butoxymethyl)oxirane and (isobutoxymethyl)oxirane (for acute toxicity and reproductive toxicity)
- 2-amino-2-methylpropanol (for several human health hazards)
- allyl glycidyl ether and butyl glycidyl ether (for acute toxicity and reproductive toxicity)
- beflubutamid (for several human health hazards)
- bis(pentane-2,4-dionato)calcium (for acute oral toxicity, eye damage and skin sensitisation)
- resorcinol (for endocrine disruption)
- sodium chlorite (for several human health hazards)

European Chemicals Agency (2024). Harmonised classification and labelling consultations.

EFSA...

...re-evaluation of fluoride

EFSA's Scientific Committee was asked to update its risk assessment for fluoride in food and drinking water. The main concern of fluoride is its effects on the Central Nervous System (CNS), thyroid and bone. Current exposure from drinking water alone at the current legal limit of 1.5 mg/L could potentially result in the tolerable upper intake levels of 1, 1.6 and 2 mg/day for infants, toddlers and children, respectively, being exceeded. The safe limit of 3.3 mg/day for pregnant women and groups over the age of 8 years might also be exceeded if other sources of fluoride exposure are also taken into account (diet, fluoridated salt, and ingested dental care products). The Committee therefore argues that the legal limit in drinking water of 1.5 mg/L is not protective of human health and should be re-evaluated.

European Food Safety Authority (2024). Draft scientific opinion on updated consumer risk assessment of fluoride in food and drinking water including the contribution from other sources of exposure.

...assessment of bisphenol A (BPA) alternatives

EFSA's proposal that the Tolerable Daily Intake (TDI) of BPA be drastically reduced has resulted in a rise in the development and production of BPA alternatives. Bisphenol E (BPE) and bisphenol P (BPP) were tested in four *in vitro* assays, in an attempt to (i) address data gaps in their genotoxicity profiles, and (ii) validate some "new advanced models" (specifically 3D liver spheroids) against standard genotoxicity assays. Both compounds were found to induce chromosome damage (mainly numerical in the case of BPE) in human peripheral blood lymphocytes. There was a lack of genotoxic effects in the 3D spheroid model, and it was suggested that 3D spheroids might be better at mimicking genotoxic activity under *in vivo* conditions than some of the standard *in vitro* assays. However, these are only preliminary findings in need of confirmatory testing.

European Food Safety Authority (2024). New advanced models (NAMs) for risk assessment of bisphenol A alternatives. EFSA Journal. 22: e2221116.

...reference chemicals for developmental neurotoxicity

In 2023, the Organisation for Economic Cooperation and Development (OECD, Series on Testing & Assessment No. 337) released its initial recommendations on the evaluation of data from the Developmental Neurotoxicity *In Vitro* Battery (DNT IVB), including a draft list of around 100 reference chemicals that might be used to evaluate current DNT-IVB performance against existing *in vivo* DNT

studies. An externally produced scientific report submitted to, and released by, EFSA now lists 174 DNT reference chemicals, 164 of which have shown evidence of DNT *in vivo* (the positives) and the remaining ten of which have not (the negatives). The aim is for the compounds on this latest list to be considered for the first update to Appendix A of OECD 337, although it was stressed that there are considerable uncertainties around both the individual compounds and the DNT studies.

European Food Safety Authority (2024). Recommended DNT Reference Chemical Test Set For *In Vitro* Assay Development. External Scientific Report.

...assessment of perchlorate in food

The CONTAM Panel has updated its 2014 risk assessment on perchlorate in food. Perchlorate can inhibit the uptake of iodine into the thyroid, and exposure during pregnancy can lead to neurodevelopmental toxicity. Whilst the derivation of an Acute Reference Dose (ARfD) was not considered necessary, the Panel has increased the Tolerable Daily Intake (TDI) from 0.3 to 1.4 µg/kg bw, based on the inhibition of thyroid iodine uptake in healthy adults. An assessment of chronic dietary exposure led the Panel to conclude that perchlorate does not raise a concern for any population group.

European Food Safety Authority (2024). EFSA Panel on Contaminants in the Food Chain. Update of the Scientific Opinion on the risks for human health related to the presence of perchlorate in food.

...evaluation of citric acid esters of mono- and diglycerides (E472c)

The EFSA FAF Panel has re-evaluated the safety of E472c as a food additive for infants below 16 weeks of age. As the Panel considered that its metabolism is similar in both infants and adults, additional toxicological studies were not considered necessary. It was concluded that E472c does not present a safety concern at the reported levels of use or at the maximum permitted levels in food for infants below 16 weeks of age. Recommended changes were also proposed to the existing EU specifications for E472c in Commission Regulation (EU) No 231/2012.

European Food Safety Authority (2025). Panel on Food Additives and Flavourings (FAF). Re-evaluation of citric acid esters of mono- and diglycerides of fatty acids (E 472c) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation. EFSA Journal. 23: e9202.

...assessment of 2,2′-oxydiethylamine in a Food-Contact Material (FCM)

The EFSA FCM Panel assessed the safety-in-use of 2,2′-oxydiethylamine in polyamide films. The compound and two representative mixed oligomers were not genotoxic to bacteria or mammalian cells, while a 90-day dietary study in rats with one of the oligomers (1-oxa-4,11,18-triazacyclo-eicosane-5,10,17-trione) provided no evidence of systemic toxicity at up to 1040 mg/kg bw/day (the highest dose tested). The Panel concluded that, for FCMs used for all types of food except infant formula and human milk, 2,2′-oxydiethylamine can be considered safe as a co-monomer at up to 14% w/w (subject to a maximum migration limit of 0.05 mg/kg food), as are its oligomers of molecular weight <1000 Da (with a migration limit of 5 mg/kg food).

European Food Safety Authority (2024). Panel on Food Contact Materials (FCM). Safety assessment of the substance 2,2′-oxydiethylamine for use in plastic food contact materials. EFSA Journal. 22: e9105.

...in other news...

EFSA's Pesticides Peer Review Unit has launched an open consultation on a Member State assessment report on the active substance beflubutamid, as well as on cymoxanil in the context of endocrine disruption. In addition, peer reviews of the initial risk assessments of lysate of *Willaertia magna* C2c Maky (a fungicide against downy mildew) and phosphine (a post-harvest indoor insecticide) have been published. These assessments outline the reliable endpoints for use in regulatory risk assessment and identify data gaps and other areas of concern.

European Food Safety Authority (2024). Pesticides Peer Review Unit and Pesticide peer reviews.

The FEEDAP Panel has released opinions on the safety and efficacy of the animal feed additives canthaxanthin, chromium propionate, peppermint oil and sage oil.

European Food Safety Authority (2024-2025). Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Feed additives.

The FEZ Panel evaluated the safety of the food enzymes, endo-1,4-beta-xylanase, endo-polygalacturonase, fructan beta-fructosidase, beta-fructofuranosidase, and beta-glucosidase, and concluded that they do not give rise to safety concerns under the intended conditions of use.

European Food Safety Authority (2024). Panel on Food Enzymes (FEZ). Food enzymes.

The NDA Panel has released a safety assessment on a mineral salt containing potassium and magnesium as a novel food, concluding that it is safe under the proposed conditions of use.

European Food Safety Authority (2025). Panel on Nutrition, Novel Foods and Food Allergens (NDA). Novel food.

DFG MAK value documentations issued for five chemicals

MAK values define maximum air concentrations which would not be expected to cause adverse health effects in workers. Such values have been published by DFG in its latest addition to the English language MAK Collection for Occupational Health and Safety (Volume 9, Issue 4). The documentation includes reviews of pertinent toxicological data on:

- 1,1-dimethylhydrazine
- 1,2-dimethylhydrazine
- monomethylhydrazine
- toluene
- triphenylphosphine

Deutsche Forschungsgemeinschaft (original German reports dated 2021-2022). German Research Foundation. MAK Value Documentations. The MAK Collection for Occupational Health and Safety 2024 Vol 9, No. 4.

SCCS preliminary opinion on butylparaben

SCCS has reviewed the safety of butylparaben when used as a preservative in dermal and oral cosmetic products intended for use in children aged 10 years and under. The Committee concluded that the use of butylparaben at a maximum concentration of 0.14% (as 4-hydroxybenzoic acid) is not safe when used in body lotion. In the Committee's opinion, to be safe, the maximum concentration in body lotion should not exceed 0.028% (as acid).

Scientific Committee on Consumer Safety (2025). Opinion on butylparaben (CAS No. 94-26-8, EC No. 202-318-7). Children exposure. SCCS/1674/25. Preliminary Opinion.

United Kingdom

MHRA Guidance Hub for e-cigarette and vape products

In its new "Guidance Hub", the MHRA has compiled all of its relevant guidance documents intended to inform and assist consumers, retailers, producers and manufacturers of e-cigarettes and vape products. This includes guidance on emissions, ingredients, nicotine doses, and product labelling.

Medicines and Healthcare products Regulatory Agency (2025). MHRA E-cigarette and Vape Products Guidance Hub.

United States

US EPA...

...IRIS reviews on perfluorohexanesulfonic acid (PFHxS) and inorganic arsenic

The US EPA has finalised its IRIS review on PFHxS and related salts, which summarises the key scientific issues and current toxicological reference values. In humans, the evidence indicates that PFHxS is likely to cause thyroid and developmental immune effects, while both human and animal studies suggest that it may also cause hepatic, neurodevelopmental and cardiometabolic effects. Subchronic and chronic oral Reference Doses (RfDs) of 4×10^{-10} mg/kg bw/day were determined, based on immune (developmental) effects. The Agency also concluded that there is inadequate information to assess the carcinogenic, haematopoietic, reproductive and renal toxicity potential of PFHxS.

The IRIS review on inorganic arsenic has also been finalised. The evidence in humans has demonstrated that it causes diseases of the circulatory system (including Ischemic Heart Disease, IHD) and diabetes. It is also considered likely to adversely affect pregnancy and birth outcomes and cause neurodevelopmental effects. A chronic oral RfD of 0.06 µg/kg bw/day was calculated, based on increased incidences of IHD and diabetes. The classification of inorganic arsenic as carcinogenic to humans (Group 1) has been retained and an oral Cancer Slope Factor (CSF) of 3.17×10^{-2} $(\mu g/kg\text{-}day)^{-1}$ for combined cancer risk (bladder and lung) has been derived.

US Environmental Protection Agency (2025).
IRIS toxicological review of perfluorohexanesulfonic acid (PFHxS, CASRN 335-46-4) and related salts. EPA/635/R-25/012Fa.
IRIS toxicological review of inorganic arsenic CASRN 7440-38-2. EPA/635/R-25/005Fa.

...risk evaluations for formaldehyde and three phthalates

The US EPA has finalised its risk evaluation on formaldehyde. Short-term inhalation exposure could cause sensory irritation and respiratory inflammation, whilst long-term exposure may reduce lung function, increase asthma and allergy-related conditions, and cause cancer. Dermal exposures could also provoke allergic reactions. The EPA concluded that formaldehyde presents an unreasonable risk of injury to human health for 58 of the 63 conditions of use assessed.

The Agency has also finalised its risk evaluations of di-isodecyl phthalate (DIDP) and di-isononyl phthalate (DINP), concluding that both could cause developmental toxicity and liver damage. DINP has also produced evidence of cancer in laboratory animals, whereas the existing data on DIDP were not considered adequate to determine its carcinogenic potential. The EPA concluded that six of the 49 conditions of use of DIDP and four of the 47 conditions of use of DINP contribute to the unreasonable risk to human health.

In a draft preliminary risk evaluation of dicyclohexyl phthalate (DCHP), the US EPA determined that this phthalate has the potential to cause developmental toxicity, particularly in the developing male reproductive system (phthalate syndrome), as well as skin sensitisation and liver toxicity. The Agency concluded that exposure to DCHP presents an unreasonable risk of injury to the health of workers.

US Environmental Protection Agency (2024).
Risk Evaluation for formaldehyde and Risk evaluation for diisodecyl phthalate (DIDP) and Risk evaluation for diisononyl phthalate (DINP) and Draft risk evaluation for dicyclohexyl phthalate (DCHP).

...technical support documents for four phthalates

The Agency has released draft technical support documents for diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), diethylhexyl phthalate (DEHP) and butyl benzyl phthalate (BBP), covering their physical chemistry and environmental fate, environmental hazard, and non-cancer hazard to human health. These documents implement a relative potency factor approach which relies on a common hazard outcome (in this case, reduced foetal testicular testosterone). The non-cancer hazard values will be used in future risk evaluations.

US Environmental Protection Agency (2025).
Draft non-cancer human health hazard assessment for diisobutyl phthalate (DIBP).
Draft non-cancer human health hazard assessment for dibutyl phthalate (DBP).
Draft non-cancer human health hazard assessment for diethylhexyl phthalate (DEHP).
Draft non-cancer human health hazard assessment for butyl benzyl phthalate (BBP).

…risk assessments for florylpicoxamid, thiophanate-methyl and carbendazim

The Health Effects Division (HED) of the US EPA has completed its human health risk assessment of the new fungicide active ingredient, florylpicoxamid. In studies where adverse effects were observed, a decrease in body weight was the most consistent. No adverse effects were seen in other studies at up to 1000 mg/kg bw/day. For the proposed uses of florylpicoxamid, the HED concluded that there were no dietary, occupational, residential or aggregate health risks of concern.

The HED also updated its draft human health risk assessment on thiophanate-methyl and carbendazim. Notably, it concluded that cancer risk for carbendazim is no longer a concern as the chronic RfD of 0.14 mg/kg bw/day would adequately account for it. Dietary exposure was not considered a concern for either compound.

US Environmental Protection Agency (2025).
Florylpicoxamid: human health risk assessment for the new active ingredient.
Thiophanate-methyl and carbendazim: amended draft human health risk assessment for registration review

OEHHA…

…new chemicals added to California's Proposition 65 list

The OEHHA has added two compounds to the list of chemicals known to the State of California to cause cancer and/or reproductive toxicity for the purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), effective from 3rd January 2025. Bisphenol S was added due to its male reproductive toxicity and vinyl acetate for cancer.

In addition, OEHHA has released a publication detailing the evidence on the carcinogenicity of vinyl acetate in support of its Proposition 65 listing.

California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (2024-2025).
Safe Drinking Water and Toxic Enforcement Act OF 1986. Proposition 65 list of carcinogens or reproductive toxicants. January 3, 2025.
Proposition 65. Evidence on the carcinogenicity of vinyl acetate. October 2024

CIR Panel meeting

Following its 170th meeting in September 2024, the CIR Expert Panel has released final safety assessments on 4-amino-*m*-cresol, butylated hydroxyanisole (BHA), t-butyl alcohol, lanolin, methyl isobutyl ketone, pentapeptides and toluene, summarising their chemical properties, manufacture and use, and the available toxicology data. In addition, two tentative safety assessments were released on copper gluconate and 2,4-diaminophenoxyethanol hydrochloride.

Cosmetic Ingredient Review (2024). Findings of 170th meeting held on 30th September – 1st October 2024.

Australia and New Zealand

AICIS evaluation statements on six substances/groups

The AICIS has finalised evaluation statements summarising the human health risks of the following chemicals:

- 1H-benzotriazole and its mono-substituted derivatives
- benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester (homosalate)
- bisphenol A
- extracts and essential oils primarily composed of methyl salicylate
- phenolic benzotriazoles
- tellurium and its inorganic compounds

Australian Industrial Chemicals Introduction Scheme (2024). Evaluation statements. 16 December 2024.

FSANZ application for propyl oligopeptidase

The FSANZ has recently called for comments on an application for the use of propyl oligopeptidase from Genetically Modified *Trichoderma reesei* as a processing aid. The call is supported by the publication of a risk and technical assessment that outlines the critical safety data. An oral Acceptable Daily Intake (ADI) of "not specified" was considered appropriate in the absence of any identifiable hazards.

Food Standards Australia and New Zealand (2024). Risk and technical assessment. Application A1311. Prolyl oligopeptidase from GM Trichoderma reesei as a processing aid.

Canada

Health Canada assessment of iron in drinking water

In a guideline technical document for iron, Health Canada confirmed its previous Tolerable Upper Intake Level (UL) of 45 mg/day (originally set by the US Institute of Medicine in 2001), based on gastrointestinal toxicity in humans seen at higher doses.

Health Canada (2024). Guidelines for Drinking Water Quality: Iron. Guideline Technical Document.

Cover image: A burger.

See also: Our article on page 7 relating to the EFSA assessment of perchlorate in food. This chemical can be found in a wide range of food products, such as baby food, fast food, and fruits and vegetables.

Further information: The toxicologists at bibra are experts at evaluating the hazards and risks associated with food products.

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