toxicology and regulatory news

October 2024

Interpreting EOGRT studies

Extended One-Generation Reproductive Toxicity (EOGRT) studies, as outlined in OECD Test Guideline 443, assess sexual function, fertility and development across multiple life stages. They also examine a range of endocrine-sensitive parameters to identify potential endocrine mechanisms underlying any observed effects. The assessment typically focuses on the parental (F0) and first-generation offspring (F1), with the option to include a second-generation (F2) if needed.

A scientist at the European Chemicals Agency (ECHA) has recently analysed the results of 112 EOGRT studies. The results show that the co-occurrence of treatment-related reproductive and endocrine effects across different life stages and generations within the same study is rather low. He therefore concluded that findings observed exclusively in one life stage and/or generation should not be dismissed due to a lack of continuity; rather, they should be evaluated on their own merits.

Bichlmaier I (2024). Differences in endocrine and reproductive responses to substance exposure across generations: highlighting the importance of complementary findings. Archives of Toxicology 98, 3215-3230.

Toxicology and Regulatory News

Contents

Toxicology and Regulatory News

Here at TRN, our aim is to keep the **bibra** toxicologists – and our wider readership – fully up to date on:

- Pertinent pronouncements on **toxicology** from national and international authorities, government departments and other expert groups
- Major health-related findings (including key legislative developments) that may affect **product safety** and **regulatory acceptability**

In this publication you will find brief commentaries written by **bibra** toxicologists that aim to bring to the attention of their peers important news relating to chemical toxicology and its associated regulatory application. The documents they highlight are identified by diligent and intelligent screening of a large number of key websites and publications from official bodies, national/international authorities, government departments and expert groups.

All documents – and others of a less-newsworthy but nonetheless important nature – are indexed with key terms and details are added to our searchable chemical toxicity database (TRACE).

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International

IARC monograph on aspartame, methyleugenol and isoeugenol

IARC has released its latest monograph assessing the carcinogenicity of aspartame, methyleugenol and isoeugenol. Following a review of all available evidence at a June 2023 meeting, methyleugenol was classified as "probably carcinogenic to humans" (Group 2A) based on "sufficient" evidence in experimental animals with "strong" mechanistic support. Isoeugenol and aspartame were both classified as "possibly carcinogenic to humans" (Group 2B). For isoeugenol, there was "sufficient" evidence in experimental animals with "inadequate" mechanistic support, whilst for aspartame there was "limited" evidence in humans and experimental animals and "limited" mechanistic support. For both methyleugenol and isoeugenol, the evidence in humans was "inadequate".

International Agency for Research on Cancer (2024). Aspartame, methyleugenol, and isoeugenol. IARC Monographs on the Identification of Carcinogenic Hazards to Humans. Volume 134.

Europe

EFSA...

...report on the immunotoxicity of per- and polyfluoroalkyl substances (PFAS)

PFAS are a class of synthetic chemicals widely used in industry. Subsequent to its 2020 opinion on the human health risks of PFAS in food, EFSA has filled data gaps on their immunotoxic potential using New Approach Methodologies (NAMs). The immunotoxic effects of four PFAS were investigated using a battery of *in vitro* assays. Physiological Based Kinetics (PBK) modelling was then used to extrapolate *in vitro* effective concentrations to external doses, and to estimate the immunotoxicity risk posed. Overall, the approach and results allowed successful filling of some of the existing data gaps and clearly demonstrated the usefulness of NAMs in providing supportive mechanistic information to predict PFAS immunotoxicity without the need for animal studies.

European Food Safety Authority (2024). EFSA Project on the use of NAMs to explore the immunotoxicity of PFAS. EFSA Supporting publication 2024:EN-8926.

...evaluation of human-identical milk oligosaccharides (HiMOs) as novel foods

In recent years, there has been an increase in the number of authorisations for the use of HiMOs as novel foods, resulting in concerns that the intake of these substances by infants from multiple HiMO-containing products may exceed that of human milk oligosaccharides (HMOs) from human breast milk, thus presenting a health risk. In light of this, EFSA has conducted revised intake assessments for HiMOs and HMOs. It concluded that, for exclusively formula-fed infants up to 16 weeks of age, the highest daily intakes of single HiMOs and the summed intake of all authorised / assessed HiMOs are within the HMO intake range. As such there are no safety concerns from their concurrent combined uses.

European Food Safety Authority (2024). Scientific and technical assistance report on the evaluation of human-identical milk oligosaccharides (HiMOs) as novel foods. EFSA Supporting publication 2024:EN-8994.

...in other news...

EFSA's Pesticides Peer Review Unit has launched open consultations on Member State assessment reports on the active substances, choline hydrogen phosphonate, and 8-methyldecan-2-yl propanoate, as well as on clodinafop in the context of endocrine disruption.

In addition, EFSA has peer reviewed the initial risk assessments of amidosulfuron (a post-emergence herbicide on winter cereals, spring cereals, flax and grass/pasture) and 1-methylcyclopropene (a plant growth regulator for post-harvest storage). The reports outline the reliable endpoints for use in regulatory risk assessment and identify remaining areas of concern and data gaps.

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

ECHA...

...requests evidence on asbestos fibres

ECHA has announced a call for evidence, by 16th October 2024, on the non-intentional presence of asbestos fibres, such as crocidolite and amosite, in natural minerals and products. The information received will be used to assess the need to prepare an Annex XV restriction dossier.

European Chemicals Agency (2024). Restriction proposals - current calls for comments and evidence.

…consultation on a REACH Substance of Very High Concern (SVHC)

Member State Competent Authorities (MSCAs) and ECHA may prepare Annex XV dossiers for the identification of SVHCs that are Carcinogenic, Mutagenic or Reprotoxic (CMR), Persistent, Bioaccumulative and Toxic (PBT), Very Persistent and Very Bioaccumulative (vPvB) or of an Equivalent Level of Concern (ELoC). With regard to human health, a dossier focusing on the reproductive toxicity of 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid has been released by the Austrian competent authority.

European Chemicals Agency (2024). Annex XV reports. Proposals for identification of substances of very high concern on the basis of the criteria set out in REACH Article 57.

…requests data on mammalian testing proposals for 14 REACH substances

ECHA has requested information from third parties, by 7th October 2024, on *in vivo* testing proposals for various REACH-registered substances, notably the following related to mammalian toxicity:

- (thiodi-4,1-phenylene)-bis-(diphenylbis)(OC-6,11)hexafluoroantimonate for genotoxicity
- 1,1,1-tri((1,3-dioxobutoxy)-methyl)-propane for repeated-dose oral toxicity and developmental toxicity
- 1,1,3,3-tetramethyldisiloxane for developmental toxicity
- 3-(diethoxymethylsilyl)propylamine for repeated-dose oral toxicity and developmental toxicity
- 3-[(phenylcarbamoyl)amino]phenyl 4-methylbenzene-1-sulfonate for repeated-dose oral toxicity and developmental toxicity
- 4,4'-isopropylidenediphenol, ethoxylated for genotoxicity and reproductive toxicity
- 4,4'-isopropylidenediphenol, ethoxylated, esters with fatty acids, coco for genotoxicity
- alpha,alpha,alpha-trifluorotoluene for repeated-dose oral toxicity and developmental toxicity
- cyclobutanecarboxylic acid, 1-[[(1,1-dimethylethoxy)carbonyl]amino]- for genotoxicity
- ethane-1,2-diyl palmitate for genotoxicity
- furan-2,5-dicarboxylic acid for reproductive toxicity
- hexamethylene diisocyanate oligomers, iminooxadiazindione for reproductive toxicity
- polysulfides, di-tert-butyl for repeated-dose oral toxicity and reproductive/developmental toxicity
- reaction mass of isopentyl hexadecanoate and isopentyl 8-(3-octyloxiran-2-yl)octanoate and isopentyl 8-(3-((3-pentyloxiran-2-yl)methyl)oxiran-2-yl)octanoate for reproductive/ developmental toxicity

European Chemicals Agency (2024). Testing proposals.

...consultations on 3-iodo-2-propynylbutylcarbamate and medetomidine

Calls for information, by 6th November 2024, have been issued on the biocidal active substances 3-iodo-2-propynylbutylcarbamate and medetomidine. This information will be used by the European Commission together with Member States to assess whether these substances are potential candidates for substitution and/or whether derogation from the exclusion criteria may be possible (for example, if it can be shown that the risk to human health, under worst-case conditions of use/exposure, is negligible).

European Chemicals Agency (2024). Consultations on potential candidates for substitution and on derogations conditions.

Classification and labelling...

...proposal for the CLH of choline hydrogen phosphonate

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, a CLH report has been submitted by the Belgian authority to standardise the classification and labelling of choline hydrogen phosphonate for several human health hazards. The deadline for comments is 25th October 2024.

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

...RAC opinions on the CLH of lithium salts and methyl methacrylate

Following a request from the European Commission, ECHA's Committee for Risk Assessment (RAC) has re-reviewed its earlier opinions on the harmonised classification of three lithium salts (the carbonate, chloride and hydroxide) and methyl methacrylate, concluding that classification for reproductive toxicity (Category 1A) and for respiratory sensitisation (Category 1), respectively, is warranted.

European Chemicals Agency (2024). Opinions of the RAC adopted under specific ECHA's Executive Director requests.

...RAC opinion on the CLH of talc

ECHA's RAC has considered an earlier CLH proposal from the Netherlands. The Committee agreed to the proposed classification for specific target organ toxicity - repeated exposure (Category 1), causing damage to the lungs via inhalation, but adopted a more severe classification for carcinogenicity (Category 1B, rather than Category 2) and without designating a particular exposure route. If adopted by the European Commission, this cancer classification will have significant ramifications for the use of talc, for example in the cosmetics sector.

ECHA (2024). Annex to news: Highlights from September RAC and SEAC meetings.

EMA...

...releases draft herbal monographs and final addenda

EMA's Committee on Herbal Medicinal Products (HMPC) has released herbal monographs on Ribwort plantain (*Plantago lanceolata*) leaf and pink rock-rose (*Cistus criticus*), both used to treat oral and throat irritation, and coughs. The monographs and list of references are released alongside related assessment reports containing relevant toxicity data.

The committee has also released addenda to existing assessment reports on mastic (*Pistacia lentiscus*) gum and refined soyabean (*Glycine max*) oil. These describe new data made available since the previous evaluations, which were not considered sufficient to justify full revisions.

European Medicines Agency (2024). EU herbal monographs and associated assessment reports, references and addenda.

...more Acceptable Intakes (AIs) for nitrosamines in pharmaceuticals

Pharmaceuticals should be manufactured in such a way that the presence of nitrosamines is prevented or mitigated as much as possible. In an updated appendix to its question-and-answer document on nitrosamine impurities in human medicinal products, EMA has established AIs for eleven more nitrosamines, and updated four of its existing entries, bringing the current number of AIs in this appendix up to 172.

European Medicines Agency (2024). Appendix 1: Acceptable intakes established for N-nitrosamines. Last updated 4 September 2024. EMA/393815/2024/Rev.6.

SCCS finalises opinion on skin sensitisation potential of citral

Scientists from the International Fragrance Association (IFRA) used a refined Quantitative Risk Assessment (QRA2) methodology, developed as part of the International Dialogue for the Evaluation of Allergens (IDEA) project, to define safe levels of exposure to the fragrance allergen, citral. In its (now finalised) evaluation of the submitted dossier to establish whether these levels provide an adequate level of protection to consumers, SCCS concluded that citral can be considered safe in relation to the induction of skin sensitisation at the proposed concentrations (up to 4.2%, depending on product type). It did note, however, that some aspects of the QRA2 methodology needed clarification and refinement.

European Commission. Scientific Committee on Consumer Safety (2024). Opinion on citral (CSA No. 5392-40-5, EC No. 226-394-6) sensitisation endpoint. SCCS/1666/24. Final opinion.

BfR evaluation of food supplements containing melatonin

Melatonin is an endogenous hormone that is involved in controlling the human sleep-wake rhythm, and can also be found in small amounts in certain foods, particularly of plant origin. BfR has expressed concern regarding the uncontrolled use of melatonin in oral supplements, particularly over a long-term period. Exposure groups at particular risk were considered to include children, pregnant or breast-feeding women, patients with autoimmune conditions or epilepsy, those with altered liver/kidney function, and those with an increased risk of type 2 diabetes. Interactions with prescribed medications were also considered possible.

German Federal Institute for Risk Assessment (BfR) (2024). [Food supplements containing melatonin: BfR points out possible health risks] (in German). Statement 038/2024.

DECOS...

...recommended occupational exposure limit for carbon monoxide

DECOS has derived a Health-Based Recommended Occupational Exposure Limit (HBR-OEL) of 7.5 mg/m^3 air (6.4 ppm) for carbon monoxide. The critical effect was an increased risk of myocardial infarction. The HBR-OEL is three times lower than the current Scientific Committee on Occupational Exposure Limit (SCOEL) value of 23 mg/m^3 (20 ppm). A Short-Term Exposure Limit (STEL) could not be calculated.

Dutch Expert Committee on Occupational Safety (2024). Carbon monoxide. Health-based recommended occupational exposure limit. Nr. 2024/12.

...draft advisory reports on molybdenum and styrene

Occupational exposure to molybdenum and its inorganic compounds can occur following their release into the air during industrial processes, such as the production of cast iron and stainless steel. DECOS has assessed the potential adverse fertility and developmental effects of exposure on workers. While human data were insufficient, reductions in sperm count and quality in rodents led DECOS to recommend the classification of molybdenum and its selected inorganic compounds as suspected human reproductive toxins (Repr. 2) under CLP Regulation (EC) 1272/2008.

DECOS also assessed the mutagenicity and carcinogenicity of styrene, with occupational exposure possible in the production of plastic products and epoxy resins. Laboratory evidence of somatic cell DNA and chromosomal damage led the committee to recommend that styrene be classified as a suspected germ cell mutagen (Muta. 2). Limited evidence of carcinogenicity in humans and laboratory animals supported its classification as a substance presumed to be carcinogenic to humans (Carc. 1B) under CLP.

Dutch Expert Committee on Occupational Safety (2024).
Molybdenum and selected inorganic molybdenum compounds. Evaluation of the effects on reproduction, recommendation for classification. Public draft.
Styrene. Evaluation of the carcinogenicity and mutagenicity. Public draft.

...work with NEG on occupational exposure limits for crystalline silica

Respirable crystalline silica (RCS) can pose serious risks, including silicosis and lung cancer, to workers in a range of different industries including mining, farming, construction, foundry processes, and the production of glass, artificial stone, ceramics and cement. Using human lung cancer data and an assumption of non-threshold carcinogenicity, Dutch (DECOS) and Norwegian (NEG) experts have together derived Health-Based Calculated Occupational Cancer Risk Values (HBC-OCRVs) for RCS. Figures of 0.00038 mg/m^3 (corresponding to four additional deaths from lung cancer per 100,000 workers) and 0.0363 mg/m^3 (four additional deaths from lung cancer per 1000 workers) were established as target (low) and prohibition (high) risk levels, respectively. It was considered that the setting of such Occupational Exposure Limits (OELs) based on lung cancer would also protect against other RCS-induced toxicity.

Dutch Expert Committee on Occupational Safety (2024). Respirable crystalline silica. Evaluation of health hazards as basis for an occupational exposure limit.
Nordic Expert Group for Criteria Documentation of Health Risks from Chemicals and the Dutch Expert Committee on Occupational Safety (2024). 156. Respirable crystalline silica. No. 2024;58(2).

Danish EPA...

...assessment of substances in non-biocidal antifouling paints

Private boats are regularly painted with antifouling paints or coatings to prevent the accumulation of aquatic life on the hull. Most of these paints and coatings contain biocides which can be released into the marine environment, harming both target and non-target organisms. The Danish EPA has carried out an assessment of non-biocidal antifouling paints to see whether these were better for human health and the environment. Of the 13 paints assessed, seven substances of concern for human health were identified, and these were evaluated further. Health effects related to the use of some non-biocidal antifouling products could not be excluded, with particular risks posed by the constituents 4-methylpentan-2-one (MIBK) and 4-methylpentan-2-oxime.

Danish Environmental Protection Agency (2024). Survey and risk assessment of chemical substances in non-biocidal antifouling paints for private pleasure boats. Survey of chemical substances in consumer products No. 197. September 2024.

...consideration of food proteins in cosmetic products

While food-based ingredients are widely used in the production of cosmetic products, dermal exposure to these products, particularly early in life (before oral tolerance has been established) can result in the development of new food allergies. The Danish EPA has assessed the risk of food proteins in cosmetic products, with particular focus on products aimed at children. It was concluded that current knowledge does not allow for the setting of safe limits for food proteins in children's cosmetic products, particularly given uncertainties over the influence of skin condition and exposure duration, and on the correlation between allergen potency and the doses causing sensitisation. However, emphasis was placed on the importance of establishing oral tolerance through ingestion before exposure to new proteins via the skin.

Danish Environmental Protection Agency (2024). Mapping and risk assessment of food proteins in cosmetic products. Survey of chemical substances in consumer products No. 196. August 2024.

United Kingdom

COT statement on the safety of titanium dioxide as a food additive

In its 2021 opinion, the EFSA Panel on Food Additives and Flavourings (FAF) concluded that the use of titanium dioxide (E171) as a food additive could no longer be considered safe primarily due to genotoxicity concerns associated with titanium dioxide nanoparticles. The COT and COM have subsequently conducted safety assessments of titanium dioxide, concluding that there was little evidence in the literature to suggest that there was a health concern related to genotoxicity induction by (micro-sized) titanium dioxide, particularly via the oral route. The COT has now released the executive summary of its most recent review of titanium dioxide, which describes the establishment of a new oral Health-Based Guidance Value (HBGV) of 10 mg/kg bw/day derived from repeated-dose toxicity studies in rats in which no adverse effects were observed at up to 1000 mg/kg bw/day. Overall, it was concluded that dietary exposure to food-grade titanium dioxide is unlikely to pose a health risk to the UK population.

Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (2024). COT statement on the Safety of titanium dioxide (E171) as a food additive. Executive summary.

COT and FCMJEG assessment of tetramethyl bisphenol F diglycidyl ether (TMBF-DGE)

The safety-in-use of TMBPF-DGE in coatings for canned food packaging materials has been evaluated by COT and FCMJEG. Although there were no genotoxicity data on TMBF-DGE, its epoxy resin was clearly mutagenic and clastogenic *in vitro*, while a follow-up *in vivo* test showed no signs of genotoxicity. While there were some uncertainties concerning the polyploidy observed in an *in vivo* spermatogonial chromosomal aberration test, TMBF-DGE was considered to be non-genotoxic *in vivo*. A HBGV was not established due to the lack of a long-term toxicity study and other database deficiencies. However, based on a No-Observed-Adverse-Effect Level (NOAEL) of 100 mg/kg bw/day from an oral 28-day rat study and a resultant Margin of Exposure of >67,000, it was concluded that there were no safety concerns for TMBPF-DGE at the current estimated intakes resulting from its use in can coatings.

Joint statement by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and the Joint Expert Working Group on Food Contact Material (FCMJEG) (2024). Safety assessment of tetra-methyl bisphenol F diglycidyl ether (TMBPF-DGE) for use in coating in canned food packaging materials.

ACNFP September meeting on two novel foods

At its most recent meeting, the ACNFP discussed papers on dry cacaofruit cascara (the outer husk of the cacao fruit) and krill protein hydrolysate as novel foods. The available documents include their compositions, uses and intakes, as well as nutritional and toxicological information.

The Advisory Committee on Novel Foods and Processes (2024). 168th Meeting of the ACNFP 17th and 18th September 2024. ACNFP/168/04-07.

UK HSA updates toxicological overviews of chlorine and toluene

In its 'Chemical Hazards Compendium' collection, the UK HSA has recently updated its toxicological overviews of the potential health effects of exposure to chlorine and toluene.

UK Health Security Agency (2024). Chemical Hazards Compendium. Toxicological overviews for chlorine and toluene.

United States

US FDA...

...guidance on nitrosamine impurities in pharmaceuticals

The US FDA has updated its guidance on the control of nitrosamine impurities in human drugs. The revised guidance now describes two general structural classes of nitrosamine impurities: small-molecule nitrosamine impurities that are not structurally similar to an Active Pharmaceutical Ingredient (API) and Nitrosamine Drug Substance-Related Impurities (NDSRIs) which are structurally similar to the API. The guidance describes their potential root causes and mitigation strategies to prevent or reduce their presence in drug products.

US Food and Drug Administration (2024). Control of nitrosamine impurities in human drugs. Guidance for Industry. Revision 2.

...draft guidance on chemical analysis for biocompatibility assessment

Draft guidance on chemical analysis for the biocompatibility assessment of medical devices has been issued by the US FDA. This document describes the recommended methodological approaches for chemical characterisation, including screening for extractables to evaluate certain biocompatibility

endpoints in a toxicological risk assessment, and chemical equivalency comparison to a device with previously demonstrated biocompatibility. It provides guidance on information gathering, test article extraction, chemical analysis and data reporting.

US Food and Drug Administration (2024). Chemical analysis for biocompatibility assessment of medical devices. Draft guidance for industry and food and drug administration staff.

US EPA...

...IRIS review of formaldehyde

The US EPA has finalised its IRIS review of formaldehyde, which summarises the key scientific issues and presents toxicological reference values. In humans, the existing evidence demonstrates that inhalation of formaldehyde leads to increased sensory irritation and respiratory tract pathology, and is likely to cause decreased pulmonary function, an exacerbation of existing asthma symptoms, and increased allergic responses. The Agency concluded that formaldehyde is carcinogenic to humans by the inhalation route of exposure, and derived a Reference Concentration (RfC) of 0.007 mg/m^3 and an Inhalation Unit Risk (IUR) of 1.1 x 10^{-2} per mg/m^3.

US Environmental Protection Agency (2024). IRIS Toxicological review of formaldehyde (inhalation). EPA/635/R-24/162aF.

...draft risk evaluation for diisononyl phthalate (DINP)

The US EPA has recently released a draft risk evaluation on DINP, a substance primarily used as a plasticiser in polyvinyl chloride (PVC). The Agency's preliminary determination was that DINP has the potential to cause developmental toxicity, particularly in the developing male reproductive system (phthalate syndrome), cancer at higher levels of exposure, and liver toxicity. The EPA concluded that DINP does not pose unreasonable risk of injury to the general population, although it does present an unreasonable risk to workers in two out of the 47 conditions of use evaluated (the industrial use in adhesives and sealant chemicals, and in construction, paint, and metal products) and to consumers in one condition of use (furnishing, cleaning, treatment/care products).

US Environmental Protection Agency (2024). Draft Risk Evaluation for Diisononyl Phthalate (DINP) CASRNs: 28553-12-0 and 68515-48-0. EPA Document# EPA-740-D-24-015.

NTP review of fluoride

Fluoride is a common chemical in the environment and human exposure comes primarily from drinking water, food, beverages and dental products. The NTP, having shown in 2016 that fluoride could potentially affect learning and memory, conducted a systematic review of the literature to evaluate the relationship between fluoride exposure and neurodevelopmental and cognitive effects in humans. It concluded, with low confidence, that fluoride exposure is associated with adverse effects on adult cognition and, with moderate confidence, that high exposures (those above the WHO guideline level of 1.5 mg/L) are consistently associated with lower IQ in children.

National Toxicology Program (2024). NTP monograph on the state of the science concerning fluoride exposure and neurodevelopment and cognition: a systematic review. NTP Monograph 08. August 2024.

Australia and New Zealand

APVMA…

…public release summary on cyclobutrifluram

A public release summary reviews the toxicological effects of cyclobutrifluram, an active constituent used in nematicides. An Acceptable Daily Intake (ADI) of 0.08 mg/kg bw was established based on a chronic dietary study in rats. An Acute Reference Dose (ARfD) was considered unnecessary due to the compound's low acute oral toxicity and the absence of neurological effects and developmental toxicity.

Australian Pesticides and Veterinary Medicines Authority (2024). Public Release Summary on the evaluation of the new active cyclobutrifluram in the product TREFINITI Turf Nematicide. APVMA product number 91438/132224. August 2024.

…final pesticide technical report for diazinon

APVMA has released a final review of diazinon, an active constituent in insecticides and acaricides, following human health and environmental concerns. The report concludes that both the previously established ADI of 0.001 mg/kg bw and the ARfD of 0.01 mg/kg bw should remain.

Australian Pesticides and Veterinary Medicines Authority (2024). Diazinon final review technical report. September 2024.

FSANZ supporting documents for four substances

FSANZ has released supporting documents for the risk assessment of the following compounds:

- 2-methyloxolane as a processing aid
- d-allulose as a novel food
- glucoamylase (from Genetically Modified (GM) *Aspergillus niger*) as a processing aid
- triacylglycerol lipase (from GM *Komagataella phaffi*) as a processing aid

An oral ADI of "not specified" was considered appropriate for glucoamylase and d-allulose, while an ADI of 1.0 mg/kg bw was derived for 2-methyloxolane. An ADI was not calculated for triacylglycerol lipase. All substances were considered safe under the proposed conditions of use.

Food Standards Australia New Zealand (2024). Risk and technical assessments. Supporting documents.

Canada

Health Canada evaluation of PFAS in drinking water

In order to reduce the potential exposure to per- and polyfluoroalkyl substances (PFAS) through drinking water while a reassessment of the guidelines and screening values are being completed, Health Canada has released a document outlining the objectives for PFAS levels in drinking water. An objective value (a target maximum concentration) of 30 ng/L for the sum of 25 specific PFAS was established.

Health Canada (2024). Objective for Canadian drinking water quality. Per- and polyfluoroalkyl substances. August 2024.

Cover image: Halloween chocolates.

See also: Our article on page 12 relating to the ACNFP meeting on two novel foods, one of which was dry cacaofruit cascara (the outer husk of the cacao fruit).

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

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