toxicology and regulatory news

April 2024

The US EPA's TSCA evaluation of formaldehyde

Formaldehyde is a colourless, flammable gas with a strong odour that is found ubiquitously in the environment. It is used in the manufacture of many products, including composite wood, plastics, paints, adhesives, and sealants, from which it can be released over time.

On 15th March 2024, the US EPA released a draft risk evaluation of formaldehyde under the Toxic Substances Control Act (TSCA) for public comment and peer review. The Agency's preliminary findings were that "formaldehyde presents an unreasonable risk of injury to human health", although as it is only certain activities using formaldehyde and formaldehyde-containing products that present these risks, they will not apply to everyone. The unreasonable risks arising from most of the occupational and consumer uses are for non-cancer effects, with just one occupational activity potentially posing an unreasonable risk due to nasopharyngeal cancer.

In view of the high production volume of this compound (about 21 million tonnes/year worldwide), this draft risk evaluation is expected to attract a lot of attention. Public comments will be accepted for a period of 60 days following its publication. A virtual peer review public meeting will be held for the Science Advisory Committee on Chemicals (SACC) to discuss the draft on 20th–23rd May 2024.

US Environmental Protection Agency (2024). Draft risk evaluation for formaldehyde under the TSCA.

Toxicology and Regulatory News

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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
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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

ISO updates 18562 series

ISO has revised Parts 1-4 of the ISO 18562 series on the biological evaluation of medical devices that come into contact with breathing gas pathways, addressing the potential contamination of the gas stream with hazardous particulates, volatiles and leachables. The updates of all Parts of the series include clarification of terms and definitions, and the addition of informative mapping annexes.

For Part 1, noteworthy changes include: expansion of patient subgroups to include premature infants and adolescents, introduction of the "inhalation dose" metric, updates to the Threshold of Toxicological Concern (TTC) values, expansion of the range of Volatile Organic Substances (VOS) required to be analysed, and clarification of appropriate breathing gas volumes. In Part 3, the VOS are now separated into groups based on boiling point. And finally, Part 4 now describes how to (i) determine the volume of condensate that might reach the patient and (ii) calculate the resultant exposure to any potential leachables.

International Organization for Standardization (2024).
Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process. ISO 18562-1:2024(en). Second edition.
Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter. ISO 18562-2:2024(en). Second edition.
Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic substances. ISO 18562-3:2024(en). Second edition.
Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate. ISO 18562-4:2024(en). Second edition.

ICH updated guideline on residual solvents

The latest iteration of ICH's guideline on residual solvents in pharmaceuticals, Q3C(R9), has now reached "step 4" of the formal adoption process. Minor revisions have been made to include consideration of solvent volatility for analytical methods.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (2024). ICH harmonised guideline impurities: guideline for residual solvents Q3C(R9). Current Step 4 version dated 24th January 2024.

FAO/WHO framework for evaluating exemptions for food allergens

The FAO and WHO have released Part 4 of their series on risk assessment of food allergens. The Joint Expert Committee has developed a framework intended to inform evaluators as to whether certain foods, such as highly refined foods, or ingredients derived from foods known to cause allergic reactions, can be exempted from mandatory declaration and labelling. The Committee felt that the current accepted exemptions have a history of safe consumption, and that dividing the relevant Reference Dose (RfD) value by 30 appeared to provide an adequate Margin of Exposure (MoE) for safety assessment under reasonable and worst-case consumption scenarios. As such, those foods assessed by this process and meeting the threshold criterion (RfD/30) may not require clinical testing to establish safety and may be exempt from mandatory declaration.

Food and Agriculture Organisation of the United Nations and World Health Organization (2024). Risk assessment of food allergens – Part 4: Establishing exemptions from mandatory declaration for priority food allergens. Food Safety and Quality Series, No. 17. Rome.

JECFA summary and conclusions on certain veterinary drug residues

The summary and conclusions from JECFA's ninety-eighth meeting (held in February 2024) are now available. At this meeting, the Committee evaluated the safety of clopidol and fumagillin, and completed the safety assessment of imidacloprid. The following decisions were of particular interest:

- clopidol: the Committee set an Acceptable Daily Intake (ADI) of 0-0.04 mg/kg bw. The setting of an Acute Reference Dose (ARfD) was not considered necessary.
- fumagillin: an ADI of 0-0.003 mg/kg bw was set for fumagillin itself and 0-0.02 mg/kg bw for the dicyclohexylamine (DCH) salt. Although the Committee considered it unnecessary to set an ARfD for fumagillin, it established an ARfD of 0.7 mg/kg bw for DCH.
- imidacloprid: the ADI was set at 0-0.05 mg/kg bw and the existing ARfD of 0.09 mg/kg bw was retained.

Joint FAO/WHO Expert Committee on Food Additives (2024). Ninety-eighth meeting (Safety evaluation of certain veterinary drug residues). FAO headquarters, 20–29 February 2024. Summary and conclusions. Issued on 11th March 2024.

JMPR evaluation of pesticide residues

Full reports are now available of JMPR's September 2023 meeting. The group evaluated 35 pesticides, including seven new ones (1,4-dimethylnaphthalene, florylpicoxamid, fluazinam, isocycloseram, isotianil, mepiquat chloride and tricyclazole) and a re-evaluation of four compounds for toxicity and/or residue data. ADIs and ARfDs were established where possible, and Maximum Residue Levels (MRLs) were recommended for each of the pesticides.

Joint FAO/WHO Meeting on Pesticide Residues (2024). Report 2023: Pesticide residues in food.

Europe

EFSA...

...draft opinion on the Tolerable Upper Intake Level (UL) for iron

Systematic reviews of the literature examining the relationship between high iron intake and the risks of chronic disease, gastrointestinal effects and adverse effects in pregnancy, infancy and young childhood established that systemic iron overload in humans leads to iron accumulation in organs, such as the liver, and subsequent toxicity. However, based on the available data, a UL could not be derived. The only indicator of excess iron intake for which a dose-response could be characterised was black stools (reflecting unabsorbed iron). Although not an adverse effect per se, this provided a conservative endpoint for establishing safe levels of intake. Based on human intervention studies in which black stools did not occur following iron supplementation, safe intake levels from all sources were established, 40 mg/day for adults (including pregnant and lactating women) and 10-35 mg/day for children and adolescents aged 1-17 years. As infants below 1 year have a higher iron requirement during months 7-11, the safe intake level for iron from food supplements and fortified foods was determined as 5 mg/day for this age group (7-11 months), which was then extended to cover infants aged 4-6 months too. The NDA Panel noted that these safe levels of intake are more limited than a UL because the intake level at which the risk of adverse effects starts to increase is not defined.

European Food Safety Authority (2024). Panel on Nutrition, Novel Foods and Food Allergens (NDA). Draft scientific opinion on the tolerable upper intake level for iron.

...in other news...

EFSA's Pesticides Peer Review Unit has launched open consultations on Member State assessment reports on the active substances, chlorantraniliprole, mandestrobin, quinmerac, sedaxane and sulcotrione, as well as on buprofezin in the context of endocrine disruption.

European Food Safety Authority (2024). Pesticides Peer Review Unit.

The FEEDAP Panel has released opinions on the safety and efficacy of the following animal feed additives:

- carboxymethyl cellulose
- ethyl cellulose
- hydroxypropyl cellulose
- hydroxypropyl methyl cellulose
- methyl cellulose
- microcrystalline cellulose
- monensin sodium
- propyl gallate

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

ECHA...

...consults on two Substances of Very High Concern (SVHCs)

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). The latest dossiers, released by authorities in France and Norway, cover triphenyl phosphate for endocrine disruption (environment) and bis(alpha,alpha-dimethylbenzyl) peroxide for reproductive toxicity, respectively.

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.

…invites comments on the POPRC risk management evaluation of chlorpyrifos

The Persistent Organic Pollutants Review Committee (POPRC), in its draft risk evaluation of chlorpyrifos, stated that this pesticide "is likely, as a result of long-range environmental transport, to lead to significant adverse effects on human health and/or the environment such that global action is warranted". The Committee concluded that chlorpyrifos should be listed as a Persistent Organic Pollutant (POP) under the Stockholm Convention in Annex A (without exemptions) or Annex B (with specific exemptions). ECHA invites comments on this report by 8th May 2024.

European Chemicals Agency (2024). Risk management evaluation of chlorpyrifos. Second draft. February 2024.

…requests data on mammalian *in vivo* testing proposals for eight substances

ECHA has requested information from third parties by 22nd April 2024 on testing proposals for various REACH registered substances, notably the following related to mammalian toxicity:

- [3-(2,3-epoxypropoxy)propyl]trimethoxysilane for reproductive toxicity
- 2-[(2-methoxy-4-nitrophenyl)azo]-*N*-(2-methoxyphenyl)-3-oxobutyramide for repeated-dose inhalation toxicity
- 3-[(5-cyano-6-hydroxy-1,4-dimethyl-2-oxo-1,2-dihydropyridin-3-yl)diazenyl]phenyl benzoate for *in vivo* genotoxicity
- 4-methylcyclohexanone for repeated-dose oral toxicity and developmental toxicity
- calcium 4-chloro-2-(5-hydroxy-3-methyl-1-(3-sulfonatophenyl)pyrazol-4-ylazo)-5-methylbenzenesulfonate for developmental toxicity
- copper (I, II) sulfite for *in vivo* genotoxicity
- *N*-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide for repeated-dose inhalation toxicity and developmental toxicity
- *N,N,N',N'*-tetramethyl-2,2'-oxybis(ethylamine) for reproductive toxicity and developmental toxicity

European Chemicals Agency (2024). Testing proposals for submission by 22nd April 2024.

Classification and labelling…

…proposal for Harmonised Classification and Labelling (CLH) of four 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 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 authorities in France and Germany, to standardise the classification and labelling of:

- 1,3-diphenylguanidine for several human health hazards
- 2-(2H-benzotriazol-2-yl)-p-cresol for skin sensitisation
- 2,2'-iminodiethanol for several human health hazards
- benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene for reproductive toxicity
- reaction products of diphenylamine with branched nonene for reproductive toxicity

The deadlines for comments are 3rd, 10th and 17th May 2024.

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

…RAC opinion on the CLH of penconazole

ECHA's Committee for Risk Assessment (RAC) has drafted its opinion on the Harmonised Classification and Labelling (CLH) of penconazole, considering an earlier proposal from a Norwegian authority. The report covers a wide range of endpoints for this fungicide.

European Chemicals Agency (2023). Opinion proposing harmonised classification and labelling at EU level of penconazole. 30th November 2023.

EMA revises herbal monographs on fumitory and fennel

EMA's Committee on Herbal Medicinal Products (HMPC) has revised its herbal monographs on fumitory (*Fumaria officinalis*), used to aid digestive issues, and on bitter and sweet fennel (*Foeniculum vulgare* and *dulce*), for gastrointestinal complaints, menstrual cramps, and coughs and colds. The monographs are released alongside related assessment reports containing relevant toxicity data.

European Medicines Agency (2023-4). EU herbal monographs and associated assessment reports and references.

Cosmetics Europe and EFfCI guidance on the EU microplastics restriction

Under regulation (EU) 2023/2055, amending the REACH Regulation (EC) 1907/2006, synthetic polymer microparticles (SPM) are subject to restriction, including in cosmetics. Following on from this, Cosmetics Europe and EFfCI have released guidance to help companies interpret the new requirements.

Cosmetics Europe and the European Federation for Cosmetic Ingredients (2024). CE/EFfCI Guidance on the EU microplastics restriction. Version 1: February 2024.

SCCS opinion on hydroxypropyl *p*-phenylenediamine

SCCS has released a final opinion on the safety of hydroxypropyl *p*-phenylenediamine and its dihydrochloride salt in oxidative hair-colouring products. Although they were described as moderate skin sensitisers (based on laboratory animal data), and mild to moderate eye irritation could also not be excluded, both chemicals were considered safe at up to a maximum on-head concentration of 2%.

European Commission. Scientific Committee on Consumer Safety (2024). Opinion on hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165) (CAS/EC No. 73793-79-0/827-723-1 and 1928659-47-5/-). SCCS/1659/23. Final opinion.

ECETOC...

...recommendations on dose level selection for DART studies

An ECETOC working group has considered the selection of dose levels for Developmental And Reproductive Toxicity (DART) studies. While guidance from the ECHA recommends the selection of a high dose expected to cause clear signs of toxicity in parental animals, the ECETOC group argues that excessive dosing can induce secondary effects not relevant to human health assessments.

Lewis RW *et al.* (2024). European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). Considerations for the development of guidance dose level selection for developmental and reproductive toxicity studies. Regulatory Toxicology and Pharmacology 148, 105585.

…best practices in building quantitative Adverse Outcome Pathways (qAOPs)

An AOP is a sequence of steps leading from a Molecular Initiating Event (MIE), such as a chemical binding to a receptor, to a particular adverse outcome, such as cancer. Incorporating a quantitative element can enable AOPs to provide points of departure for risk assessment. ECETOC has released a report from its workshop on the best practices for developing qAOPs. Among its recommended next steps is the development of harmonised guidance on qAOP validation and reporting.

European Centre for Ecotoxicology and Toxicology of Chemicals (2024). Exploring best practices in building quantitative AOPs (qAOPs). Workshop Report No. 38.

RIVM…

…releases guidance on double-stranded RNA-based pesticides

RNA interference (RNAi) is a biological process in which small RNA molecules inhibit gene expression, and this process is behind the development of pesticides containing double-stranded RNA (dsRNA). RIVM has released guidance on the risk assessment of dsRNA-based sprayable pesticides, which may be inhaled or come into contact with the skin. This provides an overview of RNAi, highlights specific issues with dsRNA-based products, and explains how exposure, human health and environmental risk assessments may differ from those of conventional chemical pesticides.

Dutch National Institute for Public Health and the Environment (RIVM) (2024). Risk assessment of plant protection products based on dsRNA/RNAi. RIVM report 2023-0456.

…evaluates the human health risks of three herbal preparations

RIVM has evaluated the human health effects of the following herbal preparations:

- Ashwagandha (*Withania somnifera*)
- Iboga (*Tabernanthe iboga*)
- toothed clubmoss (*Huperzia serrata*)

It concludes that all may be harmful to human health and none should be consumed, especially (in the case of Ashwagandha and toothed clubmoss) during pregnancy.

Dutch National Institute for Public Health and the Environment (RIVM) (2024). Risk assessments of herbal preparations containing *Huperzia serrata*, *Withania somnifera* or *Tabernanthe iboga*. RIVM letter reports 2024-0028-30.

BfR assesses the health effects of n-hexyl phthalates

Following evidence of increased exposure in humans, BfR has released a preliminary assessment of the health effects of mono-n-hexyl phthalate (MnHexP) and its metabolic precursors (primarily di-n-hexyl phthalate, DnHexP). Current levels of urinary MnHexP did not give rise to health concerns. An additional assessment of sunscreen products using UV filters contaminated with up to 0.03% DnHexP found health impairment to be unlikely. BfR noted that, regardless of these assessments, DnHexP is toxic to reproduction and development, and further work should be undertaken to determine its source so that intake levels can be reduced.

German Federal Institute for Risk Assessment (BfR) (2024). [MnHexP in urine samples: initial assessments of health effects (in German).] Statement 011/2024.

United Kingdom

COM evaluation of titanium dioxide genotoxicity studies

At its February meeting, the COM reviewed the *in vitro* and *in vivo* genotoxicity studies considered by the European Food Safety Authority (EFSA) in its assessment of titanium dioxide as a food additive, with a focus on the relevance and reliability of each individual study. The Committee found that, of the eleven *in vivo* studies, only two micronucleus tests (neither of which detected any signs of genotoxic activity) had a sufficiently robust methodology. It was concluded that there is little evidence that titanium dioxide is genotoxic *in vitro* or *in vivo*.

Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (2024). 29th February 2024: agenda and meeting papers. MUT/2024/01-02.

COT statement on vitamin D in infant and follow-on formula

The COT has assessed vitamin D exposure levels in formula-fed infants and children, alone and in combination with supplements and/or breast milk. It was concluded that an increase in the minimum vitamin D content of infant and follow-on formula to 2 µg/100 kcal would not give rise to any toxicological concerns.

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (2024). Statement on vitamin D exposure levels in formula fed infants and children. TOX 22-27. Final statement.

FSA risk assessment of microcystins in fish

Microcystins are cyanobacterial toxins found in fish. The FSA has recently evaluated the human health risks of consuming microcystin-contaminated fish. Although the individual microcystins may differ in their toxic potencies, estimated dietary exposures (total mycotoxins) were deemed unlikely to exceed the World Health Organization (WHO) provisional Tolerable Daily Intake (pTDI) for microcystin-LR of 0.04 µg/kg bw. Adverse effects were therefore not anticipated.

Food Safety Authority (2024). Microcystins in fish. Executive summary.

United States

US EPA...

...assessment on malathion

As part of its periodic review of registered substances, the US EPA has revised its assessment of the organophosphate insecticide, malathion. The document summarises exposure estimates, describes the potential risk to different exposed populations (such as workers or consumers), and discusses its mode of action and its potential to cause endocrine disruption. It also describes a Physiologically Based PharmacoKinetic PharmacoDynamic (PBPK-PD) model used to predict human points of departure for different lifestages and exposure scenarios and to refine uncertainty factors. No concerns were identified for any potential route of malathion (or its active metabolite malaoxon) from registered uses, including consideration of aggregate risks.

US Environmental Protection Agency (2024). Malathion: Updated draft human health risk assessment for registration review. EPA-HQ-OPP-2009-0317-0161.

...IRIS review on perfluorononanoic acid (PFNA) and related salts

The US EPA has released a draft IRIS review on PFNA and its related salts, which summarises the key scientific issues and establishes new toxicological reference values. In humans, the ingestion of PFNA causes developmental effects. PFNA is also considered likely to cause hepatic and male reproductive effects. The US EPA derived a lifetime and subchronic oral Reference Dose (RfD) of 7×10^{-9} mg/kg bw/day based on decreased birth weight observed from a ten-study meta-analysis in humans. The US EPA was

unable to assess the carcinogenic potential of PFNA by the oral or inhalation routes of exposure, due to inadequate information.

US Environmental Protection Agency (2024). IRIS toxicological review of perfluorononanoic acid (PFNA) and related salts. EPA/635/R-24/031a. External Review Draft. March 2024.

OEHHA issues a cancer risk factor report on isoprene

The OEHHA has released a draft technical support document describing the available cancer data on isoprene and deriving a cancer Inhalation Unit Risk (IUR) factor, used to estimate lifetime cancer risks. The proposed IUR for isoprene is 5.4×10^{-6} per µg/m^3. A cancer slope factor of 1.9×10^{-2} per mg/kg bw/day was also calculated.

California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (2024). Isoprene. Cancer inhalation unit risk factor technical support document for cancer potency factors. Appendix B. Air Toxics Hot Spots Program. Public Review Draft. February 2024.

California lawmakers plan to prohibit certain phthalate-containing medical devices

California legislators have proposed a novel bill to ban certain medical devices containing di-(2-ethylhexyl) phthalate (DEHP). This includes the prohibition of in-state manufacture, sale or distribution of IntraVenous (IV) solution containers made with intentionally added DEHP from 1 January 2026, extending to IV tubing for use in neonatal intensive care units, nutrition infusions, or oncology treatment infusions from 1 January 2031. The bill also notes that other ortho-phthalates are toxic chemicals and therefore the legislation would also prevent the replacement of DEHP with any of the following substances:

- benzyl butyl phthalate
- di-butyl phthalate
- di-cyclohexyl phthalate
- di-ethyl phthalate
- di-isobutyl phthalate
- di-isodecyl phthalate
- di-isoheptyl phthalate
- di-isononyl phthalate
- di-n-hexyl phthalate
- di-n-octyl phthalate
- di-n-pentyl phthalate

California Legislative Information (2024). Assembly bill No. 2300.

Australia and New Zealand

AICIS assessment statements on a number of substances

The AICIS has released assessment statements summarising the human health risks of the following chemicals:

- 1,3-dioxane, 2-(3,3-dimethyl-1-cyclohexen-1-yl)-2,5,5-trimethyl
- 2H-pyran, 3,6-dihydro-4-methyl-2-[(2,2,3- trimethyl-3-cyclopenten-1-yl)methyl]-
- 2H-pyran, 3-heptyltetrahydro-
- 2H-pyran, 5,6-dihydro-4-methyl-2-[(2,2,3- trimethyl-3-cyclopenten-1-yl)methyl]-
- 2H-pyran, tetrahydro-3-(phenylmethyl)-
- 2H-pyran, tetrahydro-4-methylene-2-[(2,2,3- trimethyl-3-cyclopenten-1 yl)methyl]-
- 2H-pyran-2-one, tetrahydro-5-propyl-
- 2H-pyran-4-ol, 2-(1-ethylpropyl)tetrahydro-4-methyl
- 2-pentanol, 1-[[(2*S*,5*R*)-1,4,4-trimethyltricyclo[6.3.1.02,5]dodec-8-yl]oxy]-, (2*R*)- and (2*S*)-
- 2-pentanol, 1-[[(2*S*,5*R*)-4,4,8-trimethyltricyclo[6.3.1.02,5]dodec-1-yl]oxy]-, (2*R*)- and (2*S*)-
- 2-pentanone, 4-methyl-, oxime
- 7-nonenal, 6,8-dimethyl-
- 9-decen-2-one
- amides, from alkanediamine, decanoic acid, hydrogenated plant-based oil fatty acids and octanoic acid
- amides, from alkanoic acid, ethylenediamine, hydrogenated plant-based oil fatty acids and octanoic acid
- hexanal, 6-cyclopentylidene-
- L-lysine, *N*-(3-carboxy-1-oxopropyl) derivatives, sodium and calcium salts

Australian Industrial Chemicals Introduction Scheme (2023-24). Chemical assessment statements. 12th March 2024.

APVMA pesticide technical reports for diazinon and neomycin

The APVMA has released a review of diazinon, an active constituent in insecticides and acaricides, following human health and environmental concerns. The report concludes that both the previously established Acceptable Daily Intake (ADI) of 0.001 mg/kg bw and the Acute Reference Dose (ARfD) of 0.01 mg/kg bw should remain unchanged.

Neomycin, an antibiotic in bactericidal products, has also been reviewed following concerns relating to residues of the active constituent. The report retains the previously established ADI of 0.06 mg/kg bw, while an ARfD has not been established.

Australian Pesticides and Veterinary Medicines Authority (2024).
Diazinon review technical report. March 2024.
Neomycin review technical report. February 2024.

FSANZ...

...risk assessment of triacylglycerol lipase and 2'-fucosyllactose

FSANZ has released supporting documents for the risk assessment of triacylglycerol lipase (from Genetically Modified (GM) *Trichoderma reesei*) for use as a processing aid and 2'-fucosyllactose (2'-FL; from GM *Corynebacterium glutamicum*) for use as a nutritive substance in infant formula products. It concluded that both substances are safe under the proposed conditions of use. An oral ADI of "not specified" was considered appropriate for triacylglycerol lipase in the absence of any identifiable hazards.

Food Standards Australia New Zealand (2024).
Risk and technical assessment. Application A1284. Triacylglycerol lipase from GM Trichoderma reesei as a processing aid.
Risk and technical assessment. Application A1283. 2'-FL from GM Corynebacterium glutamicum in infant formula products.

Cover image: Spring sunshine.

See also: Our article on page 11 relating to the COT statement on vitamin D in infant and follow-on formula.

Further information: The toxicologists at bibra are experts at evaluating the risks associated with chemicals in food.

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