toxicology and regulatory news

July 2024

Dates for your diary - meet us at …

Live Online Training Event: Human Health Endocrine Disruption of Pesticides and Biocides by the Chemicals Regulation Division (CRD) of the Health and Safety Executive (HSE)

This event will focus on the toxicological endocrine disruption assessment of pesticide and biocide active substances and biocide products and will present the current evaluation approach used by HSE

17-18th July 2024

Look (virtually) for Craig Freeman (Toxicologist)

Toxicology and Regulatory News

Contents

Toxicology and Regulatory News is issued as an e-mail version which is fully searchable and, for the convenience of our readers, the hyperlinks to the relevant websites are all active and checked for accuracy. The hyperlinks are shown as underlined blue text. The opinions expressed in this publication do not necessarily reflect the views of the company. While the information provided is believed to be accurate at the time of publication, **bibra toxicology advice & consulting** does not accept responsibility for the consequences of any errors or omissions.

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).

If you are interested in:

- An individual item or items herein
- Receiving Toxicology and Regulatory News on a regular basis
- Commenting on this publication
- The TRACE database on chemical toxicity and related information
- **bibra** membership
- Alerts relating to specific chemicals
- The safety-in-use of a specific substance, product or mixture

…then please do not hesitate to visit our website (www.bibra-information.co.uk), or contact us by e-mail (info@bibra.co.uk) or telephone (+44 (0)20 8619 0770).

We'd love to hear from you!

A trusted consultancy, run by experienced toxicologists

At bibra, we provide an exceptional standard of chemical hazard and risk assessments across a broad range of industries, including medical devices, pharmaceuticals, food additives/contaminants, pesticides/biocides, industrial chemicals and consumer products. Our goal is always to help our clients cope with the complex and ever-changing regulations framed to protect human health, in a way that meets their time and budgetary needs.

We are a world-class team of scientists; an impressive group of 15+ highly skilled toxicologists who have decades of experience in evaluating data related to chemical safety. It is this depth and breadth of knowledge backed up by bibra's unique in-house databank and associated database, TRACE, that enables us to support you whenever chemical toxicology is on the agenda.

Whether you are bringing a new product to market, re-evaluating an established product, dealing with a contamination crisis or submitting a dossier to a regulator, we have the experience to assist.

Expertise. Knowledge. Integrity.

bibra toxicology advice & consulting

International

OECD case study on the classification of three surfactants as eye irritants

A rule-based Defined Approach for Surfactants (DASF) was developed by OECD for the purpose of classification and labelling for eye irritation without the use of animal testing. It is based on a combination of Reconstructed human Cornea-like Epithelium (RhCE) test methods and a modification of the Short Time Exposure (STE) test method involving rabbit corneal epithelial cells. OECD has issued a case study in which three surfactants were selected to illustrate the use of the DASF for distinguishing between the three Globally Harmonized System (GHS) categories for eye hazard identification. The predictions from the DASF were that ethylhexyl acid phosphate ester at a concentration of 6% (and above) is classified in Cat. 1 for eye irritation; 10% cetylpyridinium promide is classified in Cat. 1 and 1% in Cat. 2, while 0.1% is not classified; and 0.1% Tween 80 is not classified. These results are in agreement with the GHS classifications of these chemicals based on *in vivo* eye irritation studies, demonstrating the validity of this defined approach.

Organisation for Economic Co-operation and Development (2024). Case study on the use of integrated approaches for testing and assessment for "eye hazard identification" of "surfactants". Ninth review cycle (2023). Series on Testing and Assessment, No. 391. ENV/CBC/MONO(2024)6.

FAO risk assessment of 3-MCPD and fatty acid esters

Lipid-based Nutrient Supplements (LNS) and Ready-to-Use Therapeutic Food (RUTF) are used to prevent and treat malnutrition in children, and often include edible oils to ensure adequate product shelf-life. However, during the refining process of these oils, heat-induced contaminants such as 3-monochloropropane-1,2-diol (3-MCPD) and its fatty acid esters, and glycidyl fatty acid esters (GEs), may be formed. As these substances or their metabolites have been shown to be genotoxic and carcinogenic, their presence in foods is a concern. The FAO evaluated the health risks resulting from exposure to these contaminants from LNS/RUTF for a maximum duration of 1 year and concluded that their concentrations in these products are of low concern.

Food and Agriculture Organization of the United Nations (2024). Food safety in the context of limited food availability – Risk assessment of 3-MCPD and fatty acid esters in nutrient supplements and therapeutic food. Food Safety and Quality Series, No. 25.

JECFA...

...evaluation of certain veterinary drug residues in human food

The technical report from JECFA's ninety-eighth meeting (held in February 2024) has now been released. The following decisions made at this meeting were of particular interest:

- clopidol: an Acceptable Daily Intake (ADI) of 0.04 mg/kg bw was set, based on a Lowest-Observed-Adverse-Effect Level (LOAEL) of 40 mg/kg bw/day for decreases in maternal body-weight gain and foetal body weight seen in a developmental toxicity study in rats. The setting of an Acute Reference Dose (ARfD) was not considered necessary.
- fumagillin: an ADI of 0-0.003 mg/kg bw was set, based on rat studies with the dicyclohexylamine (DCH) salt, DCH being the counterion used to stabilise fumagillin and improve its water solubility. The No-Observed-Adverse-Effect Level (NOAEL) in both a 90-day study and a developmental toxicity study was 1.73 mg/kg bw/day (expressed as fumagillin), based on decreased body-weight gain in adult rats and foetuses, and associated morphological changes in the foetuses, at 4.32 mg/kg bw/day. For DCH, an ADI of 0-0.02 mg/kg bw was set, based on a NOAEL of 10 mg/kg bw/day from a 90-day rat study in which haematological and clinical chemical changes were observed at the next dose up (30 mg/kg bw/day). The Committee considered it unnecessary to set an ARfD for fumagillin, but did set one for DCH of 0.7 mg/kg bw.
- imidacloprid: the ADI was set at 0-0.05 mg/kg bw, based on a NOAEL of 5.25 mg/kg bw/day for decreased body weight gain in an extended one-generation reproductive toxicity study (EOGRTS) in rats. The existing ARfD of 0.09 mg/kg bw was retained.

Joint FAO/WHO Expert Committee on Food Additives (2024). Evaluation of certain veterinary drug residues in food: ninety-eighth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, No. 1055.

...evaluation of certain food additives (including aspartame)

Toxicological monographs from JECFA's ninety-sixth meeting (held in June 2023) have now been released. In this meeting, aspartame's use as a food additive was re-evaluated. JECFA concluded that there was no convincing evidence of an association between aspartame consumption and cancer in humans, together with no concern for genotoxicity. The Committee retained the ADI of 40 mg/kg bw which it originally set in 1981. In addition, for the first time, the Committee evaluated six additional flavouring agents in the group of esters of aliphatic acyclic primary alcohols with branched-chain aliphatic acyclic acids, and nine additional flavouring agents in the group of hydroxy- and alkoxy-substituted benzyl derivatives. It

concluded that these flavouring compounds would not give rise to safety concerns at current estimated dietary exposure levels.

Joint FAO/WHO Expert Committee on Food Additives (2024). Safety evaluation of certain food additives: prepared by the ninety-sixth meeting of the Joint FAO/WHO Expert Committee on Food Additives. WHO Food Additives Series, No. 87.

Europe

EFSA...

...assessment of Food-Contact Material (FCM) ingredients

The CEP Panel has assessed the safety of "amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil" for use in FCMs. As there were no toxicological data on the vegetable-sourced substance, studies on the tallow-derived substance were considered, as both were said to consist of essentially the same components. In the available *in vitro* studies, the tallow-sourced substance and specific components (di-C14-C20-alkyl amines and nitrones and C14-C20-alkyl oximes and aldehydes) showed a lack of genotoxic potential in bacteria and mammalian cells. The Panel concluded that the vegetable-sourced substance is not a safety concern when used in the manufacture of polyolefin FCMs at 0.1% w/w, although such material should not be used for the storage of infant formula and human milk.

European Food Safety Authority (2024). Panel on Food Contact Materials, Enzymes and Processing Aids (CEP). Safety assessment of the substance amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil, for use in food contact materials. EFSA Journal 22, e8769.

...final 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). Scientific opinion on the tolerable upper intake level for iron. EFSA Journal 22, e8819.

…opinion on the safety of plant preparations

The NDA Panel evaluated the safety of plant preparations from the root or rhizome of *Rheum palmatum L.*, *Rheum officinale* Baill. and their hybrids (Chinese rhubarb), the bark of *Rhamnus frangula* L. and *Rhamnus purshiana* DC. (types of buckthorn) and the leaf or fruit of *Cassia senna* L. (a type of senna). Whilst the plant preparations themselves showed a lack of genotoxic potential, the Panel noted that the preparations may contain low concentrations of known genotoxic compounds including some hydroxyanthracene derivatives. As such, the Panel could not rule out a concern for genotoxicity and was unable to evaluate their safety.

European Food Safety Authority (2024). Panel on Nutrition, Novel Foods and Food Allergens (NDA). Scientific Opinion on additional scientific data related to the safety of preparations of *Rheum palmatum* L., *Rheum officinale* Baill. and their hybrids, *Rhamnus purshiana* DC., *Rhamnus frangula* L. and *Cassia senna* L., submitted pursuant to Article 8(4) of Regulation (EC) No 1925/2006. EFSA Journal 22, e8766.

…opinion on the UL for preformed vitamin A and for beta-carotene

The UL for preformed vitamin A and beta-carotene has been revised by the NDA Panel. Systematic reviews of the literature were conducted for adverse health effects associated with excess vitamin A intake, particularly teratogenicity, hepatotoxicity and endpoints related to bone health. Based on the teratogenic effects seen in humans, the Panel proposed retaining the UL for preformed vitamin A, expressed as retinol equivalents (RE), of 3000 µg RE/day for adults (including pregnant, lactating and post-menopausal women), a value that was scaled down for other population groups and ranged from 600 µg RE/day for infants aged 4-11 months to 2600 µg RE/day for adolescents aged 15-17 years. For beta-carotene, the Panel identified lung cancer risk as the critical effect; although there was no indication that the intake of this provitamin A carotenoid from the background diet is associated with adverse health effects, a UL could not be established due to insufficient data.

European Food Safety Authority (2024). Panel on Nutrition, Novel Foods and Food Allergens (NDA). Scientific opinion on the tolerable upper intake level for preformed vitamin A and β-carotene. EFSA Journal 22, e8814.

...in other news...

The NDA Panel has released safety assessments on vitamin D2 mushroom powder and magnesium L-threonate as novel foods.

European Food Safety Authority (2024). Panel on Nutrition, Novel Foods and Food Allergens (NDA). Novel food.

The CEP Panel has evaluated the safety of the food enzymes, alpha-amylase, inulinase and laccase.

European Food Safety Authority (2024). Panel on Food Contact Materials, Enzymes and Processing Aids (CEP). Food ingredients and packaging.

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

- cedarwood Texas oil
- citronella oil
- clove tincture
- eucalyptus tincture
- ginkgo tincture
- *Macleaya cordata* extract
- salinomycin sodium

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

EFSA's Pesticides Peer Review Unit has launched open consultations on Member State assessment reports on the active substances dodine and flonicamid, as well as on pirimiphos-methyl in the context of endocrine disruption.

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

ECHA...

...calls for comments on authorisation applications for chromium trioxide

ECHA has issued a call for comments, by 10th July 2024, on several applications for the authorisation of various specific uses of chromium trioxide.

European Chemicals Agency (2024). Applications for authorisation – current consultations.

…updates its report on Key Areas of Regulatory Challenge (KARCs)

This report has been updated to provide more detailed information on the four KARCs, including the following three that are of particular relevance to human health:

- providing protection against the most harmful chemicals, by expanding the current focus (on carcinogens, mutagens and reprotoxins) to also include neurotoxins, immunotoxins and endocrine disruptors
- shifting away from animal testing, ensuring continued development and application (when appropriate) of read-across methods, New Approach Methodologies (NAMs), ADME predictions and physiologically-based kinetic models
- improving the availability of chemical data, with particular focus on polymers and micro-/nano-sized materials

European Chemicals Agency (2024). Key areas of regulatory challenge.

…requests evidence on various substances

ECHA has announced a call for evidence, by 15th August 2024, on certain chromium(VI) substances. The information received will be used to assess the need to prepare an Annex XV restriction dossier.

In relation to the evaluation of exposure limits in the workplace, ECHA has issued calls for evidence, by 2nd–17th September 2024, on anthraquinone, oximes (butanone oxime and acetone oxide) and *N*-(hydroxy-methyl)acrylamide. The aim is to gather new information on uses, exposure, health effects, toxicology, epidemiology and modes of action.

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

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

ECHA has requested information from third parties, by 29th July 2024, on testing proposals for various REACH-registered substances, notably the following related to mammalian toxicity:

- tetramethylammonium chloride for developmental toxicity
- a sophorolipid UVCB for developmental toxicity
- *N*-ethyldiethanolamine for repeated-dose oral toxicity and developmental toxicity

European Chemicals Agency (2024). Testing proposals.

Classification and labelling…

…proposal for the CLH of six 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, Dutch, Finnish, Irish and Spanish authorities to standardise the classification and labelling of:

- 1-ethoxy-2-(2-methoxyethoxy)ethane for reproductive toxicity
- dodine for several human health hazards
- flonicamid for acute oral toxicity
- *O*-isopropyl ethylthiocarbamate for reproductive toxicity
- pyrogenic and precipitated silica for specific target organ toxicity – repeated exposure

The deadlines for comments are between 26th July and 9th August 2024.

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

…RAC opinions on the CLH of seven REACH substances

ECHA's Committee for Risk Assessment (RAC) has considered earlier proposals from authorities in Austria, Ireland, Slovenia, Spain and Sweden and has adopted opinions on the CLH of:

- bisphenol F
- bronopol
- *N*-1,3-dimethylbutyl-*N*'-phenyl-*p*-phenylenediamine
- pentapotassium bis(peroxymonosulphate) bis(sulphate)
- piperonal
- thymol

European Chemicals Agency (2024). Annex to news.

Biocidal Products Regulation…

…consultations on various active substances

A call for information (by 23rd July 2024) has been issued on the following active substances:

- *alpha*-bromadiolone
- bromadiolone
- brodifacoum
- chlorophacinone
- coumatetralyl
- difenacoum
- difethialone
- *epsilon*-metofluthrin
- flocoumafen
- iodine
- polyvinylpyrrolidone iodine

This information will be used by the European Commission together with Member States to assess whether a substance is a potential candidate for substitution and/or whether derogation to the exclusion criteria may be possible.

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

EMA monograph on arctic rose

EMA's Committee on Herbal Medicinal Products (HMPC) has finalised its monograph on arctic rose (*Rhodiola rosea*) rhizome and root, used to relieve symptoms of stress. The monograph is released alongside an assessment report containing relevant toxicity data.

European Medicines Agency (2024). European Union herbal monograph on *Rhodiola rosea* L., rhizoma et radix. Final – Revision 1. 20 March 2024. EMA/HMPC/24177/2023.

SCCS…

…opinion on new coating for nano-form titanium dioxide

Due to a number of uncertainties and data gaps, SCCS could not establish the safety of nano-titanium dioxide coated with a combination of aluminium hydroxide (6%), sodium myristoyl sarcosinate (14%) and dimethicone (10%) ("Eclipse 70"), when used as a UV filter in dermal cosmetic products. In particular, the Committee expressed the need for toxicity test data specifically on Eclipse 70.

Scientific Committee on Consumer Safety (2024). Opinion on new coating for titanium dioxide (nano form). SCCS/1667/24. Preliminary opinion.

…evaluation of titanium dioxide in cosmetics with potential oral exposures

While cosmetic products are not intended to be ingested, incidental exposure to titanium dioxide can occur when products like mouthwash or toothpaste are swallowed. The uptake of nanoparticles through the oral mucosa has also been observed. In its finalised opinion, SCCS could not conclude on safe limits in cosmetics of the different grades of titanium dioxide where ingestion may occur. In particular, genotoxicity could not be excluded for nearly all grades.

Scientific Committee on Consumer Safety (2024). Scientific advice on titanium dioxide (TiO_2) (CAS/EC numbers 13463-67-7/236-675-5, 1317-70-0/215-280-1, 1317-80-2/215-282-2). SCCS/1661/23. Final document.

ACSH priority chemicals for EU Binding Occupational Exposure Limits (BOELs)

ACSH has produced two lists of priority chemicals for new or revised BOEL values: one for priority under the Chemical Agents Directive (CAD) (98/24/EC), and the other under the Carcinogens, Mutagens and Reprotoxic substances Directive (CMRD) (2004/37/EC). Both directives concern the protection of human health from chemical exposures at work.

European Commission. Advisory Committee on Safety and Health at Work (2024). Opinion on priority chemicals for new or revised occupational exposure limit values under EU OSH legislation. Doc. 006-24. Adopted on 29/05/2024.

BfR…

…supports threshold toxicity for four endocrine disruptors

Some scientists have raised concerns over whether Endocrine-Disrupting Chemicals (EDCs) may lack a "safe" threshold dose, such that any exposure would come with a non-zero risk of producing an adverse effect. A panel at BfR has put this view to the test, analysing the existing data on four pesticide active substances: dimethomorph, metiram, propiconazole and epoxiconazole. For all four EDCs, the data support the existence of thresholds for endocrine disruption, below which no adverse effects would be expected.

German Federal Institute for Risk Assessment (BfR) (2024). Hormonally active chemicals: a question of dose. Communication 022/2024. Relating to Choi *et al.* (2024). Thresholds of adversity for endocrine disrupting substances: a conceptual case study. Archives of Toxicology 98, 2019–2045.

…assesses the health effects of methylmercury (MeHg) in fish and seafood

MeHg is produced from inorganic mercury by aquatic bacteria and can accumulate in fish and seafood that are part of the human diet. BfR found no significant health risks from the consumption of such MeHg-contaminated products for most of the German population, although high-consuming adolescents and young adults may be exposed to levels that exceed the EFSA Tolerable Weekly Intake (TWI) of 1.3 µg/kg bw.

German Federal Institute for Risk Assessment (BfR) (2024). Methylmercury in fish and seafood – health assessment of new data from the BfR. MEAL study. Statement 023/2024.

VKM updates its guidance on Plant Protection Products (PPPs)

A VKM Panel has updated its guidance on the human and environmental risk assessment of PPPs (Norway having adopted the EU PPP regulations). As regards human health, the update now details the criteria for identifying endocrine-disrupting substances, provides harmonised guidance for non-dietary exposure assessments, and includes further discussion of relevant non-animal testing methods.

Norwegian Scientific Committee for Food and Environment (VKM) (2024). VKM's methodology document for health and environmental risk assessments for use in the Panel on Plant Protection Products. VKM bulletin 2024: 04.

United Kingdom

SACN review of vitamin D fortification

According to Public Health England, substantial portions of the UK population have poor vitamin D status and are not receiving the Reference Nutrient Intake (RNI) of 10 µg/day. SACN was therefore asked to consider whether the mandatory fortification of food and drink with vitamin D might improve public health. It has released a report summarising its findings, which provides scientific advice to UK policy makers. Although no final recommendations are given, the Committee does seem to support vitamin D food fortification in the UK.

Scientific Advisory Committee on Nutrition (2024). Fortifying foods and drinks with vitamin D: main report. May 2024.

COT May meeting

At its most recent meeting (21st May 2024), the COT discussed the safety of titanium dioxide (E171) as a food additive. Based on the existing data and the Acceptable Daily Intake (ADI) of 10 mg/kg bw, it was concluded that current dietary exposures to E171 in the UK are unlikely to pose a risk to human health.

Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment (2024). Fifth draft statement on the safety of titanium dioxide (E171) as a food additive. TOX/2024/18.

HSE reports on the safety of elemental iron

The HSE has released supporting documents for the public consultation of elemental iron (which closes on 11th August), detailing the uses and evaluating the risks associated with combined exposure for both workers and consumers.

Health and Safety Executive (2024). PPP NAS 006 – Elemental Iron.

United States

US EPA…

…preliminary assessment of two phthalates

The US EPA has recently released a draft risk evaluation on di-isodecyl phthalate (DIDP), and five draft hazard assessments on di-isononyl phthalate (DINP) covering its physical chemistry, fate, environmental hazard, and non-cancer and cancer hazards in humans. A full risk evaluation on DINP will be released later this year. The EPA provisionally determined that both phthalates can cause developmental toxicity and liver damage. DINP has produced evidence of cancer in laboratory animals, whereas the existing data on DIDP were not considered sufficient to determine its carcinogenicity. The EPA concluded that DIDP presents an unreasonable risk to human health, albeit for only one out of the 47 conditions of use evaluated (the industrial use of adhesives and sealants, due to high-pressure spray applications).

US Environmental Protection Agency (2024).
Draft risk evaluation for diisodecyl phthalate (DIDP) (1,2-benzene-dicarboxylic acid, 1,2-diisodecyl ester).
Draft hazard assessment for diisononyl phthalate (DINP) (1,2-benzene-dicarboxylic acid, 1,2-diisononyl ester).

...human health risk assessment for glufosinate-P

The Health Effects Division (HED) of the US EPA has completed its human health hazard and risk assessment of the new herbicide active ingredient, glufosinate-P. Neurotoxicity was observed after acute, subchronic and chronic oral administration to rats, mice and dogs. Effects on the kidney (rats and mice), thyroid (rats) and adrenals (mice) were also reported. However, for the proposed uses of glufosinate-P, the HED concluded that there were no dietary, residential or aggregate health risks of concern.

US Environmental Protection Agency (2024). Glufosinate-P. Human Health Risk Assessment for New Active Ingredient Isomer.

NTP technical report on triclosan

The NTP has finalised its technical report on the toxicology and carcinogenicity of the antimicrobial, triclosan. A 2-year study was conducted, in which mice were treated dermally (7 days/week) at 1.25-12.5 mg/kg bw/day. Non-neoplastic changes at the site of application were observed at each dose level and included minimal to mild epidermal hyperplasia (both sexes), suppurative inflammation (males), and ulceration (males); the highest incidence occurred at the top dose. The NTP concluded that triclosan showed "some evidence of carcinogenic activity" in male mice based on the increased incidences of hepatocellular adenoma or carcinoma (combined), and "equivocal evidence of carcinogenic activity" in female mice based on higher occurrences of pancreatic islet adenomas.

National Toxicology Program (2024). NTP technical report on the toxicology and carcinogenesis study of triclosan (CASRN 3380-34-5) administered dermally to B6C3F1/N mice. NTP TR 604. May 2024.

Canada

Health Canada...

...assessments of piperazine and gas oils/kerosenes

Health Canada has recently released assessments discussing the human health effects of piperazine and the Gas Oils and Kerosenes (GOKs) group. It concluded that the 16 GOKs met the relevant criteria set out in the Canadian Environmental Protection Act (CEPA) to be defined as "toxic" in terms of their risk to human health. Piperazine did not meet the criteria and therefore was not defined as "toxic".

Health Canada/Environment and Climate Change Canada (2024). Assessment. Piperazine and Draft assessment. Gas oils and kerosenes with uses in products available to consumers group.

Cover image: sea creatures.

See also: Our article on page 12 relating to the BfR assessment of the health effects of methylmercury in fish and seafood.

Further information: The toxicologists at bibra are experts at assessing the risks associated with food products (including food contaminants).

BTS House, 69-73 Manor Road, Wallington, Surrey, SM6 0DD, United Kingdom
Tel: +44 (0)20 8619 0770 | info@bibra.co.uk | www.bibra-information.co.uk