Escalex® LIMITS food regulation and compliance

NEWS & ALERTS

A monthly snapshot of key regulatory updates from across the globe

www.ifis.org April 2020

Why Escalex Limits News & Alerts?

One of the biggest challenges faced by food business operators today is to comply with multiple regulations on maximum residue limits (MRLs). Producers, processors and traders engaged in the food chain all need to meet rules on residues in food, irrespective of the region in which they operate. However, identifying and monitoring rules on MRLs is no easy task. Food is governed by a complex and dynamic set of rules. In addition to international instruments, several jurisdictions establish and regularly update their own prescriptions in terms of residue levels, making it difficult for businesses to keep track of the frequent regulatory changes and variations from jurisdiction to jurisdiction.

This difficulty has recently been evidenced in our 2019 market research study on the crucial pain points the food industry has to endure when navigating food regulatory data. The survey identified that 72% of international food industry professionals interviewed found regulatory limits on additives, contaminants, nutrients, microbiological criteria, veterinary drugs, food contact materials and pesticides difficult to locate, interpret and apply to their food businesses.

Our News & Alerts intends to assist the food and beverage industry in their compliance needs with MRLs' legal requirements. Published once a month, it captures national and international updates on regulatory limits for several jurisdictions – Australia, Canada, China, EU harmonised law, US federal law and California state law, and New Zealand – providing an easily accessible platform for the food community to stay in touch with legal developments and upcoming legislation. When possible, links are given to relevant websites from where further information is available.

Here is the latest from Escalex Limits!

Amina Lattanzi
Food Law Editor
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IFIS food and health information

molecular connections

Escalex Limits Updates

Escalex Limits is a new regulatory database, which IFIS has been working on to create over the past four years. Escalex Limits aims to make finding, understanding and applying legislation covering limits data easier for food industry and regulatory professionals. In particular, our database covers limits data on the following substances: additives, contaminants, microbiological criteria, pesticides, veterinary drugs, nutrients and food contact materials.

During the month of April, we have been focusing on collating additional market feedback from the international food industry, ensuring that future developments with the Escalex service are in line with the needs of the food industry. We have created and sent out a variety of market research surveys to capture this information from our food community. If this is something you would like to be involved in and if you would like to express your views and opinions, we provide more information on our latest survey and how you can participate on the last page of our Newsletter. Alternatively, please contact our Senior Regulations & Compliance Executive - Joanna Becker (j.becker@ifis.org) for further details on the project.

HOT TOPICS

ADDITIVES

CANADA

Health Canada updates List of Permitted Colouring Agents

Health Canada adopted the Notice of Modification to the List of Permitted Colouring Agents to enable the use of lycopene extract from tomato as a food colouring agent in sports drinks and in certain non-carbonated sweetened flavoured water-based beverages with added vitamins and mineral nutrients. The maximum level of use is set at 3 ppm.

The above modification came into force on 12 March 2020.

By Shiro Yamamoto_www.unsplash.com

Notice of Modification to the Lists of Permitted Food Additives

Effective as of 8 April 2020, the Notice refers to the use of potassium phosphate, dibasic, and extends it to the same foods and levels of use as currently permitted for sodium phosphate, dibasic.

Lists involved by the modification include the List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents, the List of Permitted Food Additives with Other Accepted Uses, the List of Permitted pH Adjusting, Agents, Acid-Reacting Materials and Water Correcting Agents, and the List of Permitted Sequestering Agents.

Notice of Modification to the List of Permitted Food Enzymes

Effective as of 30 March 2020, the Notice enables the use of aspergillus fijiensis as a source organism for invertase, based on Health Canada's Food Directorate evaluation supporting the re-identification of the source organism name for invertase "aspergillus japonicus" to "aspergillus fijiensis" in the List of Permitted Food Enzymes.

Following a review of scientific and taxonomic data, the Directorate concludes that updating the source organism name, based on re-identification of the source organism, does not need a pre-market safety assessment.

EUROPEAN UNION HARMONISED LAW

New EU Regulation on polyglycerol polyricinoleate

The Commission Regulation 2020/355 of 26 February 2020 amends Annex II to Regulation 1333/2008 on food additives as regards the use of polyglycerol polyricinoleate (E 476) in liquid vegetable oil emulsions.

The Regulation authorises the use of polyglycerol polyricinolate (E 476) as an emulsifier in liquid vegetable oil emulsions for sale to the final consumer, having a fat content of 70% or less, at 4.000 mg/kg.

The European Commission amends existing rules on citric acid in chocolate

The new Commission Regulation 2020/351 of 28 February 2020 amends Annex II to Regulation 1333/2008 on food additives as regards the use of citric acid (E 330) in cocoa and chocolate products.

The new Regulation authorises the use of citric acid at 10.000 mg/kg in milk chocolate.

The European Commission tackles food additive in carbonated beverages

The new Commission Regulation 2020/356 of 4 March 2020 amends Annex II to Regulation 1333/2008 on food additives as regards the use of polysorbates (E 432-436) in carbonated beverages.

The new rules apply to flavoured drinks, cider and perry, fruit wine and made wine and other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol, authorizing the use of polysorbates (E 432-436) as an antifoaming agent at 10 mg/l.

The Regulation has entered into force on 25 March 2020.

EU seeks to ban some botanical ingredients in food

The draft Commission Regulation intends to amend Annex III to Regulation 1925/2006 with regards to botanical species containing hydroxyanthracene derivatives, such as those found in aloe extracts.

The commenting period closed on 22 April 2020.

By Jennifer Pallian_www.unsplash.com

CONTAMINANTS

CALIFORNIA STATE LAW

California initiates process to develop public health goals for contaminants in drinking water

The California Office of Environmental Health Hazard Assessment (OEHHA) announced the development of public health goals (PHGs) for 1,4-dioxane and an update of the goals for n-nitrosodimethylamine. PHGs - levels of chemicals not considered to produce health effects - are used as the health basis to support California's primary drinking water standards (Maximum Contaminant Levels) established by the State Water Resources Control Board for chemicals subject to regulation.

OEHHA is inviting public comments on these contaminants to assist in the PHGs assessment. Deadline: 27 May 2020.

By KOBU Agency_www.unsplash.com

CODEX ALIMENTARIUS COMMISSION

The Codex Secretariat extends commenting periods for several Circular Letters

The extensions to requests for comments - new deadline 30 June 2020 - involve:

- CL 2020/22/OCS-CF: Proposed draft revision of the Code of Practice for the prevention and reduction of lead contamination in foods (CXS 56-2004);
- CL 2020/21/OCS-CF: Proposed draft MLs for lead in selected commodities for inclusion in the GSCTFF (CXS 193-1995);
- CL 2020/20/OCS-CF: Proposed draft Code of practice for the prevention and reduction of cadmium contamination in cocoa beans;
- CL 2020/19/OCS-CF: Proposed draft maximum levels for cadmium in chocolates and cocoa-derived products.

The commenting period for CL 2020/24-CF - Request for comments on the Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA has also been extended. New deadline: 28 January 2021.

HONG KONG

2018 rules on metallic contamination of food to come into effect in November 2020

The Food Adulteration (Metallic Contamination) (Amendment) Regulation, adopted in October 2018, will take effect on 1 November 2020 with regards to all non-fresh foods. The Amendment Regulation already came into operation in November 2019 with regards to certain types of fresh food (e.g. fresh fruits and vegetables, fresh meat and poultry eggs).

MICROBIOLOGICAL CRITERIA

CODEX ALIMENTARIUS COMMISSION

Extended commenting period for aflatoxins

The extension refers to CL 2020/23/OCS-CF: Proposed draft MLs for total aflatoxins in certain cereals and cereal-based products including foods for infants and young children. New deadline: 30 June 2020.

EUROPEAN UNION HARMONISED LAW

Amendment regarding salmonella in reptile meat

Commission Regulation 2020/205 of 14 February 2020 amends Regulation 2073/2005 as regards salmonella in reptile meat. The latter lays down microbiological criteria for micro-organisms and the implementing rules to be complied with by food business operators in respect of the general and specific hygiene requirements referred to in article 4 of Regulation 852/2004.


By Walter Otto_www.unsplash.com

EFSA assesses human health risks of aflatoxins in food

Following a request from the European Commission, the Panel on Contaminants in the Food Chain published on 9 March 2020 a Scientific Opinion on the human health risks related to the presence of aflatoxins in food. EFSA evaluated the toxicity of aflatoxins and examined the dietary exposure of the EU-based population to aflatoxins.

The assessment confirms previous conclusions that aflatoxins are genotoxic and carcinogenic. More information can be found here.

The European Commission publishes Q&A on food safety during COVID-19

The new document seeks to address crucial questions on risks of infection through food consumption, Coronavirus contamination of packaging and hygiene of food business premises. The European Commission also confirms that, to this day, there is no evidence that food poses a risk to public health with regards to COVID-19 and that there has been no report of transmission of the virus via consumption of food so far.

PESTICIDES

AUSTRALIA

Trifludimoxazin under review by Australian Pesticides and Veterinary Medicines Authority

The APVMA has assessed an application for the new agricultural active constituent trifludimoxazin for use as a herbicide, concluding that there are no toxicological concerns regarding its use and establishing an Acceptable Daily Intake (ADI) of 0.1 mg/kg bw/d. More details can be found at p. 15 of the Australian Pesticides and Veterinary Medicines Authority's Gazette, published on 7 April 2020.

Consultation on use patterns for anticoagulant rodenticides

The public consultation – deadline 3 July 2020 - involves all registered products containing the following active constituents: warfarin, coumatetralyl, diphacinone, brodifacoum, bromadiolone, difenacoum, difethialone, flocoumafen.


By Nadine Primeau_www.unsplash.com

CANADA

Established maximum residue limit for clopyralid

The new MRLs for clopyralid were established between 11 and 18 March 2020 via entry into the Maximum Residue Limits Database:

- 7.0 ppm in annual canarygrass bran;
- 3.0 ppm in annual canarygrass seeds;
- 0.05 ppm in pome fruits (crop group 11-09).

By Chandra Oh_www.unsplash.com

Established maximum residue limit for dimethomorph

The following maximum residue limit for dimethomorph was adopted via entry into the Maximum Residue Limits Database on 11 March 2020: 60 ppm in leaf lettuce.

Adoption of proposed maximum residue limits for chlorfenapyr, malathion and prometryn

The following MRLs were adopted on 18 March 2020 and established via entry into the Maximum Residue Limits Database:

- chlorfenapyr: 0.5 ppm in cucumbers;
- malathion: 0.8 ppm in annual canarygrass seeds;
- prometryn: 15 ppm in dried parsley leaves, 3 ppm in fresh parsley leaves.

Health Canada consults on new MRLs for mefentrifluconazole

Health Canada's Pest Management Regulatory Agency invites public comments on the proposed maximum residue limits for mefentrifluconazole in or on various food commodities. The consultation will close on 23 May 2020

More information on proposed levels and commodities involved can be found here.

EUROPEAN UNION HARMONISED LAW

Several pesticides under review in the EU

The draft Commission Regulation involves bupirimate, carfentrazone-ethyl, emamectin, ethirimol, and pyriofenone and concerns the review of their existing MRLs in or on certain products.

Proposed residue levels can be found here.

Review of the existing MRLs for fluopyram

According to article 12 of Regulation 396/2005, EFSA has reviewed the maximum residue levels currently established in the EU for the pesticide active substance fluopyram in plants, processed commodities, rotational crops and livestock.

The Reasoned Opinion was published in the EFSA Journal on 14 April 2020.

Evaluation of confirmatory data following MRL review for sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate (sodium nitrocompounds)

EFSA's Reasoned Opinion was published on 31 March 2020, based on a request to the competent national authority to assess the confirmatory data for the pesticide active substances sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate (sodium nitrocompounds) in the framework of the maximum residue level review under article 12 of Regulation 396/2005.

EFSA concludes that the new information submitted does not require a revision of the current residue levels for the three substances.

Peer review of the pesticide risk assessment of blood meal

Published on 27 February 2020, the conclusions of the European Food Safety Authority are based on the evaluation of the uses of blood meal as a game repellent on deciduous and coniferous trees in forestry, orchard trees and ornamental plants and as a vole repellent on deciduous and coniferous trees in forestry.

Peer review of the pesticide risk assessment of kieselgur

Published on 19 March 2020, the conclusions of the European Food Safety Authority follow the peer review of the initial risk assessments undertaken by rapporteur and co-rapporteur national competent authorities for the pesticide active substance kieselgur (diatomaceous earth).

The conclusions are based on the evaluation of kieselgur (diatomaceous earth) used as an insecticide and acaricide on stored cereals, empty storage rooms and storage rooms, mills and warehouses (with stored goods).

Chlordecone in certain products of animal origin under examination in the EU

On 3 March 2020, EFSA published the Statement on the dietary exposure assessment for the temporary maximum residue levels for chlordecone in certain animal products. The proposed MRLs were recommended by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) and are lower than the current levels established under Regulation 396/2005.

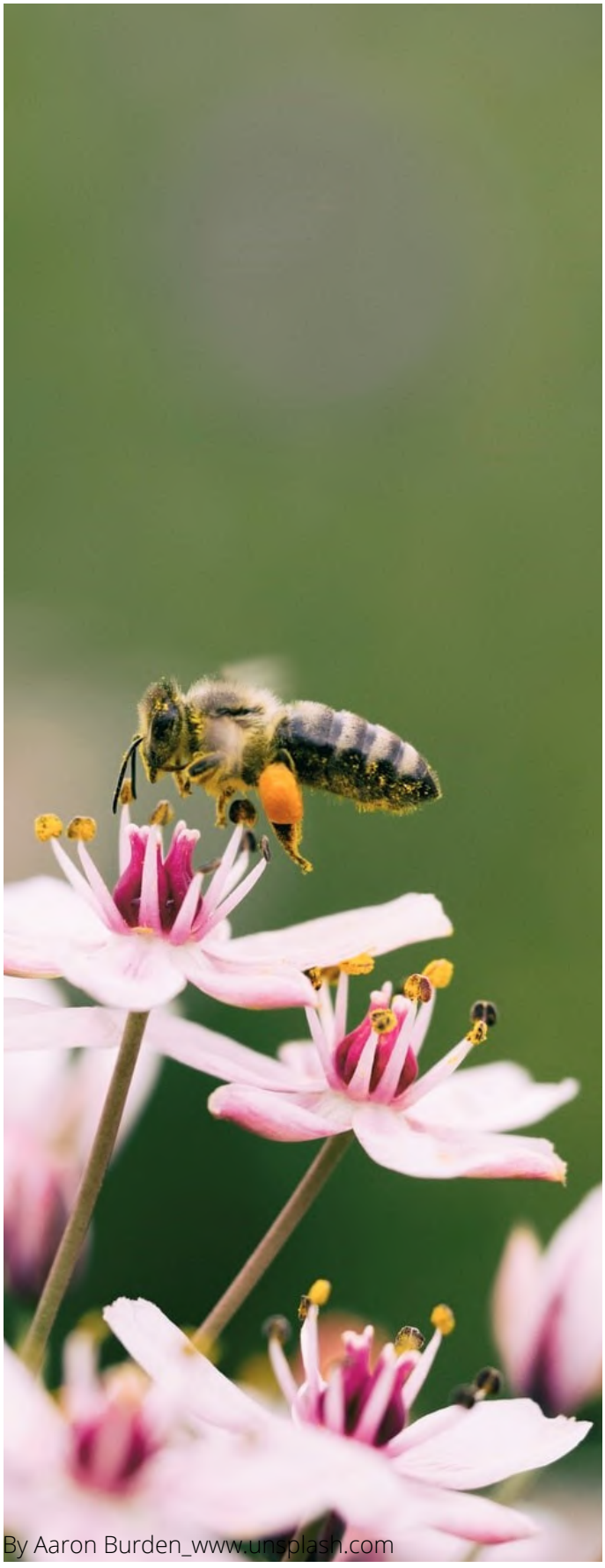
EFSA concludes that short-term and long-term intakes of chlordecone residues at the level of the proposed MRLs for animal products is not expected to exceed the toxicological reference values derived by French authorities.

Public consultation on difenoconazole

On 31 March 2020, EFSA opened a public consultation on the active substance difenoconazole. Deadline: 31 May 2020.

A parallel consultation on a harmonised classification and labelling (CLH) proposal is ongoing on the European Chemicals Agency's website and will close on 1 June 2020.

By Markus Spiske_www.unsplash.com


By Aaron Burden_www.unsplash.com

Bees and pesticides: EFSA asks for more comments

The European Food Safety Authority is carrying out a third consultation of stakeholders in relation to its guidance review on the impact of pesticides on bees. The request for feedbacks is focused on crop attractiveness and risk assessment methodologies.

The European Commission publishes SCoPAFF Summary Reports

The Summary Reports of the Standing Committee on Plants, Animals, Food and Feed involve the Section on Phytopharmaceuticals and include the following meetings:

- the Phytopharmaceuticals - Pesticide Residues meeting of 17-18 February 2020;
- the Phytopharmaceuticals - Legislation meeting of 18 February 2020 (subsection of Phytopharmaceuticals - Pesticide Residues PAFF Committee of 17-18 February 2020).

EU latest annual report on pesticide residues found in food

Published on 2 April 2020, EFSA's 2018 Report is based on data from Member States' 2018 control activities as well as those carried out by Iceland and Norway and includes both targeted and random sampling. For 2018, 95.5% of the 91,015 samples analysed fell below the maximum residue level required. Table grapes and sweet peppers were among the commodities that most frequently exceeded respective MRLs. More information can be found here.

UNITED STATES FEDERAL LAW

The Environmental Protection Agency sets tolerances for residues of several pesticides

The new Regulations involve:

- trifloxystrobin in or on pea and bean, dried shelled, except soybean, subgroup 6C, effective as of 6 March 2020;
- penoxsulam in or on globe artichoke, effective as of 9 March 2020;
- cyazofamid in or on multiple commodities, effective as of 18 March 2020.

EPA's final rules on exemptions from residue tolerances

The EPA has established exemptions from the requirement of a tolerance for residues of:

- propanamide, 2-hydroxy-N, N-dimethyl-, when used as an inert ingredient in pesticides applied to growing crops and raw agricultural commodities after harvest, or in pesticides applied to animals, limited to 50% by weight in the pesticide formulations. The new Regulation is effective as of 14 February 2020;
- chrysodeixis includens nucleopolyhedrovirus isolate #460 in or on all food commodities when used in accordance with label directions and good agricultural practices. The new Regulation is effective as of 9 March 2020.

Pesticide petition filed for residues of pesticide chemicals in or on various commodities

The Environmental Protection Agency announced receipt of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities. The petition was filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a.

Deadline for comments closed on 2 April 2020.

EPA sued over re-approval of glyphosate

On 20 March 2020, a large coalition of stakeholders – including Center for Food Safety, Beyond Pesticides, and the Rural Coalition – have filed a federal lawsuit against the Environmental Protection Agency over its January 2020 decision to re-approve glyphosate, herbicide commonly used to control broadleaf weeds and grasses.

VETERINARY DRUGS

AUSTRALIA

Updated guidelines on active constituents for veterinary products

On 2 April 2020, the Australian Pesticides and Veterinary Medicines Authority published on its website an updated version of the July 2014 guidelines on active constituents for veterinary products. The goal of the new guidance is to ensure its consistency with legislative requirements for approval of individual sources of veterinary active constituents and to provide clarity on the data required for new sources of active constituents.

By William Moreland_www.unsplash.com

CODEX ALIMENTARIUS COMMISSION

Commenting period on AMR closes on 30 April 2020

The Codex Secretariat has closed its request for comments on the proposed draft revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance. Further details can be found here: CL 2020/04/OCS-AMR.

EUROPEAN UNION HARMONISED LAW

Outcome of 2018 monitoring activities of veterinary medicinal products residues: safety levels compliance still high

Published on 31 March 2020, EFSA's Technical Report analyses data collected in 2018 from monitoring activities of veterinary medicinal products residues and other substances in live animals and animal products in the European Union. Compared to the 2017 outcomes, the 2018 Report shows a slight increase of non-compliant results for antithyroid agents, steroids, and 'others' and a slight decrease for antibacterials, anthelmintics, non-steroidal anti-inflammatory drugs, 'other pharmacologically active substances', organochlorine compounds, chemical elements, mycotoxins and dyes.

A total of 657,818 samples were checked by 28 EU Member States. More information can be found here.


By Alex Azabache_www.unsplash.com

UNITED STATES FEDERAL LAW

Veterinary drugs now included in the US-EU Mutual Recognition Agreement for good manufacturing practice inspections

On 13 March 2020, the Food and Drug Administration announced the decision to include veterinary pharmaceuticals as part of the Mutual Recognition Agreement with the EU for pharmaceutical good manufacturing practice inspections.

GENERAL

AUSTRALIA & NEW ZEALAND

Proposed variation of Schedule 20 of the Australia New Zealand Food Standards Code

Food Standards Australia New Zealand is seeking to amend Schedule 20 – Maximum residue limits in the Australia New Zealand Food Standards Code with regards to various agricultural and veterinary chemicals.

Substances involved include, among others:

- paracetamol in pigs, bupirimate in tomatoes, cyanamide in almonds, cyazofamid in poppy seeds and all other foods except animal food commodities, diafenthiuron in peanuts and soya beans (dry), fludioxonil in papaya, propamocarb in leafy vegetables. Call for written comments closed on 7 April 2020;
- tetraniliprole in various commodities, trifludimoxazin in various commodities, chlorantraniliprole in almonds, pistachio nuts, root and tuber vegetables, walnuts, potatoes, root and tuber vegetables and tree nuts, fluopyram in assorted tropical and sub-tropical fruits. Deadline for public submissions: 5 May 2020.

CALIFORNIA STATE LAW

California's changes to Proposition 65 warnings

Effective as of 1 April 2020, the amendments under California's Proposition 65 "Clear and Reasonable Warning" Regulations refer to the responsibility to provide consumers product exposure warnings for chemicals listed under Proposition 65. The amendments' goal is to ensure greater clarity to actors in the supply chain in terms of warning requirements, especially clarifying how intermediate parties in the chain of distribution can satisfy their obligations under Proposition 65.

By Sebastian Pena Lambarri_www.unsplash.com

CODEX ALIMENTARIUS COMMISSION

Forthcoming Codex meetings rescheduled due to COVID-19: update

Postponements include this year's Codex Committee on General Principles, Codex Committee on Pesticides Residues and the Executive Committee of the Codex Alimentarius Commission. Any update will be posted on the Codex meetings reports' page.

The Codex Committee on Food Additives is still planned for 22-26 June 2020 in Lanzhou, China. The Codex Committee on Contaminants in Foods has been moved to May 2021 in the Netherlands.

EUROPEAN UNION HARMONISED LAW

Modification of existing rules on organic production

Commission Delegated Regulation 2020/427 of 13 January 2020 amends Annex II to Regulation 2018/848 as regards certain detailed production rules for organic products. The amendment involves sprouted seeds, bees and marine fish species.

EEA Joint Committee Decisions on veterinary and phytosanitary matters published in the EU Official Journal

Fifteen Decisions on veterinary and phytosanitary matters of the European Economic Area Joint Committee, dated 13 December 2019, have been published in the Official Journal of the EU of 5 March 2020.

EFSA updates toxicity database for food and feed

On 27 March 2020, the European Food Safety Authority has announced the latest update of its OpenFoodTox database, launched in 2017 to provide a unique platform for summary toxicological data on substances assessed by EFSA. Its goal is to enable users to better determine the toxicity of substances in food and feed, including pesticides, additives, and contaminants. OpenFoodTox now incorporates toxicity data on almost 5,000 chemicals drawn from scientific evaluations carried out by the Authority since 2002.

NEW ZEALAND

Proposals to amend the Food Notice on maximum residue levels for agricultural compounds

New Zealand Food Safety is inviting public comments on amendment proposals to the New Zealand (Maximum Residue Levels for Agricultural Compounds) Food Notice.

The proposed modifications include:

- an amendment to the existing exemption Plant Extracts (unrefined) in Schedule 2 of the Food Notice, for which compliance with an MRL is not required for agricultural chemical compounds. This amendment seeks to add clitorea ternatea (butterfly pea) and allow extracts from this plant to be used as an insecticide without the need for compliance with an MRL;
- a new exemption for medium chain fatty acids and their mono-, di-, and triglycerides in Schedule 3 of the Food Notice, for which compliance with a maximum residue level is not required for veterinary medicine compounds. The fatty acids are used as antimicrobials in teat sanitisers to prevent mastitis in dairy animals.

Closing date: 16 June 2020.

New Organic Standard currently in the works before New Zealand Parliament: update

The draft Organic Products Bill aims at developing mandatory national standards for organic products, detailing production and compliance requirements for certain products.

The proposed legislation was introduced on 27 February 2020 and has now been referred to the Primary Production Committee. Public comments are accepted up until 28 May 2020. The proposed date of adoption is December 2020.

UNITED STATES FEDERAL LAW

FDA updates Fish and Fishery Products Hazards and Controls Guidance

The update refers to Appendix 5, listing EPA and FDA safety levels in fish and fishery products. The Appendix is divided into veterinary drugs, biological criteria, chemicals, natural toxins and physical criteria and lays down respective limits. More information can be found here.

By Bruna Branco_www.unsplash.com

IFIS UPDATES

Market Research Survey

As anticipated in the Escalex Limits Updates section of our Newsletter, we are currently conducting market research to ensure our developments with Escalex meet the food industries needs and wants. The survey is directed to food scientists/researchers and professionals involved in regulatory affairs within the food industry. The survey intends to help us find out more about the challenges the food industry faces when trying to identify and locate food science research and international food regulations. The survey also aims to explore how these challenges impact food industry professionals day-to-day roles and what tools would be useful to make their daily work and research more efficient.

If this is something you feel you could help us with, you can access our 5-minute survey via this link. Your valued opinions and views will be essential in making Escalex the very best tool for the food industry! If you have any further questions about the survey or the research we are carrying out, then please do not hesitate to contact our Senior Regulations & Compliance Executive - Joanna Becker (j.becker@ifis.org) for more details on the project.

THANK YOU

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IFIS maintains a global network of legal experts and consultants in the area of food law and regulation. Locate a food law expert or find out more here: www.ifis.org/meet-the-experts.

Interested in working in partnership with Escalex?
Email Joanna Becker at j.becker@ifis.org for more information.

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