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Editorial: OpenFoodTox: EFSA's open source toxicological database on chemical hazards in food and feed

Jean Lou Dorne^a, Jane Richardson^b, Georges Kass^a, Nikolaos Georgiadis^c,
Mario Monguidi^d, Luca Pasinato^d, Stefano Cappe^e, Hans Verhagen^f and
Tobin Robinson^g

Since its inception in 2002, the European Food safety Authority (EFSA) has produced risk assessments for more than 4,400 substances in over 1,650 Scientific Opinions, Statements and Conclusions through the work of its Scientific Panels, Units and Scientific Committee. For each individual substance, a summary of human health, animal health and ecological hazard assessments has been collected and structured into EFSA's Chemical Hazards Database: OpenFoodTox. OpenFoodTox provides open source data for substance characterisation, links to the relevant EFSA output, background regulations and summaries of critical toxicological endpoints. An online MicroStrategy¹ tool enables the downloading of summary data sheets for each individual substance in PDF or Excel format. OpenFoodTox is a valuable tool and source of information for scientific advisory bodies and stakeholders with an interest in chemical risk assessment. This editorial provides a snapshot description of OpenFoodTox as an open source toxicological database for chemical risk assessment.

EFSA provides scientific advice to risk managers and decision makers through risk assessment and risk communication on all issues related to 'food and feed safety, animal health and welfare, plant health, nutrition, and environmental issues' (Regulation EC No 178/2002²). Risk assessment has been defined as 'a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation' (Regulation EC No 178/2002; WHO, 2009).

In food safety, hazard identification and characterisation aims to determine safe levels of exposure for substances for human health, animal health or the environment from pivotal toxicology studies that provide the basis for a reference point. The reference points are then divided by uncertainty factors to derive reference values. Examples of reference points/points of departure for human health and animal

¹ <https://dwh.efsa.europa.eu/bi/asp/Main.aspx?rwtrep=400>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32002R0178>

About the Author(s): ^aSenior Scientific Officer, EFSA Scientific Committee and Emerging Risks Unit; ^bLead Expert in Open Data, Evidence Management (Data) Unit; ^cScientific Officer, Scientific Committee and Emerging Risks Unit; ^dScientific Officer, Evidence management (Data) Unit; ^eTeam Leader, Evidence management (Data) Unit; ^fDirector of Department of Risk Assessment and Scientific Assistance; ^gHead of the Scientific Committee and Emerging Risks Unit.

Correspondence: scer@efsa.europa.eu

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health effects include lowest or no-observed-adverse-effect-level (LOAEL/NOAEL), benchmark dose limit (BMDL, e.g. BMDL₁₀), lethal dose (LD₅₀), or no observed effect concentration (NOEC) for ecotoxicological effects (*Daphnia*, fish, bees, etc.). Examples of reference values include health-based guidance values for setting safe levels of chronic exposure in humans such as acceptable daily intake (ADI) for food and feed additives, pesticides and food contact materials, tolerable upper intake levels (UL) for vitamins and minerals, and tolerable daily intake (TDI) for contaminants. OpenFoodTox provides a database to access reference points and reference values for all the substances assessed by EFSA.³

Since 2002, EFSA has assessed over 4,400 substances and contaminants in over 1,650 outputs on single substances and groups of substances (e.g. flavourings). For regulated compounds, these risk assessments have been performed by a number of scientific panels and supporting units:

- a) the Scientific Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel and Food Ingredients and Packaging (FIP) Unit) and b) the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel and FIP unit, formerly the Scientific Panel on Food Additives Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel)): both panels deal with human health risk assessment;
- b) the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA Panel and unit) dealing with human health risk assessment of vitamins, minerals and novel foods;
- c) the Scientific Panel on Additives, Products and Substances used in Animal Feed (FEEDAP Panel and unit) performing human health, animal health and ecological risk assessments for feed additives;
- d) the Pesticides Unit dealing with the peer review of plant protection product opinions (PPPs) and producing conclusions on single pesticides dealing with human health, animal health and ecological risk assessments.

For contaminants, the Panel on Contaminants in the Food Chain (CONTAM panel and BIOCONTAM unit) have dealt with human health and animal health risk assessments for contaminants of anthropogenic origin (e.g. brominated flame retardants, dioxins), environmental contaminants (e.g. heavy metals), compounds resulting from food and/or feed processing (e.g. acrylamide), and natural toxins produced as undesirable substances in food and feed by plants, fungi and other microorganisms (e.g. alkaloids, mycotoxins and marine biotoxins). Finally, for compounds falling under the remit of more than one panel (e.g. carvone), the risk assessments have been performed by the EFSA's Scientific Committee⁴ (EFSA Scientific Committee, 2014).

From all these risk assessments performed at EFSA, it has been recognised that a structured database summarising the toxicological endpoints and reference values on a substance-specific basis would be instrumental in disseminating these results to a wider community, and would be of great support for the work of EFSA experts and staff in providing scientific advice. Consequently, over the last 5 years, summary data related to human health, animal health and ecological hazard assessment have been systematically collected and structured into OpenFoodTox. The database has been designed and developed using a data model taking into account the OECD harmonised templates⁵ to collect and structure the data in a harmonised manner. Detailed descriptions of the data and the structure of OpenFoodTox have been published elsewhere (S-IN 2013, 2014, 2015).

For the user, OpenFoodTox provides options to search data for each substance using chemical descriptors and generate an individual summary datasheet (PDF/Excel) using an online MicroStrategy tool for each of the following:

- Chemical characterisation (e.g. name, formula, CAS and EU numbers, IUPAC, SMILE, etc.);
- EFSA outputs (Scientific opinions, Statement or Conclusions) and background regulations. The corresponding bibliographic details, digital object identifiers and links are provided;

³ OpenFoodTox is part of the open data policy undertaken by EFSA to harmonise the methodology for assessing the safety of chemicals used in food. OpenFoodTox has no legal or regulatory force and may not be used as support or evidence in any disagreement or dispute pertaining to the legal classification of products or substances.

⁴ The Scientific Committee develops harmonised risk assessment methodologies on scientific matters of a horizontal nature in the fields within EFSA's remit where the EU-wide approaches are not already defined. It provides general coordination to ensure consistency in the scientific opinions prepared by the EFSA's scientific panels. It also provides strategic scientific advice to the EFSA's management.

⁵ <http://www.oecd.org/ehs/templates/>

- Critical toxicological study including study design (length of study, species, type), reference point for human health, animal health or ecological endpoints;
- Conclusions on the mutagenicity/genotoxicity of the substance;
- Reference values and uncertainty factors applied for the derivation of health-based guidance values for humans (e.g. ADI, TDI) and environmental standards (e.g. NOECs or predicted NOECs).

Overall, OpenFoodTox contributes actively to objective 2 of EFSA's 2020 Science Strategy⁶ which aims at 'widening EFSA's evidence base and optimise access to its data' as a valuable open source database that can be shared with all scientific advisory bodies and stakeholders with an interest in chemical risk assessment. In addition, OpenFoodTox has been submitted to the OECD's Global Portal⁷ to Information on Chemical Substances (eChemPortal) so that individual substances can be searched as part of the national and international databases. By making this summary data available in a readily accessible format, it is anticipated that this will stimulate further analysis of the data by the wider scientific community, so generating new knowledge in the area of chemical risk assessment.

Finally, EFSA has recently published a scientific report on 'modern methodologies and tools for human hazard assessment of chemicals' (e.g. -omics, toxicokinetic and *in silico* models such as QSAR models and read-across tools) which provided, through consultation of the EFSA staff, panels and other international organisations, recommendations for further work in these areas. The further development of QSAR models and read-across tools in chemical risk assessment was identified as a key priority to develop predictive tools and reduce animal testing particularly for compounds for which toxicity data are not available (EFSA, 2014). In this context, OpenFoodTox is currently being explored as a data source to support the development of innovative *in silico* tools such as QSAR models. These tools will be illustrated in a technical report to be published later this year together with a new version of OpenFoodTox with enhanced features.

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⁶ <http://www.efsa.europa.eu/en/corporate/pub/strategy2020>

⁷ http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en