Animal dietary exposure: overview of current approaches used at EFSA

European Food Safety Authority (EFSA), Michele Ardizzone, Marco Binaglia, Bruce Cottrill, Jean-Pierre Cugier, Lucien Ferreira, Jose Angel Gomez Ruiz, Matteo Innocenti, Sofia Ioannidou, Secundino Lopez Puente, Caroline Merten, Marina Nikolic and Giovanni Savoini

Abstract

At EFSA, animal dietary exposure estimates are undertaken by several Panels/Units to assess the risk of feed contaminants, pesticide residues, genetically modified feed and feed additives. Guidance documents describing methodologies for animal dietary exposure assessment are available both at EFSA and international levels. Although appropriate within pertinent regulatory frameworks, the methodologies used to assess animal dietary exposure vary across risk assessment areas. There are different approaches ranging from quick worst-case estimations to more refined methods assessing actual exposure, resulting from the use of a heterogeneous selection of animal populations and default values to estimate feed intake. Furthermore, current feed classification systems in place at international and national levels contain a large and heterogeneous number of feed materials, which may benefit from further harmonisation efforts. This technical report presents an overview of the current approaches in place at EFSA to assess the exposure to chemicals in feed. The possibility for a greater harmonisation of feed classification and terminology is also addressed by comparing the structure of the EU catalogue of feed materials and the Harmonised OECD tables of feedstuffs derived from field crops with the EFSA FoodEx2 system.

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: Animal dietary exposure, feed classification, feed intake, FoodEx2 system, EU catalogue of feed materials, Harmonised OECD tables of feedstuffs

Requestor: EFSA

Question number: EFSA-Q-2018-01020

Correspondence: gmo_secretariat_applications@efsa.europa.eu
Acknowledgements: EFSA wishes to thank the following for the support provided to this output: staff members Davide Arcella, Anne Theobald and Frederique Istace; the members of the GMO Panel and its Working Group on Food and Feed; and all the members of the Panels on Contaminants in the Food Chain, Additives and Products or Substances used in Animal Feed, and Plant Protection Products and their Residues.

Suggested citation: EFSA (European Food Safety Authority), Ardizzone M, Binaglia M, Cottrill B, Cugier J-P, Ferreira L, Gómez Ruiz JA, Innocenti M, Ioannidou S, López Puente S, Merten C, Nikolic M and Savoini G, 2019. Scientific report on the animal dietary exposure: overview of current approaches used at EFSA. EFSA Journal 2019;17(11):5896, 18 pp. https://doi.org/10.2903/j.efsa.2019.5896

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Table of contents

Abstract .................................................................................................................................................. 1
1. Introduction ...................................................................................................................................... 4
   1.1. Background ............................................................................................................................... 4
2. Data and methodologies ................................................................................................................... 4
3. Assessment ..................................................................................................................................... 5
   3.1. Introduction to risk assessment of feed at EFSA ................................................................. 5
   3.2. Introduction to animal dietary exposure assessment .............................................................. 6
   3.2.1. Chemical concentration data ............................................................................................... 6
   3.2.2. Feed intake .......................................................................................................................... 7
   3.3. Feed material classification and terminology ........................................................................ 7
   3.3.1. The EU catalogue of feed materials .................................................................................... 8
   3.3.2. The Harmonised OECD tables of feedstuffs derived from field crops ................................ 9
   3.3.3. EFSA’s FoodEx2 system ..................................................................................................... 9
3.4. Animal dietary exposure assessment at EFSA .......................................................................... 9
   3.4.1. Animal population for dietary exposure used at EFSA ...................................................... 9
   3.4.1.1. Representative population (CONTAM Panel) ................................................................. 9
   3.4.1.2. Representative population (PRES/PREV Units on pesticides) ........................................ 10
   3.4.1.3. Representative population (GMO Panel) ....................................................................... 10
   3.4.1.4. Representative population (FEEDAP Panel) ................................................................. 10
   3.4.2. Feed intake data used at EFSA ............................................................................................ 11
   3.4.2.1. Feed intake data (CONTAM Panel) ................................................................................ 11
   3.4.2.2. Feed intake data (PRES/PREV Units on pesticides) ........................................................... 12
   3.4.2.3. Feed intake data (GMO Panel) ....................................................................................... 12
   3.4.2.4. Feed intake data (FEEDAP Panel) ................................................................................ 12
   3.4.3. Approaches used at EFSA to assess animal dietary exposure .......................................... 13
   3.4.3.1. Approach based on the use of ‘standard diets’ (the CONTAM approach) .................. 13
   3.4.3.2. Approach based on a worst-case scenario (the PREV/PRES approach) ...................... 14
   3.4.3.3. Approaches based on the 100% replacement scenario (the GMO approach) ............ 15
   3.4.3.4. Approach based on the use of ‘maximum safe concentration in feed’ (the FEEDAP case) 15
4. Discussion .................................................................................................................................... 16
References ......................................................................................................................................... 17
Abbreviations .................................................................................................................................. 17
Appendix 1A – Mapping of the EU Catalogue of feed materials (Regulation (EU) 2017/1017) to the EFSA FoodEx2 system ............................................................... 18
Appendix 1B – Mapping of the OECD GD on residues in livestock (OECD, 2013) to the EFSA FoodEx2 system 18
1. Introduction

Animal dietary exposure assessment is a prerequisite for the EFSA risk assessment of feed contaminants and undesirable substances (i.e. the Panel on Contaminants in the Food Chain (CONTAM Panel)), pesticide residues\(^1\) resulting from the uses of plant protection products (i.e. PREV/PRES Unit), new constituents (e.g. newly expressed proteins) and/or endogenous constituents with levels altered as a result of a genetic modification (i.e. the Panel on Genetically Modified Organisms (GMO Panel)), and feed additives including substances, preparations and/or microorganisms (i.e. the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel)).

Estimates of animal dietary exposure for farmed and companion animals\(^2\) are based on concentration data for chemicals\(^3\) in feed commodities and feed intake data available in the literature (e.g. OECD and EFSA Guidance documents), which may result in the use of heterogeneous default values and different animal species/categories.

A wide range of feedstuff is used as feed for farmed and companion animals, but their nomenclature is inconsistent, and several feed classification systems are currently in place at the international and national levels.

This technical report presents an overview of the current approaches in place at European Food Safety Authority (EFSA) to assess the exposure to chemicals in feed commodities, and addresses the need for an improved harmonisation of feed classification and terminology, by gathering together in the EFSA FoodEx2 system\(^4\) the structure of the EU catalogue of feed materials (Section 3.3.1) and of the Harmonised OECD tables of feedstuffs derived from field crops (Section 3.3.2).

The technical report was presented and endorsed at the 95th Scientific Committee Plenary on the 12th of September.

1.1. Background

Assessment of dietary exposure to chemicals in feed relies on their specific concentrations in feed materials and the amount of feed consumed.

While for human dietary exposure food consumption data for the European population are systematically collected and made available in the EFSA Comprehensive European Food Consumption Database\(^5\) (EFSA, 2011), the collection of consumption data for farmed and companion animals is less advanced. To date there is no common database to predict feed intakes for all classes of livestock and production systems in the European Union (EU), and therefore the approaches adopted rely on the use of default values available for the total amount of feed consumed daily, the inclusion rate of feedstuffs in standard diets, and animal body weights.

Awareness of the different approaches that are being used to estimate animal dietary exposure in the context of specific regulatory frameworks triggered EFSA to prepare a technical report which aimed to: (1) gather information on the current uses of default values for feed intake in several areas of feed risk assessment; (2) harmonise the feed classification and terminology proposed in the EU catalogue of feed materials and the Harmonised OECD tables of feedstuffs derived from field crops, improving those proposed in the FoodEx2 system, currently used in the EFSA Standard Sample Description (Section 3.3.3).

While this technical report provides an overview of the current methods used to estimate the animal exposure, it is not intended to give new recommendations on how to conduct and report animal dietary exposures to EFSA Panels or Units, stakeholders and customers.

2. Data and methodologies

This technical report is the output of the EFSA Working Group on Animal Dietary Exposure (ADE WG) and provides an overview of the current approaches in place at EFSA for the assessment of

---

1 ‘Pesticide residues’ refers to an active substance and its potential metabolites, breakdown or reaction products.

2 Unless clearly specified, when referring more generally to animals or farmed and companion animals in this document, both food-producing and non-food-producing species are included.

3 When referring to chemicals in this document we focus on those substances constituting the target of the feed risk assessment at EFSA: e.g. contaminants and undesirable substances as defined by Directive 2002/32/EC; pesticide residues resulting from the uses of plant protection products; new constituents and/or endogenous constituents with levels altered as a result of a genetic modification; feed additives including substances, preparations and/or microorganisms.

4 FoodEx2 is a comprehensive food and feed classification and description system set up by EFSA, describing food and feed data collections across different safety domains, further described in Section 3.3.3.

5 https://www.efsa.europa.eu/en/data/food-consumption-data
animal dietary exposure to chemicals in feed, together with a proposal for the harmonisation of feed classification and terminology in the FoodEx2 system.

The members (experts of the EFSA Panels and Units) appointed to the ADE WG had expertise in animal dietary exposure, collection of data for the management of the FoodEx2 system and harmonisation of cross-cutting issues among the Panels and Units.

In developing this technical report, they considered the principles and requirements defined in feed-related EU legislation as detailed in Section 3.1. The scientific literature was also considered, when relevant, as discussed in Section 3.2.2.

The final draft version of this technical report was presented to the EFSA CONTAM, PPR, GMO and FEEDAP Panels, and relevant feedbacks were taken into account before presenting the final version to the Scientific Committee for endorsement.

3. Assessment

3.1. Introduction to risk assessment of feed at EFSA

Safe animal feed is essential for the health of animals and the safety of food of animal origin. European legislation provides a framework to ensure that feed does not pose a risk to animals, humans or the environment, covering the possible impact of a large variety of chemicals in feed commodities.

The risk assessment of a chemical in feed is a scientifically based process aimed at giving an indication (risk characterisation) of the nature and incidence of adverse effects (e.g. impact on health or productivity) in a given population, posed by the presence of a hazard (hazard identification and characterisation), and the likelihood that animals are exposed to that substance through feed (exposure assessment).

EFSA assesses the risk from undesirable substances and pesticide residues in feed commodities, genetically modified feed and the use of feed additives in animal nutrition.

The CONTAM Panel provides scientific advice on the potential risk to public and animals health from contaminants in the food and feed chains and undesirable substances such as natural toxicants, mycotoxins and residues of unauthorised substances. Chemical substances not intentionally added to feed commodities (feed contaminants) may be present as a result of the various varietal or environmental effects, methods of feed production, processing or transport or as a result of environmental contamination. EFSA collects occurrence data on contaminants in feed, supporting the coordination of data collection and monitoring by Member States. The main EU legislation in this area is Directive 2002/32/EC on undesirable substances in animal feed.

The PRES/PREV Units on pesticides provide scientific advice on the potential risk to public and animals health from pesticide residues resulting from the uses of plant protection products in food and feed commodities. Plant protection products are used in agriculture to keep crops healthy and prevent them from being destroyed by disease and infestation, and include mainly herbicides, fungicides, insecticides, acaricides, plant growth regulators and repellents. As part of this evaluation, EFSA reviews the information provided by applicants on the potential risk to humans, animals and the environment from the active substances used in plant protection products and the information available on their maximum residue levels (MRLs). Plant protection products are principally regulated by Regulation (EC) No 1107/2009 while matters related to MRLs for pesticide residues in food and feed commodities are covered by Regulation (EC) No 396/2005. However, as the list of feed commodities to which MRLs apply has not yet been finalised, MRLs have only been established for food commodities (although they may include some commodities such as cereal grains, carrots and potatoes used as feed) and not for feed commodities (e.g. grass, hay, cereal straw).

The GMO Panel provides scientific advice on the safety of genetically modified (GM) plants for public and animal health and the environment, before market authorisation for import and/or

6 Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement. OJ L 140, 30.5.2002, p. 10–22.
7 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
8 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
cultivation, and for their renewal. As part of this process, EFSA reviews the information provided by applicants on GM plants and assesses the safety of the derived GM food and feed. The principal EU legislation in this area is Regulation (EC) 1829/2003 on genetically modified food and feed and its implementing Regulation (EC) 503/2013 on the preparation and presentation of applications for authorisation of food and feed products containing, consisting of, or produced from the genetically modified plant. Directive 2001/18/EC regulates the deliberate release into the environment of genetically modified organisms.

The FEEDAP Panel provides scientific advice on the safety of feed additives, widely used in animal nutrition, for which a prior authorisation is needed to enter the EU market. As part of this process, EFSA reviews the information provided by applicants on additive identity, conditions of use and control methods, and assesses the efficacy and safety of the additive for target animals and humans (consumers of food of animal origin and users), and the environment. The main EU legislation in this area is Regulation (EC) No 1831/2003 on additives for use in animal nutrition and its implementing Regulation (EC) No 429/2008 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.

3.2. Introduction to animal dietary exposure assessment

Exposure assessment is one of the pillars of risk assessment, together with hazard identification, hazard characterisation and risk characterisation. More generally, it is defined as the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food (or feed) as well as other sources, if relevant (EFSA Scientific Committee, 2012). When the focus of the assessment is on animal exposure to chemicals in feed commodities, we refer to animal dietary exposure assessment.

In order to estimate animal dietary exposure to a chemical of interest, data on its concentration in feed and on the daily consumption (intake) of that feed are needed. By combining these two variables and considering the body weight of the subjects, dietary exposure, expressed as kg body weight per day, is estimated as follows:

\[
\text{(concentration of chemical in feedstuff)} \times \text{(amount of feedstuff consumed)} / \text{(body weight)}
\]

In this technical report, the focus is to describe the current approaches to estimate feed consumption (intake) in the absence of feed consumption (intake) databases, in the different areas of the risk assessment of feed.

3.2.1. Chemical concentration data

There are different ways to collect concentration data on chemicals in feed commodities for risk assessment purposes, based on the type of substance under investigation. Data on feed contaminants are gathered via national monitoring and surveillance programmes, projects run and funded by public organisations or quality control and monitoring programmes in the feed manufacturing chain. These data are collected by the Evidence Management (DATA) Unit at EFSA via calls for continuous collection of chemical contaminant occurrence data in food and feed commodities.\(^{14}\) Information on the concentration of pesticide residues comes from experimental data from field trials made available as part of the application dossiers. Concentration data for newly expressed proteins, other new constituents and/or endogenous constituents with levels altered as a result of genetic modification

---

9 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.
10 Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006. OJ L 157, 8.6.2013, p. 1–48.
11 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration. OJ L 106, 17.4.2001, p. 1–39.
12 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29–43.
13 Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1–65.
14 https://www.efsa.europa.eu/en/consultations/call/190410
come from experimental data (e.g. field trials) and are made available as part of the application
dossiers; occasionally, concentration data from the literature may be used, as in the case of the
comparative exposure approach. For chemicals deliberately added to feed commodities at known
levels, such as additives, the use levels can be proposed directly by industry, and should be below the
maximum threshold established by the authorisation.

3.2.2. Feed intake

Through selective breeding, farmed and companion animals have become notably different from
their wild ancestors. Nowadays, these animals are commonly fed *ad libitum* with balanced diets to
ensure that nutritional needs for maintenance and productive processes are met. To achieve this, an
accurate estimate of feed intake (amount of feed consumed in a given period of time) together with
the selection of appropriate feed materials, is required.

The amount of feed consumed by animals is influenced by many factors including the size and type
of animal, its level of productivity and the physiological status. The diet itself may consist of a single
feedstuff or – more commonly – a mixture of feeds. While the balanced diet is formulated to meet the
nutritional needs of the animal, the choice of ingredients will be influenced principally by their
nutritional composition, availability and cost.

Theoretical feed intake is estimated based on default values (i.e. body weight, energy and nutrient
requirements, environmental conditions) available for each of the farmed and companion animal
species. It must be stressed, however, that there is considerable variation in feeding systems and that
any of the possible default values used to simulate standard rations for a specific category of animal
might not represent the absolute ‘average’, nor necessarily reflect a ‘typical’ feeding system applicable
to all production systems in Europe.

To date, information on quantitative and qualitative estimates of feed intake for farmed and
companion animals is available from a wide variety of publicly available sources. These include
scientific books and publications, guidance documents and recommendations from international
regulatory agencies and organisations involved in feed safety assessment and agriculture development,
such as EFSA, the Food and Agriculture Organization of the United Nations\(^\text{15}\) (FAO), or the
Organisation for Economic Co-operation and Development\(^\text{16}\) (OECD).

In addition, information on feed intake is also available from several national organisations active in
the sectors of the animal feed chain, husbandry and animal nutrition and feeding: e.g. Institut National
de la Recherche Agronomique\(^\text{17}\) (INRA), Centre de Coopération Internationale en Recherche
Agronomique pour le Développement\(^\text{18}\) (CIRAD), Association Française de Zootechnie\(^\text{19}\) (AFZ),
Federatie Nederlandse Diervoederketen,\(^\text{20}\) Fundación Española para el Desarrollo de la Nutrición
Animal,\(^\text{21}\) Luonnonvarakeskus\(^\text{22}\) and the National Research Council, USA.\(^\text{23}\)

3.3. Feed material classification and terminology

‘Feed’ is the term commonly used to describe any edible material which, after ingestion, is capable of
being digested, absorbed and utilised by animals to meet their physiological needs. Similarly, according to
Regulation (EC) No 178/2002\(^\text{24}\), a feed (or feedingstuff) is defined as ‘any substance or product,
including additives, whether processed, partially processed or unprocessed, intended to be used for oral
feeding to animals’. The same definition is also referred to in Regulation (EC) No 1829/2003 on
genetically modified food and feed, Regulation (EC) No 767/2009\(^\text{25}\) on the placing on the market and use

\(^{15}\) http://www.fao.org

\(^{16}\) http://www.oecd.org

\(^{17}\) http://www.inra.fr

\(^{18}\) https://www.cirad.fr

\(^{19}\) https://www.zootechnie.fr

\(^{20}\) https://www.diervoederketen.nl

\(^{21}\) http://www.fundacionfedna.org

\(^{22}\) https://www.luke.fi

\(^{23}\) http://www.nationalacademies.org

\(^{24}\) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general
principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in
matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

\(^{25}\) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market
and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive
79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and
96/25/EC and Commission Decision 2004/217/EC. OJ L 229, 1.9.2009, p. 1–28.
of feed, and is in line with the definition of feed materials and feedingstuffs set out in Directive 2002/32/EC on undesirable substances in animal feed.

Several feed classification systems are in place at international and national levels. While some are officially part of the EU regulatory frameworks (e.g. *EU catalogue of feed materials; Harmonised OECD tables of feedstuffs derived from field crops*), others have been developed to meet the particular needs of feed suppliers or national organisations (Table 1).

**Table 1:** Online databases proposing feed material classification, as published by national organisations in the EU (non-exhaustive examples)

| Organisation | Website |
|--------------|---------|
| Spanish Foundation for the Development of Animal Nutrition | [http://www.fundacionfedna.org/ingredientes-para-piensos](http://www.fundacionfedna.org/ingredientes-para-piensos) |
| | [http://www.fundacionfedna.org/forrajes/introducci%C3%B3n-forrajes](http://www.fundacionfedna.org/forrajes/introducci%C3%B3n-forrajes) |
| Dutch Animal Feed Chain Federation | [http://www.cvbdiervoeding.nl/bestand/10501/cvb-feed-table-2018-edition-2.pdf.ashx](http://www.cvbdiervoeding.nl/bestand/10501/cvb-feed-table-2018-edition-2.pdf.ashx) |
| Natural Resources Institute Finland | [https://portal.mtt.fi/portal/page/portal/Rehutaulukot/feed_tables_english](https://portal.mtt.fi/portal/page/portal/Rehutaulukot/feed_tables_english) |
| INRA-CIRAD-AFZ | [https://www.feedtables.com](https://www.feedtables.com) |
| INRA, CIRAD, AFZ and FAO | [https://www.feedipedia.org](https://www.feedipedia.org) |

Due to the large number of feed materials available for farmed and companion animals and the lack of harmonisation, for the purpose of this document it was agreed to take as a reference the feed classification proposed in international databases that are officially part of the EU regulatory framework (i.e. the *EU catalogue of feed materials* and the *Harmonised OECD tables of feedstuffs derived from field crops*), and to harmonise feed and feed material terminology and descriptions with those already present in the EFSA FoodEx2 system (EFSA, 2015), which improves data interoperability, facilitates data sharing and enables more detailed data analysis.

### 3.3.1. The EU catalogue of feed materials

The *EU catalogue of feed materials*, established by Article 24 of Regulation (EC) No 767/2009 as a tool to improve the labelling of feed materials and compound feed, provides a detailed, although non-exhaustive, classification and description of feed materials. The first version of the catalogue was adopted with Regulation (EU) 242/2010, then repealed and returned in a much more complete form by Regulations (EU) 575/2011 and (EU) 68/2013. The version of the catalogue currently in force under Regulation (EU) 2017/1017 has two major sections: the glossary of 69 procedures applicable to feed, which include descriptions of processes with definitions of the terms of current use (as Part B), and the list of feed materials containing 650 feed items (as Part C), subdivided into 13 macrocategories listed below. For each feed item listed in the catalogue, descriptions of the source and the process it has been subjected to, are also given.

1) Cereal grains and products derived thereof  
2) Oil seeds, oil fruits, and products derived thereof  
3) Legume seeds and products derived thereof  
4) Tubers, roots, and products derived thereof  
5) Other seeds and fruits, and products derived thereof  
6) Forages and roughage, and products derived thereof  
7) Other plants, algae and products derived thereof  
8) Milk products and products derived thereof  
9) Land animal products and products derived thereof  
10) Fish, other aquatic animals and products derived thereof  
11) Minerals and products derived thereof  
12) Products and by-products obtained by fermentation using microorganisms, inactivated resulting in absence of live microorganisms  
13) Miscellaneous.

---

26 Commission Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials. C/2017/3980. OJ L 159, 21.6.2017, p. 48-119.
3.3.2. The Harmonised OECD tables of feedstuffs derived from field crops

The Harmonised OECD tables of feedstuffs derived from field crops have been published in two OECD guidance documents relevant to the risk assessment of pesticide residues in food products of animal origin, resulting from the transfer of residues in plants to animals: the OECD Guidance Document on overview of residue chemistry studies (OECD, 2009) and the OECD Guidance Document on residues in livestock (OECD, 2013).

The Harmonised OECD tables of feedstuffs derived from field crops provides a detailed classification and description of feed materials classified into specific categories, according to the International Feed Nomenclature 27 used by the FAO, in four macro categories:

1) Forages/fodders
2) Roots and tubers
3) Cereal grains and crops seeds
4) By-products.

The format used for the Harmonised OECD tables of feedstuffs derived from field crops shows data for 136 individual feed commodities provided in separate columns, representative of each country or region (i.e. USA, Canada, EU, Australia, Japan) reporting feed materials for livestock consumption (i.e. cattle, swine, poultry and sheep). For the purpose of this document, a total of 103 feed materials commonly present in EU countries were considered.

3.3.3. EFSA’s FoodEx2 system

FoodEx2 is a comprehensive classification and description system used for the description of food and feed matrices within the data collections of different safety domains relevant to EFSA. It describes individual food and feed items aggregated into groups and broader categories in a hierarchical parent–child relationship structure. The description of individual food and feed items can be complemented by additional information through the use of facets (EFSA, 2015). The entire system is code-based. Each entry is identified by a unique five-digit alphanumerical code for the food/feed item or food/feed grouping, which in turn is associated with a proper description specifying which food/feed items are included in, or excluded from, the group.

The FoodEx2 system consists of eight different hierarchies, being MTX (FoodEx2 Matrix), Reporting, Zoonoses, Feed, Exposure, VetDrugRes, Botanicals and FeedAddExpo.

When the FoodEx2 system was first developed, it was focused on foods. For the creation of the feed hierarchy, the comprehensive list of feed materials and related processing factors established in Regulation (EU) No 575/2011 on the EU catalogue of feed materials 28 was used as a basis. The current version of the feed hierarchy consists of 13 main feed groups from the catalogue of feed materials (Section 3.3.1) plus compound feed, which is further disaggregated to ‘complete feed’ and ‘complementary feed’ for the different livestock species. The total number of feed entries is 723 which can be further complemented with the use of facet descriptors (e.g. process, source).

3.4. Animal dietary exposure assessment at EFSA

The different approaches used by EFSA to estimate animal dietary exposure to chemicals in feed commodities are determined by the specific regulatory frameworks. This is further complicated by the absence of comprehensive databases for feed intake that impose the use of default values for total amount of feed consumed daily by animals, inclusion rate of feedstuffs in standard diets/rations, and animal body weights.

3.4.1. Animal population for dietary exposure used at EFSA

There is not a standard rule for selecting the animal species and related categories for dietary exposure to chemicals in feed commodities, and different requirements may play a role in the specific assessments.

3.4.1.1. Representative population (CONTAM Panel)

The reference regulatory framework for feed contaminants concerns the dietary exposure for farmed and companion animals, with the objective of assessing the risk of a feed contaminant to

27 http://www.fao.org/3/x5738e/x5738e09.htm#2.%20an%20international%20feed%20nomenclature
28 Subsequently repealed and replaced by Regulation (EU) No 68/2013.
animal health and to estimate the carry-over from feed into food of animal origin, when relevant. Exposure assessment is based on animals considered representative of the EU population (Table 2), selected on a case-by-case basis depending on the nature of the feed contaminant and on the animal species potentially exposed to it.

3.4.1.2. Representative population (PRES/PREV Units on pesticides)

The reference regulatory framework for plant protection products concerns the calculation of dietary exposure for livestock animals, with the main objective of assessing the impact of pesticide use on the food chain (i.e. risk for human consumption associated with a potential transfer of residues in food commodities of animal origin). Therefore, the target animal species (Table 2) correspond to livestock animals during the food production phase. These animal categories are defined in OECD guidance documents (OECD, 2009, 2013). Furthermore, a specific methodology has been developed to address the case of farmed fish (Schlechtriem et al., 2016) which will form the basis for upcoming guidance on this matter.

The impact of pesticide use on animal health is based on the exposures calculated for wild non-food-producing animals (wild birds, mammals and fish). This risk assessment is performed separately by experts in ecotoxicology and environmental risk assessment. Specific exposure calculations are performed that consider the energy needs of wild species of birds and mammals assuming that they obtain food (e.g. plant materials and insects) from treated fields after the use of plant protection products. As regards non-farmed fish, the exposure is based on the predicted concentration in surface water. It is noted that there is currently no model to assess the exposure for companion animals.

3.4.1.3. Representative population (GMO Panel)

In the area of GM feed products, the reference regulatory framework assumes that dietary exposure will be calculated for groups representative of the EU animal population (food-producing and non-food-producing) with the objective of assessing the risk of GM feed to animal health. However, no further recommendations are given on the species and categories of animals to be considered. So far, most applicants provide exposure calculations selecting animal species and categories recommended in OECD guidance documents (OECD, 2009, 2013), as listed in Table 2. Recently, other species (e.g. companion animals and farmed fish) have also been introduced and discussed by applicants.

3.4.1.4. Representative population (FEEDAP Panel)

In FEEDAP, the reference regulatory framework concerns the dietary exposure of farmed and companion animals to support the authorisation process of feed additives, with the objectives of assessing the safety of the additive for the proposed target animal species and categories, the consumers, the users/workers and the environment and its efficacy in term of its intended use. Regulation (EC) No 429/2008 identifies the target animal species for which tolerance studies are required concerning the safety assessment of the additive and studies concerning the efficacy assessment of the additive, giving in some cases a reference age to be considered in the study design (Table 2).

Table 2: Animal species and production category per Panel/Unit

| Animal species                  | CONTAM Panel(a) | PRES(V) Units and GMO Panel(b) | FEEDAP Panel(c)                                      |
|--------------------------------|-----------------|--------------------------------|-----------------------------------------------------|
| Ruminant                       |                 |                                |                                                     |
|                                |                 | Bovines: calves for rearing    |                                                     |
| Fattening cattle: beef         |                 | Cattle: beef                   | Bovines: cattle for fattening                       |
| Fattening cattle: cereal beef  |                 |                                |                                                     |
| Cattle: dairy cows, lactating  |                 | Cattle: dairy                  | Bovines: dairy cows for milk production             |
|                                |                 |                                | Bovines: cows for reproduction                      |

29 Regulation (EC) 1829/2003, Recital (8): ‘The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.’
3.4.2. Feed intake data used at EFSA

There are no comprehensive databases that provide homogeneous data on feed intake for farmed and companion animals with relevance for the EU population, and that are suitable for the determination of exposure to chemicals present in feed commodities. However, within the scope of the relevant regulations, EFSA has developed approaches for selecting default values for feed intake in conducting its risk assessments.

3.4.2.1. Feed intake data (CONTAM Panel)

A systematic approach for animal dietary exposure to feed contaminants and undesirable substances has been adopted by the CONTAM Panel. It takes into consideration the inclusion rate in standard diets of the relevant feedstuff(s) in which the substance is measured and the default values

| Animal species   | CONTAM Panel(a)                  | PRES(V) Units and GMO Panel(b) | FEEDAP Panel(c) |
|------------------|----------------------------------|--------------------------------|-----------------|
| Small ruminant   |                                  | Sheep: lamb                    | Sheep: lambs for rearing |
| Sheep: lactating | Sheep: ram/ewe                   | Sheep: dairy sheep for milk production |
| Goats: fattening |                                  | Goats: kids for fattening      |
| Goat: milking    |                                  | Goats: dairy goats for milk production |
| Horse            | Horses(e)                        | Horses: (All categories)       |
| Swine            | Pigs: piglets                    | Pigs: Piglets (suckling)       |
|                  | Pigs: Piglets (weaned)           | Pigs: Piglets (suckling and weaned) |
|                  | Pigs: fattening pigs             | Pigs: Pigs for fattening       |
|                  | Swine: breeding                  | Pigs: Pigs for fattening       |
|                  | Swine: finishing                 | Pigs: Sows for reproduction    |
| Rabbits          | rabbits suckling and weaned      | Pigs: Sows (benefit in piglets) |
| Avian            | Poultry: broilers (chickens for fattening) | Poultry: Chicks for fattening |
| Poultry: laying hens | Poultry: layer                    | Poultry: Chicks reared for laying |
| Turkeys: fattening turkeys | Poultry: turkey                | Poultry: Turkeys for fattening |
| Ducks: fattening ducks |                                  | Poultry: Turkeys reared for breeding |
| Farm fish        | Fish: salmonids                  | Salmonids(d)                   | Fish: salmon |
| Others species(e) (e.g. Carpa) | Salmonids(d)                   | Fish: salmon |
| Companion animal | Dogs                              | Pets: Dogs                     |
|                  | Cats                              | Pets: Cats                     |
| Fur animal       | Mink(e)                          | Pets: ornamental birds and fish |

(a): EFSA CONTAM Panel (2011) (with some exceptions as indicated).
(b): OECD Guidance: OECD (2009, 2013).
(c): Regulation (EC) No 429/2008.
(d): Fish diets not included in OECD (2009, 2013); EU guidance document in preparation, not yet finalised.
(e): EFSA CONTAM Panel (2017).
for daily feed intake in the main animal species and categories at specific growth rates, level of productivity or physiological state, and for a given body weight (Table 3). This approach, which has not been consolidated into a guidance or a reference document, was included for the first time in the Scientific Opinion of the CONTAM Panel on T-2 and HT-2 toxin in food and feed (EFSA CONTAM Panel, 2011), and the proposed methodology has been adapted over the years depending on the specific needs of the mandates, on the feed contaminant of interest and its presence in specific feed materials. For the purpose of this document, this Scientific Opinion is considered as the standard and any information provided from other sources will be properly referred to.

3.4.2.2. Feed intake data (PRES/PREV Units on pesticides)

The approach adopted for animal dietary exposure to pesticide residues resulting from the uses of plant protection products in feed commodities relies on estimations of feed intake based on default values for daily feed intake and body weights as reported in the OECD guidance documents (OECD, 2009, 2013). In the view of assessing the impact of pesticide use on the food chain (i.e. the risk for human consumption associated with a potential transfer of residues in food commodities of animal origin), the default values for farm livestock are considered during the food production phase (e.g. during the egg- or milk-producing stage or close to slaughter) (Table 3).

3.4.2.3. Feed intake data (GMO Panel)

In the area of GM feed products, the reference regulatory framework assumes that dietary exposure will be calculated based on representative consumption data. However, no further clarifications are given on the source of data to be considered. In the absence of clear indications, applicants provide exposure calculations mostly based on default values for body weight, daily feed intake and inclusion rate of GM feed materials in diets, as recommended for EU animals in the OECD guidance documents (OECD, 2009, 2013), as listed in Table 3. The selection of relevant feed materials entering the final diet is conducted on a case-by-case basis, with differences in the approaches among applicants.

3.4.2.4. Feed intake data (FEEDAP Panel)

The approach adopted by the FEEDAP Panel to estimate animal dietary exposure to feed additives from default values for body weight and daily feed intake is reported for the main categories of farmed and companion animals in the Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017). This guidance recommends these default values for the main animal species/categories at specific growth rates or level of productivity and physiological status which are representative of the most sensitive phases of the production cycles (Table 3).

Table 3: Assumed animal feed intake data and default values used across Panels/Units

| Animal categories (Nomenclature/Panels or Units) | Daily feed intake (kg DM/day)/body weight (kg) | Daily feed intake (g DM/kg body weight) |
|-----------------------------------------------|---------------------------------------------|----------------------------------------|
| CONTAM(a) PRES(V)/GMO(b) FEEDAP(c) | CONTAM(a) PRES(V)/GMO(b) FEEDAP(c) | CONTAM(a) PRES(V)/GMO(b) FEEDAP(c) |
| Piglets | Piglets | 1.0/20 | 0.88/20 | 50 |
| Fattening pigs | Swine finishing | 3.0/100 | 3/100 | 2.20/60 | 30 |
| Lactating sows | Sows lactating | 6.0/200 | 5.28/175 | 30 |
| Poultry: broilers | Broilers | 6/260 | | 23 |
| Laying hens | Layers | 0.12/2 | 0.12/1.7 | 0.158/2 | 60 |
| Fattening turkeys | Turkeys for fattening | 0.40/12 | 0.50/7 | 0.176/3 | 33 |
| Fattening ducks | | 0.14/3 | | 47 |
| Dairy cows | Dairy cows | 20.7/650 | 25/650 | 20/650 | 32 |

www.efsa.europa.eu/efsajournal 12 EFSA Journal 2019;17(11):5896
3.4.3. Approaches used at EFSA to assess animal dietary exposure

When dealing with dietary exposure assessment, it is important to distinguish between acute exposure and chronic exposure. In animals, acute and chronic exposure estimates mainly depend on the concentration of the chemical of interest in the feed material, considering that within a given production system, feed intake (per kg body weight (bw)) remains relatively stable from day to day, and under controlled conditions.

3.4.3.1. Approach based on the use of ‘standard diets’ (the CONTAM approach)

The approach to dietary exposure assessment adopted by the CONTAM Panel takes into consideration the distribution of the contaminant in feed materials. Where a contaminant is present in more than one feedstuff, e.g. *Fusarium* spp. which may be present in a number of cereal grains and cereal by-products, its exposure to farm and companion animals depends on the contribution of individual contaminated feedstuffs incorporated into ‘standard diets’ (see Table 4). This approach aims at giving a representative estimate of the potential exposure to a ‘chemical’ within a typical feeding regime but does not necessarily represent a worst-case scenario. However, where a contaminant is only present in one or a limited number of feed materials (e.g. glycoalkaloids in potatoes) the maximum recommended inclusion rates in the daily ration for each of the animal species may be used to provide a worst-case estimate of exposure.

### Table 4: Daily feed intake for different animal categories

| Animal categories (Nomenclature/Units) | Daily feed intake (kg DM/day)/body weight | Daily feed intake (g DM/kg body weight) |
|---------------------------------------|------------------------------------------|----------------------------------------|
| Beef fattening                        | 9.6/400                                  | 24                                     |
| Beef cereal                            | 8.4/400                                  | 21                                     |
| Veal calf                              | 1.89/100                                 | 19                                     |
| Rams/ewes                             | 2.8/80                                   | 35                                     |
| Sheep lactating                       | 2.5/75                                   | 33                                     |
| Lambs                                 | 1.7/40                                   | 43                                     |
| Goats: milking                        | 3.4/60                                   | 57                                     |
| Goats: fattening                      | 1.5/40                                   | 38                                     |
| Rabbits                               | 0.15/2                                   | 75                                     |
| Horses                                | 9/450                                    | 20                                     |
| Salmonids                             | 0.04/2                                   | 20                                     |
| Carp(d)                               | 0.02/1                                   | 20                                     |
| Dogs                                  | 0.36/25                                  | 14                                     |
| Cats                                  | 0.06/4                                   | 15                                     |
| Ornamental fish                       | 0.000054/0.012                          | 5                                      |
| Mink(d)                               | 0.075/2                                  | 37.5                                   |

DM: dry matter.

(a): EFSA CONTAM Panel (2011) (with some exceptions as indicated).
(b): OECD Guidance: OECD (2009, 2013).
(c): EFSA FEEDAP Panel (2017).
(d): EFSA CONTAM Panel (2017).
commercially manufactured feed or as individual feed mixed on the farm. Again, the composition of these is highly variable, but the CONTAM Panel has adopted typical formulations in order to assess exposure. For companion animals (dogs and cats), the CONTAM Panel has adopted typical dry feed formulations provided by FEDIAF.\(^30\) The assumed inclusion rates for feed in non-ruminant diets are given in Table 4.

**Table 4: Example of animal potential diet/ration (CONTAM panel)(a)**

| Feed commodities(b) (%) of diets | Piglets | Pigs for fattening | Lactating sows | Broilers | Laying hens | Turkeys for fattening | Ducks for fattening | Dairy cows | Cattle, cereal beef | Beef cattle-fattening | Sheep, lactating | Goats, dairy | Goats for fattening | Rabbits | Horses | Growing salmonids | Dogs | Cats |
|---------------------------------|---------|-------------------|----------------|---------|-------------|----------------------|-------------------|-----------|-------------------|---------------------|-----------------|-------------|-------------------|---------|-------|------------------|------|------|
| Wheat                            | 48      | 48                | 50             | 38      | 30          | 30                   | 45                | 15        | 14                | 14                  | 13.2           | 30.5        | 30.5              |         |       |                   |      |      |
| Barley                           | 20      | 20                | 11             | –       | –           | 35                   | 15                | 20        | 60                | 40                  | 18             | 25          | 20                | 18      |       | 12.3             | 13.2  |       |
| Maize                            | –       | –                 | 38             | 35      | –           | –                    | –                 | –         | –                 | –                   | 35             | 40          | –                 | –       | 13.2  | 13.2             |      |      |
| Oats                             | –       | –                 | –              | –       | –           | –                    | –                 | 35        | 40                | –                   | –              | –           | –                 | –       | 11.5  | 11.5             |      |      |
| Rice                             | –       | –                 | –              | –       | –           | –                    | –                 | –         | –                 | –                   | –              | –           | –                 | –       | 15    | –                 |      |      |
| Beans                            | –       | –                 | –              | –       | –           | 5                    | –                 | 10        | –                 | 11                  | 10             | –           | –                 | –       | 12.3  | –                 |      |      |
| Soybean meal                     | 22      | 11                | 15             | 15      | 22          | 15                   | 28                | 5         | –                 | 5                   | 10             | –           | –                 | –       | –     | –                 |      |      |
| Rapeseed meal                    | 3       | 4                 | –              | –       | –           | –                    | 20                | 5         | 20                | 10                  | 10             | –           | 12.3              | –       | –     | –                 |      |      |
| Sunflower meal                   | –       | –                 | –              | –       | –           | –                    | 5                 | 5         | –                 | 20                  | –              | –           | –                 | –       | –     | –                 |      |      |
| Lucerne meal                     | –       | –                 | –              | 4       | 9           | 5                    | –                 | –         | –                 | –                   | –              | –           | –                 | –       | –     | –                 |      |      |
| Dried lucerne                    | –       | –                 | –              | –       | 4           | 9                    | 5                 | –         | –                 | –                   | –              | –           | –                 | –       | –     | –                 |      |      |
| Maize gluten feed               | –       | –                 | –              | –       | –           | 10                   | 10                | 11        | –                 | –                   | 11.5           | 31.9        | 31.9              | –       | –     | –                 |      |      |
| Wheat feed                       | –       | 9                 | 14             | 1       | –           | 7                    | 10                | 4         | 15                | 10                  | 10             | –           | –                 | 30      | –     | –                 |      |      |
| Oat feed                         | –       | –                 | –              | –       | –           | –                    | –                 | –         | –                 | –                   | –              | –           | –                 | –       | –     | –                 |      |      |
| Wheat bran                       | –       | –                 | –              | –       | –           | –                    | –                 | –         | –                 | –                   | –              | 19          | –                 | –       | –     | –                 |      |      |
| Sugar beet pulp                  | –       | –                 | –              | –       | –           | 8                    | 10                | 12        | 15                | 2                   | 12             | –           | –                 | –       | –     | –                 |      |      |
| Molasses                         | 3       | 4                 | 4              | 3       | 3           | 3                    | 3                 | 2         | 4                 | 4                   | 3              | 5           | –                 | –       | –     | –                 |      |      |
| Vegetable oils                   | 1       | 1                 | 2              | 1       | 2           | 4                    | 1                 | 1         | 1                 | 1                   | 2              | 2           | –                 | –       | –     | –                 |      |      |
| Fish and vegetable oils          | –       | –                 | –              | –       | –           | –                    | –                 | –         | –                 | –                   | –              | –           | 31.9              | –       | –     | –                 |      |      |
| Fishmeal                         | –       | –                 | –              | –       | –           | –                    | –                 | –         | –                 | –                   | –              | –           | –                 | 30.5   | –     | –                 |      |      |
| Minerals and vitamins            | 3       | 3                 | 4              | 4       | 4           | –                    | 3                 | 3         | 3                 | 4                   | 3              | 1           | –                 | –       | –     | –                 |      |      |
| % of complementary feed in diet dry matter(b) | –       | –                 | –              | –       | –           | 40                   | 85                | 15        | 50                | 65                  | 40             | 50          | –                 | –       | –     | –                 |      |      |

(a): EFSA CONTAM Panel (2011).

(b): Percentage of complete feedstuffs for non-ruminants, percentage of complementary feed for ruminants and horses.

### 3.4.3.2. Approach based on a worst-case scenario (the PREV/PRES approach)

The livestock dietary exposure (also called ’dietary burden’) calculation is based on an extensive list of over 130 feed commodities (Section 3.3.2), which are classified into four specific crop categories (1 – forage/fodder; 2 – roots and tubers; 3 – cereal grains and crops seeds; 4 – by-products).

For each commodity, the experts first need to estimate the expected concentrations of pesticide residues that result when a plant protection product is used according to good agricultural practice. These ’occurrence data’ are estimated based on results from field trials that simulate the use of a plant

\(^{30}\) FEDIAF: The European Pet Food Industry (information provided by personal communication).
protection product. Two key values are derived from these experiments: the median value (also called the STMR: supervised trials median residue) and the maximum value (also called the HR: highest residue).

For each feed commodity, a maximum intake (expressed as percentage of diet) is proposed in the guidance for each animal species. Thus, the maximum possible 'consumption data' are fixed by the guidance. It is noted that these intakes represent the maximum consumption possible in a daily animal diet regulated by humans.

For European OECD member countries, the OECD guidance (OECD, 2009, 2013) considers livestock mainly reared with low-intensive to non-intensive practices and the dietary burden is therefore calculated according to the 'reasonably worst-case diet/feed' approach. For the estimation of the total residue intake per animal, only one feed item per crop category is selected: the feed commodity resulting in the highest residue intake. The contributions of these four highest contributors are summed to determine the overall residue intake for each referenced animal. When the overall diet exceeds 100% of the total dry matter (DM) intake, refinements are proposed to adjust the total diet per animal to 100% (expressed as kg DM/kg bw).

The model is designed to identify the worst-case scenario (highest exposure) among all possible scenarios. In some cases, it is noted that the model might propose a scenario which may not be realistic from a nutritional point of view.

Two different dietary burdens are calculated: the maximum dietary burden and the median dietary burden. The maximum dietary burden based on the highest residue levels31 (HR) in feed is used to derive the MRL in food of animal origin and to perform the acute consumer risk assessment. The median dietary burden based on the median residue levels in feed is used to derive median residue values in food of animal origin in order to perform the chronic consumer risk assessment.

3.4.3.3. Approaches based on the 100% replacement scenario (the GMO approach)

In the risk assessment of GM feed material, the estimation of dietary exposure mainly refers to newly expressed proteins although specific dietary exposure to other constituents is also occasionally covered (e.g. N-acetyl amino acids). Animal dietary exposure to newly expressed proteins in GM crops is estimated based on their concentration in parts of the plant intended for feed uses. A conservative approach assuming 100% replacement of conventional feed products by the GM products is considered in the first instance; mean levels of the newly expressed protein in raw materials such as grains, seeds, beans and forage (EFSA, 2018) derived from dedicated field trials, are used as occurrence data and to estimate protein concentration in derived feed materials (e.g. by-products); the levels of newly expressed proteins in by-products are indeed calculated by applying factors based on the ratio between crude protein content of the specific by-product relative to the content in grains, seeds or beans, assuming that no losses of proteins occur during processing. In most of the cases, applicants refer to crude protein data as derived from the OECD consensus document on composition for the crop of interest. The anticipated dietary intakes of newly expressed proteins are then reported for any GM product or calculated by summing up their individual dietary contributions for each reference animal. The methods applied to integrate estimated data from feed materials and estimate the overall exposure is one of the main differences observed among applicants which might benefit from further harmonisation. Moreover, ad hoc comparative approaches may be used when the purpose of the assessment is to compare exposure to a newly expressed protein in GM feed with that of a similar protein in conventional feeds, to derive a history of safe consumption. In this case, the newly expressed protein concentration data in the conventional feed may be derived from experimental and/or literature sources.

Animal dietary exposure to other new constituents or endogenous constituents with levels altered as a result of the genetic modification is conducted on a case-by-case basis adapting where possible the principles described above.

3.4.3.4. Approach based on the use of ‘maximum safe concentration in feed’ (the FEEDAP case)

To derive a safe daily dose in the target species (mg/kg bw), the no-observed-adverse-effect level or benchmark dose modelling, derived for an experimental animal species and expressed in mg/kg bw, is divided by an uncertainty factor of 100 (to cover intra- and interspecies variation)32 . The maximum

31 Except for bulked products such as cereal and oilseed grains and processed commodities for which the median values can be considered.
32 The uncertainty factor may be adjusted to take into account particular metabolic considerations, the nature and quality of the toxicological studies, etc.
safe concentration in feed (mg/kg DM) is obtained by dividing this safe daily dose by the default feed intake (expressed as g DM per kg bw, Table 3). This value can be expressed as mg/kg complete feed (as the basis) assuming 88% DM in complete feed and 94.5% DM in milk replacers for veal calves.

The default values of feed intake shown in Table 3 are derived from average values of body weight and feed intake of the animals. For animals not listed in Table 3, the applicant should propose the default values. For additives intended to be used in water, safe concentrations in water can be derived from the safe concentrations in feed (EFSA FEEDAP Panel, 2017).

4. Discussion

The assessment of animal dietary exposure to chemicals in feed is performed according to the fit-for-purpose principles provided in specific regulatory frameworks and international guidelines. There are differences in the overall approaches used to estimate exposure, such as in the selection of the representative animal population target of the assessment, the default values used to calculate feed intake and in the terminology of feed materials incorporated in theoretical or standard diets considered for the assessment. Most of these differences are justified by specific regulatory requirements for the class of chemicals occurring in feed commodities.

The different approaches used to estimate animal dietary exposure range from rough and conservative worst-case scenarios covering the maximum daily exposure to a chemical in theoretical diets (e.g. pesticide residues in feed commodities and newly expressed proteins in GM feed), to refined scenarios aimed at assessing more representative exposures to a chemical in standard-type diets (e.g. feed contaminants), up to realistic estimates derived from intended amounts of a chemical in commercial diets (e.g. feed additives). Differences in these approaches are justified by the need to fit the exposure estimations with the main purposes of the risk assessment of a chemical in feed across the respective scientific areas.

In the absence of a comprehensive database representative of feed consumption for the EU animal population, estimations of animal dietary exposure are based at EFSA on feed intake data as provided in the OECD guidance (OECD, 2009, 2013) and in EFSA guidance/outputs (e.g. EFSA CONTAM Panel, 2011; EFSA FEEDAP Panel, 2017). Although appropriate in the context of the regulatory frameworks across scientific areas and fit for the purpose of pertinent risk assessment needs, the use of different sources results in the selection of a variety of default values for body weights, daily intakes, diet and ration composition across scientific areas, and in the selection of different animal species and related categories.

There is a wide variety of feed materials available for the formulation of animal diets and rations, as reported in several classification systems (Section 3.3), characterised by different levels of detail. The use of the three classification systems described in this report varies, and as a consequence differences are observed in the reporting of feed materials.

The EU catalogue of feed materials is a comprehensive classification system used on a voluntary basis by feed suppliers to identify feed materials and for labelling purposes set by the pertinent EU legislation across different scientific areas. It includes more entries (e.g. feed materials of animal origin; minerals; products obtained by fermentation using microorganisms) than the Harmonised OECD tables of feedstuffs derived from field crops, which is limited to feed materials of crop origin only, fit for the purpose of OECD guidance (2009, 2013), which refers to recommendations for the risk assessment of pesticide residues in edible crops. However, the EU catalogue of feed materials lacks the complete feed entries, which are included in the FoodEx2 system. This system is not linked to specific regulations but was set up by EFSA with the main purposes of combining data coming from different domains, to accommodate the mapping of its terms and to integrate with those used in other classification systems. Appendix 1A and 1B propose how to link and improve the feed classification and terminology of the EU catalogue of feed materials and the Harmonised OECD tables of feedstuffs derived from field crops, with that already available in the EFSA FoodEx2 system.

The flexibility of the FoodEx2 system allows a better harmonisation of feed terminology and descriptions, helping to improve data interoperability, facilitating data sharing and exchange, and allowing more detailed data analysis. A determination of how the FoodEx2 system could be further implemented with harmonisation of data coming from a broader representation of feed material databases is recommended.

EFSA applies consolidated approaches to the performance of animal dietary exposure assessments with respect to specific regulatory frameworks and risk assessment needs. Whenever needed, guidance documents corroborate the animal dietary exposure assessment, integrating technical
aspects in support of the identification of relevant default values for feed intake estimation and listing the animal species and categories on which to perform the assessment, across most scientific areas. Moreover, where experience shows that indications are insufficiently clear or precise, such that applicants might use varied approaches in conducting animal dietary exposure assessments, new updated guidance might be proposed.

In conclusion, with the publication of this technical report, EFSA is taking the first step to create an overview of approaches to animal dietary exposure assessment across different scientific areas subject to different regulatory frameworks. Although the area of feed risk assessment, and in particular the way dietary exposure assessment is performed, would benefit in future from a greater harmonisation across scientific areas, this goes beyond EFSA’s responsibility. However, in the event of future revision of sectorial legislation impacting on feed risk assessment, a further attempt at better harmonisation should be considered.

References

EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in exposure assessment. EFSA Journal 2011;9(3):2097, 34 pp. https://doi.org/10.2903/j.efsa.2011.2097
EFSA (European Food Safety Authority), 2015. The food classification and description system FoodEx2 (revision 2). EFSA supporting publication 2015:EN-804. 90 pp. https://doi.org/10.2903/sp.efsa.2015.en-804
EFSA (European Food Safety Authority), 2018. Technical report on the explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin. EFSA supporting publication 2018:EN-1366, 9 pp. https://doi.org/10.2903/sp.efsa.2018.en-1366
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2011. Scientific Opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal 2011;9(12):2481, 187 pp. https://doi.org/10.2903/j.efsa.2011.2481
EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2017. Scientific Opinion on the risks to human and animal health related to the presence of deoxynivalenol and its acetylated and modified forms in food and feed. EFSA Journal 2017;15(9):4718, 345 pp. https://doi.org/10.2903/j.efsa.2017.4718
EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2017. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. https://doi.org/10.2903/j.efsa.2017.5021
EFSA Scientific Committee, 2012. Scientific Opinion on Risk Assessment Terminology. EFSA Journal 2012;10(5):2664, 43 pp. https://doi.org/10.2903/j.efsa.2012.2664
OECD (Organisation for Economic Co-operation and Development), 2009. Guidance document on overview of residue chemistry studies (as revised in 2009). Series on Testing and Assessment number 64 and Series on Pesticides number 32, OECD Environment, Health and Safety Publications, Paris, ENV/JM/MONO (2009) 31, 93 pp.
OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.
Schlechtriem C, Pucher J and Michalski B, 2016. Dietary burden calculations relating to fish metabolism studies. Journal of the Science of Food and Agriculture, 96, 1415–1419. https://doi.org/10.1002/jsfa.7607

Abbreviations

ADE WG EFSA Working Group on Animal Dietary Exposure
AFZ Association Francaise de Zootechnie
bw body weight
CIRAD Centre de Coopération Internationale en Recherche Agronomique pour le Développement
CONTAM EFSA Panel on Contaminants in the Food Chain
DM dry matter
FAO Food and Agriculture Organization of the United Nations
FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed
GM genetically modified
GMO EFSA Panel on Genetically Modified Organisms
HR highest residue
INRA Institut National de la Recherche Agronomique
MRL maximum residue level
OECD Organisation for Economic Co-operation and Development
STMR supervised trials median residue
Appendix 1A – Mapping of the EU Catalogue of feed materials (Regulation (EU) 2017/1017) to the EFSA FoodEx2 system

Appendix 1B – Mapping of the OECD GD on residues in livestock (OECD, 2013) to the EFSA FoodEx2 system

Appendix 1A and 1B can be found in the online version of this output (‘Supporting information’ section): https://doi.org/10.2903/j.efs.a.2019.5896. Animal dietary exposure: overview of current approaches used at EFSA. www.efsa.europa.eu/efsajournal EFSA Journal 2019;17(11):5896.