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Animal dietary exposure: overview of current approaches used at EFSA

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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.

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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 residues¹ 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 animals² are based on concentration data for chemicals³ 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 system⁴ 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 Database⁵ (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/EC⁶ 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 1107/2009⁷ while matters related to MRLs for pesticide residues in food and feed commodities are covered by Regulation (EC) No 396/2005⁸. 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) 1829/2003⁹ on genetically modified food and feed and its implementing Regulation (EC) 503/2013¹⁰ 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/EC¹¹ 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 1831/2003¹² on additives for use in animal nutrition and its implementing Regulation (EC) No 429/2008¹³ 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 Nations¹⁵ (FAO), or the Organisation for Economic Co-operation and Development¹⁶ (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 Agronomique¹⁷ (INRA), Centre de Coopération Internationale en Recherche Agronomique pour le Développement¹⁸ (CIRAD), Association Française de Zootechnie¹⁹ (AFZ), Federatie Nederlandse Diervoederketen,²⁰ Fundación Española para el Desarrollo de la Nutrición Animal,²¹ Luonnonvarakeskus²² and the National Research Council, USA.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 178/2002²⁴, 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 767/2009²⁵ 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)

Spanish Foundation for the Development of Animal Nutrition
– http://www.fundacionfedna.org/ingredientes-para-piensos
– http://www.fundacionfedna.org/forrajes/introducci%C3%B3n-forrajes
Dutch Animal Feed Chain Federation
– http://www.cvbiervoeding.nl/bestand/10501/cvb-feed-table-2018-edition-2.pdf.ashx
Natural Resources Institute Finland
– https://portal.mtt.fi/portal/page/portal/Rehutilukot/feed_tables_english
INRA-CIRAD-AFZ
– https://www.feedtables.com
INRA, CIRAD, AFZ and FAO
– 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) 2017/1017²⁶ 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 Nomenclature²⁷ 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 alphanumeric 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)²⁹ 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
			Bovines: calves for fattening
	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'.

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

(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).

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

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		44
Fattening pigs	Swine Finishing	Pigs for fattening	3.0/100	3/100	2.20/60	30	30	37
Lactating sows		Sows lactating	6.0/200		5.28/175	30		30
	Swine Breeding			6/260			23	
Poultry: broilers	Broilers	Chickens for fattening	0.12/2	0.12/1.7	0.158/2	60	71	79
Laying hens	Layers	Laying hens	0.12/2	0.13/1.9	0.106/2	60	68	53
Fattening turkeys	Turkeys	Turkeys for fattening	0.40/12	0.50/7	0.176/3	33	71	59
Fattening ducks			0.14/3			47		
Dairy cows	Dairy	Dairy cows	20.7/650	25/650	20/650	32	39	31

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)
Beef: fattening	Beef	Cattle for fattening	9.6/400	12/500	8/400	24	24	20
Beef cereal			8.4/400			21		
		Veal calf			1.89/100			19
Sheep lactating	Rams/ ewes	Sheep	2.8/80	2.5/75	1.2/60	35	33	20
	Lambs			1.7/40			43	
Goats: milking		Goats	3.4/60		1.2/60	57		20
Goats: fattening			1.5/40			38		
Rabbits		Rabbits	0.15/2		0.1/2	75		50
Horses		Horses	9/450		8.0/400	20		20
Salmonids		Salmon	0.04/2		0.0021/012	20		18
Carp ^(d)			0.02/1			20		
Dogs		Dogs	0.36/25		0.25/15	14		17
Cats		Cats	0.06/4		0.06/3	15		20
		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).

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 depends 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.

For ruminants and horses, forage, either fresh or conserved, is the primary feed. While in some production systems it may be the sole feed, it is frequently supplemented with complementary feeds where the amount or quality of forage available is insufficient to meet the nutritional requirements of the animals. The composition of complementary feed can vary significantly, depending on factors such as availability of raw materials, their price, their nutritional composition and the production facilities. In estimating exposure of ruminants and horses, the CONTAM Panel have assumed typical formulations for complementary feed, details of which are provided in the Appendices of the Opinions (Table 4).

There is a considerable range of production systems for pigs, poultry, rabbits, mink and farmed fish within the EU, and in most cases the diet is provided in the form of complete feedstuffs, either as

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	–	–	–	–	13.2	30.5	30.5
Barley	20	20	11	–	–	35	15	20	60	40	18	25	20	18	–	–	12.3	12.3
Maize	–	–	–	38	35	–	–	–	–	–	–	–	–	–	–	–	13.2	13.2
Oats	–	–	–	–	–	–	–	–	–	–	–	35	40	–	40	–	–	–
Rice	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	11.5	11.5
Beans	–	–	–	–	–	–	–	5	–	–	10	–	–	11	10	–	–	–
Soybean meal	22	11	16	15	22	15	28	5	–	–	5	10	10	–	–	–	–	–
Rapeseed meal	3	4	–	–	–	–	–	20	5	20	10	10	10	–	–	12.3	–	–
Sunflower meal	–	–	–	–	–	–	–	–	5	–	5	–	–	20	–	–	–	–
Lucerne meal	–	–	–	–	4	9	5	–	–	–	–	–	–	–	–	–	–	–
Dried lucerne	–	–	–	–	–	–	–	–	–	–	–	–	–	19	–	–	–	–
Maize gluten feed	–	–	–	–	–	–	–	10	10	11	–	–	–	–	–	11.5	31.9	31.9
Wheat feed	–	9	14	1	–	–	7	10	4	10	15	10	10	–	30	–	–	–
Oat feed	–	–	–	–	–	–	–	–	–	–	–	–	–	–	12	–	–	–
Wheat bran	–	–	–	–	–	–	–	–	–	–	–	–	–	19	–	–	–	–
Sugar beet pulp	–	–	–	–	–	–	–	8	10	12	15	–	2	12	–	–	–	–
Molasses	3	4	4	3	3	3	–	3	2	3	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	3	4	4	4	–	3	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.

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Abbreviations

ADE WG	EFSA Working Group on Animal Dietary Exposure
AFZ	Association Française 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.efsa.2019.5896>. Animal dietary exposure: overview of current approaches used at EFSA. www.efsa.europa.eu/efsajournal EFSA Journal 2019;17(11):5896.