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A proposal for the development of a feed consumption database using a standardised feed classification system

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Abstract

There is currently no comprehensive feed consumption database using a harmonised feed classification system. This means there is a lack of accurate information on the individual amount of feed consumed daily by farmed and companion animals. Such a database would support exposure assessments of feed. This report provides a complete overview of the main feed databases, their structure, and how feed materials are classified. It highlights their limits and potential and reports any differences from FoodEx2. A proposal for future updates of FoodEx2 and the development of a comprehensive feed consumption model database is provided. The proposed model database is based on three information areas represented by three Excel sheets. These represent Animal, Feed, and Consumption, allowing the determination of animal dietary exposure. A proof of concept of the developed model database was carried out by performing two case studies focused on genetically modified feed and feed contaminants. For genetically modified feed, a reduced animal dietary exposure was obtained compared to estimations reported in the scientific opinions and obtained using Excel calculators proposed by EFSA. For the contaminants in feed, differences were limited, resulting in slightly higher or lower exposure values. Weaknesses and possible mitigations are also addressed, and recommendations are made for a comprehensive feed consumption database. These include recommendations establishing an EU classification system in which the main features and items reported in the European Catalogue of Feed Materials are harmonised with FoodEx2. It is also recommended that real-life animal consumption data are collected by the feed industry, animal nutritionists, breeders, and farmers, along with the collaboration of stakeholders.

Keywords: feed classification, feed consumption database, animal species, feed categories, exposure assessment

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Summary

The overall purpose of this project (procurement OC/EFSA/GMO/2021/05) is to develop preparatory work for future implementation of a feed classification and feed consumption database. This supports a more accurate estimation of animal dietary exposure by attempting to reach the standards in place for human dietary exposure.

The project pursued four major tasks, as explained below:

Task 1

A thorough mapping of existing systems and methodologies for feed classification and feed consumption data collection was conducted. Databases, classification systems, terminology, inclusion rates, and feed consumption in each feed database were analysed. The databases showed a significant lack of homogeneity and high variability in the feed classification system. They provide limited information on the inclusion rate of each ingredient and many fail to report a reference mixture or compound feed. This limited information, combined with the absence of data on feed consumption for each species and category of animals, makes it difficult to define exposure to animal feed and to make accurate EU-wide analyses. It also complicates harmonised country-to-country comparisons, potentially introducing over or underestimations which could translate into inadequate risk characterisation.

Task 2

A further step was to develop a proposal for a future update of the current EFSA food and feed classification system (FoodEx2). Recommendations for harmonising terminology and descriptions through the same feed materials and compound feed across different databases are proposed. An analysis of "Hierarchies" and "Facets" reported in FoodEx2 was performed focusing on feed materials. When the selected databases were compared with FoodEx2, a great overlap with the European Catalogue of Feed Materials was found, while the other databases were far off in terms of structure and content from FoodEx2.

Task 3

Our proposal for a feed consumption database was developed with a focus on recommendations for data collection and structure. This considered SSD2 controlled terminologies and ensured future interoperability requirements. The model database uses standardised diets and feed classification harmonised with EFSA's current food and feed classification system (FoodEx2). The data on feed materials used in selected animal diets was obtained using the "Global Livestock Environmental Assessment Model – Interactive GLEAM-i" and scientific literature. These diets were used to populate the model database, which consists of three different Excel sheets named Animal, Feed, and Consumption.

Our model database is designed to improve and harmonise various aspects of feed exposure assessments. However, using diets from the literature in our database highlighted the lack of

comprehensive and real-life feed consumption data. It also emphasised the importance of collaborating with stakeholders and the feed industry to collect such data.

Task 4

A proof of concept for the database developed in Task 3 was conducted by retrieving animal and feed consumption data from this model database. Two case studies focused on genetically modified (GM) feed (maize) and feed contaminants (ochratoxin A) were performed. Our database first included animal diets for specific animal categories to enable a comparison of animal dietary exposure in the two case studies. The proof of concept took into account four EFSA scientific opinions published in the EFSA Journal. We compared the results of animal dietary exposure reported in the scientific opinions with those obtained using Excel calculators proposed by EFSA. Finally, we compared these results with the values obtained from the extrapolated animal and feed consumption data from the model database. Generally, for the selected case studies, we observed reduced animal dietary exposure from the input data extracted from the model database.

Overall, we found a wide variety of feed materials used in ration and diet formulations have not yet been classified under a single classification system. In fact, we revealed differences in databases published by national and international organisations. The disparities in the feed classification system, alongside different nomenclatures for animals and the lack of feed consumption data, may cause miscommunication among operators and professionals in the feed industry (e.g., farmers, feed manufacturers). It may also represent a limitation in the evaluation of animal exposure assessments.

For the future development of a feed consumption database, further work is needed. We suggest establishing an EU classification system where the main features and items reported in the European Catalogue of Feed Materials are harmonised with FoodEx2. After this harmonisation, collecting consumption data to populate the database from the feed industry, animal nutritionists, breeders, and farmers is recommended, along with collaboration with stakeholders.

During this project, initial stakeholder involvement was facilitated by organising a meeting to share preliminary information about the project and collect feedback. At the meeting, discussions revolved around setting up a uniform classification system for feed ingredients. A further workshop with stakeholders has been planned for the end of the project to present and discuss the final results and to collect final input for the development and implementation of an EU feed consumption database.

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1 Introduction

1.1 Terms of reference as provided by the requestor

This contract was awarded by EFSA to a consortium headed up by the University of Milan:

Contractor: University of Milan

Members of the consortium:

- University of Milan
- ToxHub Srl
- ISA Digital Consulting.

Contract: OC/EFSA/GMO/2021/05

1.2 Background

Food producing and non-food producing animals[1] need a balanced diet containing all the necessary nutrients, fluids, minerals, and vitamins. Proper nutrition allows animals to meet their physiological needs, grow, reproduce, defend against infections, and produce food for humans (e.g., milk, eggs, meat). For animals raised for food production, such as poultry, pigs, and aquaculture, it is crucial to optimise production and allocate nutrient supplies efficiently for maximum societal benefit. Decisions about what and how to feed animals are based on reliable information regarding the composition of all feed materials used in animal feeding. This information is fundamental in assigning priorities to the use of available feed supplies.

Animal feed is typically divided into those that come from traditional sources and those that are a mixture of additives and other raw materials. Factors such as type (e.g., classification), role (e.g., ingredient, additives), quality, and safety are essential in defining not only nutrient supply but also the welfare and health of the animals.

The risk assessment of feed involves several steps: hazard identification and characterisation to define a safe intake level for the hazard under assessment; dietary exposure assessment to estimate the exposure to the hazard linking data on feed consumption with the concentration of biological, chemical and physical agents in feed, and risk characterisation to define the overall risk.

In the European Union (EU), a comprehensive legislative framework is in place which addresses the risk assessment of biological, chemical, and physical hazards in feed. This

1 According to Reg 767/2009, companion animals are classified as non-food producing animals

includes undesirable substances, pesticides, and veterinary drug residues, feed additives, and new or endogenous constituents with altered levels due to genetic modification.

In 2019, an EFSA task force reviewed the different approaches used to estimate animal dietary exposure across scientific areas involved in the risk assessment of feed. EFSA highlighted the need to develop a harmonised feed classification system and a comprehensive feed consumption database for both food producing and non-food producing animals[1]. This aims to approach the standard in place for human dietary exposure (EFSA, 2019), which is based on a comprehensive food classification system (FoodEx2 system) (EFSA, 2015) and a food consumption database for the EU human population[2].

This technical report summarises the main relevant findings on the main feed databases, the methodologies for feed classification, and the collection of data on feed consumption. The information was complemented by a proposal for harmonisation with EFSA's current food and feed classification system (FoodEx2). A model database[3] for a feed consumption database was then proposed. To verify the functioning and viability of the proposed model, two distinct case studies were carried out, one focusing on genetically modified (GM) feed and the other on feed contaminants.

1.3 Objectives as provided by EFSA

The aim of this procurement was to outsource the preparatory work for further implementation of a harmonised feed classification system and the development of an EU feed consumption database.

The project meets EFSA's recommendations to support a more accurate estimation of animal dietary exposure by approaching the standards in place for human dietary exposure (EFSA, 2019).

The outsourced activities include:

1. mapping existing systems and methodologies for feed classification and feed consumption data collection
2. developing a proposal for future update of the current EFSA food and feed classification system (FoodEx2)
3. developing a proposal for a feed consumption database that includes data structures and guidance for data collection. This is supported by a case study applicable to the areas of

2 Food consumption data are made available in the EFSA Comprehensive European Food Consumption Database at: https://www.efsa.europa.eu/en/data-report/food-consumption-data

3 Hereinafter, we refer to the proposed feed consumption database model (section 2.3.2) with the term "model database"

EFSA risk assessment where improvements in animal dietary exposure are most urgently needed.

The long-term objectives to implement a harmonised feed classification system and to develop an EU feed consumption database represent a complex project. However, it is of recognised interest not only by EFSA but also by other organisations at the international level. A stepwise approach will reduce the overall complexity by providing the necessary preparatory work, and the tasks below have been requested.

Task 1: Map existing systems and methodologies for feed classification and feed consumption data collection.

Task 2: Develop a proposal for future update of the current EFSA food and feed classification system (FoodEx2)

Task 3: Develop a proposal for a feed consumption database, including data structures and recommendations for data collection.

Task 4: Proof of concept for the development of a feed consumption database

Task 5: Final report

2 Data and methodologies

2.1 Mapping of existing systems and methodologies for feed classification and feed consumption data collection

2.1.1 Analysis of the classification system adopted in each feed database

The first step in mapping existing systems was analysing the classification system adopted in each feed database The complete list of databases indicated in the OC/EFSA/GMO/2021/05 tender was:

- *Fundación Española para el Desarrollo de la Nutrición Animal* (FEDNA)
- Dutch Animal Feed Chain Federation (CVB System)
- Natural Resources Institute of Finland (LUONNONVARATIETO)
- INRAE-CIRAD-AFZ (FEED TABLES)
- INRAE-CIRAD-AFZ and FAO (Feedipedia)

The list was integrated by combining different approaches, as summarised in Figure 1. Specifically, a manual search was conducted using specific keywords within the Google search engine. Keywords used included *feed database*; *feed tables*; *feed database pets*; *feed tables pets*; *feed database companion animals*; and *feed tables companion animals*. Only European databases were considered; therefore, all databases based on non-EU data were excluded, with the exception of the International Aquaculture Feed Formulation Database (IAFFD).

From mapping the existing feed databases, emerged the presence of other classification systems that are even more narrative-based and informative than the classic databases considered in the previous section.

For this reason, as reported in Figure 1, the following classification systems were included manually:i) European Feed Catalogue; ii) Feed Materials Register; iii) Harmonised OECD tables of feedstuffs from field crops; iv) The International Feed Vocabulary (FAO/UNDP).

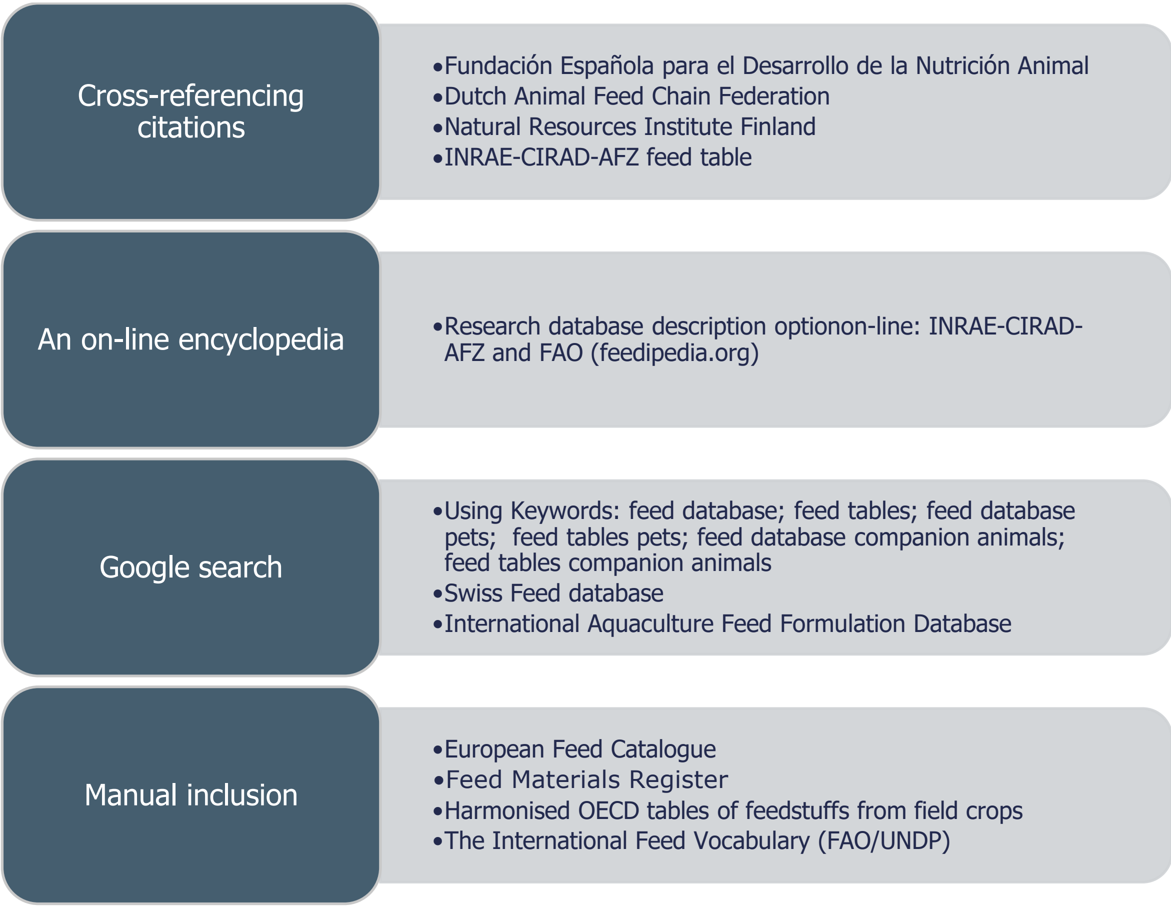

Figure 1: Methodology approach adopted to select databases and other classification systems.

2.1.2 Analysis of terminology and description of feed ingredients in selected feed databases

The analysis of terminology and description used in each feed database verified whether:

- there was an internal search engine in all the databases found when the feed databases were mapped.
- the terminology and description used in each feed database, using *Corn (grain), Maize, and Zea Mays* as keywords. Corn was chosen as the reference material due to its worldwide employment.
- the following information was reported: Name (Acronym); Origin; Language; Website; Downloadable; Narrative description of the information reported for the test feed ingredient (i.e., corn).

2.1.3 Collection of information on inclusion rates and feed consumption

Feed consumption and its efficient utilisation is one of the major concerns regarding animal nutrition. Feed consumption varies and is influenced by several factors, including animal species and size, physiological state of animals, number of animals on the farm, energy content of the diet, ambient temperature, hygienic conditions, and rearing environment.

Given the scarcity of information regarding feed consumption in the selected feed databases, the search was expanded to a non-European context with the report presented in December 2017 by the American Institute for Feed Education (IFEEDER) and Research in collaboration with Decision Innovation Solutions (DIS). This publication addresses feed consumption for food-producing animals only. It estimates the amount of feed consumed by different animal species throughout their lifetime in certain states and regions.

Another non-European source of information about feed consumption for food-producing animals is "The Agricultural Market Information System" (AMIS). In 2014, this inter-agency platform reported the pros and cons of various methodologies, discussed the data requirements for estimating feed use in the context of cereal balance sheets, and reviewed some of the options for better estimating cereal feed use.

The availability of information on feed consumption was also verified with associations or groups of stakeholders with expertise in collecting and managing data related to feed consumption in the EU for both food-producing and non-food producing animals[1] (e.g. feed producer associations, food producing animal associations, veterinary associations, pet food industry). This approach was implemented through questionnaires and online consultation (workshops).

2.2 Developing a proposal for future update of the current EFSA food and feed classification system (FoodEx2)

2.2.1 Analysis of FoodEx2: functioning, structure and available information

FoodEx2 is a comprehensive food classification and description system designed to address the need for detailed food data collection across various food safety domains (EFSA, 2015). Since its first release in 2011, the system has been extensively tested for its effectiveness in collecting data on food consumption and chemical occurrences. It has involved several Member State organisations that operate in practical data collection scenarios.

The testing phase identified strengths and weaknesses of the food classification system, leading to suggestions for improvement and the identification of specific areas for enhancement. Consequently, FoodEx2 was revised to better align with the needs of its diverse users. The current version includes nine hierarchies: eight domain-specific and one service hierarchy for terminology management. EFSA has consistently emphasised the importance of capturing detailed information about food groups in exposure assessments. Now, it advocates applying the same detailed process to animal feed as well.

FoodEx2 categorises feed and food items into groups and broader categories within a hierarchical parent-child relationship structure. This allows each term to be expanded to reveal more specific terms within each category. The terms in the hierarchy are denoted by a blue pyramid symbol, while generic or non-specific terms are denoted by a white or yellow sphere symbol. The red sphere represents the core terms, which indicate the minimum level of specificity recommended for data encoding. The green sphere represents the extended terms, which provide the highest level of specificity. Lastly, the orange diamond represents facets and other service terms. The entire system is code-based, with each item uniquely identified by a five-digit alphanumeric code.

The initial step in evaluating the FoodEx2 system involves analysing its functionality, structure, and the information it provides. When the FoodEx2 Matrix is accessed via the EFSA catalogue browser (EFSA & Ioannidou, 2019), users can select among different hierarchies displayed in the upper section of the Catalogue Browser. At the hierarchy level, a general description of the feed item is provided, while the facets detail additional specific aspects. The detailed analysis of these hierarchies and facets will be discussed in the following sections.

2.2.2 FoodEx2: hierarchies' analysis and comparison with selected feed databases

In the upper section of the Catalogue Browser, besides the sections for Hierarchy and Facet, a drop-down menu lists all the hierarchies. The "MTX (FoodEx2 Matrix)" serves as the main hierarchy containing all the FoodEx2 codes in the catalogue, which are then further organised into different hierarchies. Of the eight hierarchies, we only considered the Feed hierarchy for detailed evaluation.

After identifying the categories in the Feed hierarchy of FoodEx2 we compared these categories with those in other databases/sources. These sources include FEDNA, feedipedia.org, and the European Catalogue of Feed Materials. Through this evaluation, discrepancies and similarities were documented and discussed, providing a basis for proposing amendments to FoodEx2.

2.2.3 FoodEx2: facets analysis

Facets provide additional detail on a selected feed item through a list of 28[4] groups of descriptors. Facets are collections of single descriptors defined from specific viewpoints applicable to particular food items; examples include source (F01), packaging material (F19), and production method (F21).

Many facets are included, but not all are applicable to all terms. Some terms are only appropriate for a subset of base terms, such as age classes which can only be used for animals. There are general facets usable across all domains, such as part-nature, source,

4 At the time of the facet analysis in May 2023

source-commodities, and process. Specialised facets, applicable only to specific domains such as purpose-of-raising, reproductive-level, animal-age-class, and gender, are relevant only in the animal domain. The first critical aspect to consider is "applicability," which also indicates whether a facet is intended for feed. Another significant aspect is the "cardinality" of facets, which refers to the number of descriptors of the same facet that can be applied to a single base term. Cardinality and applicability can be "single" (e.g., F01 Source) or "repeatable" (e.g., F04 Ingredient). Both aspects should be considered when coding with FoodEx2, as defined in EFSA 2015: "The food classification and description system FoodEx2 - revision 2".

Facets have two roles within the system:

- **Implicit Facets**: These descriptors always apply to a specific food group and are pre-assigned in FoodEx2. Users coding a food item do not need to enter these facets, and it is advised never to report implicit facets in coded datasets.

- **Added Facets**: These descriptors are added to a code while coding a food item. They describe a characteristic that distinguishes one specific food item from others within the same food group, as defined by a chosen base term.

Facets are reported with a code that includes a header defining the facet (e.g., "Fxx") and a unique term code defining the descriptor. For example, a code for a facet might be: F02.A0F0Y (Feed-related as part-nature).

The FoodEx2 code integrates various pieces of coded information into a single string. The code includes a base term (the food or feed being analysed), followed by a hash "#" and a sequence of facet codes. These codes are added at the coder's discretion, separated by dollar signs "$". The number of added facets is unlimited, and it is best to arrange facets in alphabetical order.

Regarding the two case studies on maize/corn and soy, typical FoodEx2 codes are reported below:

A07XG#F02.A0F0Y$F01.A059G$F27.A07XG$F23.A07TV$F28.A07LA

The first part of the code (A07XG) means "Maize grain (feed)". After the hash, the four implicit facets follow automatically (F02 Part-nature=Feed-related (as part-nature), F01 Source, F27 Source-commodities and F23 Target-consumer). Considering maize/corn as a feed ingredient, some other information can be added (added Facets). For example, selecting Facet F28 (process), Grinding/milling/crushing (A07LA).

With regards to Processed maize-based flakes (feed):

A0EFQ#F02.A0F0Y$F27.A07XG$F23.A07TV$F28.A07GP

The first part of the code (A0EFQ) means "Processed maize-based flakes (feed)". After the hash, the four implicit facets follow automatically (F02 Part-nature=Feed-related (as part-nature), F27 Source-commodities, and F23 Target-consumer). After that, other Facets can be added, for example, F28 Process, "steaming" (A07GP).

With regards to soy:

A0EHX#F02.A0F0Y$F01.A05HX$F27.A0EHX$F23.A07TV.A07GQ$F28.A07HC

The first part of the code (A0EHX) means "Soya (beans) (feed)". After the hash, four implicit facets follow, (F02 Part-nature=Feed-related (as part-nature), F01 Source, F27 Source-commodities, and F23 Target-consumer). Considering soy as a feed ingredient, other information, for example can be added, F28 Process, "Toasting" (A07HC).

With regards to soy (bean) meal (feed):

A0BFJ#F02.A0F0Y$F27.A0EHX$F23.A07TV$F10A0CJE

The first part of the code (A0BFJ) means "Soya (bean) meal (feed)". After the hash, the implicit facets are automatically added (F02 Part-nature=Feed-related (as part-nature), one implicit facet, like F27 Source-commodities, and F23 Target-consumer that is used when not obvious, or when this information makes the difference). After that, the added facet is F10 Qualitative-info, "Proteins-related info" (A0CJE).

2.2.4 Comparison of terminology between FoodEx2 and selected feed databases/sources

We compared the terminology and level of detail between FoodEx2 and some selected feed databases/sources regarding two feed ingredients, namely corn/maize and soy.

2.2.5 MTX (FoodEx2 Matrix) integrations

The integrations that need to be done to the structure of FoodEx2 have been analysed to make it usable in the animal nutrition field. Then, we analysed how to integrate and/or link the data stored in the FoodEx2 database with the information found in other selected databases. The aim was to make the terminology uniform.

The analysis of the possible integrations was based on the MTX version of the Excel file MTX_13.2.xlsx, and the corresponding graphical interface provided by EFSA (EFSA Catalogue browser).

Specifically, the following were investigated

- Feed Hierarchy structure analysis and facets refinements
- Harmonisation of FoodEx2 with other selected databases

2.3 Developing a proposal for a feed consumption database, including data structures and recommendations for data collection

For the development of a proposal for a feed consumption database, we consulted recommendations on methodologies for the collection of feed consumption data representative for food producing and non-food producing[1] animals in the EU Member States for use in dietary exposure assessments. A feed consumption model database[3] and data structure was then built. These are available as Excel files under the Supporting Information Section of the online version of this output.

2.3.1 Test diets for modelling a feed consumption database

Harmonised classification and quantification of daily feed consumption are fundamental for accurate estimations of animal exposure to potential hazards. However, the absence of a comprehensive and centralised database containing accurate feed consumption data remains a challenge. This lack of validated and robust data on feed intake and consumption, which includes both food-producing and non-food-producing animals, significantly limits accurate risk assessments due to potential over or underestimations of feed consumption.

Consequently, the goal is to lay the groundwork for amending the current feed section of the FoodEx2 system by developing a proposal for a feed consumption database that integrates feed classification, animal categories, and consumption data. To achieve this goal, selecting specific diets for various species across different growth, maintenance, and production phases is essential. In this context, the FAO "Global Livestock Environmental Assessment Model – interactive GLEAM-i" (https://gleami.apps.fao.org) was utilised. GLEAM-i is a unique source of information that offers reference diets applicable to specific countries and production systems, including industrial and backyard setups. However, the FAO "Global Livestock Environmental Assessment Model – interactive GLEAM-i" often uses generic terms for feed ingredients and does not account for variations in age or weight among the animals considered for specific diets. To address these limitations, we supplemented GLEAM-i with diet recommendations from the literature, particularly for species not initially covered by GLEAM-i. By merging these data sources, a selection of representative diets for each feed consumption simulation was developed.

2.3.2 Development of a proposal for a feed consumption database

A feed consumption model database[3] was proposed. Pigs, dairy cows, and laying hens' diets were selected as test cases due to their widespread presence across the European Union. Moreover, simplified test diets for Atlantic salmons and adult dogs were included to provide a wider selection of food-producing animals and to include a non-food-producing[1] animal category.

As a data structure for the feed consumption database, an Excel file was compiled using the Standard Sample Description 2 (SSD2) (EFSA, 2013) controlled terminologies, particularly the FoodEx2 classification system. The file is organised into three different sheets called Animal, Feed, and Consumption. The Animal and Feed sheets store information on animals and feed, respectively, and are linked by the Consumption which specifies the type and quantity of feed consumed by each animal per day.

The Animal sheet describes properties/features that are relevant for determining their feed consumption. A row regards a specific kind of animal with related features, and is associated with a unique identifier and a textual description. The animal characteristics are listed in columns, and they can be gender, physiological conditions (e.g. pregnancy or lactation), health possible dietary requirements (e.g. maintenance, veterinary diets), and details about the geographic area/country where the animals are raised. Other properties regard the weight, the method used to measure the animal weight, and the overall daily feed consumption of the animal expressed in kg of dry matter (DM). A given animal type, for example the fattening pig, can appear in multiple rows, each characterised by different identifiers and property values. For instance, "Fattening pig20" and "Fattening pig40" can be the identifiers of two distinct rows of pigs characterised by a weight of 20 and 40 kg, respectively, with different amounts of daily feed consumption. Further rows differentiate the daily feed consumptions of pigs when they reach a greater weight, or if they are farmed in different geographic areas e.g. northern or southern Europe.

The Feed sheet describes the properties/features that are relevant for categorising feed composition and nutritional information. Rows refer to a specific feed with related features, and are associated with a unique identifier as well as a textual description, both in the original language and in English. Columns are used to store the corresponding FoodEx2 code of the considered feed and for any comment. A row can be used to describe individual feed materials, which can then be included in a complete diet for a specific animal type (e.g. "Complete feed for fattening pigs", "Complete feed for dairy cows"), or which can be given to the animals as a single feed material alone, like for example "Corn", "Soybean meal", or "Corn silage".

The Consumption sheet links the other two sheets, and details the type and the quantity of feed consumed daily by each kind of animal. Rows regard the consumption of a specific feed by a specific kind of animal. They are associated with a unique identifier, a reference to the identifier of the considered animal in the Animal sheet, and a reference to the identifier of the considered feed in the Feed sheet. Other columns specify the inclusion rate of such a feed in the daily diet, the quantity in kg of such a feed eaten by the given animal in a day, the brand of the feed, and its corresponding FoodEx2 code. When the feed material is part of a complete diet, information about the total amount in kg of such a recipe is also recorded. For instance, a row can be used to specify that fattening pigs of 20 kg, referenced in the Animal sheet with the identifier "Fattening pig20", eat 0.325 kg of corn per day as part of a complete diet of 1.3 kg per day.

2.4 Proof of concept for the development of a feed consumption database

To validate our database[3], two case studies were conducted: the first on genetically modified (GM) feed, specifically maize, and the second on contaminants, particularly ochratoxin A.

First, three EFSA scientific opinions published in the EFSA Journal were considered. An additional EFSA scientific opinion on GM feed was considered to include Atlantic salmon and dogs, i.e. to represent the fish and companion animal categories (Appendix C).

The selected EFSA scientific opinions, published in the EFSA Journal, are:

- GM feed Example 1: Assessment of genetically modified maize MON 95379 for food and feed uses, under Regulation (EC) No 1829/2003 (EFSA GMO Panel 2022a)
- GM feed Example 2: Assessment of genetically modified maize DP4114 x MON89034 x MON 87411 x DAS-40278-9 and sub-combinations, for food and feed uses, under Regulation (EC) No 1829/2003 (EFSA GMO Panel 2022b)
- Contaminants Example: Risks for animal health related to the presence of ochratoxin A (OTA) in feed (EFSA CONTAM Panel 2023)

GM feed Example 3 (Appendix C): Assessment of genetically modified maize DP202216 for food and feed uses, under Regulation (EC) No 1829/2003 (EFSA GMO Panel 2024)

2.4.1 Elaboration of the model database

To directly compare animal exposure data reported in the EFSA scientific opinions (EFSA GMO Panel 2022a, EFSA GMO Panel 2022b, EFSA CONTAM Panel, 2023) with the results obtained using the model database[3], the model database[3] was further elaborated. The elaboration included animal data and diets for specific animal categories into physiological states, with relative feed materials and feed products (e.g. maize gluten feed) intakes, in order to compare animal dietary exposure.

Animal data (body weight, total daily intake) are reported in Appendix A.1.1. Tables 27, 29, 31, 33, 35 and the diets with inclusion rates were reported in Appendix A.1.1. Tables 28, 30, 32, 34, and 36.

2.4.2 Step-by-step procedure for retrieving data from the model database

The model database[3] (see Section 2.3.2) was generated in Excel and each Excel sheet is organised into columns, which are the variables of the data model (Figures 2, 3 and 4).

A	B	C	D	E	F	G	H	I	J	K
ORANIMALCODE	ANIMALDESC	GENDER	WEIGHT	MWEIGHT	TOTALDAILYINTAKE	SPECIALCON	SPECDIET	COUNTRY	AREA	COMMENTSANIMAL

Figure 2: Animal data sheet variables of the database

A	B	C	D	E
ORFEEDCODE	ORFEEDNAME	ENFEEDNAME	FOODEXCODE	COMMENTSFEED

Figure 3: Feed sheet variables of the database

A	C	D	E	F	G	H	I	J	K
RECORDIDENTIFIER	ORANIMALCODE	ORRECIPECODE	FOODEXRCODE	AMOUNTRECIPE	ORFEEDCODE	IR	AMOUNT	BRAND	FOODEXCODE

Figure 4: Consumption sheet variables of the database

For the proof of concept of the model database[3], we had to retrieve animal, feed material and consumption data relative to six animal categories (broiler, fattening pig, finishing pig, lactating dairy cows, dairy sheep, Atlantic salmon, dog) of interest.

Here is a step-by-step procedure of how we retrieved this data:

1. In the <u>Animal sheet</u>, we searched for our animal of interest (e.g. dairy cow) (column B, "ANIMALDESC")

2. We selected the animal with the diet of interest from the correct source (e.g. Darabighane et al., 2020) (column K, "COMMENTSANIMAL").

3. We noted down the unique animal code (column A, "ORANIMALCODE") and used it in Step 5

4. We retrieved the **animal body weight** in column D ("WEIGHT") and **total daily intake** in column F ("TOTALDAILYINTAKE") corresponding to the selected animal.

5. In the Consumption sheet, we searched for the unique animal code (e.g. Dairy cow623) noted down in Step 3 (column C, "ORANIMALCODE")

6. We retrieved all the **feed materials inclusion rates** (column H, "IR") of the rows presenting the unique animal code of interest (column C, "ORANIMALCODE")

7. We retrieved the feed code (column G, "ORFEEDCODE") corresponding to each IR (column H, "IR").

8. In the Feed sheet, we used the feed codes (e.g. R09.I01) retrieved in Step 7 in order to trace the corresponding feed names (column C, "ENFEEDNAME") of the feed materials in the diet.

The feed names (Feed sheet, column C, "ENFEEDNAME") correspond to the same naming of feed materials as reported in the EU feed catalogue. Their FoodEx2 codes can be found in the Feed sheet, column D, "FOODEXCODE".

2.4.3 Standardisation of feed material and animal categories nomenclature

Data regarding body weight and feed consumption (feed materials total daily intake, feed materials inclusion rate) of each selected animal category were extrapolated from our model database[3], as outlined in Section 2.4.2.

To estimate animal dietary exposure, EFSA employs various approaches across several Panels/Units. These methodologies assess the risks associated with GM feed, feed contaminants, pesticide residues, and feed additives. In 2019, EFSA provided a comprehensive overview of these current approaches and introduced a general formula for estimating animal dietary exposure to a chemical of interest. This calculation requires data on the chemical concentration in the feed and the daily consumption (intake) of that feed. By combining these variables and considering the animals' body weight, dietary exposure can be calculated as follows:

(concentration of chemical in feedstuff) x (amount of feedstuff consumed) / (body weight)

In GM feed, the concentration data for newly expressed proteins primarily derives from experimental data, and literature data can facilitate a comparative exposure approach.

In studies involving dietary exposure to contaminants in feed, the daily intake of feed material for each animal category is multiplied by its corresponding OTA contamination level, as outlined in the OTA scientific opinion (EFSA CONTAM Panel 2023). The feed materials are then aggregated to calculate the entire daily diet for the specific animal category.

The amount of feedstuff consumed (intake) is typically estimated based on default values, such as animal body weight and nutrient requirements, which are available from various sources, including scientific literature and guidance documents from European and international organisations, e.g. FAO, OECD, EFSA).

3 Assessment/Results

3.1 Mapping of existing systems and methodologies for feed classification and feed consumption data collection

In order to map the feed classification systems, a total of 12 International and European databases and other classification systems were considered. This included the five databases listed in the EFSA procurement, further augmented by three databases found on the web, and four other classification systems. For each database considered, the classification of feed ingredients was assessed, including their division into categories and sub-categories.

The analysis highlighted significant variability in the complexity of the classification of feed material. Some databases, such as the Dutch CVB system, rely on a limited number of categories or do not have sub-categories, while others adopt a complex and detailed classification (e.g. *Fundacion Espanola para el Desarollo de la Nutrition Animal*). The analysis highlighted that there is no clear consensus on the classification of feed ingredients among the different databases considered (Appendix B.1. Table 40).

3.1.1 Analysis of the classification system adopted in each feed database

Fundación española para el desarrollo de la nutrición animal (FEDNA)

FEDNA is the Spanish Foundation for the Development of Animal Nutrition, created in 1989 by a collaboration between Spanish universities and private industry. The website covers different topics on animal nutrition. In accordance with the classification of feed material, which is provided in the section 'Tablas FEDNA - Compositión Alimentos Valor Nutritivo', the feed ingredients are allocated into three main groups, each corresponding to a specific table, as follows:

- *Ingredientes para piensos* (feed ingredients – compound feeds)
- *Forrajes* (fodder – forage)
- *Subproductos fibrosos humedos* (wet fibrous by products)

INRAE-CIRAD-AFZ (feed tables)

The INRAE-CIRAD-AFZ feed tables are a French feed database resulting from the collaboration between National Research Institute for Agriculture, Food and the Environment (INRAE), *Centre de Coopèration Internationale en la Recherche Agronomique pour le development* (CIRAD), and *Association Francaise de Zootechnie* (AFZ). The INRAE-CIRAD-AFZ feed tables contain chemical data, nutritional data, as well as environmental data on feeds for ruminants, pigs, poultry, rabbits, horses, and fish (salmonids). No information is given on the inclusion limits of the raw materials in the diets of the different animal species, and there are no examples of feed consumption or formulations.

Dutch animal feed chain federation (CVB SYSTEM)

The CVB system operates under the CVB foundation, with activities conducted by Wageningen Livestock Research (WLR) and the Flemish Research Institute for Agriculture, Fisheries and Food (ILVO). The CVB collects data on the chemical composition of feedstuffs and feed materials, as well as data on digestibility for different farm animal categories. However, it does not provide information on the inclusion limits of raw materials in the diets of various animal species, nor does it offer examples of feed consumption or formulations.

Natural Resources Institute of Finland - Finnish feed tables (Luonnonvaratieto)

The Finnish feed tables are published by Natural Resources Institute Finland (Luke), under a mandate from the Finnish Ministry of Agriculture and Forestry. The Feed Tables and Nutrient Requirements website offers official Finnish Feed Tables and equations for calculating feed values and nutrient requirements. The animal species include ruminants, pigs, poultry, horses, and fur animals.

Nordic feed evaluation system (NorFor)

In the late 1990s, dairy farmers from the Nordic countries created a common feed evaluation system and replace various existing systems in Denmark, Norway, Sweden, and Iceland. The NorFor Model serves as an evaluation system, featuring the NorFor Feed Table as one of its main components. This model does not provide details about the inclusion limits for raw materials or examples of feed consumption or formulations.

The Swiss feed database (FeedBase)

FeedBase is a Swiss system that provides information on the composition and nutritional value of over 600 raw materials and roughages in Switzerland. Users can freely search the database for averaged feed data on all individual feeds and roughages. Results from the roughage survey are also available for open access (single value query). The recorded feed values in the database represent processed averages based on dry matter, with considerations for data coherence and representativeness. FeedBase also allows users to retrieve data on feed ingredients based on their Nutrients and Nutritive Values, tailored to various animal species, including ruminants, fattening calves, pigs, poultry, and horses.

International aquaculture feed formulation database (IAFFD)

The IAFFD is an open-access database designed to support aquaculture feed formulation. It provides industry stakeholders with essential information on the nutritional requirements of numerous species at different life stages and the characterisation of the nutritive value of various feed ingredients. The ingredients are listed without categorical or alphabetical organisation but each is assigned a numerical code, allowing for selection and comparison.

Feedipedia

Feedipedia is an online encyclopaedia of animal feed, jointly developed principally by INRAE, CIRAD, AFZ, and the Food and Agriculture Organization (FAO). Feedipedia is open access and provides information on the nature, occurrence, chemical composition, nutritional value, and safe use of nearly 1400 livestock feeds worldwide. Generally no information is provided regarding the inclusion limits for the raw materials, except for that based on data retrieved from the scientific literature.

The European Catalogue of Feed Materials

The EU Catalogue of Feed Materials was established by Article 24 of Regulation (EC) No 767/2009 to improve the labelling of feed materials and compound feed. It provides a detailed, though non-exhaustive, classification and description of feed materials. The first version of the catalogue was adopted with Regulation (EU) 242/2010, then repealed and reinstated 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: a glossary of 69 procedures applicable to feed, which includes descriptions of processes with definitions of the terms currently in use (as Part B), and the list of feed materials containing 650 feed items (as Part C), subdivided into 13 macro categories listed below. For each feed item listed in the catalogue, descriptions of the source and the process it has undergone are also given. The feed materials are presented in the form of tables, where the name of the feed ingredient, the identification number, a brief description, and, when relevant, the compulsory declarations are reported.

The harmonised OECD tables of feedstuffs from field crops

The Harmonised OECD tables of feedstuffs from field crops have been published by the Organisation for Economic Co-operation and Development (OECD), an intergovernmental organisation composed of representatives from industrialised countries in North America, Europe, Asia, the Pacific Region, and the European Commission. These tables classify individual feed commodities into four specific feedstuff categories and aim to determine the quantity of pesticide residues in products of animal origin that result from residues in feedstuffs (including fodder crops) or from direct application to livestock. Information on the percentage of the diet for each feedstuff is provided, based on national agricultural practices, the typical body weight of the finished animal, and daily feed consumption parameters. Additionally, for each animal species and category, information is divided into regions (USA/Canada, EU, Australia, and Japan). For each region, the reference body weight (kg) and daily intake (DM in kg) are reported. No information on the chemical composition of the different feedstuffs is provided, nor are any examples of formulas given.

The International Feed Vocabulary (FAO/UNDP)

The International Feed Vocabulary is not a real database but is helpful for our proposed classification "levels." It was published in 1978 as part of the report on the FAO/UNDP Training

Course in Fish Feed Technology, held at the College of Fisheries, University of Washington, Seattle, Washington (USA), where a new international system was proposed by Harris (1963) and Harris et al. (1968) to overcome inconsistencies in naming feeds. This system was modified and is now known as The International Feed Vocabulary. The International Feed Vocabulary is designed to name each feed as concisely as possible. Each feed name is coined using descriptors taken from one or more of six facets. In this way, over 18,000 feeds have been recorded and assigned International Feed Descriptions or Names in English, German, and French. Additionally, descriptions of the chemical and non-chemical characteristics and quality of the main cereal grains are available.

3.1.2 Analysis of terminology and description of feed ingredients in selected feed databases

For each of the databases and other classification systems, the terminology and description of feed ingredients were assessed following a systematic approach, using Corn as reference material.

Three keywords, namely *Corn, Maize,* and *Zea mays,* were selected and searched for within each database. The information provided in each database was compared. We found that some databases provide a detailed description of the feed ingredients, sometimes also including images and photos. In other databases there is just a summary description.

Fundación española para el desarrollo de la nutrición animal (FEDNA)

There is no 'Search' functionality on the Spanish feed database FEDNA. Consequently, to find a feed material within the feed database, one needs to know to which feed category the material belongs. By narrowing down the search to *Corn*, only two items are left: *Maíz nacional* (Corn from Spain) and *Maíz rico en aceite* (Corn, high in oil). In the case of *c*orn from Spain, a detailed description is provided. This includes the scientific name of the product, the various types of corn available on the market (including the genetic lines that have been selected for their specific features), the characteristics of the feed in terms of energetic value, fibrous fraction, mineral-vitamin content. It also includes the digestibility of proteins and amino acids, fermentability in ruminants and monogastric, storage stability and mycotoxins content. This information is also reported in tables.

INRAE-CIRAD-AFZ (Feed Tables)

In the French feed database, there is a “Search box” in each section of the website (Home, Tables, Charts, Nomenclature, Construction). By typing a specific quest within this box (e.g. the name of a feed ingredient), the research is performed within the entire website and not only within the feed tables. Therefore, many of the results obtained are not consistent with the search performed and need to be filtered. In Feed Profiles, tables with the nutritional values of the ingredients are reported. In this section, it is not possible to type and search for a specific feed ingredient, but a complete list of all the feed ingredients is provided, where the feed materials are listed in alphabetical order. By default, maize is shown as the first ingredient. In this section, the search for the keywords *Maize, Corn,* and *Zea Mays* returns 17, 2, and 0 items, respectively.

Dutch Animal Feed Chain Federation (CVB SYSTEM)

The CVB system consists of a .pdf file, so navigation is limited. However, by typing a query into the search box, which covers the entire document and not only within the section dedicated to the feed ingredients. With previous knowledge of the category to which the feed ingredients belong, searches can be made in the appropriate categories. The CVB system has five main categories: Compound feedstuffs, High moisture industrial co-products, Roughages and related products, Mineral feedstuffs, and Miscellaneous. In the example of corn, within the category Compound feedstuffs, the search returns 0 items for *Corn* and *Zea Mays* and 18 items for *Maize*. For High moisture industrial co-products, the search returns 3 items for Corn and Maize and 0 items for *Zea Mays*. For Roughages and related products, the search returns 1 item for *Corn*, 4 items for *Maize* and 0 items for *Zea Mays*. By narrowing down the search to corn grain, only 1 item is left: Maize 1002.000/0/0.

Natural Resources Institute of Finland - Finnish feed tables (Luonnonvaratieto)

On the Natural Resources Institute of Finland website, there are feed tables, and it is possible to select the animal species (ruminants, pigs, poultry, horses, fur animals). There are also tables for Minerals and Amino acids. If users do not know the category to which the feed material of interest belongs, they can select All feeds in the first box. Selecting Ruminants and typing in the Search box of the first box Feed (mandatory) the keywords *Corn, Maize*, and *Zea Mays*, the output is 0, 5, and 0, respectively. While in the second box Feed data (mandatory) there are 19 nutrient items (chemical composition, feed values, digestibility coefficients). After this selection, the output is a table with all the data that was chosen. In the case of ruminants and horses, the 5 items with the keyword *Maize* are maize grain, maize gluten, maize gluten feed, maize stand, and maize silage.

Nordic Feed Evaluation System (NorFor)

The feed table of the Nordic Feed Evaluation System (NorFor) is an interactive database, where it is possible to actively search for specific terms, e.g. feed ingredients. If users do not know the category to which the feed material of interest belongs, they can type the name of the feed ingredient in the "Feed name" tab, without selecting any other parameter. This means that the search will be performed within the entire database. By searching for the keywords *Corn, Maize*, and *Zea Mays* in the "Feed name" tab, a total of 0, 38, and 0 results are obtained, respectively.

The Swiss feed database (FeeDBase)

The Swiss feed database "FeeDBase" is a very interactive database but specific feed ingredients cannot be found directly as there is no search engine. Therefore, to find feed material within the feed database, a good knowledge of how the database works is required. To find a feed material within the feed database, users need to know to which feed category the material belongs. To search for a feed ingredient, users can select Reference Data and choose between Raw materials or Roughage in the section Feed Type. Additionally, in the section Nutrients, users can choose from different nutrients and different animal categories (ruminants, fattening calves, pigs, poultry, and horses). When selecting Raw Materials, a window with different feed categories appears, and at the bottom of this window, a search box is provided, where the name of the feed ingredient can be inserted. Searching for the keywords *Corn, Maize*, and *Zea Mays*, the output is 7, 10, and 1, respectively. Selecting Roughage and searching in the box at the bottom of the box for the keywords, the output is 19, 28, and 20, respectively.

International aquaculture feed formulation database (IAFFD)

The IAFFD database is divided into three different modules. Here, for the sake of this document, the focus is on the Feed Ingredient Composition Database (FICD), dedicated to feed ingredients, which provides tables of the chemical composition of feed ingredients. This database is focused on aquaculture, but some data also refer to pig and poultry production. In the FICD, there is a search box named Description. The search by the keyword Corn returns 38 items, while no items are reported searching by *Maize* and *Zea Mays* as keywords.

Feedipedia

Feedipedia's search engine can be used from a section on the website, including Feed categories, Scientific names, Tool, and Resources. Additionally, in the "All Feeds" section under Feed Categories, there is a list of 778 feeds. Here, searches can be performed by category, datasheet name, common name, scientific name synonym, and status. All feed datasheets consistently present information about world production, the use of the feed ingredient in different livestock animals, and the possible environmental impact. For example, setting "any" as a category and searching for *Corn* or *Maize* yields 20 and 12 items, respectively; searching for *Zea mays* yields 14 items. It is also possible to select a specific feed category, which requires previous knowledge of the category to which the feed ingredient belongs. Searching the keywords *Corn, Maize*, and *Zea mays* in the category Cereal and grass forages returns 9, 5, and 5 items respectively; while in the category Cereal Grains and by-products, the same search returns 12 items for *Corn*, 10 for *Maize*, and 12 for *Zea mays*. In the Forage plants category, the search returns 8, 3, and 3 items for *Corn, Maize*, and *Zea mays*, respectively; while in the Legume forages category, it results in only 1 item for all the keywords. In the Oil plants and by-products categories, the search returns only 1 item for all the keywords. In the "Other plants by-products" category, it returns no items for *Corn* and 1 item for *Maize* and *Zea mays*. Similarly, searching the keywords in the "Other products" category yields 1 item for all the keywords. Finally, searching in the Plant product and by-products category returns 11 items for *Corn,* 8 for *Maize*, and 10 for *Zea mays*.

The European Catalogue of Feed Materials

The European Catalogue of Feed Materials is a .pdf file with limited navigation. However, entering a query in the search box scans the entire document. Having prior knowledge of the category to which the feed ingredient belongs, one can search in the appropriate category. Ingredients are classified into 13 main categories. When searching the keywords *Corn, Maize,* and *Zea Mays* focusing exclusively on the results in the "Name" column of the table, the outcomes are 1, 18, and 0 results, respectively. Specifically, for *Corn*, only one item is found under the category “1. Cereal grains and products derived thereof.” For *Maize*, 17 results are returned under the same category, and 1 under the category “6. Forages and roughage, and products derived thereof.”

The Harmonised OECD Tables of feedstuffs from field crops

The Harmonised OECD tables of feedstuffs from field crops is a .pdf file but the search engine works the entire document. With prior knowledge of the category to which the feed ingredient belongs, in the tables, ingredients are sorted into four main categories: Forages/Fodders, Roots & Tubers, Cereal Grains/Crop Seeds, and By-products. In the example of corn, within the Forages/Fodders category, the search returns 5 items for *Corn*, and 0 for *Maize* and *Zea Mays*; no items are found in the Roots & Tubers category for any terms; 2 items are found for *Corn* and none for *Maize* and *Zea Mays* in the Cereal Grains/Crop Seeds category; and 6 items for *Corn* and none for *Maize* and *Zea Mays* in the by-products category.

The International Feed Vocabulary (FAO/UNDP)

The International Feed Vocabulary serves as a basic guide to overcoming inconsistencies in naming feeds but is not accessible as a system; though the structure is described. One significant limitation highlighted by The International Feed Vocabulary is the use of short names for feed materials, which are commonly utilised in Feed Composition Tables for specific countries or regions when it is impractical to use the longer, more precise International Feed Description. However, this short nomenclature is not recommended for describing a feed in a database. To address naming issues in some countries, feeds have been given official names. Generally, these names are not utilised as international feed descriptions because they are either incomplete or do not start with the origin or parent material.

3.1.3 Collection of information on inclusion rates and feed consumption

While studying the databases and other considered classification systems, it was assessed whether information on inclusion rates of feed materials in rations, diets, and formulas for compound feed fed to food-producing and non-food-producing animals was available. For each source, the presence or absence of inclusion rates of feed ingredients in the diets for all animal species was assessed, and where available, information on the inclusion limits was noted. It was found out that information on this topic was scarce and that most of the databases and classification systems do not provide information on mixtures or examples of compound feed, with the exception of NorFor and IAFFD. No information on feed consumption was found.

Due to the lack of information on feed consumption and the methodologies currently used to measure it, it was decided to extend the search outside Europe. A relevant report by the Institute for Feed Education and Research (IFEEDER) in collaboration with Decision Innovation Solutions (DIS) was included, which addresses the Animal Food Consumption (https://ifeeder.org/feeddata/). This publication, which was drafted in the USA, discusses feed consumption across different food-producing and non-food-producing animals[1], aiming to estimate the amount of feed consumed by different animal species throughout their lifetimes, in selected states and regions. These estimations are based on the total quantities of feed ingredients that typically pass through feed mills. This entails determining and assigning a general diet to each livestock species and using the quantity of animal-source food produced to estimate total feed consumption.

The Agricultural Market Information System (AMIS), an inter-Agency platform, describes three methods for estimating feed use in the context of cereal balance sheets: the survey approach, the balance sheet approach, and the demand approach for estimating animal feed requirements.

Even though these examples from outside Europe can provide predictive information on feed consumption data and market supply and demand, they are derived from production estimations and not directly from actual animal consumption.

Precise and comprehensive information on inclusion rates and consumption of feed materials in rations and diets of food-producing and non-food-producing animals[1] is very limited. Given the importance of such information, especially in the context of risk assessment related to animal dietary exposure, addressing this aspect is crucial.

Although an estimation approach like that described by IFEEDER could be used for general predictions, it might be more insightful and beneficial to gather information through direct contact with industries involved in the feed supply chain to obtain actual consumption data. However, considering the extensive nature of the feed industry and the broad range of feed ingredients and animal species involved, this approach would be challenging and time-consuming. Therefore, if this approach is to be implemented, it would require a dedicated project.

3.2 Developing a proposal for future update of the current EFSA food and feed classification system (FoodEx2)

3.2.1 FoodEx2 Feed hierarchy

The Feed hierarchy consists of 14 main feed categories/groups, listed below:

1. Cereal grains and products derived thereof (feed) [A0BBA],
2. Oil seeds, oil fruits, and products derived thereof (feed) [A0BEB],

3. Legume seeds and products derived thereof (feed) [A0BG2],
4. Tubers, roots and products derived thereof (feed) [A0BH7],
5. Other seeds and fruits, and products derived thereof (feed) [A0BJL],
6. Forages and roughage, and products derived thereof (feed) [A0BKT],
7. Other plants, algae and products derived thereof (feed) [A0BLK],
8. Milk products and products derived thereof (feed) [A0BM9],
9. Land animal products and products derived thereof (feed) [A0BMY],
10. Fish, other aquatic animals and products derived thereof (feed) [A0BNJ],
11. Minerals and products derived thereof (feed) [A0BP4],
12. Fermentation (by-)products from microorganism the cells of which have been inactivated or killed (feed) [A0BRA],
13. Miscellaneous (feed) [A0BRR],
14. Compound feed (feed) [A0BT0]

3.2.2 FoodEx2 feed categories comparison with selected feed databases

Table 1 compares the feed categories proposed in the selected databases/sources and those in FoodEx2. It highlights the discrepancies and similarities, starting with the categories.

The FoodEx2 Feed hierarchywas developed based on a comprehensive list of feed materials and related processing factors established in Regulation (EU) No 68/2013 of 16 January 2013 (EFSA, 2019). It thus completely aligns with the first 13 categories of feed from FoodEx2 and those from the European Catalogue of Feed Materials, except for the 14th category (i.e., Compound feed), which is absent in the European Catalogue of Feed Materials.

When comparing FoodEx2 with FEDNA, using Maize/Corn as an example, it is evident that FoodEx2 provides more detailed information, corresponding to a greater number of entries/items. For instance, FEDNA lists an item as "Corn heat treated"; however, according to its website description which states that "Thermal processing includes procedures such as cooking-lamination, micronization, expansion, extrusion, etc. […]", it is challenging to align this term with the corresponding terms in FoodEx2, where multiple entries refer to corn treated with heat, such as Processed maize-based flakes [A0EFQ] or Maize puffed [A0BC5]. In some instances, FEDNA offers more details than FoodEx2.

FEDNA further categorises items based on the percentage of crude protein (CP), resulting in different items such as "Corn gluten feed 19% CP" and "Corn gluten feed 20.5% CP". Similarly, Distillers' grain and solubles. In FoodEx2, they are represented by one item [A0BE3], while FEDNA subdivides them according to the percentage of ether extract (EE) and starch, resulting in three different items: "Corn DGGs 7.5% EE-6.8% starch", "Corn DGGs 12.5% EE- 3.5% starch", and "Corn DGGs 12.5% EE-6.8% starch".

A similar situation is observed with soy products. In FEDNA, there are four different items for soybean meal, differentiated by CP content: "Soybean meal 44%", "Soybean meal 45.5%", "Soybean meal 47%", and "Soybean meal 48.5%". Conversely, in FoodEx2, there is only one item listed as "Soya (bean) meal feed [A0EHT]".

In comparing Feedipedia.org with the FoodEx2 system, the pattern mirrors the comparison with FEDNA. FoodEx2 typically offers more detailed entries than Feedipedia.org. However, there are some items featured by Feedipedia.org that are absent or unmatchable in the FoodEx2 system, such as Ear Maize, Maize green forage, and Maize stover. These items should be integrated into FoodEx2 for completeness.

Table 1: Comparison between FoodEx2 main categories and European Catalogue of feed materials, FEDNA and Feedipedia.org main categories.

European Catalogue of Feed Materials	FEDNA	Feedipedia.org	FoodEx2
1. *Cereal grains and products derived thereof*	1. Granos de cereales (cereal grains)	1. Forage plants	1. Cereal grains and products derived thereof (feed)
2. *Oil seeds, oil fruits, and products derived thereof*	2. Cereales procesados por calor (heat treated cereals)	2. Plant products/ by-products	2. Oil seeds, oil fruits, and products derived thereof (feed)
3. *Legume seeds and products derived thereof*	3. Subproductos de cereals (cereal by-products)	3. Feed of animal origin	3. Legume seeds and products derived thereof (feed)
4. *Tubers, roots, and products derived thereof*	4. Frutos y tubérculos. Melazas y vinazas (Fruits & tubers. Molasses & vinasses)	4. Other feeds	4. Tubers, roots and products derived thereof (feed)
5. *Other seeds and fruits, and products derived thereof*	5. Concentrados proteína vegetal (vegetal protein concentrates)		5. Other seeds and fruits, and products derived thereof (feed)
6. *Forage and roughage, and products derived thereof*	6. Alimentos fibrosos (fibrous feeds)		6. Forages and roughage, and products derived thereof (feed)
7. *Other plants, algae and products derived thereof*	7. Concentrados de proteína animal (animal protein concentrates)		7. Other plants, algae and products derived thereof (feed)
8. *Milk products and products derived thereof*	8. Productos lácteos (dairy procucts)		8. Milk products and products derived thereof (feed)
9. *Land animal products and products derived thereof*	9. Grasas y aceites (fats and oils)		9. Land animal products and products derived thereof (feed)
10. *Fish, other aquatic animals and products derived thereof*	10. Minerales (minerals)		10. Fish, other aquatic animals and products derived thereof (feed)
11. *Minerals and products derived thereof*	11. Microingredientes (microingredients)		11. Minerals and products derived thereof (feed)
12. *Products and by-products obtained by fermentation using micro-organism, inactivated resulting in absence of live micro-organisms*			12. Fermentation (by-) products from microorganism the cells of which have been inactivated or killed (feed)
13. *Miscellaneous.*			13. Miscellaneous (feed)
			14. Compound feed (feed)

3.2.3 FoodEx2 facets analysis

Considering the 28 facets available in the FoodEx2 catalogue, F01 source, F02 part-nature, F04 ingredient, F07 fat-content, F09 fortification-agent, F10 qualitative info, F19 packaging material, F21 production method, F22 preparation-production-place, F23 target consumer, F26 generic term, F27 source commodities, F28 process, F29 purpose of raising, F30 reproductive-level, F31 animal-age-class, F32 gender, and F33 legislative-class were deemed suitable for feed description. Additionally, six facets were potentially suitable for feed description: F03 physical state, F06 surrounding-media, F08 sweetening-agent, F18 packaging-format, F20 part-consumed-analysis, and F25 risky-ingredient. Four facets were not suitable for feed description: F11 alcohol-content, F12 dough-mass, F17 extent-of-cooking, and F24 intended-use.

Among these facets, some are particularly important for amendments in the feed area, having been mentioned in other documents (EFSA 2021 and 2022), such as in the case of F23. Other relevant facets that require amendments for feed include F25, F29, and F30. Notably, F06 refers to fortification, which has a completely different nutritional implication in the case of animals.

3.2.4 Proposal for amendments to FoodEx2 catalogue

The first amendment to be implemented is to change the name of the category "Fermentation (by-) products from microorganisms, the cells of which have been inactivated or killed (feed)" (i.e., the 12th category) to align with the European Catalogue of Feed Materials as shown in Table 2.

Table 2: Update of the name of the 12th category of the feed Hierarchy

termCode	**termExtendedName**	**termScopeNote**
A0BRA	Products and by-products obtained by fermentation using micro-organism, inactivated resulting in absence of live micro-organisms (feed)	Feed ingredient group consisting of Fermentation (by-)products from microorganisms the cells of which have been inactivated or killed

The values of the termExtendedName and termScopeNote need updating.

A significant change is required to address the limitations on the use of the Compound feed category (i.e., the 14th category) of the Feed Hierarchy, which is absent in the European Catalogue of Feed Materials. Currently, when a coder wants to add ingredients to compound feed, only food-related items appear for selection/use. For this reason, we recommend adding a new "Feed Ingredient Facet" to allow the use of feed materials as part of Compound feed.

Further integrations of the FoodEx2 catalogue, stemming from the case studies considered, have been made on corn/maize and soy items. Additionally, the catalogue could be enriched with new information such as links to external databases and images. The following table highlights the inserted and updated items (Table 3).

The following information could be added/updated in the FoodEx2 catalogue:

- FEDNA id of the corresponding item in the FEDNA database, if there is a match,
- Feedipedia.org link to the corresponding item in the Feedipedia.org database, if there is a match,
- *termExtendedName* to align the item name with the one used in the European Catalogue of Feed Materials,
- *termScopeNote* to align the item description with the one used in the European Catalogue of Feed Materials,
- *commonNames* to store all the alternative names for a specific item.

Table 3: Example of integrations and updates regarding the corn/maize and the soy items

Term Code	termExtended Name	termScopeNote	common Names	EUFee dReg	FEDNA	Feedipedia .org	images
A07XG	Maize (feed)	Grains of Zea mays L. ssp. mays	Corn grain$ Maize grain$ Corn$Maíz [Spanish]$ Mais [Italian, German]$ Maïs [French]	1.2.1	https:// www.fundacionfedna.org/node/370	https://www.feedipedia.org/node/556	img1.jpg
A0EFQ	Maize flakes (feed)	Product obtained by steaming or infrared micronising and rolling dehusked maize. It may contain a small proportion of maize husks		1.2.2			img2.jpg
A0BC0	Maize protein [Maize Gluten] (feed)	Product from the manufacture of maize starch. It consists principally of protein (prolamins) obtained during separation of starch	Corn gluten meal	1.2.8	http://www.fundacionfedna.org/ingredientes_para_piensos/gluten-de-maíz-60	https://www.feedipedia.org/node/715	img3.jpg

Term Code	termExtended Name	termScopeNote	common Names	EUFeedReg	FEDNA	Feedipedia .org	images
A0BC1	Maize protein feed [Maize Maize Gluten feed] (feed)	Product obtained during the manufacture of maize starch. It is composed of bran and maize solubles. The product may also include broken maize and co-products from oil extraction of maize germs. Other products derived from starch and from the refining or fermentation of starch products may be added. May contain up to 2 % sodium and 2 % chloride					
A0BC7	Sweet maize silage (feed)	Co-product of the sweet corn processing industry, composed of centre cobs, husks, base of the kernels, chopped and drained or pressed. Generated by chopping sweet corn cobs, husks and leaves, with presence of sweet corn kernels		1.2.16			
A0BFR	Co-product from soybean preparation (feed)	Products obtained when processing soybeans to obtain soybean food preparations		2.18.10			

3.3 Developing a proposal for a feed consumption database, including data structures and recommendations for data collection

3.3.1 Test diets for modelling a feed consumption database suitable for FoodEx2 development

Pigs

Using the "Global Livestock Environmental Assessment Model – Interactive GLEAM-i," it was possible to gather information about "typical" industrial pig diets across the first seven EU countries in pig production. For the potential test diets for the simulations proposed in this report, four major feed materials were identified from the list utilised in the seven leading pig-producing countries: grains from maize, barley, wheat, and soy by-products. Subsequently, data from GLEAM were combined with diets detailed in selected papers (Pastorelli et al. 2022 and Millet et al. 2012), which considered various pig rearing phases. This integration was essential as GLEAM diets are average industrial diets without specific references to the target age of animals. Consequently, two reference diets for pigs—both weaned and growing—have been developed and are shown in Table 4 and Table 5.

Table 4: Feed materials (%) of weaning diet (DM). Pigs of 9-20 kg of body weight.

Feed materials	**Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	**9-20 kg** (%)
Corn grain	1.2.1 Maize	29
Barley grain	1.1.1. Barley	25
Whey powder	8.17.1 Whey/whey powder	12.5
Hulled barley	1.1.6 Barley hulls	12.5
Soybean meal 48%	2.18.4 Soya (bean) meal, dehulled	11.5
Wheat bran	1.11.7 Wheat bran	6.0
Coconut oil	2.20.1 Vegetable oil and fat	1.0
Dextrose monohydrate	13.2.2. Dextrose	1
Vitamin-Mineral premix+AA	N.A.	2.35
Feed consumption (kg/die)		1.1

Table 5: Feed materials (%) of growing diets (DM). Pigs of 20-110 kg of body weight.

Feed materials	**Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	**20-40 kg** (%)	**40-70 kg** (%)	**70-110 kg** (%)
Corn grain	1.2.1 Maize	25.00	25.00	20.4
Barley grain	1.1.1. Barley	22.11	25.00	25.00
Wheat grain	1.11.1 Wheat	20.00	21.37	25.00
Soybean meal (48% CP)	2.18.4 Soya (bean) meal, dehulled	19.01	12.51	11.58
Molasses	4.1.4. (Sugar) beet molasses	4.00	5.00	6.00
Alfalfa meal	6.10.5 Lucerne meal (alfalfa meal)	3.90	3.56	3.41
Full fat soybeans	2.18.6 Soya beans, extruded	1.35	4.34	5.96
Soybean oil	2.18.10 Co-product from soybean preparation	1.41	0.17	-
Vitamin and mineral premix+AA	N.A.	3.22	3.07	2.64
Feed consumption (kg/die)		1.30	1.98	2.40

Dairy cows

Using the "Global Livestock Environmental Assessment Model – Interactive GLEAM-i"," information was obtained about "typical" industrial diets for lactating dairy cows in the top seven EU dairy production countries. To establish potential reference diets for the simulations, six primary feed materials commonly used in cows' diets were identified from the list available in these countries: fresh grass, hay or silage from cultivated grass, silage from the whole maize plant, grains, a fresh mixture of grass and legumes, and maize.

Given that GLEAM proposes these diets as average industrial standards without specific age references and uses some generic terms, these data were supplemented with information from a study (Phipps et al., 2003) that considered lactating cows. In this study, all cows (BW 641kg; 61 days in milk (DIM); Milk Yield 46.7 kg/day) received a total mixed ration with a forage to concentrate ratio of 55:45 DM. The ingredients of these total mixed diets are detailed in Table 6.

Table 6: Feed materials (%) of lactating cows' diet (DM).

Feed materials	Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)	(%)
Corn silage	6.11.1 Maize silage	41.2
Grass silage	6.6.4 Green silage	13.8
Ground corn grain	1.2.17 crushed degerminated (degermed) maize	18.5
Soybean meal (48% CP)	2.18.4 Soya (bean) meal, dehulled	13.0
Rapeseed meal	2.14.3 Rape seed meal	12.5
Minerals	N.A.	1.0
Feed consumption (kg/die)		24

The diet specified does not include fresh grass due to its generic definition and variability in DM content and types of grasses (e.g., gramineous vs. leguminous) across different countries. Thus, a silage-based diet was chosen for its consistency.

Laying hens

Similarly, using the "Global Livestock Environmental Assessment Model – Interactive GLEAM-i" we obtained information about diets for laying hens in the top seven EU producers. From the list of potential feed materials in these countries, four major feed materials typically used in laying hens' diets were identified: maize grain, wheat grain, soybeans, and rapeseed.

This baseline information proposed by GLEAM reflects average industrial diets without reference to specific life stages of animals. To develop potential reference diets for our simulations, a diet incorporating specific ingredients such as tallow and oyster shell was created, drawing on selected scientific literature. The approach was to also include feed materials like tallow and oyster shell, to cover specific ingredients. Table 7 reports a diet for laying hens (Saky et al., 2019), considering a body weight of 1.5 kg and a daily feed consumption of 0.080 kg/bird/per day (NRC 1994).

Table 7: Feed materials (%) of laying hens' diet (DM).

Feed materials	Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)	(%)
Corn	1.2.1 Maize	60.75
Soybean meal (44%)	2.18.3 Soya (bean) meal	21.38

Feed materials	Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)	(%)
Corn gluten meal	1.2.9 Maize protein feed (Maize gluten feed)	2
Oats	1.4.1 Oats	1
Corn oil	1.2.13 Crude maize germ oil	0.63
Tallow	9.13.1 Greaves	3
Oyster Shell	11.1.2 calcareous marine shells	1.5
Vitamin and mineral premix	N.A.	9.74
Feed consumption (kg/die)		0.080

Atlantic salmons

Fish nutrition has high protein requirements, specific requirements for n-3 fatty acids, and is low in carbohydrates and dietary fibre. The formulation of fish feeds is thus based on a relatively small number of raw materials. Therefore, we have provided information for feed materials that are currently used in aquaculture. To propose potential reference diets for our simulations, a diet for Atlantic salmon was based on a scientific study (Weththasinghe et al. 2021). Table 8 reports a diet for Atlantic salmon with a body weight of 2 kg and a feed consumption of 0.040 kg per day.

Table 8: Feed materials (%) of Atlantic salmon diet (DM).

Feed materials	Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)	(%)
Soy protein concentrate	2.18.7 Soya (bean) protein concentrate	34.5
Fishmeal	10.4.2 fish meal	22.5
Fish oil	10.4.6 Fish oil	16
Wheat meal	1.11.1 Wheat	14
Wheat bran	1.11.7 Wheat bran	5.5
Corn gluten	1.2.8 Maize protein (Maize gluten)	5.5
Vitamin and mineral premix	N.A.	2
Feed consumption (kg/die)		0.040

Adult dogs

A balanced diet is critical to a dog's maintenance, growth, and health. The amount of feed for adult dogs should be based on their size and energy output. Activity levels can vary dramatically among dogs and play an important role in determining caloric intake. Their tooth structure and intestinal tract have become adapted to an omnivorous diet, so under normal circumstances, dogs can meet their nutritional needs by consuming a combination of plant and animal foods. Table 9 presents a premium diet for an adult dog (Biagi et al. 2021). For this report, we used an adult dog with a body weight ranging from 10 kg to 25 kg and a feed consumption ranging from 0.2 kg per day to 0.4 kg per day, as outlined in the feeding guide available at https://alacarte4k9.com.au/feeding-guide/.

Table 9: Feed materials (%) of adult dog (10 kg) diet (DM).

Feed materials	**Feed materials code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	**(%)**
Dried Chicken	9.4.1 Processed animal protein	27
Rice	1.6.16 Rice	26
Potato	4.8.1 Potatoes	24
Fresh chicken meat	9.14.1 Products of animal origin	14
Chicken fat	9.2.1 Animal Fat	4.3
Animal protein (from heart and liver)	9.1.1 Animal by-products	1.5
Flaxseed/linseeds	2.8.1 Linseed	1.4
Brewer's yeast	12.1.5 Yeast, inactivated (brewer's yeast, inactivated, if appropriate)	0.5
Fish oil	10.4.6 Fish oil	0.4
Chicory pulp dried	4.4.5 Dried chicory pulp	0.2
Sunflower oil	2.20.1 Vegetable oil and fat	0.1
Mix of aromatic herbs and spices	7.7.1 Leaves, dried	0.5
Dried Yucca Schidigera	7.12.1 Mojave yucca	0.1
Feed consumption (kg/die)		0.2

3.3.2 Development of a proposal for a feed consumption database

This section details the structure of the proposed feed consumption database, and some examples of database population are provided. As mentioned in Section 2.3.2, the database has three sheets: Animal, Feed, and Consumption.

Animal sheet

In the animal sheet, each row describes a specific animal/livestock category. The following properties are in columns:

- ORANIMALCODE (mandatory): unique animal identifier.
- ANIMALDESC (mandatory): description/name of the animal.
- GENDER (mandatory): gender of the animal.
- WEIGHT (mandatory): weight of the animal, expressed in kg, at the beginning of the given diet.
- MWEIGHT (mandatory): method used to measure the weight of the animal.
- TOTALDAILYINTAKE (mandatory): total daily feed consumption, expressed in kg of DM.
- SPECIALCON (mandatory): condition of the animal.
- SPECDIET (mandatory): diet of the animal.
- COUNTRY: country in which the animal was raised.
- AREA: geographical area in which the animal was raised (northern/southern Europe).
- COMMENTSANIMAL: text field for additional information about the animals or the related diet.

An example of the Animal sheet is given in Table 10, where some rows referring to pigs are shown.

Table 10: Example of Animal sheet referred to pigs.

ORANIMAL CODE	ANIMAL DESC	GEN DER	WEI GHT	MWEI GHT	TOTALDAILY INTAKE	SPECIAL CON	SPEC DIET	COUN TRY	AREA	COMMENTS ANIMAL
Piglet9	Piglet	G3	9	X1	0.50	C1	D1	IT	Southern Europe	Pastorelli et al, 2022
Fattening pig20	Fattening pig	G3	20	X1	1.30	C1	D1	BE	Northern Europe	Millet et al, 2012
Piglet10	Piglet	G3	10	X3	0.50	C5	D5			EFSA 2019 (50 g DM / kg BW)

This example shows the values associated with piglets of 9 kg, and the general information regarding their diet. The weight of 9 kg is intended as the weight that the piglets have at the beginning of the proposed diet; as soon as they reach a weight of 20 kg, the next diet is provided to them, that is the one for the fattening pigs of 20 kg, corresponding to the second row in the example. The ORANIMALCODE ("Piglet9") is generated by linking the ANIMALDESC value ("Piglet") and the WEIGHT value ("9"). The GENDER value is set as unclassified ("G3"), as the proposed diet can be given to both male and female piglets. The weight of the piglets is measured (the MWEIGHT value is set to "X1").

In this example, the diet given to piglets of 9 kg is 0.5 kg of DM per day, and this value is stored in the TOTALDAILYINTAKE field. This diet is defined as a normal diet (the SPECDIET value is set to "D1"), and it is meant for piglets in normal conditions (the SPECIALCON value is set to "C1"). The COUNTRY and the AREA values specify that the breeding takes place in Italy ("IT") and "southern Europe". Finally, the COMMENTSANIMAL field specifies the reference to this diet for the piglets of 9 kg, namely "Pastorelli et al., 2022".

In the second row, the general information regarding the diet given to the fattening pigs which start from a weight of 20 kg is provided. In particular, the ORANIMALCODE ("Fattening pig20") is generated by linking the ANIMALDESC value ("Fattening pig") and the WEIGHT value ("20"). The GENDER value is set as unclassified ("G3"), as the proposed diet can be given to both male and female fattening pigs. The weight of the fattening pig is measured (the MWEIGHT value is set to "X1"). The diet considered for fattening pigs of 20 kg is 1.30 kg of DM per day, and this value is stored in the TOTALDAILYINTAKE field. Again, the diet is defined as a normal diet (the SPECDIET value is set to "D1"), and is meant for fattening pigs in normal conditions (the SPECIALCON value is set to "C1"). The COUNTRY and the AREA values specify that the breeding takes place in Belgium ("BE") and "northern Europe". The diet is taken from the reference "Millet et al. 2012", as specified in the COMMENTSANIMAL field value.

In the third row, the ORANIMALCODE ("Piglet10") is generated by linking the ANIMALDESC value ("Piglet") and the WEIGHT value ("10"). In this case, the diet given to Piglet10 corresponds to an amount of 0.5 kg of DM per day, and this value is stored in the TOTALDAILYINTAKE field. The COMMENTSANIMAL field specifies the reference (EFSA, 2019) in which, for the piglet category, daily feed intake is calculated applying the formula 50 g DM/kg BW.

Feed sheet

In the feed sheet, each row represents a specific feed for animals, which can be part of a complete diet, or which can be given to the animals as a single feed material alone. The sheet is modelled according to the following properties on columns:

- ORFEEDCODE (mandatory): unique feed identifier
- ORFEEDNAME (mandatory): feed description in the original language.

- ENFEEDNAME (mandatory): feed description in the English language.
- FOODEXCODE (mandatory): EFSA feed identifier
- COMMENTSFEED: text field for additional information about the feed.

An example of the Feed sheet is given in Table 11.

Table 11: Example of Feed sheet.

ORFEEDCODE	ORFEEDNAME	ENFEEDNAME	FOODEXCODE	COMMENTSFEED
R01.I01	Farina di mais	Corn meal	A07XG	

This example shows the description of the feed ingredient "Corn meal", in English (ENFEEDNAME value), namely "Farina di mais" in Italian (ORFEEDNAME value). The FOODEXCODE field is filled with the value of the EFSA FoodEx2 feed identifier ("A07XG").

Consumption sheet

In the consumption sheet, each row specifies an animal with the corresponding type and quantity of feed per day. Both the animal and the feed have references to corresponding records in the *Animal* and *Feed* sheets, respectively. The sheet is modelled according to the following properties on columns:

- RECORDIDENTIFIER (mandatory): unique record identifier.
- ORANIMALCODE (mandatory): unique animal identifier. The values in this column refer to the records of the Animal sheet.
- FOODEXRCODE (mandatory only if the row refers to a feed material in a complete diet): EFSA feed identifier belonging to the "Complete feed" category.
- AMOUNTRECIPE (mandatory only if the row refers to a feed material in a complete diet): amount of the complete feed eaten by the animal in a day, expressed in kg. This amount must be repeated for each feed material belonging to the complete feed diet.
- ORFEEDCODE (mandatory): unique identifier of a specific feed material. The values of this column refer to the records of the Feed sheet.
- IR (mandatory): inclusion rate of the single feed material in the daily diet (percentage).
- AMOUNT (mandatory): amount of the single feed material eaten by the animal in a day, expressed in kg.
- BRAND: name of the brand of a specific feed.
- FOODEXCODE (mandatory): EFSA feed identifier.

An example of the *Consumption* sheet referring to pigs is given in Table 12.

Table 12: Example of Consumption sheet referred to pigs.

RECORD IDENTIFIER	ORANIMAL CODE	FOODEXR CODE	AMOUNT RECIPE	ORFEED CODE	IR	AMOUNT	BRAND
Piglet9_1	Piglet9	A0BT6	0.50	R01.I01	29.00	0.1450	
Piglet9_2	Piglet9	A0BT6	0.50	R01.I02	25.00	0.1250	

This example shows the daily feed consumption of two feed materials in the diet of piglets weighing 9 kg. The RECORDIDENTIFIER ("Piglet9_1") is generated by linking the ORANIMALCODE value ("Piglet9") with a progressive number. The FOODEXRCODE value ("A0BT6") is the EFSA identifier for "Piglet Starter I (pre-starter) / Complete feed (feed)". The AMOUNTRECIPE value ("0.50") reports, in kg, the total amount of the complete feed provided. The ORFEEDCODE value of the first row in the example ("R01.I01") is a reference to the record of the Feed sheet describing the corn meal, which is a single feed material that is part of the complete feed diet provided to the piglets weighing 9 kg. The IR value ("29,00") indicates the inclusion rate, that is, the percentage, of corn meal eaten in a day by the piglets. The AMOUNT value ("0.1450") indicates, in kg, the amount of this specific feed ingredient (corn meal) eaten in a day by the piglets. The BRAND value of such feed material is not specified since it is not available. Finally, the FOODEXCODE value reports the EFSA FoodEx2 identifier for corn meal ("A07XG").

In the second row of the example, the ORFEEDCODE value ("R01.I02") is a reference to the record of the Feed sheet describing the barley meal, which is another feed material that is part of the complete feed diet provided to the piglets weighing 9 kg. The IR value ("25,00") indicates the inclusion rate of barley meal eaten in a day by the piglets. The AMOUNT value ("0,1250") indicates, in kg, the amount of this specific feed material (barley meal) eaten in a day by the piglets. The BRAND value of such feed material is not specified too since it is not available. Finally, the FOODEXCODE value reports the EFSA FoodEx2 identifier for barley meal ("A05CR"). Thus, to provide the description of a complete feed diet for piglets of 9 kg, the sum of the values in the IR column must be of 100.00 (100%), and the sum of the values in the AMOUNT column must correspond to the value specified in the AMOUNTRECIPE column ("0.50").

The same approach was used for dairy cows, laying hens, Atlantic salmons, and adult dogs. Specific examples of the Consumption sheet referring to these species are reported in Table 13.

Table 13: Example of Consumption sheet referred to dairy cows, laying hens, Atlantic salmons and adult dogs.

RECORD IDENTIFIER	ORANIMAL CODE	FOODEX RCODE	AMOUNT RECIPE	ORFEED CODE	IR	AMOUNT	BRAND
Dairy cow641_1	Dairy cow641	A0BT5	24.00	R03.I01	41.20	9.8880	
Laying hen1,5_1	Laying hen1,5	A0BTK	0.80	R04.I01	60.75	0.4860	
Dog10_1	Dog10	A0BTV	0.20	R05.I01	27.00	0.0540	
Salmon2_1	Salmon2	A16AX	0.04	R06.I01	34.50	0.0138	

3.4 Proof of concept for the development of a feed consumption database

3.4.1 Animal selection

Animal categories selected for the two case studies were chosen to ensure representation of large ruminants, small ruminants, monogastric animals, and poultry. For the GMO case, dairy cows, dairy sheep, finishing pigs, and broilers were chosen for their respective categories. Similarly, for the contaminant case, dairy cows, dairy sheep, fattening pigs, and broilers were selected. All animal categories were chosen as they are most comparable to those present in each scientific opinion. Additionally, a GM case study including Atlantic salmon and dogs, representing fish and companion animal categories, is included in Appendix C.

3.4.2 First case study: GM feed

GM feed Example 1

The scientific opinion for GM feed Example 1 (EFSA GMO Panel 2022a) assesses the risk of GM maize MON 95379, to confer insect protection against certain lepidopteran species through the expression of Cry1Da_7 and Cry1B.868 proteins.

According to the scientific opinion (EFSA GMO Panel 2022a), dietary exposure to Cry1Da_7 and Cry1B.868 proteins was estimated through the consumption of maize grains, gluten feed, gluten meal, and silage across three animal categories: broilers, finishing pigs, and lactating dairy cows. The intake of maize grains, gluten feed, and gluten meal was evaluated for broilers and finishing pigs, as well as maize gluten feed, gluten meal, and silage for lactating dairy cows.

Dietary exposure estimates to Cry1Da_7 and Cry1B.868 proteins relied on default values for animal body weight, daily feed intake, and inclusion rates of maize feedstuffs in diets, as recommended by the OECD (2009). A scenario assuming 100% substitution of traditional maize products with maize MON 95379 products was considered.

Mean protein levels of Cry1Da_7 and Cry1B.868, measured in grains and forages, served as occurrence data to estimate the average levels (dry weight) of these proteins in the maize by-products gluten feed and gluten meal, which were expected to be 2.6 and 7.1 times higher, respectively, than in grains. This adjustment accounted for the relative protein content in these feed materials compared to maize grain (OECD, 2002), assuming no protein degradation during processing.

In developing the proof of concept for the proposed database, animal dietary exposure to Cry1Da_7 and Cry1B.868 proteins, measured in mg/kg BW per day based on the intake of maize grains, gluten feed, gluten meal, and silage, was detailed as outlined in the selected scientific opinion (EFSA GMO Panel 2022a) (see Appendix B.2.1. Table 41).

The EFSA statement from 2023 (EFSA GMO Panel, 2023) regarding "animal dietary exposure in the risk assessment of feed derived from genetically modified plants", " suggested using an Excel calculator to consistently report predicted dietary exposure estimates for newly expressed proteins. Implementing this recommendation, the animal dietary exposure to Cry1Da_7 and Cry1B.868 was recalculated using the proposed Excel calculator for the designated animal species. This calculator facilitated daily dietary exposure calculations, as reported in Appendix B.2.1, Table 42.

Subsequently, feed intake data for the selected feed materials (grain, gluten feed, gluten meal) were extracted from the elaborated model database, which incorporated additional dietary formulations from the literature relevant to the GM feed and contaminants case studies. An assessment of animal dietary exposure to Cry1Da_7 and Cry1B.868 proteins was conducted by substituting the standard animal and consumption data with the data derived from the expanded model database[3] (Appendix B.2.1. Table 43).

Dairy sheep were included as representatives of the small ruminant category to enhance the comparison between GM feed Examples 1 and 2. During the use of the expanded model database[3] for animal dietary assessment, discrepancies in animal and feed material nomenclature were noted compared to those in the Examples. To address this, three tables (Appendix A.1.2, Tables 37, 38, and 39) were prepared to align animal names with the database and feed material names with the EU Catalogue of Feed Materials.

Finally, daily dietary exposure (DDE) results from the EFSA scientific opinion (EFSA GMO Panel 2022a), findings from the Excel calculator (EFSA GMO Panel 2023), and outcomes from the model database are presented in Appendix B.2.1, Table 44.

The table highlights a noticeable reduction in DDE for finishing pigs consuming maize gluten feed, as detailed with the data from the model database. This variance is attributed to differing inclusion rates of maize gluten feed in the diets; whereas in GM feed Example 1 the inclusion rate was 20%, it was only 5% in the model database diet. Furthermore, there was a notable difference in animal body weight, shifting from 100 kg in GM feed Example 1 (Appendix B.2.1. Table 41) to 121.6 kg (Appendix B.2.1. Table 43) in the model database, although total daily intake amounts were similar at approximately 2.875 kg^{DM}/animal in the model database and 3 kg^{DM}/animal in GM feed Example 1.

The only slight increase in DDE obtained with the input data from the model database, compared to the DDE reported in the scientific opinion (EFSA GMO Panel 2022a), was in dairy cows consuming maize gluten feed. This is due to the combination of a lower animal body weight (623 kg compared to 650 kg) and a slightly higher total daily intake (25.82 kg^{DM}/animal compared to 25 kg^{DM}/animal) in the model database compared to GM), despite a slightly lower maize protein feed inclusion rate (18.81% compared to 20% in GM feed Example 1) in the model database.

GM feed Example 2

The scientific opinion (EFSA GMO Panel 2022b) selected for the GM feed Example 2 regards the risk assessment of the GM maize DP4114 x MON 89034 x MON 87411 x DAS-40278-9 (four-event stack maize). This GM maize was developed to help protect the crop against lepidopterans (through the expression of Cry1F, Cry1A.105 and Cry2Ab2 proteins), coleopterans (Cry34Ab1/Cry35Ab1 and Cry3Bb1 proteins), western corn rootworms (DvSnf7 dsRNA). It also deals with tolerance to glufosinate-ammonium herbicide (PAT proteins), glyphosate herbicide (CP4 EPSPS protein), as well as aryloxyphenoxypropionate (AOPP) herbicide degradation and tolerance to 2,4-D herbicides (through expression of AAD-1 protein).

Dietary exposure to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins in the four-event stack maize was estimated by the consumption of maize grains and forage. Nine animal categories were considered: beef cattle, dairy cattle, rams/ewes, lambs, breeding pigs, finishing pigs, broilers, layers, and turkeys.

The consumption of maize grain was reported for all nine species. The consumption of forage and forage inclusion were reported only for beef cattle, dairy cattle, lambs, breeding pigs and layers. The estimation of dietary exposure to newly expressed proteins was based on default values for animal body weight, daily feed intake, and inclusion rates (percentage) of maize grain and forage in diets/rations (OECD, 2013).

A conservative scenario with 100% replacement of conventional maize products by four-event stack maize products was considered. Mean protein levels of Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins analytically determined in grain and forage were used as occurrence data. The animal dietary exposure (mg/kg BW per day) based on the consumption of maize grain and forage was reported in EFSA GMO Panel 2022b.

As with the GM feed Example 1, in the GM feed Example 2 we also reported the animal dietary exposure as outlined in EFSA GMO Panel 2022b (Appendix B.2.1. Table 45).

Next, we calculated the animal dietary exposure to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins using the Excel calculator proposed in the EFSA (2023) statement (EFSA GMO Panel 2023). The Excel calculator was used for the DDE calculation (Appendix B.2.1. Table 46).

Finally, the animal dietary exposure to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins was assessed by replacing the default animal and consumption data with the extracted values from the model database[3] (Appendix B.2.1. Table 47).

Appendix B.2.1. Table 48 shows the DDE results from i) EFSA GMO Panel 2022b, ii) the Excel calculator (EFSA GMO Panel 2023), and iii) the model database.

Table 48 shows a notable DDE decrease in the results obtained with the input data from the model database for dairy cows consuming maize silage. This can be explained by the different inclusion rates of the maize silage in the dairy cow diets. However, in the GM feed Example 2, the maize silage inclusion rate was 60% (Appendix B.2.1. Table 45), and in the model database the inclusion rate in the diets was 21.23% (Appendix B.2.1. Table 47).

The inclusion rate difference is higher than the slight difference in animal body weight, from 650 kg of the GM feed Example 2 to 623 kg and the small total daily intake increase from 25 kg^{DM}/animal of the GM feed Example 2 to 25.82 kg^{DM}/animal from the model database. All the other animals consuming maize also showed a notable decrease in DDEs. In the case of dairy sheep, the inclusion rate of maize (41% compared to 30%) in the model database was higher than in GM feed Example 2 and the animal body weight (57 kg compared to 75 kg) was lower. Despite these changes, the total daily intake (1.22 kg^{DM}/animal compared to 2.5 kg^{DM}/animal) was significantly lower in the model database compared to GM feed Example 2, leading to a decrease in the DDE value.

3.4.3 Discussion and comparative considerations of GM feed Examples 1 and 2

To evaluate the animal daily dietary exposure, the DDE was calculated, considering the following input values:

- Total daily intake
- Animal body weight
- Inclusion rate of feed materials

Any variation in these parameters leads to a proportional difference in daily dietary intake, as the daily dietary intake is calculated as follows:

[(Total Daily Intake X Inclusion rate %)/ Body Weight] X 1000.

A difference in the daily dietary intake would directly influence the DDE, as it is calculated as follows:

Daily dietary intake X NEP level.

While the total daily intake, feed material inclusion rate, daily dietary intake and NEP level are directly proportional to the DDE values, animal body weight is inversely proportional to the DDE values.

NEP levels exhibited a direct correlation with the DDE values, however they are obtained analytically or calculated in derived or processed feed by conversion factors. They are specific to the respective genetically modified plant and therefore do not contribute to the differences in the DDE value reported in the GM feed examples and the DDE value obtained using input data from the model database[3].

Another factor that could lead to a further change in DDE values is the selection of feed materials to estimate exposure. This selection could include a single feed material (e.g. maize), but also its products (e.g. maize gluten feed, gluten meal) and by-products (e.g. milled by-products).

This is crucial because it impacts the total inclusion rate of individual maize feed materials, maize products and by-products in the total DDE estimation. For example, the diets in the model database[3] include maize, maize gluten feed, maize gluten and maize forage. Maize milled by-products are not considered in any of the proposed diets, thus no DDE is derived from them, whereas they are included in the current GMO approach (EFSA GMO Panel 2023). This leads to a further difference in the total DDE. Additionally, with a consumption database that includes different diets, the incorporation of further maize feed materials and maize by-products cannot be precluded, which thus affects the estimation.

Another key factor is the methodology for animal dietary exposure (ADE).

In the EFSA 2023 statement (EFSA GMO Panel, 2023), the GMO Panel reported a notable absence of specific recommendations of methodologies to estimate and present ADE associated with GM feed, thus leading to inconsistent approaches.

As evident from Examples 1 and 2, different approaches have also been adopted in these examples. In GM Feed Example 1, only three animal categories (broilers, finishing pigs, lactating dairy cows) were considered, while GM Feed Example 2 covers a broader range of nine animal categories (beef cattle, dairy cattle, rams/ewes, lambs, breeding pigs, finishing pigs, broilers, layers, turkeys). Furthermore, there is a disparity in the evaluation of maize itself. In the GM Feed Example 1, the animal dietary exposure to maize, gluten feed, gluten meal and silage was assessed, whereas, in GM Feed Example 2, the focus was on the exposure to maize grain and forage.

To further harmonise the application dossiers, the GMO Panel provided advice in their 2023 statement (EFSA GMO Panel, 2023) on the selection of appropriate feed consumption and feed concentration data, and on the reporting of exposure estimates. The panel proposed a list of animal species, recommending limiting the estimations of expected animal dietary exposure only to some animal species and using selected feed materials. These recommendations would facilitate the selection of animal species and feed materials, harmonising the reporting of the information in the application dossiers.

Given that there is no comprehensive feed consumption database, the EFSA GMO panel recommended using default values for feed consumption, including animal body weight, daily feed intake and inclusion rates of feed materials in diets, derived from the most pertinent sources in the literature. The implementation of such a database, as proposed in this project, could help prevent the reliance on default values. In fact our database could facilitate precise EU-wide analyses, thus minimising the introduction of over or underestimations that could result in an inadequate risk characterisation.

The overestimations observed for both Example 1 and Example 2 are due to a very conservative scenario where an animal diet consisted of 90-100% maize feed materials for the GM feed Example 1 and 30-90% maize feed materials in GM feed Example 2, for the selected animal categories. These diets would be nutritionally unbalanced and impractical for real-world applications because they do account for the inclusion rates of other feed materials in the diet.

The importance of the model database[3] and of developing a European Union feed consumption database lies in its potential to address these limitations. It would provide more comprehensive and realistic feed consumption data and contribute to the development of more accurate and harmonised risk assessments.

3.4.4 Second case study: feed contaminant

Ochratoxin A, produced by fungi such as Aspergillus and Penicillium, belongs to the class of mycotoxins, which are natural products generated as secondary metabolites during fungal development. Mycotoxins are commonly found in food, feed, and agricultural environments due to the growth of toxin-producing fungi in soil, hay, decaying vegetation, and grains (Dhakal et al. 2023).

The Commission Recommendation 2006/576/EC, amended by Commission Recommendation 2016/1319/EC, provides guidance values for ochratoxin A (OTA) in feed, expressed as mg/kg based on a dry matter of 88%. For cereals and cereal products, the OTA's guidance value levels are set at 0.25 mg/kg of feed.

The EFSA expert panel estimated the animal dietary exposure to OTA according to data from the EFSA Data Warehouse, accessed on 28 November 2022. The exposure considered intervals of exposure, including the mean lower bound (LB), upper bound (UB), and 95th percentile LB and UB, taking into account compound and/or complementary feed, and the following feed materials: barley grain, maize grain, maize protein, oat grains, oat feed, rice, broken, wheat grains, wheat feed, rape seed, rape seed (expeller + meal), soybean (expeller + meal), soybean hulls, soybean, protein concentrate, sunflower (expeller + meal), carobs, horse beans, pea flour, grass meal, hay and alfalfa, lucerne meal (alfalfa meal), and maize silage.

The scientific opinion (EFSA CONTAM Panel 2023) considered dairy cows, cattle for fattening, veal calves, dairy goats, fattening goat kids, dairy sheep, fattening lambs, horses, weaned piglets, fattening pigs, lactating sows, fattening chickens, laying hens, turkeys, ducks, fattening rabbits, salmon, dogs, dogs fed a vegetarian diet, and cats.

The default values for average feed intakes and body weights used to calculate animal dietary exposure to OTA were based on published guidelines on nutrition and feeding (NRC, 2006; Leeson and Summers, 2008; EFSA FEEDAP Panel, 2017; see Annex C, Table C.1 of the OTA scientific opinion), and have been extensively described in previous scientific opinions (EFSA CONTAM Panel 2011, 2012) and subsequently updated in 2023.

Various scenarios, using model diets or compound feed (complete feed or complementary feed plus forage), were employed for dietary exposure assessment. For the model diet, the scientific opinion (EFSA CONTAM Panel 2023) lists the feed intake of each animal category considering 100% dry matter. The animal dietary exposure to OTA (mg/kg dry matter, µg/kg BW/day and µg/day) was determined, based on a model diet and on compound feed, considering mean LB and UB, median LB and UB, 75^{th} percentile LB and UB and 95th percentile LB and UB as exposure scenarios. In the scientific opinion (EFSA CONTAM Panel 2023), only the 95^{th} percentile mean LB, UB and the high LB, UB exposures were reported. Additionally, for feed ingredients for which data for the 95^{th} percentile contamination was not available, the 75^{th} percentile LB and UB data were considered.

The proof of concept for the proposed feed consumption database for OTA was performed by replacing the animal and consumption data provided in the EFSA scientific opinion (EFSA CONTAM Panel 2023) with the corresponding extracted values from the model database[3].·The Excel calculator originally used to calculate the OTA exposure in the opinion (EFSA CONTAM Panel 2023) was used, inserting feed data from the model diets retrieved from the model database[3].

Animal exposure to OTA was thus obtained, expressed as µg/kg feed, µg/day feed, 100% dry matter, and µg/kg BW/day.

The following tables show the results obtained by applying the contamination data reported in the EFSA scientific opinion (EFSA CONTAM Panel 2023) and in the Excel calculator fed with the model diets retrieved from the model database[3]. Model diets as retrieved from the model database[3], and default values for live weight and feed intake of animal categories are reported in Appendix A.

Dairy Cows

Table 14: Dairy cow exposure to OTA (mg/kg, 100% Dry Matter) based on model database diet, as calculated in the Excel calculator, considering 1 kg/feed, compared to exposure to OTA residues (mg/kg, 100% DM; 70% concentrate and 30% forages) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg feed)	EFSA OTA scientific opinion diet (mg/kg Dry Matter; 70% concentrate and 30% forages)	Variation
Mean lower bound	1.71	1.80	↓
Mean upper bound	3.60	3.80	↓
High lower bound	3.50	3.20	↑
High upper bound	7.83	9.20	↓

Table 15: Dairy cow exposure to OTA (mg/day, 100% Dry Matter) based on model database diet, as calculated in the Excel calculator, taking into account the amount of feed material consumption per day, compared to exposure to OTA (mg/kg, 100% Dry Matter; 70% concentrate and 30% forages) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/day)	EFSA OTA scientific opinion diet (µg/day)	Variation
Mean lower bound	44.22	35.00	↑
Mean upper bound	92.90	77.00	↑
High lower bound	90.46	64.00	↑
High upper bound	202.27	183.00	↑

Table 16: Dairy cow exposure to OTA (mg/kg BW/day, 100% dry matter) based on model database weight as calculated in the Excel calculator, compared to exposure to OTA residues (mg/kg BW/day, 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg BW/day)	EFSA OTA scientific opinion diet (µg/kg BW/day)	Variation
Mean lower bound	0.07	0.05	↑
Mean upper bound	0.15	0.12	↑
High lower bound	0.14	0.10	↑
High upper bound	0.32	0.28	↑

For the cow diets, some adjustments were made: for the feed material maize gluten feed (20% CP), OTA contamination data from maize protein were considered, and for the feed material maize grain, ground, data from maize grain were considered. No contamination data was available for the feed material mineral and vitamin mix, beet pulp and fat powder.

Dairy Sheep

Table 17: Dairy sheep exposure to OTA (mg/kg 100% Dry Matter, 35% concentrate and 65% forage) based on model database diet, as calculated in the Excel calculator, considering 1 kg/feed compared to exposure to OTA (mg/kg 100% Dry Matter; 35% concentrate and 65% forage) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg feed, µg/kg feed, 35% concentrate and 65% forage)	EFSA OTA scientific opinion diet (mg/kg Dry Matter; 35% concentrate and 65% forage)	Variation
Mean lower bound	1.94	1.40	↑
Mean upper bound	4.59	3.80	↑
High lower bound	2.22	2.10	↑
High upper bound	11.27	10.80	↑

Table 18: Dairy sheep exposure to OTA (mg/day 100% Dry Matter, 35% concentrate and 65% forage) based on model database diet, as calculated in the Excel calculator, considering the amount of feed material consumption per day.

	OTA model database diet (µg/day, 35% concentrate and 65% forage, 88% dry matter)
Mean lower bound	2.36
Mean upper bound	5.60
High lower bound	2.70
High upper bound	13.74

Table 19: Dairy sheep exposure to OTA (mg/kg BW/day, 100% dry matter, 35% concentrate and 65% forage) based on model database weight as calculated in the Excel calculator.

	OTA model database diet (µg/kg BW/day, 35% concentrate and 65% forage)
Mean lower bound	0.04
Mean upper bound	0.09
High lower bound	0.04
High upper bound	0.24

For the dairy sheep diet, the following adjustments were made: for the feed material Maize gluten meal (60% CP) and Maize gluten feed (20% CP), OTA contamination data were retrieved from maize protein. Additionally, no data were reported for the alfalfa hay high (95%) UB and LB contamination level, thus only mean LB and UB contamination data were taken into consideration, using the same approach as the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023). No contamination data was available for the feed materials wheat straw and mineral and vitamin mix.

A comparison of the results in Tables 18 and 19 with the data in the EFSA scientific opinion (EFSA CONTAM Panel 2023) was not possible

Fattening Pigs

Table 20: Fattening pig exposure to OTA (mg/kg 100% Dry Matter) based on model database diet, as calculated in the Excel calculator, taking into account 1 kg/feed, compared to exposure to OTA (mg/kg 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg feed)	EFSA OTA scientific opinion diet (mg/kg feed)	Variation
Mean lower bound	1.74	1.80	↓
Mean upper bound	3.08	3.00	↑
High lower bound	5.57	4.10	↑
High upper bound	6.21	6.10	↑

Table 21: Fattening pig exposure to OTA (mg/day 100% Dry Matter) based on model database diet, as calculated in the Excel calculator, taking into account the amount of feed material in each animal diet per day, compared to exposure to OTA (mg/kg BW/day 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/day)	EFSA OTA scientific opinion diet (µg/day)	Variation
Mean lower bound	3.80	3.90	↓
Mean upper bound	6.73	6.70	=
High lower bound	12.13	9.00	↑
High upper bound	13.54	13.50	=

Table 22: Fattening pig exposure to OTA (mg/kg BW/day, 100% dry matter) based on model database weight as calculated in the Excel calculator, compared to exposure to OTA (mg/kg bw/day 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg BW/day)	EFSA OTA scientific opinion diet (µg/kg BW/day)	Variation
Mean lower bound	0.09	0.06	↑
Mean upper bound	0.15	0.11	↑
High lower bound	0.28	0.15	↑
High upper bound	0.31	0.22	↑

For the fattening pig diet, the following adjustments were made: for the feed material maize, OTA data contamination for maize grain was considered, while for the maize gluten feed material (20% CP), OTA contamination data were retrieved from maize protein. No contamination data was available for the molasses cane and mineral and vitamin mix feed materials.

Broilers

Table 23: Broiler exposure to OTA (mg/kg, 100% Dry Matter) based on model database diet, as calculated in the Excel calculator, taking into account 1 kg/feed, compared to exposure to OTA (mg/kg BW/day 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg feed)	EFSA OTA scientific opinion diet (mg/kg feed)	Variation
Mean lower bound	1.03	1.20	↓
Mean upper bound	1.91	2.60	↓
High lower bound	2.99	4.10	↓
High upper bound	4.06	5.70	↓

Table 24: Broiler exposure to OTA (mg/day 100% Dry Matter) based on model database diet, as calculated in the Excel calculator, taking into account the amount of feed material in each animal diet per day, compared to exposure to OTA (mg/kg BW/day 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/day)	EFSA OTA scientific opinion diet (µg/day)	Variation
Mean lower bound	0.14	0.20	↓
Mean upper bound	0.25	0.40	↓
High lower bound	0.40	0.65	↓
High upper bound	0.54	0.90	↓

Table 25: Broiler exposure to OTA (mg/kg bw/day, 100% Dry Matter) based on model database weight as calculated in the Excel calculator, compared to exposure to OTA (mg/kg BW/day 100% Dry Matter) as reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

	OTA model database diet (µg/kg BW/day)	EFSA OTA scientific opinion diet (µg/kg BW/day)	Variation
Mean lower bound	0.08	0.10	↓
Mean upper bound	0.15	0.20	↓
High lower bound	0.23	0.33	↓
High upper bound	0.32	0.45	↓

For the broiler diet, the following adjustments were made: for the feed material maize, ground OTA data contamination for maize grain was considered, for the maize gluten feed (20% CP), OTA contamination data were retrieved from maize protein, while for sunflower oil contamination data were retrieved from sunflowers (expeller + meal). No contamination data was available for the feed materials sorghum, ground and mineral and vitamin mix.

3.4.5 Discussion and considerations of contaminant case.

To evaluate the animal daily dietary exposure to OTA, the following parameters were considered:

- Contamination levels of feed material;
- Diet composition
- Total daily feed intake;
- Animal body weight.

OTA contamination levels of feed materials were expressed as lower and upper bounds levels (LB and UB, respectively), thus the exposure results to OTA, expressed in µg/kg dry matter, µg/kg bw/day and µg/day, were reported considering the mean LB, UB and the high LB, UB exposures. Calculations were performed using the Excel calculator provided by EFSA, as in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023).

As can be seen in the tables reported in the Results section, different exposure values were obtained for the animal categories, due to differences in the animal weights, feed intake and diet composition compared to those reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023). For instance, fattening pigs showed an overall higher exposure to OTA than the diet considered in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023) for all exposure scenarios except for the mean LB, which was due to the different diet compositions.

For dairy cows, the OTA exposure calculated per kilogram of body weight/day was greater for the model database[3] diet, due to body weight differences considered for this animal species. Nevertheless, such differences were limited, resulting in slightly higher or lower exposure values than those reported in the EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023). As for dairy cows, the diet retrieved from the model database[3] already contained maize silage as a feed material. It was thus not possible to determine the OTA contamination exposure following the approach reported in the EFSA OTA scientific opinion (EFSA CONTAM Panel 2023), in which the contamination for dairy cows was calculated considering 70% concentrated dry matter and 30% forage dry matter, maize silage. In our case this method would lead to an overestimation of OTA exposure due to the redundant inclusion of maize silage. The comparisons reported in Tables 14, 15 and 16 thus only consider the model diet proposed in the model database, which already contains forage, without adapting the values for 70% concentrate and 30% forage.

Animal body weight is a crucial factor in exposure estimation, as different physiological stages and breeds can result in a wide range of weights that impact the calculations. Another significant factor influencing the daily exposure values is the selection of feed materials in the diet composition. This selection can include individual feed materials (e.g., molasses cane), processed products (e.g., soybean meal), and by-products (e.g., milled byproducts). The choice of feed materials significantly affects the total inclusion rate of individual components and the related contamination levels in the overall exposure estimation.

Looking at CONTAM Panel evaluations, the recent evaluation on OTA exposure reported in the considered EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023) was performed according to methodologies already used and described in previous scientific opinions, with some modifications related to feed intake and diet composition assessed by the CONTAM Panel in May 2023 in line with current with common practices and published guidelines. The amendments aimed to harmonise the CONTAM Panel and the FEEDAP Panel when dealing with compounds in feed. The estimated feed intakes were based on published guidelines on nutrition and feeding (NRC, 2006; Leeson and Summers, 2008; EFSA FEEDAP Panel, 2017).

Without a comprehensive feed consumption database, the EFSA CONTAM panel used default values for feed consumption, including animal body weight, daily feed intake and inclusion rates of feed materials in diets, derived from the most pertinent and applicable sources within the published literature. These recommendations are based on a scientific analysis of findings from the literature, given the current lack of a comprehensive feed consumption database. Similar to GMO evaluations, the implementation of such a database, as proposed in this project, has the potential to eliminate reliance on default values. Such a database could facilitate precise EU-wide analyses, minimising the risk of overestimations or underestimations that could lead to inadequate risk characterisation.

Potential errors in reporting the contaminant occurrence data in the classification of the feed category in EFSA CONTAM Panel OTA scientific opinion (EFSA CONTAM Panel 2023) were identified, for example the use by data providers of feed categories at high (often not enough specified) FoodEx/FoodEx2 levels. The correct classification and harmonisation of feed nomenclature proposed in the present project could help prevent these kinds of biases.

A comprehensive database encompassing more variability in weights, feed intakes and feed materials, would not only enhance its applicability across a wider range of cases and uses, but would also contribute to a more accurate and harmonised exposure evaluation and risk assessment. End users would be able to tailor the database outcomes to their specific situations, rather than depending on default values.

4. Weaknesses and recommendations for future developments

Feed materials

The results reported in the previous sections revealed several differences among databases and classification systems. Of these different systems, the European Catalogue of Feed Materials is the best-known and has the strongest legal basis.

Although it only provides information of a qualitative nature (description of the product), stakeholders see it as the main reference in terms of feed classification and the majority use it within a legal framework, thus for placing products on the market and for labelling purposes.

Our first proposed intervention for the development of a feed consumption database is to define a unique EU classification system in which the main features and items reported in the European Catalogue of Feed Materials are harmonised with FoodEx2. This involves a systematic review of the contents of both the European Catalogue of Feed Materials and FoodEx2. This systematic review would represent not only a milestone for defining a complete list of similarities and differences but also for harmonising feed materials reported in FoodEx2 and in the European Catalogue of Feed Materials. Therefore, a future step towards an exhaustive feed classification would be to align the FoodEx2 feed hierarchy with any updated version of the EU Catalogue of Feed Material, which currently seems to be the most complete list available.

Animals

The animal categories included in our database[3] are focused on a limited number of selected animal categories, as requested by the procurement for this preparatory work.

The proof of concept was thus conducted considering a limited number of animals, representative of large ruminants, small ruminants, monogastric animals, poultry animals, fish and companion animals.

For a more comprehensive feed consumption database, a wider range of food producing animals and non-food-producing animals is needed, e.g. those published in the overview of the EFSA current approaches to animal dietary exposure, reporting animal and production categories per Panel/Unit (Table 2, EFSA 2019). All these categories with different ages (e.g. cattle, young cattle, calves, heifers), physiological and productive phases (e.g. dairy calves, veal calves) should be included in the feed consumption database. However they should also have a harmonised nomenclature, not only to prevent different naming across different areas of risk assessment (e.g. swine vs pig, salmonids vs salmon) but also to create a harmonised database.

Feed consumption data

This project highlighted the lack of a reference feed consumption database that is recognised by the entire scientific community. Such a database could be used to harmonise animal exposure estimations and risk assessments. To address this issue, we have developed a proposal for a reference feed consumption database. To date, the model database[3] only includes data generated from the FAO "*Global Livestock Environmental Assessment Model – interactive GLEAM-i*" along with selected scientific literature, given the limited access to exhaustive real-life animal consumption data. For future developments, the model database[3] should be populated with thousands of records regarding real-life feed consumption data.

A good starting point would be the "Feed Modelling" project supported by DG-AGRI. This was mentioned in a workshop held with stakeholders within the framework of the present EFSA procurement. The aim was to acquire knowledge on the consumption of cereals and other crops by food producing animals. To improve the European Commission's ability to assess the demand for EU raw materials used in animal feed, the Directorate General for Agriculture and Rural Development of the European Commission (DG AGRI) decided to develop a quantitative model via the study 'Modelling feed consumption in the EU'. This model, called FeedMod, is a computer-based model that estimates the tonnage of raw materials used to produce industrial and on-farm compound feed in the EU 28. In 2009, the first version, jointly created by Tallage and Céréopa, was presented to the European Commission. A further study[5] conducted in 2014 led to an update of the model, which considered new raw materials and introduced a new method for an on-farm feed consumption forecast. This approach represents an excellent starting point especially if the feed industry and farmers/breeders are involved.

A key milestone will thus be to collect information from industry, nutritionists, breeders, farmers, etc. regarding the representative/typical diets that can be used for simulations and as reference formulas. Methodologies for data collection, such as surveys (which could mirror surveys used for human consumption) can provide accurate insights into diet compositions and comprehensive feed material inclusion rates covering real-world diets and applications. This will help identify the key ingredients and define possible scenarios for future animal dietary exposures, which is one of the pillars of risk assessment (EFSA 2019). Obtaining information on how much an animal species (and within a species for each animal category) eats is thus indispensable. This would entail collecting a large amount of data on different ingredients, combined in different diets and different inclusion rates, as well as a variety of animal species (e.g. bovines, poultry, pigs, fish, pets) with their age/weight stages (e.g. calves under 1-year, young cattle, adult cattle, piglets, sows, laying hens, chicks, dogs, puppies).

The collection of survey data from farmers could be further facilitated by the development of a web application with a smart, intuitive interface. A harmonised list of feed ingredients and

5 Available online: https://agriculture.ec.europa.eu/system/files/2019-12/ext-study-feed-mod-fulltext_2014_en_0.pdf

animals could be pre-entered, so that those filling in the survey could choose the specific feed material and animal of interest for a considered diet to input into the database. This list should be open-ended, meaning users could propose new feed materials as needed so as to keep pace with the evolving market. A database manager could evaluate each submission to verify whether it truly represents a new feed material thus ensuring there is no overlap of feed materials under different names. Additionally, the web application should include a feed recipe database enabling users to submit, update and adjust feed recipes along with specifying the quantities or weights of each ingredient. The main weaknesses and recommendations are summarised in Table 26.

Table 26: Main weaknesses and recommendations

Category	Weaknesses	Recommendations
Feed Materials	Differences among databases and classification systems	Define a complete list of feed materials by aligning the FoodEx2 feed hierarchy with any updated version of the EU Catalogue of Feed Material
	Limited feed materials in the proposed model database[3]	Include the defined and harmonised feed materials in the future feed consumption database with an open-ended option
	Limited feed recipe in the proposed model database[3]	Include a feed recipe database
Animals	Lack of harmonised nomenclature across different risk assessment areas	Harmonise nomenclature of food-producing and non-food-producing animals, starting from those listed in the EFSA current approaches for animal dietary exposure (EFSA, 2019)
	Limited animal categories in the proposed model database[3]	Include the harmonised list of food-producing and non-food-producing animals in the future feed consumption database
Feed Consumption Data	Absence of a reference feed consumption database recognized by the scientific community	Develop a web application for survey data collection, with pre-entered harmonised lists of feed ingredients and animals
	Limited real-life animal consumption data available	Collect data consumption information from the industry, stakeholders, nutritionists, breeders and farmers
	Consumption data from the literature in the proposed model database[3]	Include the real-life data consumption in the future feed consumption database

5. Conclusion

Task 1

The classification systems and databases analysed in this project have highlighted a considerable lack of homogeneity in terms of the subdivision into groups or categories and subcategories, as well as in the description and nomenclature of each feed.

The classification systems and databases have different approaches to classifying feed ingredients. Some provide a general division between forage and concentrate feeds (e.g. FEDNA and FeeDBase), while others provide no such distinction. Some databases do not even include forages, such as INRAE-CIRAD-AFZ Tables. Some databases present an additional level of classification that includes the use of numerical and/or alphanumerical codes, while others do not.

This heterogeneity and variability could be problematic and present limitations in the attempt to harmonise the different feed classification systems. Of the databases and classification systems analysed, the European Catalogue of Feed Materials is considered the most reputable and widely used within the legal framework for placing products on the market and for labelling purposes.

Moreover, precise and comprehensive information is severely lacking on the inclusion rates and consumption of feed materials in the rations and diets of food producing and non-food producing[1] animals. Due to the importance of such information, especially within the context of risk assessments related to animal dietary exposure, this data gap should be addressed.

Task 2

Our analysis of FoodEx2 revealed that the hierarchical structure closely aligns with the classification of feed materials in the European Catalogue of Feed Materials. For an exhaustive and harmonised feed classification system, further alignment of the FoodEx2 feed hierarchy with the EU Catalogue of Feed Materials is recommended.

We propose the following additions/updates for the FoodEx2 catalogue:

- FEDNA id of the corresponding item in the FEDNA database, if there is a exists,
- Feedipedia.org link to the corresponding item in the Feedipedia.org database, if there is a match,
- termExtendedName to align the item name with the one used in the European Catalogue of Feed Materials,
- termScopeNote to align the item description with the one used in the European Catalogue of Feed Materials,
- commonNames to store all the alternative names for a specific item

Task 3

A model feed consumption database was created consisting of three different Excel sheets: *Animal, Feed* and *Consumption*. The model database[3] was populated by feed consumption data obtained using FAO "*Global Livestock Environmental Assessment Model – interactive GLEAM-i*" along with the selected scientific literature. This highlighted the lack of comprehensive and real-life feed consumption data and the importance of collaborating with stakeholders and the feed industry to collect such data.

Task 4

To evaluate the feasibility and limitations of our model database[3], two case studies were conducted, one involving NEPs expressed in a GM crop, and the second involving a contaminant (OTA). The results of animal dietary exposure reported in the selected EFSA scientific opinions were compared with those obtained using Excel calculators and those obtained from animal dietary exposure assessments using data extracted from the model database[3]. Overall, lower animal dietary exposure levels were obtained using data extracted from the model database[3] in the selected case studies, which were more marked in the GMO examples, except for Atlantic salmon (Appendix C). In the OTA example, lower animal dietary exposure was also observed, although some animal categories showed slightly higher dietary exposure.

Overall conclusion

To date no common database is available that can predict feed intake for food producing animals and non-food-producing animals in the European Union. Different approaches therefore rely on different sources of default values for animal body weights, total amount of daily consumed feed and inclusion rates of feedstuffs (e.g. OECD 2009, 2013; EFSA CONTAM Panel, 2011; EFSA FEEDAP Panel, 2017; US National Research Council; INRA; CIRAD; AFZ and FAO). Thus, collecting real-life data on feed consumption from stakeholders, industry, nutritionists, breeders, and farmers is recommended. However, considering the extensive nature of the feed industry and the wide range of feed ingredients and animal species involved, this approach would be difficult and time-consuming, and therefore a dedicated project is needed. The collected data should be used to develop a comprehensive feed consumption database for a selected and harmonised list of food producing and non-food producing animals. This would enable more realistic exposure assessments and more accurate and harmonised risk assessments.

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6 Abbreviations

2,4-D	2,4-dichlorophenoxyacetic acid
AA	Amino acids
AAD-1	aryloxyalkanoate dioxygenase
ADE	animal dietary exposure
AFZ	Association Francaise de Zootechnie
AMIS	Agricultural Market Information System
AOPP	aryloxyphenoxypropionate
BW	body weight
CIRAD	Centre de Coopèration Internationale en la Recherche Agronomique pour le Development
CONTAM	EFSA Panel on Contaminants in the Food Chain
CP	Crude protein
CVB	Centraal Veevoerder Bureau
DDE	daily dietary exposure
DG-AGRI	Directorate-General for Agriculture and Rural Development
DIM	days in milk
DIS	Decision Innovation Solutions
DM	dry matter
DW	dry weight
EE	ether extract
EFSA	European Food Safety Authority
EPSPS	5-enolpyruvylshikimate-3-phosphat synthase
EU	European Union
F	forage
FAO	Food and Agriculture Origanization of the United Nations
FEDNA	Fundaciòn Española para el Desarrollo de la Nutrición Animal
FeeDBase	Swiss Feed Database

FEEDAP	EFSA Panel on on additives and products or substances used in animal feed
FICD	Feed Ingredients Composition Database
FoodEx2	EFSA food and feed classification system
G	grain
GLEAM-i	Global Livestock Environmental Assessment Model – interactive
GM	genetically modified
GMO	genetically modified organism
GMO Panel	EFSA Panel on Genetically Modified Organisms
IAFFD	International Aquaculture Feed Formulation Database
ICAR	International Committee for Animal Recording
IFEEDER	Institute for Feed Education and Research
ILVO	Flemish Research Institute for Agriculture, Fisheries and Food
INRA	Institut National de la Recherche Agronomique
IR	inclusion rate
LB	lower bound
LOQ	limit of quantification
MTX	matrix
NEP	newly expressed proteins
NorFor	Nordic Feed Evaluation System
NRC	National Research Council
OECD	Organisation for Economic Co-operation and Development
OTA	ochratoxin A
PAFF	Practical aquaculture feed formulation database
PAT	phosphinothricin acetyltransferase enzyme
PoC	Proof of concept
SSD2	Standard Sample Description 2
TDI	tolerable daily intake
RPCs	Raw primary commodities

SCF	Scientific Committee on Food
UB	upper bound
UNDP	United Nations Development Programme
WHO	World Health Organization
WLR	Wageningen Livestock Research

APPENDIX A: Data and methodology tables

A.1. Proof of concept for the development of a feed consumption database

A.1.1. Analysis of the model database[3]

Table 27: Animal data on dairy cow (Darabighane et al., 2020).

ANIMAL	Animal body weight (kg)	Total daily intake (kg^{DM}/animal)
Dairy cow	623	25.82

Table 28: Dairy cow diet, with corresponding feed materials inclusion rates (Darabighanee et al., 2020)

FEED MATERIALS		Inclusion rate (IR%)
Literature terminology	**Code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	
Corn silage	6.11.1 Maize silage	21.23
Corn gluten feed (20% CP)	1.2.9 Maize gluten feed	18.81
Beet pulp	4.1.10 Dried (sugar) beet pulp	2.64
Corn grain, ground	1.2.1 Maize	18.09
Barley grain, ground	1.1.1 Barley	14.57
Soybean meal (44%)	2.18.3 Soya (bean) meal	14.5
Canola meal	2.14.3 Rape seed meal	5.00
Fat powder	13.6.4 Salts of fatty acids	2.30
Mineral & vitamin mix	N.A.	2.86
Total		100

Table 29: Animal data on fattening pigs (Sevillano et al., 2018).

ANIMAL	Animal body weight (kg)	Total daily intake (kg^{DM}/animal)
Fattening pig	43.5	2.187

Table 30: Fattening pig diet, with corresponding feed materials inclusion rates (Sevillano et al., 2018).

FEED MATERIALS		Inclusion rate (IR%)
Literature terminology	**Code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	
Corn	1.2.1 Maize	69.84
Soybean meal (48%)	2.18.4 Soya (bean) meal, dehulled	18.05
Molasses cane	7.6.1 (Sugar) cane molasses	5.00
Corn Gluten Feed (20% CP)	1.2.9 Maize gluten feed	2.50
Mineral & vitamin mix	N.A.	4.61
TOTAL		100

Table 31: Animal data on finishing pigs (Sevillano et al., 2018)

ANIMAL	Animal body weight (kg)	Total daily intake (kg^{DM}/animal)
Finishing pig	121.6	2.875

Table 32: Finishing pig diet, with corresponding feed materials inclusion rates (Sevillano et al., 2018)

FEED MATERIALS		Inclusion rate (IR%)
Literature terminology	**Code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	
Corn	1.2.1 Maize	75.51
Soybean meal (48%)	2.18.4 Soya (bean) meal, dehulled	9.83
Molasses cane	7.6.1 (Sugar) cane molasses	5.00
Corn Gluten Feed (20% CP)	1.2.9 Maize gluten feed	5.00
Mineral & vitamin mix	N.A.	4.66
TOTAL		100

Table 33: Animal data on broilers (Abdel-Wareth et al., 2019).

ANIMAL	Animal body weight (kg)	Total daily intake (kg^{DM}/animal)
Broiler	1.707	0.1343

Table 34: Broiler diet, with corresponding feed materials inclusion rates (Abdel-Wareth et al., 2019).

FEED MATERIALS		Inclusion rate (IR%)
Literature terminology	**Code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	
Corn, ground	1.2.1 Maize	30.00
Sorghum, ground	1.8.1 Sorghum	30.00
Soybean meal (44%)	2.18.3 Soya (bean) meal	25.00
Corn Gluten Meal (60% CP)	1.2.8 Maize Gluten	6.00
Sunflower Oil	2.20.1 Vegetable oil and fat	5.52
Mineral & vitamin mix	N.A.	3.48
TOTAL		100

Table 35: Animal data on dairy sheep (Milis et al., 2004).

ANIMAL	Animal body weight (kg)	Total daily intake (kg^{DM}/animal)
Dairy sheep	57	1.22

Table 36: Dairy sheep diet, with corresponding feed materials inclusion rates (Milis et al., 2004).

FEED MATERIALS		Inclusion rate (IR%)
Literature terminology	**Code and terminology referred to European Catalogue of Feed Materials (Reg. EU 2022/1104)**	
Corn grain	1.2.1 Maize	41.00
Alfalfa hay	6.10.2 Lucerne, field dried; alfalfa field dried	30.00
Wheat Straw	6.3.1 Cereals Straw	5.00
Corn Gluten Meal (60% CP)	1.2.8 Maize gluten	10.00
Corn Gluten Feed (20% CP)	1.2.9 Maize gluten feed	10.00
Mineral & vitamin mix	N.A.	4.00
TOTAL		100

A.1.2. Standardisation of feed material and nomenclature of animal categories

Table 37: Standardisation of feed materials for GMO case

GMO case		
Feed materials as reported in GM feed Example 1	**Feed materials as reported in model database**	**Feed materials chosen for standardisation**
Maize Grain	Maize	Maize
Maize Gluten feed	Maize gluten feed	Maize gluten feed
Maize Gluten meal	Maize gluten	Maize gluten

GMO case		
Feed materials as reported in GM feed Example 1	**Feed materials as reported in model database**	**Feed materials chosen for standardisation**
Maize Forage/Silage	Maize silage	Maize silage
Feed materials as reported in GM feed Example 2	Feed materials as reported in model database	Feed materials chosen for standardisation
Maize grain	Maize	Maize
Maize Forage	Maize silage	Maize silage

Table 38: Standardisation of feed materials for feed contaminant case

GMO case			
Feed materials as reported in EFSA OTA scientific opinion – Annex A	**Feed materials as reported in EFSA OTA scientific opinion – Table 7**	**Feed materials as reported in model database**	**Feed materials chosen for standardisation**
Wheat	Wheat grains	Wheat (Grains of Triticum aestivum L., Triticum durum Desf. and other wheat cultivars)	Wheat
Wheat feed	Wheat feed	Wheat feed	Wheat Feed
Barley	Barley grain	Barley	Barley grain
Maize	Maize grain	Maize	Maize
	Maize protein	Maize Protein (Maize Gluten) Maize protein feed (Maize gluten feed)	Maize Protein
	Maize silage	Maize silage	Maize silage
Soybean meal	Soybean (expeller + meal)	Soya (bean) meal Soya (bean) expeller Soya (bean) meal, dehulled	Soybean (expeller + meal)

GMO case			
Feed materials as reported in EFSA OTA scientific opinion – Annex A	**Feed materials as reported in EFSA OTA scientific opinion – Table 7**	**Feed materials as reported in model database**	**Feed materials chosen for standardisation**
	Soybean hulls Soybean, protein concentrate	Soya (bean) hulls Soya (bean) protein concentrate	Soybean hulls Soybean, protein concentrate
Rapeseed meal	Rape seed Rape seed (expeller + meal)	Rape seed Rape seed expeller Canola meal	Rape seed Rape seed (expeller + meal)
Vegetable oils and fats	--	Vegetable oil and fat	Vegetable oil and fat
Sugar beet pulp	--	Dried (sugar) beet pulp	Beet pulp
Molasses	--	(Sugar) beet molasses	(Sugar) beet molasses
Sunflower meal	Sunflower (expeller + meal)	Sunflower Oil	Sunflower Oil
Horse beans	Horse beans	Horse Beans	Horse Beans
Mineral salts	--	Minerals and products derived thereof	Minerals and products derived thereof
Premix	Premix	Premix	Premix
Forage	Grass meal, hay and alfalfa Lucerne meal (Alfalfa meal)	Forage meal, grass meal, green meal Hay Lucerne meal (alfalfa meal)	Forage Lucerne meal (alfalfa meal)

Table 39: Standardisation of animal categories

GMO case		
Animal categories as reported in GM feed **Example 1**	**Animal categories as reported in model database**	**Animal categories chosen for standardisation**
Lactating dairy cow	Dairy cow	Dairy cow
Finishing pig	Finishing pig	Finishing pig
Broiler	Broiler	Broiler
Animal categories as reported in GM feed Example 2	Animal categories as reported in model database	Animal categories chosen for standardisation
Dairy cattle	Dairy cow	Dairy cow
Ram/ewe	Dairy sheep	Dairy sheep
Finishing pigs	Finishing pig	Finishing pig
Broiler	Broiler	Broiler
Animal categories as reported in GM feed **Example 2**	**Animal categories as reported in model database**	**Animal categories chosen for standardisation**
Dairy cattle	Dairy cow	Dairy cow
Ram/ewe	Dairy sheep	Dairy sheep
Finishing pigs	Finishing pig	Finishing pig
Broiler	Broiler	Broiler
Feed contaminant case		
Animal categories as reported in EFSA OTA scientific opinion	**Animal categories as reported in model database**	**Animal categories chosen for standardisation**
Dairy cows	Dairy Cow	Dairy cow
Dairy sheep	Dairy sheep	Dairy sheep
Pigs for fattening	Fattening pig	Fattening pig
Chickens for fattening	Broiler	Broiler

APPENDIX B: Assessment/Result tables

A.2. Methodologies for mapping and describing the classification system adopted in the selected feed database

Table 40: List of the classification categories in each selected feed database

Database	Groups/Categories
FEDNA	1. Granos de cereales (cereal grains) 2. Cereales procesados por calor (heat treated cereals) 3. Subproductos de cereals (cereal by-products) 4. Frutos y tubérculos. Melazas y vinazas (Fruits & tubers. Molasses & vinasses) 5. Concentrados proteína vegetal (vegetal protein concentrates) 6. Alimentos fibrosos (fibrous feeds) 7. Concentrados de proteína animal (animal protein concentrates) 8. Productos lácteos (dairy procucts) 9. Grasas y aceites (fats and oils) 10. Minerales (minerals) 11. Microingredientes (microingredients)
INRAE-CIRAD-AFZ	Cereal grains Cereal by-products Legumes and oilseeds Oil by-products Roots and by-products Fruits and by-products Other plant products Animal products Dairy products Oils and fats Mineral products

Database	Groups/Categories
CVB	Amino acids
	Compound feedstuffs[a]
	High moisture industrial co-products
	Roughages and related products
	Mineral feedstuffs
	Miscellaneous
Luonnonvaratieto	01. Grains and seeds
	02. Cakes and meals
	03. Plant by-products
	04. Feeds of animal origin
	05. Roots, tubers, fruits and cabbages,
	06. Fresh forages and pasture
	07. Grass silages
	08. Other silages
	09. Hay and artificially dried grasses
	10. Straw
	11. Minerals
	90. Other feeds
NorFor	1. Grains
	2. Oil seeds
	3. Legume seeds
	4. Tubers and roots
	5. Other seeds and fruits
	6. Forages and roughage
	7. Other plants
	8. Milk products
	9. Animal products
	10. Marine products

Database	Groups/Categories
	11. Minerals
	12. Miscellaneous
	13. Feed additives
	14. Standard feed mixtures
	18. Commercial products
	97. Special feedstuff company mixture
FeedBase	Raw materials
	Roughage
IAFFD	Feed Ingredient composition database (FICD)- no categories
Feedipedia	Forage plants
	Plant products/ by-products
	Feed of animal origin
	Other feeds
The European Catalogue of Feed Material[b]	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. Forage 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 micro-organism, inactivated resulting in absence of live micro-organisms
	13. Miscellaneous

Database	
	Groups/Categories
The Harmonised OECD tables of feedstuffs from field crop	1. Forages/Fodders 2. Roots & Tubers 3. Cereal Grains/Crops Seeds 4. By-products
The international Feed Vocabulary (FAO/UNDP)	1. Dry forages and roughages 2. Pasture, range plants, and forages fed green 3. Silages 4. Energy feeds 5. Protein supplements 6. Mineral supplements 7. Vitamin supplements (including ensiled yeast) 8. Additives

(a): In CVB the term compound feed is used instead of raw materials (single ingredients)
(b): The Feed Register has been not included since it uses the same categories of the European Catalogue of Feed material

A.3. Proof of concept for the development of a feed consumption database

A.3.1. First case study: GM feed

GM feed Example 1

Table 41: Animal dietary exposure to Cry1Da_7 and Cry1B.868 proteins (mg/kg BW per day) based on the consumption of maize grains, gluten feed, gluten meal and silage in selected animals, as reported in the GM feed Example 1 (EFSA GMO Panel 2022a)

Animal categories BW (kg)/total diet intake (kg dw)	Feed material	IR%	Cry1Da_7	Cry1B.868
Broiler	Grain	70	12.35	1,285
1.7/0.12	Gluten feed	10	4.6	477.1
	Gluten meal	10	12.5	1,305
	Total	90	29	3,065
Finishing pig	Grain	70	5.25	546
100/3	Gluten feed	20	3.9	405.6
	Gluten meal	10	5.3	555
	Total	100	14	1,505
Lactating dairy cow 650/25	Gluten feed	20[(a)]	5	520
	Gluten meal	20	13.6	1,423
	Forage/Silage	60	600	2,538
	Total	100	619	4,478

Table 42: Animal daily dietary exposure to Cry1Da_7 and Cry1B.868 proteins (mg/kg BW per day) performed with the Excel calculator (EFSA GMO Panel 2023)

Protein	Feed material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	$\mu g^{NEP}/g^{DM}$	$\mu g^{NEP}/kg^{BW}$
Cry1B.868	**Grain**	Dairy cow 650/25	30	0.25	2.88
		Finishing pig 100/3	70	0.25	5.25
		Broiler 2/0.158	70	0.25	13.83
		Dairy Sheep 80/2.8	25	0.25	2.19
	Gluten feed	Dairy cow 650/25	30	0.65	7.47
		Finishing pig 100/3	20	0.65	3.89
		Broiler 2/0.158	10	0.65	5.12
		Dairy Sheep 80/2.8	10	0.65	2.27
	Gluten meal	Dairy cow 650/25	20	1.79	13.77
		Finishing pig 100/3	10	1.79	5.37
		Broiler 2/0.158	10	1.79	14.14
		Dairy Sheep 80/2.8	10	1.79	6.27
	Forage/silage	Dairy cow 650/25	60	26.00	600.00
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA

Protein	Feed material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	µg^NEP/g^DM	µg^NEP/kg^BW
		Dairy Sheep 80/2.8	80	26.00	728.00
	Milled by-products	Dairy cow 650/25	30	0.25*	2.88
		Finishing pig 100/3	75	0.25*	5.63
		Broiler 2/0.158	60	0.25*	11.85
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	627.01
		Finishing pig 100/3	175	NA	20.13
		Broiler 2/0.158	150	NA	44.93
		Dairy Sheep 80/2.8	125	NA	738.72
Cry1B.868	Grain	Dairy cow 650/25	30	26.00	300.00
		Finishing pig 100/3	70	26.00	546.00
		Broiler 2/0.158	70	26.00	1437.80
		Dairy Sheep 80/2.8	25	26.00	227.50
	Gluten feed	Dairy cow 650/25	30	67.34	777.00
		Finishing pig 100/3	20	67.34	404.04
		Broiler 2/0.158	10	67.34	531.99
		Dairy Sheep 80/2.8	10	67.34	235.69

Protein	Feed material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	µg^NEP/g^DM	µg^NEP/kg^BW
	Gluten meal	Dairy cow 650/25	20	186.00	1432.00
		Finishing pig 100/3	10	186.00	558.48
		Broiler 2/0.158	10	186.00	1470.66
		Dairy Sheep 80/2.8	10	186.00	651.56
	Forage/silage	Dairy cow 650/25	60	110.00	2538.46
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA
		Dairy Sheep 80/2.8	80	110.00	3080.00
	Milled by-products	Dairy cow 650/25	30	26.00*	300.00
		Finishing pig 100/3	75	26.00*	585.00
		Broiler 2/0.158	60	26.00*	1232.40
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170.00	NA	5347.46
		Finishing pig 100/3	175.00	NA	2093.52
		Broiler 2/0.158	150.00	NA	4672.85
		Dairy Sheep 80/2.8	125.00	NA	4194.75

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposure calculations were done.

The total inclusion rate for dairy cow, finishing pig, broiler, dairy sheep is >100%, resulting in an overestimation in the DDE to each protein.

* The GMO panel did not recommend specific data for a conversion factor so the value of 1 was selected.

Table 43: Animal daily dietary exposure to Cry1Da_7 and Cry1B.868 proteins (mg/kg BW per day) performed with the model database[3] input data.

Protein	Feed material	Animal categories BW (kg)/total diet intake (kg dw)	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	µgNEP/gDM	µgNEP/kgBW
Cry1Da_7	**Maize**	Dairy cow 623/25.82	18.09	0.25	1.87
		Finishing pig 121.6/2.875	75.51	0.25	4.46
		Broiler 1.707/0.1343	30	0.25	5.90
		Dairy sheep 57/1.22	41	0.25	2.19
	Maize gluten feed	Dairy cow 623/25.82	18.81	0.65	5.05
		Finishing pig 121.6/2.875	5	0.65	0.77
		Dairy sheep 57/1.22	10	0.65	1.39
	Maize gluten	Broiler 1.707/0.1343	6	1.79	8.45
		Dairy sheep 57/1.22	10	1.79	3.83
	Maize silage	Dairy cow 623/25.82	21.23	26.00	228.77
	TOTAL	Dairy cow 623/25.82	58.13	NA	235.69
		Finishing pig 121.6/2.875	80.51	NA	5.23

Protein	Feed material	Animal categories BW (kg)/total diet intake (kg dw)	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	µgNEP/gDM	µgNEP/kgBW
		Broiler 1.707/0.1343	36	NA	14.35
		Dairy sheep 57/1.22	61	NA	7.41
Cry1B.868	Maize	Dairy cow 623/25.82	18.09	26.00	194.93
		Finishing pig 121.6/2.875	75.51	26.00	464.18
		Broiler 1.707/0.1343	30	26.00	613.67
		Dairy sheep 57/1.22	41	26.00	228.16
	Maize gluten feed	Dairy cow 623/25.82	18.81	67.34	524.96
		Finishing pig 121.6/2.875	5	67.34	79.61
		Dairy sheep 57/1.22	10	67.34	144.13
	Maize gluten	Broiler 1.707/0.1343	6	186.00	878.78
		Dairy sheep 57/1.22	10	186.00	398.45
	Maize silage	Dairy cow 623/25.82	21.23	110.00	967.86
	TOTAL	Dairy cow 623/25.82	58.13	NA	1687.75
		Finishing pig 121.6/2.875	80.51	NA	543.78
		Broiler 1.707/0.1343	36	NA	1492.45
		Dairy sheep 57/1.22	61	NA	770.74

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposure calculations were done.

Table 44: Summary of DDE results to Cry1Da_7 and Cry1B.868 proteins (mg/kg BW per day) reported in the EFSA scientific opinion (EFSA GMO Panel 2022a), results obtained using the Excel calculator (EFSA GMO Panel 2023) and results obtained using the model database[3].

Protein	Feed material	Animal species	DDE scientific Opinion	DDE Excel calculator	DDE model database
		Category	$\mu g^{NEP}/kg^{BW}$	$\mu g^{NEP}/kg^{BW}$	$\mu g^{NEP}/kg^{BW}$
Cry1Da_7	**Maize**	Dairy cow	NA	2.88	1.87
		Finishing pig	5.25	5.25	4.46
		Broiler	12.35	13.83	5.90
		Dairy Sheep	NC	2.19	2.19
	Maize gluten feed	Dairy cow	5.00*	7.47	5.05
		Finishing pig	3.90*	3.89	0.77
		Broiler	4.60*	5.12	NA
		Dairy Sheep	NC	2.27	1.39
	Maize gluten	Dairy cow	13.60*	13.77	NA
		Finishing pig	5.30*	5.37	NA
		Broiler	12.50*	14.14	8.45
		Dairy Sheep	NC	6.27	3.83
	Maize silage	Dairy cow	600.00*	600.00	228.77
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NC	728.00	NA
	Maize milled by-products	Dairy cow	NA	2.88	NA
		Finishing pig	NA	5.63	NA
		Broiler	NA	11.85	NA
		Dairy Sheep	NC	NA	NA
	TOTAL	Dairy cow	619.00*	627.01	235.69

Protein	Feed material	Animal species	DDE scientific Opinion	DDE Excel calculator	DDE model database
		Category	µg^NEP/kg^BW	µg^NEP/kg^BW	µg^NEP/kg^BW
		Finishing pig	14.00*	20.13	5.23
		Broiler	29.00*	44.93	14.35
		Dairy Sheep	NC	738.72	7.41
Cry1B.868	**Maize**	Dairy cow	NA	300.00	194.93
		Finishing pig	546.00*	546.00	464.18
		Broiler	1285.00*	1437.80	613.67
		Dairy Sheep	NC	227.50	228.16
	Maize gluten feed	Dairy cow	520.00*	777.00	524.96
		Finishing pig	405.60*	404.04	79.61
		Broiler	477.10*	531.99	NA
		Dairy Sheep	NC	235.69	144.13
	Maize gluten	Dairy cow	1423.00*	1432.00	NA
		Finishing pig	555.00*	558.48	NA
		Broiler	1305.00*	1470.66	878.78
		Dairy Sheep	NC	651.56	398.45
	Maize silage	Dairy cow	2538.00*	2538.46	967.86
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NC	3080.00	NA
	Maize milled by-products	Dairy cow	NA	300.00	NA
		Finishing pig	NA	585.00	NA
		Broiler	NA	1232.40	NA
		Dairy Sheep	NC	NA	NA
	TOTAL	Dairy cow	4478.00*	5347.46	1687.75

Protein	Feed material	Animal species	DDE scientific Opinion	DDE Excel calculator	DDE model database
		Category	μg^NEP/kg^BW	μg^NEP/kg^BW	μg^NEP/kg^BW
		Finishing pig	1505.00*	2093.52	543.78
		Broiler	3065.00*	4672.85	1492.45
		Dairy Sheep	NC	4194.75	770.74

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposures were calculated.

NC indicates that the animal category was not considered in the scientific opinion (EFSA GMO Panel 2022a)

* indicates that zero digits were added to the original value (Table 41) to obtain three digits after the decimal point.

GM feed Example 2

Table 45: Animal dietary exposure to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins (mg/kg BW per day) in selected animals, based on the consumption of maize grain and forage, as reported in the GM feed Example 2 (EFSA GMO Panel 2022b).

Cry1F	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[a]	500	12	80	80	0.033	0.10	0.14
Dairy cattle	650	25	30	60	0.02	0.12	0.14
Ram/ewe	75	2.5	30	NA	0.017	NA	NA
Lamb	40	1.7	30	30	0.022	0.069	0.091
Breeding pigs	260	6	70	20	0.027	0.025	0.052
Finishing pigs	100	3	70	NA	0.036	NA	NA
Broiler	1.7	0.12	70	NA	0.084	NA	NA
Layer	1.9	0.13	70	10	0.081	0.037	0.12
Turkey	7	0.50	50	NA	0.061	NA	NA

Cry34Ab1	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[(a)]	500	12	80	80	0.36	1.50	1.9
Dairy cattle	650	25	30	60	0.22	1.80	2.0
Ram/ewe	75	2.5	30	NA	0.19	NA	NA
Lamb	40	1.7	30	30	0.24	0.99	1.2
Breeding pigs	260	6	70	20	0.31	0.36	0.67
Finishing pigs	100	3	70	NA	0.40	NA	NA
Broiler	1.7	0.12	70	NA	0.94	NA	NA
Layer	1.9	0.13	70	10	0.91	0.53	1.4
Turkey	7	0.50	50	NA	0.68	NA	NA

Cry35Ab1	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[(a)]	500	12	80	80	0.015	0.40	0.42
Dairy cattle	650	25	30	60	0.009	0.48	0.49
Ram/ewe	75	2.5	30	NA	0.0078	NA	NA
Lamb	40	1.7	30	30	0.010	0.27	0.28
Breeding pigs	260	6	70	20	0.013	0.10	0.11
Finishing pigs	100	3	70	NA	0.016	NA	NA
Broiler	1.7	0.12	70	NA	0.039	NA	NA
Layer	1.9	0.13	70	10	0.037	0.14	0.18
Turkey	7	0.50	50	NA	0.028	NA	NA

PAT	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[(a)]	500	12	80	80	0.00058	0.035	0.035
Dairy cattle	650	25	30	60	0.00035	0.042	0.042
Ram/ewe	75	2.5	30	NA	0.00030	NA	NA
Lamb	40	1.7	30	30	0.00038	0.023	0.023
Breeding pigs	260	6	70	20	0.00048	0.0083	0.0088
Finishing pigs	100	3	70	NA	0.00063	NA	NA
Broiler	1.7	0.12	70	NA	0.0015	NA	NA
Layer	1.9	0.13	70	10	0.0014	0.012	0.014
Turkey	7	0.50	50	NA	0.0011	NA	NA

Cry1A.105	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[(a)]	500	12	80	80	0.035	0.18	0.22
Dairy cattle	650	25	30	60	0.021	0.22	0.24
Ram/ewe	75	2.5	30	NA	0.018	NA	NA
Lamb	40	1.7	30	30	0.023	0.12	0.14
Breeding pigs	260	6	70	20	0.029	0.043	0.072
Finishing pigs	100	3	70	NA	0.038	NA	NA
Broiler	1.7	0.12	70	NA	0.089	NA	NA
Layer	1.9	0.13	70	10	0.086	0.064	0.15
Turkey	7	0.50	50	NA	0.064	NA	NA

Cry2Ab2	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[(a)]	500	12	80	80	0.06	1.02	1.1
Dairy cattle	650	25	30	60	0.035	1.2	1.3
Ram/ewe	75	2.5	30	NA	0.030	NA	NA
Lamb	40	1.7	30	30	0.038	0.68	0.71
Breeding pigs	260	6	70	20	0.05	0.24	0.29
Finishing pigs	100	3	70	NA	0.06	NA	NA
Broiler	1.7	0.12	70	NA	0.15	NA	NA
Layer	1.9	0.13	70	10	0.14	0.36	0.51
Turkey	7	0.50	50	NA	0.11	NA	NA

Cry3Bb1	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle[(a)]	500	12	80	80	0.086	1.06	1.1
Dairy cattle	650	25	30	60	0.052	1.27	1.3
Ram/ewe	75	2.5	30	NA	0.045	NA	NA
Lamb	40	1.7	30	30	0.057	0.70	0.76
Breeding pigs	260	6	70	20	0.073	0.25	0.33
Finishing pigs	100	3	70	NA	0.095	NA	NA
Broiler	1.7	0.12	70	NA	0.22	NA	NA
Layer	1.9	0.13	70	10	0.22	0.38	0.59
Turkey	7	0.50	50	NA	0.16	NA	NA

CP4 EPSPS	BW (kg)	TDI feed (kg DM/animal)	IR (%) grains	IR (%) forage	Grain (G)	Forage (F)	G + F
Beef cattle(a)	500	12	80	80	0.056	0.31	0.36
Dairy cattle	650	25	30	60	0.033	0.37	0.40
Ram/ewe	75	2.5	30	NA	0.029	NA	NA
Lamb	40	1.7	30	30	0.037	0.20	0.24
Breeding pigs	260	6	70	20	0.047	0.07	0.12
Finishing pigs	100	3	70	NA	0.061	NA	NA
Broiler	1.7	0.12	70	NA	0.14	NA	NA
Layer	1.9	0.13	70	10	0.14	0.11	0.25
Turkey	7	0.50	50	NA	0.10	NA	NA
AAD-1	**BW (kg)**	**TDI feed (kg DM/animal)**	**IR (%) grains**	**IR (%) forage**	**Grain (G)**	**Forage (F)**	**G + F**
Beef cattle(a)	500	12	80	80	0.096	0.21	0.31
Dairy cattle	650	25	30	60	0.058	0.25	0.31
Ram/ewe	75	2.5	30	NA	0.05	NA	NA
Lamb	40	1.7	30	30	0.064	0.14	0.20
Breeding pigs	260	6	70	20	0.081	0.05	0.13
Finishing pigs	100	3	70	NA	0.11	NA	NA
Broiler	1.7	0.12	70	NA	0.25	NA	NA
Layer	1.9	0.13	70	10	0.24	0.075	0.31
Turkey	7	0.50	50	NA	0.18	NA	NA

(a): The inclusion rate for beef cattle would be 160% of the diet, resulting in the DDE to each protein an overestimation.

NA indicates that a forage inclusion rate was not provided in the reference and therefore no exposure calculations were done.

Table 46: Animal daily dietary exposure to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins (mg/kg BW per day) performed with the Excel calculator (EFSA GMO Panel 2023)

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	**Category**	**IR%**	**$\mu g^{NEP}/g^{DM}$**	**mg^{NEP}/kg^{BW}**
Cry1F	**Grain**	Dairy cow 650/25	30	1.70	0.020
		Finishing pig 100/3	70	1.70	0.036
		Broiler 2/0.158	70	1.70	0.094
		Dairy Sheep 80/2.8	25	1.70	0.015
	Gluten feed	Dairy cow 650/25	30	4.40	0.051
		Finishing pig 100/3	20	4.40	0.026
		Broiler 2/0.158	10	4.40	0.035
		Dairy Sheep 80/2.8	10	4.40	0.015
	Gluten meal	Dairy cow 650/25	20	12.17	0.094
		Finishing pig 100/3	10	12.17	0.037
		Broiler 2/0.158	10	12.17	0.096
		Dairy Sheep 80/2.8	10	12.17	0.043
	Forage/silage	Dairy cow 650/25	60	5.40	0.125
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	80	5.40	0.151
	Milled by-products	Dairy cow 650/25	30	1.70*	0.020
		Finishing pig 100/3	75	1.70*	0.038
		Broiler 2/0.158	60	1.70*	0.081
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	0.308
		Finishing pig 100/3	175	NA	0.137
		Broiler 2/0.158	150	NA	0.306
		Dairy Sheep 80/2.8	125	NA	0.224
Cry34Ab1	**Grain**	Dairy cow 650/25	30	19.00	0.219
		Finishing pig 100/3	70	19.00	0.399
		Broiler 2/0.158	70	19.00	1.051
		Dairy Sheep 80/2.8	25	19.00	0.166
	Gluten feed	Dairy cow 650/25	30	49.21	0.568
		Finishing pig 100/3	20	49.21	0.295
		Broiler 2/0.158	10	49.21	0.389

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	10	49.21	0.172
	Gluten meal	Dairy cow 650/25	20	136.04	1.046
		Finishing pig 100/3	10	136.04	0.408
		Broiler 2/0.158	10	136.04	1.075
		Dairy Sheep 80/2.8	10	136.04	0.476
	Forage/silage	Dairy cow 650/25	60	78.00	1.800
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA
		Dairy Sheep 80/2.8	80	78.00	2.184
	Milled by-products	Dairy cow 650/25	30	19.00*	0.219
		Finishing pig 100/3	75	19.00*	0.428
		Broiler 2/0.158	60	19.00*	0.901
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	3.853
		Finishing pig 100/3	175	NA	1.530
		Broiler 2/0.158	150	NA	3.415

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	125	NA	2.999
Cry35Ab1	**Grain**	Dairy cow 650/25	30	0.78	0.009
		Finishing pig 100/3	70	0.78	0.016
		Broiler 2/0.158	70	0.78	0.043
		Dairy Sheep 80/2.8	25	0.78	0.007
	Gluten feed	Dairy cow 650/25	30	2.02	0.023
		Finishing pig 100/3	20	2.02	0.012
		Broiler 2/0.158	10	2.02	0.016
		Dairy Sheep 80/2.8	10	2.02	0.007
	Gluten meal	Dairy cow 650/25	20	5.58	0.043
		Finishing pig 100/3	10	5.58	0.017
		Broiler 2/0.158	10	5.58	0.044
		Dairy Sheep 80/2.8	10	5.58	0.020
	Forage/silage	Dairy cow 650/25	60	21.00	0.485
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	80	21.00	0.588
	Milled by-products	Dairy cow 650/25	30	0.78*	0.009
		Finishing pig 100/3	75	0.78*	0.018
		Broiler 2/0.158	60	0.78*	0.037
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	0.569
		Finishing pig 100/3	175	NA	0.063
		Broiler 2/0.158	150	NA	0.140
		Dairy Sheep 80/2.8	125	NA	0.621
PAT	**Grain**	Dairy cow 650/25	30	0.03	0.00035
		Finishing pig 100/3	70	0.03	0.00063
		Broiler 2/0.158	70	0.03	0.00166
		Dairy Sheep 80/2.8	25	0.03	0.00026
	Gluten feed	Dairy cow 650/25	30	0.08	0.00090
		Finishing pig 100/3	20	0.08	0.00047
		Broiler 2/0.158	10	0.08	0.00061

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	10	0.08	0.00027
	Gluten meal	Dairy cow 650/25	20	0.21	0.00165
		Finishing pig 100/3	10	0.21	0.00064
		Broiler 2/0.158	10	0.21	0.00170
		Dairy Sheep 80/2.8	10	0.21	0.00075
	Forage/silage	Dairy cow 650/25	60	1.80	0.04154
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA
		Dairy Sheep 80/2.8	80	1.80	0.05040
	Milled by-products	Dairy cow 650/25	30	0.03*	0.00035
		Finishing pig 100/3	75	0.03*	0.00068
		Broiler 2/0.158	60	0.03*	0.00142
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	0.04478
		Finishing pig 100/3	175	NA	0.00242
		Broiler 2/0.158	150	NA	0.00539

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	125	NA	0.05169
Cry1A.105	**Grain**	Dairy cow 650/25	30	1.80	0.021
		Finishing pig 100/3	70	1.80	0.038
		Broiler 2/0.158	70	1.80	0.100
		Dairy Sheep 80/2.8	25	1.80	0.016
	Gluten feed	Dairy cow 650/25	30	4.66	0.054
		Finishing pig 100/3	20	4.66	0.028
		Broiler 2/0.158	10	4.66	0.037
		Dairy Sheep 80/2.8	10	4.66	0.016
	Gluten meal	Dairy cow 650/25	20	12.89	0.099
		Finishing pig 100/3	10	12.89	0.039
		Broiler 2/0.158	10	12.89	0.102
		Dairy Sheep 80/2.8	10	12.89	0.045
	Forage/silage	Dairy cow 650/25	60	9.40	0.217
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	μg^{NEP}/g^{DM}	mg^{NEP}/kg^{BW}
	Milled by-products	Dairy Sheep 80/2.8	80	9.40	0.263
		Dairy cow 650/25	30	1.80*	0.021
		Finishing pig 100/3	75	1.80*	0.041
		Broiler 2/0.158	60	1.80*	0.085
	TOTAL	Dairy Sheep 80/2.8	NA	NA	NA
		Dairy cow 650/25	170	NA	0.411
		Finishing pig 100/3	175	NA	0.145
		Broiler 2/0.158	150	NA	0.324
Cry2Ab2	**Grain**	Dairy Sheep 80/2.8	125	NA	0.340
		Dairy cow 650/25	30	3.00	0.035
		Finishing pig 100/3	70	3.00	0.063
		Broiler 2/0.158	70	3.00	0.166
	Gluten feed	Dairy Sheep 80/2.8	25	3.00	0.026
		Dairy cow 650/25	30	7.77	0.090
		Finishing pig 100/3	20	7.77	0.047
		Broiler 2/0.158	10	7.77	0.061

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	**Category**	**IR%**	**$\mu g^{NEP}/g^{DM}$**	**mg^{NEP}/kg^{BW}**
		Dairy Sheep 80/2.8	10	7.77	0.027
	Gluten meal	Dairy cow 650/25	20	21.48	0.165
		Finishing pig 100/3	10	21.48	0.064
		Broiler 2/0.158	10	21.48	0.170
		Dairy Sheep 80/2.8	10	21.48	0.075
	Forage/silage	Dairy cow 650/25	60	53.00	1.223
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA
		Dairy Sheep 80/2.8	80	53.00	1.484
	Milled by-products	Dairy cow 650/25	30	3.00*	0.035
		Finishing pig 100/3	75	3.00*	0.068
		Broiler 2/0.158	60	3.00*	0.142
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	1.547
		Finishing pig 100/3	175	NA	0.242
		Broiler 2/0.158	150	NA	0.539

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	125	NA	1.613
Cry3Bb1	**Grain**	Dairy cow 650/25	30	4.50	0.052
		Finishing pig 100/3	70	4.50	0.095
		Broiler 2/0.158	70	4.50	0.249
		Dairy Sheep 80/2.8	25	4.50	0.039
	Gluten feed	Dairy cow 650/25	30	11.66	0.134
		Finishing pig 100/3	20	11.66	0.070
		Broiler 2/0.158	10	11.66	0.092
		Dairy Sheep 80/2.8	10	11.66	0.041
	Gluten meal	Dairy cow 650/25	20	32.22	0.248
		Finishing pig 100/3	10	32.22	0.097
		Broiler 2/0.158	10	32.22	0.255
		Dairy Sheep 80/2.8	10	32.22	0.113
	Forage/silage	Dairy cow 650/25	60	55.00	1.269
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
	Milled by-products	Dairy Sheep 80/2.8	80	55.00	1.540
		Dairy cow 650/25	30	4.50*	0.052
		Finishing pig 100/3	75	4.50*	0.101
		Broiler 2/0.158	60	4.50*	0.213
	TOTAL	Dairy Sheep 80/2.8	NA	NA	NA
		Dairy cow 650/25	170	NA	1.755
		Finishing pig 100/3	175	NA	0.362
		Broiler 2/0.158	150	NA	0.809
CP4 EPSPS	**Grain**	Dairy Sheep 80/2.8	125	NA	1.733
		Dairy cow 650/25	30	2.90	0.033
		Finishing pig 100/3	70	2.90	0.061
		Broiler 2/0.158	70	2.90	0.160
	Gluten feed	Dairy Sheep 80/2.8	25	2.90	0.025
		Dairy cow 650/25	30	7.51	0.087
		Finishing pig 100/3	20	7.51	0.045
		Broiler 2/0.158	10	7.51	0.059

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	10	7.51	0.026
	Gluten meal	Dairy cow 650/25	20	20.76	0.160
		Finishing pig 100/3	10	20.76	0.062
		Broiler 2/0.158	10	20.76	0.164
		Dairy Sheep 80/2.8	10	20.76	0.073
	Forage/silage	Dairy cow 650/25	60	16.00	0.369
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA
		Dairy Sheep 80/2.8	80	16.00	0.448
	Milled by-products	Dairy cow 650/25	30	2.90*	0.033
		Finishing pig 100/3	75	2.90*	0.065
		Broiler 2/0.158	60	2.90*	0.137
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	0.683
		Finishing pig 100/3	175	NA	0.234
		Broiler 2/0.158	150	NA	0.521

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy Sheep 80/2.8	125	NA	0.572
AAD-1	Grain	Dairy cow 650/25	30	5.00	0.058
		Finishing pig 100/3	70	5.00	0.105
		Broiler 2/0.158	70	5.00	0.277
		Dairy Sheep 80/2.8	25	5.00	0.044
	Gluten feed	Dairy cow 650/25	30	12.95	0.149
		Finishing pig 100/3	20	12.95	0.078
		Broiler 2/0.158	10	12.95	0.102
		Dairy Sheep 80/2.8	10	12.95	0.045
	Gluten meal	Dairy cow 650/25	20	35.80	0.275
		Finishing pig 100/3	10	35.80	0.107
		Broiler 2/0.158	10	35.80	0.283
		Dairy Sheep 80/2.8	10	35.80	0.125
	Forage/silage	Dairy cow 650/25	60	11.00	0.254
		Finishing pig 100/3	NA	NA	NA
		Broiler 2/0.158	NA	NA	NA

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	**Category**	**IR%**	**$\mu g^{NEP}/g^{DM}$**	**mg^{NEP}/kg^{BW}**
		Dairy Sheep 80/2.8	80	11.00	0.308
	Milled by-products	Dairy cow 650/25	30	5.00*	0.058
		Finishing pig 100/3	75	5.00*	0.113
		Broiler 2/0.158	60	5.00*	0.237
		Dairy Sheep 80/2.8	NA	NA	NA
	TOTAL	Dairy cow 650/25	170	NA	0.794
		Finishing pig 100/3	175	NA	0.403
		Broiler 2/0.158	150	NA	0.899
		Dairy Sheep 80/2.8	125	NA	0.522

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposures were calculated.

The total inclusion rate for dairy cow, finishing pig, broiler and dairy sheep is >100%, resulting in an overestimation in the DDE to each protein.

* The GMO panel did not recommend specific data for a conversion factor so the value of 1 was selected.

Table 47: Animal daily dietary exposure to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins (mg/kg BW per day) performed with the model database[3] input data

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
Cry1F	Maize	Dairy cow 623/25.82	18.09	1.70	0.013
		Finishing pig 121.6/2.875	75.51	1.70	0.030
		Broiler 1.707/0.1343	30	1.70	0.040
		Dairy sheep 57/1.22	41	1.70	0.015
	Maize gluten feed	Dairy cow 623/25.82	18.81	4.40	0.034
		Finishing pig 121.6/2.875	5	4.40	0.005
		Dairy sheep 57/1.22	10	4.40	0.009
	Maize gluten	Broiler 1.707/0.1343	6	12.17	0.057
		Dairy sheep 57/1.22	10	12.17	0.026
	Maize silage	Dairy cow 623/25.82	21.23	5.40	0.048
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.095
		Finishing pig 121.6/2.875	80.51	NA	0.036
		Broiler 1.707/0.1343	36	NA	0.098
		Dairy sheep 57/1.22	61	NA	0.050
Cry34Ab1	Maize	Dairy cow 623/25.82	18.09	19.00	0.142

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	µg^{NEP}/g^{DM}	mg^{NEP}/kg^{BW}
		Finishing pig 121.6/2.875	75.51	19.00	0.339
		Broiler 1.707/0.1343	30	19.00	0.448
		Dairy sheep 57/1.22	41	19.00	0.167
	Maize gluten feed	Dairy cow 623/25.82	18.81	49.21	0.384
		Finishing pig 121.6/2.875	5	49.21	0.058
		Dairy sheep 57/1.22	10	49.21	0.105
	Maize gluten	Broiler 1.707/0.1343	6	136.04	0.642
		Dairy sheep 57/1.22	10	136.04	0.291
	Maize silage	Dairy cow 623/25.82	21.23	78.00	0.686
	TOTAL	Dairy cow 623/25.82	58.13	NA	1.212
		Finishing pig 121.6/2.875	80.51	NA	0.397
		Broiler 1.707/0.1343	36	NA	1.091
		Dairy sheep 57/1.22	61	NA	0.563
Cry35Ab1	**Maize**	Dairy cow 623/25.82	18.09	0.78	0.006
		Finishing pig 121.6/2.875	75.51	0.78	0.014
		Broiler 1.707/0.1343	30	0.78	0.018

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy sheep 57/1.22	41	0.78	0.007
	Maize gluten feed	Dairy cow 623/25.82	18.81	2.02	0.016
		Finishing pig 121.6/2.875	5	2.02	0.002
		Dairy sheep 57/1.22	10	2.02	0.004
	Maize gluten	Broiler 1.707/0.1343	6	5.58	0.026
		Dairy sheep 57/1.22	10	5.58	0.012
	Maize silage	Dairy cow 623/25.82	21.23	21.00	0.185
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.206
		Finishing pig 121.6/2.875	80.51	NA	0.016
		Broiler 1.707/0.1343	36	NA	0.045
		Dairy sheep 57/1.22	61	NA	0.023
PAT	**Maize**	Dairy cow 623/25.82	18.09	0.03	0.00022
		Finishing pig 121.6/2.875	75.51	0.03	0.00054
		Broiler 1.707/0.1343	30	0.03	0.00071
		Dairy sheep 57/1.22	41	0.03	0.00026
	Maize gluten feed	Dairy cow 623/25.82	18.81	0.08	0.00061

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Finishing pig 121.6/2.875	5	0.08	0.00009
		Dairy sheep 57/1.22	10	0.08	0.00017
	Maize gluten	Broiler 1.707/0.1343	6	0.21	0.00101
		Dairy sheep 57/1.22	10	0.21	0.00046
	Maize silage	Dairy cow 623/25.82	21.23	1.80	0.01584
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.01667
		Finishing pig 121.6/2.875	80.51	NA	0.00063
		Broiler 1.707/0.1343	36	NA	0.00172
		Dairy sheep 57/1.22	61	NA	0.00089
Cry1A.105	**Maize**	Dairy cow 623/25.82	18.09	1.80	0.013
		Finishing pig 121.6/2.875	75.51	1.80	0.032
		Broiler 1.707/0.1343	30	1.80	0.042
		Dairy sheep 57/1.22	41	1.80	0.016
	Maize gluten feed	Dairy cow 623/25.82	18.81	4.66	0.036
		Finishing pig 121.6/2.875	5	4.66	0.006
		Dairy sheep 57/1.22	10	4.66	0.010

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
	Maize gluten	Broiler 1.707/0.1343	6	12.89	0.061
		Dairy sheep 57/1.22	10	12.89	0.028
	Maize silage	Dairy cow 623/25.82	21.23	9.40	0.083
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.133
		Finishing pig 121.6/2.875	80.51	NA	0.038
		Broiler 1.707/0.1343	36	NA	0.103
		Dairy sheep 57/1.22	61	NA	0.053
Cry2Ab2	**Maize**	Dairy cow 623/25.82	18.09	3.00	0.022
		Finishing pig 121.6/2.875	75.51	3.00	0.054
		Broiler 1.707/0.1343	30	3.00	0.071
		Dairy sheep 57/1.22	41	3.00	0.026
	Maize gluten feed	Dairy cow 623/25.82	18.81	7.77	0.061
		Finishing pig 121.6/2.875	5	7.77	0.009
		Dairy sheep 57/1.22	10	7.77	0.017
	Maize gluten	Broiler 1.707/0.1343	6	21.48	0.101
		Dairy sheep 57/1.22	10	21.48	0.046

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
	Maize silage	Dairy cow 623/25.82	21.23	53.00	0.466
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.549
		Finishing pig 121.6/2.875	80.51	NA	0.063
		Broiler 1.707/0.1343	36	NA	0.172
		Dairy sheep 57/1.22	61	NA	0.089
Cry3Bb1	**Maize**	Dairy cow 623/25.82	18.09	4.50	0.034
		Finishing pig 121.6/2.875	75.51	4.50	0.080
		Broiler 1.707/0.1343	30	4.50	0.106
		Dairy sheep 57/1.22	41	4.50	0.039
	Maize gluten feed	Dairy cow 623/25.82	18.81	11.66	0.091
		Finishing pig 121.6/2.875	5	11.66	0.014
		Dairy sheep 57/1.22	10	11.66	0.025
	Maize gluten	Broiler 1.707/0.1343	6	32.22	0.152
		Dairy sheep 57/1.22	10	32.22	0.069
	Maize silage	Dairy cow 623/25.82	21.23	55.00	0.484
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.609

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Finishing pig 121.6/2.875	80.51	NA	0.094
		Broiler 1.707/0.1343	36	NA	0.258
		Dairy sheep 57/1.22	61	NA	0.133
CP4 EPSPS	**Maize**	Dairy cow 623/25.82	18.09	2.90	0.022
		Finishing pig 121.6/2.875	75.51	2.90	0.052
		Broiler 1.707/0.1343	30	2.90	0.068
		Dairy sheep 57/1.22	41	2.90	0.025
	Maize gluten feed	Dairy cow 623/25.82	18.81	7.51	0.059
		Finishing pig 121.6/2.875	5	7.51	0.009
		Dairy sheep 57/1.22	10	7.51	0.016
	Maize gluten	Broiler 1.707/0.1343	6	20.76	0.098
		Dairy sheep 57/1.22	10	20.76	0.044
	Maize silage	Dairy cow 623/25.82	21.23	16.00	0.141
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.221
		Finishing pig 121.6/2.875	80.51	NA	0.061
		Broiler 1.707/0.1343	36	NA	0.166

Protein	Feed Material	Animal species	Inclusion rate	NEP level	Daily dietary exposure to NEP
	Maize	Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
		Dairy sheep 57/1.22	61	NA	0.086
AAD-1	**Maize**	Dairy cow 623/25.82	18.09	5.00	0.037
		Finishing pig 121.6/2.875	75.51	5.00	0.089
		Broiler 1.707/0.1343	30	5.00	0.118
		Dairy sheep 57/1.22	41	5.00	0.044
	Maize gluten feed	Dairy cow 623/25.82	18.81	12.95	0.101
		Finishing pig 121.6/2.875	5	12.95	0.015
		Dairy sheep 57/1.22	10	12.95	0.028
	Maize gluten	Broiler 1.707/0.1343	6	35.80	0.169
		Dairy sheep 57/1.22	10	35.80	0.077
	Maize silage	Dairy cow 623/25.82	21.23	11.00	0.097
	TOTAL	Dairy cow 623/25.82	58.13	NA	0.235
		Finishing pig 121.6/2.875	80.51	NA	0.105
		Broiler 1.707/0.1343	36	NA	0.287
		Dairy sheep 57/1.22	61	NA	0.148

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposures were calculated.

Table 48: Summary of DDE results to Cry1F, Cry34Ab1, Cry35Ab1, PAT, Cry1A.105, Cry2Ab2, Cry3Bb1, CP4 EPSPS and AAD-1 proteins (mg/kg BW per day) reported in the EFSA scientific opinion (EFSA GMO Panel 2022b), results obtained using the Excel calculator (EFSA GMO Panel 2023) and results obtained using input data from the model database[3]

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
Cry1F	**Maize**	Dairy cow	0.020*	0.020	0.013
		Finishing pig	0.036	0.036	0.030
		Broiler	0.084	0.094	0.040
		Dairy Sheep	0.017	0.015	0.015
	Maize gluten feed	Dairy cow	NA	0.051	0.034
		Finishing pig	NA	0.026	0.005
		Broiler	NA	0.035	NA
		Dairy Sheep	NA	0.015	0.009
	Maize gluten	Dairy cow	NA	0.094	NA
		Finishing pig	NA	0.037	NA
		Broiler	NA	0.096	0.057
		Dairy Sheep	NA	0.043	0.026
	Maize silage	Dairy cow	0.120*	0.125	0.048
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	0.151	NA
	Maize milled by-products	Dairy cow	NA	0.020	NA
		Finishing pig	NA	0.038	NA
		Broiler	NA	0.081	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	0.140*	0.308	0.095

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
		Finishing pig	0.036	0.137	0.036
		Broiler	0.084	0.306	0.098
		Dairy Sheep	0.017	0.224	0.050
Cry34Ab1	**Maize**	Dairy cow	0.220*	0.219	0.142
		Finishing pig	0.400*	0.399	0.339
		Broiler	0.940*	1.051	0.448
		Dairy Sheep	0.190*	0.166	0.167
	Maize gluten feed	Dairy cow	NA	0.568	0.384
		Finishing pig	NA	0.295	0.058
		Broiler	NA	0.389	NA
		Dairy Sheep	NA	0.172	0.105
	Maize gluten	Dairy cow	NA	1.046	NA
		Finishing pig	NA	0.408	NA
		Broiler	NA	1.075	0.642
		Dairy Sheep	NA	0.476	0.291
	Maize silage	Dairy cow	1.800*	1.800	0.686
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	2.184	NA
	Maize milled by-products	Dairy cow	NA	0.219	NA
		Finishing pig	NA	0.428	NA
		Broiler	NA	0.901	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	2.000*	3.853	1.212
		Finishing pig	0.400*	1.530	0.397

Protein	Feed Material	Animal species Category	DDE scientific opinion mg^{NEP}/kg^{BW}	DDE Excel calculator mg^{NEP}/kg^{BW}	DDE model database mg^{NEP}/kg^{BW}
Cry35Ab1	Maize	Broiler	0.940*	3.415	1.091
		Dairy Sheep	0.190*	2.999	0.563
		Dairy cow	0.009	0.009	0.006
		Finishing pig	0.016	0.016	0.014
		Broiler	0.039	0.043	0.018
	Maize gluten feed	Dairy Sheep	0.008*	0.007	0.007
		Dairy cow	NA	0.023	0.016
		Finishing pig	NA	0.012	0.002
		Broiler	NA	0.016	NA
	Maize gluten	Dairy Sheep	NA	0.007	0.004
		Dairy cow	NA	0.043	NA
		Finishing pig	NA	0.017	NA
		Broiler	NA	0.044	0.026
	Maize silage	Dairy Sheep	NA	0.020	0.012
		Dairy cow	0.480*	0.485	0.185
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
	Maize milled by-products	Dairy Sheep	NA	0.588	NA
		Dairy cow	NA	0.009	NA
		Finishing pig	NA	0.018	NA
		Broiler	NA	0.037	NA
	TOTAL	Dairy Sheep	NA	NA	NA
		Dairy cow	0.490*	0.569	0.206
		Finishing pig	0.016*	0.063	0.016
		Broiler	0.039*	0.140	0.045

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
PAT	Maize	Dairy Sheep	0.009*	0.621	0.023
		Dairy cow	0.00035	0.00035	0.00022
		Finishing pig	0.00063	0.00063	0.00054
		Broiler	0.00150*	0.00166	0.00071
	Maize gluten feed	Dairy Sheep	0.00030	0.00026	0.00026
		Dairy cow	NA	0.00090	0.00061
		Finishing pig	NA	0.00047	0.00009
		Broiler	NA	0.00061	NA
	Maize gluten	Dairy Sheep	NA	0.00027	0.00017
		Dairy cow	NA	0.00165	NA
		Finishing pig	NA	0.00064	NA
		Broiler	NA	0.00170	0.00101
	Maize silage	Dairy Sheep	NA	0.00075	0.00046
		Dairy cow	0.04200*	0.04154	0.01584
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
	Maize milled by-products	Dairy Sheep	NA	0.05040	NA
		Dairy cow	NA	0.00035	NA
		Finishing pig	NA	0.00068	NA
		Broiler	NA	0.00142	NA
	TOTAL	Dairy Sheep	NA	NA	NA
		Dairy cow	0.04200*	0.04478	0.01667
		Finishing pig	0.00063*	0.00242	0.00063
		Broiler	0.00150*	0.00539	0.00172
		Dairy Sheep	0.00030*	0.05169	0.00089

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
Cry1A.105	**Maize**	Dairy cow	0.021	0.021	0.013
		Finishing pig	0.038	0.038	0.032
		Broiler	0.089	0.100	0.042
		Dairy Sheep	0.018	0.016	0.016
	Maize gluten feed	Dairy cow	NA	0.054	0.036
		Finishing pig	NA	0.028	0.006
		Broiler	NA	0.037	NA
		Dairy Sheep	NA	0.016	0.010
	Maize gluten	Dairy cow	NA	0.099	NA
		Finishing pig	NA	0.039	NA
		Broiler	NA	0.102	0.061
		Dairy Sheep	NA	0.045	0.028
	Maize silage	Dairy cow	0.220*	0.217	0.083
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	0.263	NA
	Maize milled by-products	Dairy cow	NA	0.021	NA
		Finishing pig	NA	0.041	NA
		Broiler	NA	0.085	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	0.240*	0.411	0.133
		Finishing pig	0.038*	0.145	0.038
		Broiler	0.089*	0.324	0.103
		Dairy Sheep	0.018*	0.340	0.053
Cry2Ab2	**Maize**	Dairy cow	0.035	0.035	0.022

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg[NEP]/kg[BW]	mg[NEP]/kg[BW]	mg[NEP]/kg[BW]
		Finishing pig	0.060*	0.063	0.054
		Broiler	0.150*	0.166	0.071
		Dairy Sheep	0.030	0.026	0.026
	Maize gluten feed	Dairy cow	NA	0.090	0.061
		Finishing pig	NA	0.047	0.009
		Broiler	NA	0.061	NA
		Dairy Sheep	NA	0.027	0.017
	Maize gluten	Dairy cow	NA	0.165	NA
		Finishing pig	NA	0.064	NA
		Broiler	NA	0.170	0.101
		Dairy Sheep	NA	0.075	0.046
	Maize silage	Dairy cow	1.200*	1.223	0.466
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	1.484	NA
	Maize milled by-products	Dairy cow	NA	0.035	NA
		Finishing pig	NA	0.068	NA
		Broiler	NA	0.142	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	1.235*	1.547	0.549
		Finishing pig	0.060*	0.242	0.063
		Broiler	0.150*	0.539	0.172
		Dairy Sheep	0.030	1.613	0.089
Cry3Bb1	Maize	Dairy cow	0.052	0.052	0.034
		Finishing pig	0.095	0.095	0.080

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
		Broiler	0.220*	0.249	0.106
		Dairy Sheep	0.045	0.039	0.039
	Maize gluten feed	Dairy cow	NA	0.134	0.091
		Finishing pig	NA	0.070	0.014
		Broiler	NA	0.092	NA
		Dairy Sheep	NA	0.041	0.025
	Maize gluten	Dairy cow	NA	0.248	NA
		Finishing pig	NA	0.097	NA
		Broiler	NA	0.255	0.152
		Dairy Sheep	NA	0.113	0.069
	Maize silage	Dairy cow	1.270*	1.269	0.484
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	1.540	NA
	Maize milled by-products	Dairy cow	NA	0.052	NA
		Finishing pig	NA	0.101	NA
		Broiler	NA	0.213	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	1.300*	1.755	0.609
		Finishing pig	0.095	0.362	0.094
		Broiler	0.220*	0.809	0.258
		Dairy Sheep	0.045	1.733	0.133
CP4 EPSPS	**Maize**	Dairy cow	0.033	0.033	0.022
		Finishing pig	0.061	0.061	0.052
		Broiler	0.140*	0.160	0.068

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
		Dairy Sheep	0.029	0.025	0.025
	Maize gluten feed	Dairy cow	NA	0.087	0.059
		Finishing pig	NA	0.045	0.009
		Broiler	NA	0.059	NA
		Dairy Sheep	NA	0.026	0.016
	Maize gluten	Dairy cow	NA	0.160	NA
		Finishing pig	NA	0.062	NA
		Broiler	NA	0.164	0.098
		Dairy Sheep	NA	0.073	0.044
	Maize silage	Dairy cow	0.370*	0.369	0.141
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	0.448	NA
	Maize milled by-products	Dairy cow	NA	0.033	NA
		Finishing pig	NA	0.065	NA
		Broiler	NA	0.137	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	0.400*	0.683	0.221
		Finishing pig	0.061	0.234	0.061
		Broiler	0.140*	0.521	0.166
		Dairy Sheep	0.029	0.572	0.086
AAD-1	**Maize**	Dairy cow	0.058	0.058	0.037
		Finishing pig	0.110*	0.105	0.089
		Broiler	0.250*	0.277	0.118
		Dairy Sheep	0.050*	0.044	0.044

Protein	Feed Material	Animal species	DDE scientific opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
	Maize gluten feed	Dairy cow	NA	0.149	0.101
		Finishing pig	NA	0.078	0.015
		Broiler	NA	0.102	NA
		Dairy Sheep	NA	0.045	0.028
	Maize gluten	Dairy cow	NA	0.275	NA
		Finishing pig	NA	0.107	NA
		Broiler	NA	0.283	0.169
		Dairy Sheep	NA	0.125	0.077
	Maize silage	Dairy cow	0.250*	0.254	0.097
		Finishing pig	NA	NA	NA
		Broiler	NA	NA	NA
		Dairy Sheep	NA	0.308	NA
	Maize milled by-products	Dairy cow	NA	0.058	NA
		Finishing pig	NA	0.113	NA
		Broiler	NA	0.237	NA
		Dairy Sheep	NA	NA	NA
	TOTAL	Dairy cow	0.310*	0.794	0.235
		Finishing pig	0.110*	0.403	0.105
		Broiler	0.250*	0.899	0.287
		Dairy Sheep	0.050*	0.522	0.148

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposures were calculated.

* indicates that zero digits were added to the original value to obtain three digits after the decimal point. In the case of PAT protein, the zero digits were added to obtain five digits after the decimal point.

A.3.2. Second Case study: Feed Contaminant (OTA)

Dairy Cow

Table 49: Default values for live weight and feed intake as reported in the model database[3].

Animal category	Live weight (kg)	Feed intake (kg/day)	Reference
		Dry Matter (DM)	
Dairy Cow	623	25.82	Darabighane et al., 2020

Table 50: Dairy cow diet as reported in the model database[3].

Feed Material	Composition (%)
Maize silage	21.23
Maize gluten feed (20% CP)	18.81
Maize grain, ground	18.09
Barley grain, ground	14.57
Soybean meal (44%)	14.50
Canola meal	5.00
Mineral & Vitamin Mix	2.86
Beet pulp	2.46
Fat powder	2.30

Dairy Sheep

Table 51: Default values for live weight and feed intake as reported in the model database[3].

Animal category	Live weight (kg)	Feed intake (kg/day)	Reference
		Dry Matter (DM)	
Dairy sheep	57.00	1.22	Milis et al., 2005

Table 52: Dairy sheep diet as reported in the model database[3].

Feed Material	Composition (%)
Maize grain	41.00
Alfalfa hay	30.00
Maize gluten meal (60% CP)	10.00
Maize gluten feed (20% CP)	10.00
Wheat straw	5.00
Mineral and vitamin mix	4.00

Fattening Pig

Table 53: Default values for live weight and feed intake as reported in the model database[3].

Animal category	Live weight (kg)	Feed intake (kg/day)	Reference
		Dry Matter (DM)	
Fattening pig	43.5	2.187	Sevillano et al., 2018

Table 54: Fattening pig diet as reported in the model database[3].

Feed Material	Composition (%)
Maize	69.84
Soybean meal (48% CP)	18.5
Molasses cane	5.00
Maize gluten feed (20% CP)	2.5
Vitamin and mineral mix	4.61

Broilers

Table 55: Default values for live weight and feed intake as reported in the model database[3].

Animal category	Live weight (kg)	Feed intake (kg/day)	Reference
		Dry Matter (DM)	
Broilers	1.70	0.134	Abdel-Wareth et al., 2019

Table 56: Broiler diet as reported in the model database[3].

Feed Material	Composition (%)
Maize, ground	30.00
Sorghum, ground	30.00
Soybean meal (44%)	25.00
Maize Gluten Meal (60% CP)	6.00
Sunflower Oil	5.52
Mineral & vitamin mix	3.48

APPENDIX C: GM feed Example 3

This appendix describes a third example (Example 3) related to genetically modified (GM) feed for the proof of concept of the developed model database[3]. The focus is on Atlantic salmon and dogs, representing the fish and companion animal categories, respectively. Data on animals (body weight, feed intake) and animal diets (feed material inclusion rates) were adapted from the model database[3].

The selected scientific opinion (EFSA GMO Panel 2024) for GM feed Example 3 concerns the risk assessment of the GM maize DP202216: Assessment of genetically modified maize DP202216 for food and feed uses, under Regulation (EC) No 1829/2003 (EFSA GMO Panel 2024).

As reported in the scientific opinion (EFSA GMO Panel 2024), dietary exposure to ZMM28 and PAT proteins was estimated via the consumption of maize grain and forage. Eleven animal categories were considered: fattening chickens, laying hens, fattening turkey, fattening pigs, lactating sows, fattening cattle, dairy cows, sheep/goats, salmon, dogs, cats.

The consumption of maize grain was reported for all eleven species. The consumption of forage was reported only for laying hens, lactating sows, fattening cattle, dairy cows and a forage inclusion rate was provided only for these species. The estimations of dietary exposure to newly expressed proteins were based on default values for animal body weight, daily feed intake, and inclusion rates (percentage) of maize grain and forage in diets/rations (OECD, 2013, FAO recommendations [6]). A conservative scenario with 100% replacement of conventional maize products by the maize DP202216 products was considered.

Mean protein levels (dry weight) of ZMM28 and PAT analytically determined in grains and forage from the maize DP202216 treated with the intended herbicide used for dietary exposure were used for the animal dietary exposure assessment. Some of the grain and forage samples analysed in maize DP202216 for the presence of ZMM28 protein were below the limit of quantification (LOQ) (respectively, 0.0069 and 0.036 ng/mg dry weight). To estimate dietary exposure, a value equal to half the LOQ value was assigned to those samples to calculate the mean.

As this additional GM feed Example 3 represents fish and companion animals for the proof of concept of the feed consumption model database[3], we first reproduced the animal dietary exposure of maize DP202216 for Atlantic salmon and dogs and reported the animal exposure assessment as in the scientific opinion (EFSA GMO Panel 2024) (Table 57).

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6 https://www.fao.org/fishery/affris/species-profiles/atlantic-salmon/tables/en/–Atlantic salmon–table 3. Due to the absence of corn grain inclusion values, the corn gluten meal values were used, resulting in a conservative estimate for salmon.

Table 57: Animal dietary exposure to PAT and ZMM28 proteins as reported on the scientific opinion (EFSA GMO Panel 2024), based on the consumption of maize grain and forage.

	Animal dietary exposure (mg/kg BW per day)					
	ZMM28			PAT		
	Grain (G)	Forage (F)	G + F	Grain (G)	Forage (F)	G + F
Chicken for Fattening	0.00066	NA	NA	0.88	NA	NA
Laying hen	0.00045	0.00035	0.00080	0.59	0.20	0.79
Turkey for fattening	0.00035	–	–	0.47	–	–
Pig for fattening	0.00031	–	–	0.41	–	–
Sow lactating	0.00025	0.00040	0.00065	0.34	0.23	0.56
Cattle for fattening	0.00019	0.000106	0.00125[a]	0.26	0.61	0.86[a]
Dairy cow	0.00011	0.00123	0.00134	0.15	0.71	0.86
Sheep/goat	0.00007	–	–	0.10	–	–
Salmon	0.00002*	–	–	0.03*	–	–
Dog	0.00009	–	–	0.12	–	–
Cat	0.00006	–	–	0.08	–	–

Abbreviation: –, forage not included in the daily ration.
[a]For DP202216 maize grain+forage combination replacement scenario, the inclusion rate for cattle for fattening would be 160% of the diet; therefore, the exposure reported to each protein is an overestimation.

* Inclusion rates of maize grains in salmon diets (10%) were based on FAO recommendations[6].

We then calculated the animal dietary exposure to ZMM28 and PAT proteins using the Excel calculator proposed in the EFSA statement of 2023 (EFSA GMO Panel 2023). The Excel calculator was employed to calculate the daily dietary exposure (DDE) (Table 58).

Table 58: Animal daily dietary exposure to ZMM28 and PAT proteins (mg/kg BW per day) performed with the Excel calculator (EFSA GMO Panel 2023).

Protein	**Feed material**	**Animal Species**	**Inclusion rate**	**NEP level**	**Daily dietary exposure to NEP**
		Category	IR%	$\mu g^{NEP}/g^{DM}$	mg^{NEP}/kg^{BW}
ZMM28	**Grain**	Salmon 5/0.03	NA	NA	NA
		Dog 25/0.36	50	0.01200	0.00009
	Gluten feed	Salmon 5/0.03	10	0.03108	0.00002
		Dog 25/0.36	30	0.03108	0.00013
	Gluten meal	Salmon 5/0.03	10	0.08592	0.00005
		Dog 25/0.36	32	0.08592	0.00040
	Forage/silage	Salmon 5/0.03	NA	NA	NA
		Dog 25/0.36	NA	NA	NA
	Milled by-products	Salmon 5/0.03	NA	NA	NA
		Dog 25/0.36	NA	NA	NA
	TOTAL	Salmon 5/0.03	20	NA	0.00007
		Dog 25/0.36	112	NA	0.00062
PAT	**Grain**	Salmon 5/0.03	NA	NA	NA
		Dog 25/0.36	50	16.000	0.11520
	Gluten feed	Salmon 5/0.03	10	41.440	0.02486

Protein	Feed material	Animal Species	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	µg^{NEP}/g^{DM}	mg^{NEP}/kg^{BW}
	Gluten meal	Dog 25/0.36	30	41.440	0.17902
		Salmon 5/0.03	10	114.560	0.06874
		Dog 25/0.36	32	114.560	0.52789
	Forage/silage	Salmon 5/0.03	NA	NA	NA
		Dog 25/0.36	NA	NA	NA
	Milled by-products	Salmon 5/0.03	NA	NA	NA
		Dog 25/0.36	NA	NA	NA
	TOTAL	Salmon 5/0.03	20	NA	0.09360
		Dog 25/0.36	112	NA	0.82211

NA indicates that an inclusion rate or NEP levels were not provided and therefore no exposures were calculated.

Lastly, the animal dietary exposure to ZMM28 and PAT proteins was assessed by replacing the default animal and consumption data with the extracted values from the model database[3] (Table 59).

Table 59: Animal daily dietary exposure to ZMM28 and PAT proteins (mg/kg BW per day) performed with the model database[3] input data.

Protein	Feed material	Animal categories BW (kg)/total diet intake (kg dw)	Inclusion rate	NEP level	Daily dietary exposure to NEP
		Category	IR%	µg^{NEP}/g^{DM}	mg^{NEP}/kg^{BW}
ZMM28	**Maize**	Dog 10/0.2	26*	0.012	0.00006
	Maize gluten	Salmon 2/0.04	5.5	0.086	0.00009
PAT	**Maize**	Dog 10/0.2	26*	16.000	0.08320
	Maize gluten	Salmon 2/0.04	5.5	114.560	0.12602

* The inclusion rate of maize (26%) was adapted from the inclusion rate of rice due to the lack of data regarding maize in the dog diet reported in the model database.

Table 60 shows the DDE results from the EFSA scientific opinion (EFSA GMO Panel 2024), results obtained using the Excel calculator (EFSA GMO Panel 2023) and the results obtained using the model database[3].

Table 60: DDE results from the EFSA scientific opinion (EFSA GMO Panel 2024), results obtained using the Excel calculator (EFSA GMO Panel 2023) and the results obtained using the model database[3]

Protein	Feed material	Animal species	DDE Scientific Opinion	DDE Excel calculator	DDE model database
		Category	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}	mg^{NEP}/kg^{BW}
ZMM28	**Maize**	Atlantic Salmon	0.00002	NA	NA
		Dog	0.00009	0.00009	0.00006
	Maize gluten feed	Atlantic Salmon	NA	0.00002	NA
		Dog	NA	0.00013	NA
	Maize gluten	Atlantic Salmon	NA	0.00005	0.00009
		Dog	NA	0.00040	NA

Protein	Feed material	Animal species	DDE Scientific Opinion	DDE Excel calculator	DDE model database
		Category	mg[NEP]/kg[BW]	mg[NEP]/kg[BW]	mg[NEP]/kg[BW]
	Maize silage	Atlantic Salmon	NA	NA	NA
		Dog	NA	NA	NA
	Maize milled by-products	Atlantic Salmon	NA	NA	NA
		Dog	NA	NA	NA
	TOTAL	Atlantic Salmon	0.00002	0.00007	0.00009
		Dog	0.00009	0.00062	0.00006
PAT	**Maize**	Atlantic Salmon	0.03000*	NA	NA
		Dog	0.12000*	0.11520	0.08320
	Maize gluten feed	Atlantic Salmon	NA	0.02486	NA
		Dog	NA	0.17902	NA
	Maize gluten	Atlantic Salmon	NA	0.06874	0.12602
		Dog	NA	0.52789	NA
	Maize silage	Atlantic Salmon	NA	NA	NA
		Dog	NA	NA	NA
	Maize milled by-products	Atlantic Salmon	NA	NA	NA
		Dog	NA	NA	NA
	TOTAL	Atlantic Salmon	0.03000*	0.09360	0.12602
		Dog	0.12000*	0.82211	0.08320

NA indicates that an inclusion rate was not provided and therefore no exposure calculations were performed

* indicates that zero digits were added to the original value to obtain three digits after the decimal point.

Table 60 shows an increase in the DDE results in obtained with the input data from the model database[3] for Atlantic salmon consuming maize gluten and thus, for the total animal dietary exposure. In this case, the DDE increase can be explained by the different body weight and total daily intake. According to the Excel calculator, Atlantic salmon has a body weight of 5 kg and a total daily intake of 0.03 kg^{DM}/animal. In the model database[3], Atlantic salmon has a body weight of 2 kg and a total daily intake of 0.04 kg^{DM}/animal, leading to a higher daily dietary intake and dietary exposure to the NEPs. Moreover, different feed materials were considered in the diet of Atlantic salmon.

In the scientific opinion (EFSA GMO Panel 2024), only maize grain has a reported inclusion rate. In the Excel calculator (EFSA GMO Panel, 2023), the EFSA GMO Panel reports inclusion rates for maize gluten feed and maize gluten. In the model database[3], only maize gluten has a reported inclusion rate.

On the other hand, a decrease in DDE results was found with the input data from the model database[3] for dogs consuming maize grain. In this case, the DDE difference can be explained by the different inclusion rates of maize grain. In the Excel calculator, maize grain has an inclusion rate of 50%, while in the model database[3], the inclusion rate is 26%, leading to a lower daily dietary intake and dietary exposure to the NEPs. As with Atlantic salmon, different feed materials were considered in the diet of dogs. In the scientific opinion (EFSA GMO Panel 2024), only maize grain has a reported inclusion rate. In the Excel calculator, the EFSA GMO Panel (EFSA GMO Panel, 2023) reports inclusion rates for maize grain, maize gluten feed and maize gluten. In the model database[3], only maize grain (adapted from the inclusion rate of rice) has a reported inclusion rate, contributing to the lower total DDE in the results obtained with the input data from the model database[3].

Example 3 showed some disparities compared to Examples 1 and 2. In fact, eleven animal categories (fattening chickens, laying hens, fattening turkeys, fattening pigs, lactating sows, fattening cattle, dairy cows, sheep/goat, salmon, dogs, and cats) were considered, with the inclusion of salmon, dogs and cats which were not considered in the other two Examples. Moreover, as with Example 2, in Example 3 the focus was also exclusively on the exposure to maize grains and forage and not on other maize products (e.g. maize gluten feed, maize gluten) or maize by-products (e.g. maize milled by-products) considered in Example 1.

Annex A: Feed consumption database

Annex A is available under the Supporting Information section on the online version of the scientific output.

Annex B: Data model for feed consumption database

Annex B is available under the Supporting Information section on the online version of the scientific output.