

## Collaboration

### Maximum residue and contaminant limits in food: databases

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#### Abstract

One of the fundamental goals of food law is to ensure a high level of public health protection. In this sense, food may contain different harmful substances or organisms that are naturally present or are incorporated along the food chain, as a result of the production process or as a consequence of environmental contamination. Where the presence of these contaminants or residues poses a risk to the consumer, management measures should be taken, including the establishment of regulations limiting the presence of these contaminants in food to reduce consumer exposure.

The objective of this work is to identify the main databases of Maximum Residue Limits (MRL) of pesticides, residues of veterinary medicines and chemical, biological and radiological contaminants, internationally, as well as in the European Union and in Spain. The use of these databases can be very helpful for the competent authorities that conduct official controls of food products, as well as for the economic operators who want to import or export products, thus facilitating searches for these requirements, allowing them to know which are the legal limits required in each country and for each type of product. This is an adaptation of the final master's degree work of the same name carried out at the Spanish Agency for Food Safety and Nutrition (AESAN) and presented in the Master's Degree in Food Safety from the School of Government of the Complutense University of Madrid.

Taking into account the information offered by different databases, it is considered that the most complete and useful databases of each category for a Spanish user are the database of the European Commission for pesticides, the database of the Spanish Agency for Medicines and Health Products (AEMPS) for residues of medicines for veterinary use and the database of the Spanish Agency for Food Safety and Nutrition for chemical, microbiological and radiological contaminants.

#### Key words

AESAN, databases, food, maximum limits, residues, contaminants.

## 1. Introduction

As set out in Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, creating the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety (EU, 2002), one of the fundamental objectives of food law is to ensure a high level of protection of public health.

In this sense, food may contain different substances or organisms that have adverse health effects and are naturally present or incorporated along the food chain, as a result of the production process or as a consequence of environmental contamination. These components, contaminants or residues can pose a danger to the health of the consumer, for which an assessment of the risk of their ingestion through food should be carried out.

In cases where there is a risk to the consumer, management measures should be taken. These measures can range from the establishment of regulations that limit the presence of these contaminants in food to reduce consumer exposure, to the application of controls that allow removing from the market those products with levels of contaminants that may pose a risk to the consumer.

Measures to protect the health of consumers include the establishment of maximum limits for these contaminants in food. For example, Regulation (EEC) No. 315/93 (EU, 1993) prohibits the placing on the market of foodstuffs containing contaminants in unacceptable amounts for public health and, in particular, from a toxicological point of view. In this regard, and in order to protect public health, this Regulation lays down that maximum limits whose tolerance may be necessary for specific contaminants shall be established.

The establishment of different maximum limits for the same substance or organism by different countries may constitute a trade barrier and, therefore, a procedure for the adoption of harmonised Community regulations should be established at European Union (EU) level (EU, 1993). Also at the international level there are initiatives, such as the *Codex Alimentarius* (Codex, 2022), which harmonize the establishment of maximum limits of contaminants and residues in food so that, although their criteria are not mandatory, there are common references.

In the EU, most maximum limits are set for the Union as a whole. In some cases, there is also national legislation or it may happen that, despite the existence of a common regulation for the EU, regional circumstances are considered.

The maximum limits are dynamic, since constant scientific and technical advances allow the improvement of the quality and safety of food, for this reason, food legislation must be regularly updated, thus adapting to new information on scientific risk assessments.

From a commercial point of view, and taking into account the consolidation of global markets, it is important to know and adapt each product to the different policies, requirements or regulations on food safety of the country in which a product is intended to be marketed. Therefore, having databases that collect the regulated limits of sanitary interest in force, in addition to helping to ensure the marketing of safe food, contributes to the proper functioning of commercial exchanges.

## 2. Objectives

The objective of this work is the identification of the main databases of Maximum Residue Limits (MRL) of pesticides, residues of veterinary medicines and chemical, microbiological and radiological

contaminants, both at international level, as well as in the EU and in Spain, since the use of these databases can be of great help both to the competent authorities that conduct the official controls of food products, as well as to the economic operators that want to import or export products, thus facilitating the search for these requirements, being able to know what are the legal limits required in each of the countries and for each type of product. In addition, the regulatory characteristics of each type of residues and contaminants will be studied.

This is an adaptation of the final master's degree work of the same name carried out at the Spanish Agency for Food Safety and Nutrition (AESAN) and presented in the Master's Degree in Food Safety at the School of Government of the Complutense University of Madrid.

### 3. Methodology

The scope of this work covers pesticide residues, veterinary drugs residues and chemical, microbiological and radiological contaminants in food products. It has been decided not to include materials in contact with food, since some limits do not refer to food nor to additives but to the materials, as they are not contaminants but substances whose presence in food may be intentional and whose use is authorised in food.

The methodology used to conduct this work has focused on the bibliographical review of food legislation and on the search and analysis of databases relating to Maximum Residues Limits of pesticides, residues of veterinary medicines and contaminants. This search has been conducted on the websites of food safety agencies and authorities, both at national, European and international level, as well as on the websites of companies in the sector.

### 4. Maximum limits of parameters of health interest in food

#### 4.1 Maximum Residue Limits for pesticides

It is important to note that Maximum Residue Limits (MRL) for pesticides are not toxicological limits, but rather toxicologically acceptable limits, based on good agricultural practice and representing the maximum amount of a residue that can be found in a food of plant origin as a result of the legal use of a pesticide. They are not toxicological limits because their exceedance does not necessarily imply the existence of health risk. They are toxicologically acceptable because their compliance ensures that they do not produce toxic effects in individuals, neither acute nor chronic (AESAN, 2022a).

They are established on the basis of the conclusions of a risk assessment report prepared by an EU Member State. This report includes the four stages of a risk assessment: hazard factor identification, hazard factor characterisation, exposure estimation, and risk characterisation. The report, together with the MRL proposal, will be submitted to EFSA, which will issue an opinion based on public health aspects.

Regulation (EC) No. 396/2005 (EU, 2005a) also allows temporary MRL to be set in certain circumstances, such as, among others, where the presence of pesticides may be due to environmental pollution, where the products concerned constitute a minor fraction of the diet of consumers or animals, for honey or for herbal infusions. The validity of these temporal limits shall be reviewed at least once every 10

years and, if necessary, amended. From the moment the foodstuffs listed in Annex I to the Regulation are placed on the market as food or feed, they shall not contain any pesticide residues exceeding the MRL set out in Annex II or III (EU, 2005a), or 0.01 mg/kg in those for which no limit has been set.

It is also worth mentioning Delegated Regulation (EU) 2016/127 (EU, 2016a) and Delegated Regulation (EU) 2016/128 (EU, 2016b) concerning requirements for infants, follow-on and young children food, as well as for special medical uses, respectively. These regulations also establish more restrictive maximum limits for certain substances (such as cadusafos, ethoprophos or fipronil, among others), since they are at risk populations, as well as substances whose presence is prohibited in these products (such as fentin or aldrin). However, in these prohibited substances, plant protection products shall not be considered to have been used for control purposes if the residues do not exceed 0.003 mg/kg, since the presence in quantities below this limit may be due to crops external contamination.

Annex I to Regulation (EC) No. 396/2005 (EU, 2005a) sets maximum limits on unprocessed raw materials, meaning that, in order to know the MRL of processed products, it is necessary to apply processing factors (concentration, dilution...) on the MRL of the initial product. These factors should be included in Annex VI to Regulation (EC) No. 396/2005. However, this has not yet been developed, and its publication has been delayed for years due to the complexity of the work. For this reason, and until Annex VI is published, the factors to be taken into account in processed products should consider the information on the processing to which the raw product has been subjected. Various literature can be used to provide guidance in this regard, such as the EFSA opinions for each active substance or the *Codex Alimentarius* documents (AESAN, 2022a).

Mention should also be made of the cumulative risk assessment, which takes into account the possible health effects related to the simultaneous presence of different residues in the same food. The possible known cumulative and synergistic effects of the active substances should be taken into account when proposing the setting of a safe MRL for consumers. However, a suitable methodology has not been fully developed. This methodology should be based on the assumption that plant protection products that cause the same toxic effects can produce joint and cumulative toxicity, even if they have different modes of action (AESAN, 2022a).

#### 4.2 Maximum Residue Limits for veterinary medicinal products

As in the case of pesticides, MRL for veterinary medicinal products are not toxicological limits but toxicologically acceptable. Regulation (EC) No. 470/2009 lays down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (EU, 2009) but those limits are set out in Regulation (EU) No. 37/2010 (EU, 2010), which contains an Annex with two lists in alphabetical order, one for authorised and one for prohibited substances. This Annex specifies the limits, considering the animal species and the specific tissue, since within the same species the limit may vary from one tissue to another. It also indicates the marker residue (a residue whose concentration is in a known relationship to the total residue concentration of an edible tissue) for each pharmacologically active substance and its therapeutic classification, as well as other provisions to be considered, such as whether the use of that substance is allowed in certain species or not, or the route by which they should be administered.

For its part, Regulation (EU) No. 2019/1871 (EU, 2019a) sets reference values (the lowest values that can be detected analytically) for residues of active substances such as chloramphenicol, malachite green or nitrofurans and their metabolites, which do not have established maximum limits because their use is prohibited or not authorised in the EU. Food of animal origin, whether from third countries or the EU, that contains residues of these active substances in the same or higher concentration than the reference value will not be considered compliant with EU legislation and will not be allowed to enter the food chain, but will be accepted for placing on the market if the residues are lower than the reference values. In any case, in the event of the determination of prohibited or unauthorised substances, even if below the reference values, an investigation must be conducted to determine whether the animals have been subjected to illegal treatments.

### 4.3 Maximum limits for chemical contaminants

According to the standards established by the *Codex Alimentarius* (Codex, 1995), maximum levels of contaminants should only be established for foods that are of some importance for calculating the overall consumer exposure, and for those contaminants that present a significant risk to public health, to protect the consumer. In order to minimise the concentration of contaminants in food, good manufacturing practices and good agricultural practices should be followed. Maximum limits must be assigned to the lowest value that can reasonably be achieved but that still protects the consumer, meaning that they will not be toxicological, but toxicologically acceptable limits. As for setting MRL for pesticides, establishing maximum limits for contaminants must be based on an adequate risk assessment, for which toxicological information on the substance (identification, metabolism, acute/chronic toxicity...), analysis data (presence in food), intake data (intake data by population groups...) and technological considerations (contamination processes, production practices...) must be taken into account.

Regulation (EC) No. 1881/2006 (EU, 2006) sets maximum limits for certain contaminants in foods for nitrates, mycotoxins, metals, 3-monochloropropanediol (3-MCPD), fatty acid esters of 3-MCPD and glycidyl esters of fatty acids, dioxins and PCBs, polycyclic aromatic hydrocarbons, melamine and its structural analogues, inherent plant toxins and perchlorate. We must also mention Regulation (EU) No. 2020/2040 (EU, 2020a) and Regulation (EU) No. 2021/2142 (EU, 2021a) which have begun to be implemented as of 1 July 2022. These regulations include maximum limits for pyrrolizidine alkaloids and opiate alkaloids in certain foods.

Regulation (EC) No. 1881/2006 (EU, 2006) states that foods containing contaminants in amounts exceeding the established limits may not be placed on the market. However, it also introduces several exemptions for certain contaminants, in specific products, and for some countries, provided that the consumption occurs in the EU Member State in which it was produced. This is the case for herring, char, lamprey and trout from the Baltic Sea, which exceed the limits for dioxins, PCBs or similar, for Finland and Sweden and, in addition to these countries, in the case of Latvia, for salmon. These countries may also have higher levels of polycyclic aromatic hydrocarbons in traditionally smoked fishery products. In the case of Spain, in addition to other countries such as Ireland or Portugal, meat or meat products smoked in the traditional way may also have a polycyclic aromatic hydrocarbon content higher than those indicated in this regulation.

The Annex to the Regulation indicates the maximum permitted limits for each contaminant for each specific foodstuff. Additionally, depending on the product, there may be different limits for different factors such as type of crop, date of cultivation, whether the product will undergo a selection process or other physical treatment before human consumption, the form of marketing, or the animal species, among others (EU, 2006).

At the national level, for example, Royal Decree 3/2023 (BOE, 2023) establishes the health standards for the quality of water for human consumption. This Royal Decree also includes the maximum limits of various chemical parameters for drinking water. It is also worth mentioning Royal Decree 475/1988 (BOE, 1988) which establishes maximum limits for aflatoxins B1, B2, G1 and G2 in foods for human consumption. This Royal Decree only applies to foods that are not included in Regulation (EC) No. 1881/2006, such as *chufa* (*Cyperus esculentus*), a product that is mainly consumed in Spain (EU, 2006).

#### 4.4 Maximum limits for biological contaminants

Microbiological hazards of foodstuff are one of the major sources of food-borne diseases. Therefore, food must not contain micro-organisms or their toxins or metabolites in quantities that pose an unacceptable risk to human health.

As indicated in Regulation (EC) No. 2073/2005 (EU, 2005b), food safety is mainly ensured through a preventive approach, such as the adoption of good hygiene practices and the application of procedures based on the principles of Hazard Analysis and Critical Control Points (HACCP).

Microbiological criteria can be used in the validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of processes, as well as microbiological criteria for food safety, establishing a limit above which a foodstuff should be considered unacceptably contaminated with the micro-organisms for which the criteria have been set.

In Spain, most microbiological limits are those set for the whole of the EU, thus favouring trade, by having harmonised microbiological requirements for food products instead of national criteria.

Many of the microbiological criteria established at national level were repealed by Royal Decree 135/2010 (BOE, 2010a) which affected 25 royal decrees and orders that set microbiological criteria through Technical-Sanitary Regulations and quality or hygiene standards published between 1976 and 2000.

Currently, there are still maximum limits at the national level regulated by Royal Decree 3/2023 for water for human consumption (BOE, 2023), by Royal Decree 1798/2010 for packaged natural mineral and spring waters (BOE, 2010b) and by Royal Decree 1799/2010 for packaged prepared waters (BOE, 2010c). These royal decrees set limits for chemical, microbiological and radioactive parameters. It should also be mentioned, at the national level, the recent Royal Decree 1086/2020 (BOE, 2020), which allows the marketing of raw milk and establishes microbiological criteria against *Campylobacter* spp., *E. coli* STEC O157, *Listeria monocytogenes* and *Salmonella*, as well as limits on the number of germs and somatic cells.

At EU level, Regulation (EC) No. 853/2004 (EU, 2004) sets limits on raw cow's milk, raw cow's milk used for the preparation of milk products before being heat-treated, and on raw milk of non-cow species, in relation to the number of germs and number of somatic cells. It also establishes maximum toxin limits for bivalve molluscs (paralysing toxin, amnesic toxin, okadaic acid and dinophysistoxins, yessotoxins, and azaspiracids), and in egg products for shell residues, lactic acid and 3-OH-butyric acid.

However, it is Regulation (EC) No. 2073/2005 that sets microbiological criteria for a wider variety of products (EU, 2005b). Microbiological criterion means a criterion that defines the acceptability of a product, a batch of foodstuff or a process, based on the absence, presence or number of microorganisms, and/or the quantity of their toxins/metabolites, per unit of mass, volume, area or batch.

Regulation (EC) No. 2073/2005 sets two types of criterion: food safety criterion and process hygiene criterion. The food safety criterion defines the acceptability of a product or a batch of foodstuffs and is applicable to products placed on the market. For its part, process hygiene criterion indicates the acceptable functioning of the production process; this criterion, which is not applicable to marketed products, sets an indicative contamination value above which corrective measures are required in order to maintain process hygiene in accordance with food law (EU, 2005b).

Currently, Regulation (EC) No. 2073/2005 establishes 31 food safety criteria for 9 microbiological parameters and 29 different matrices (7 Groups), and 24 process hygiene criteria for 8 microbiological parameters and 24 different matrices (5 Groups) (Table 1).

For each microbiological food safety criterion, Regulation (EC) No. 2073/2005 sets, in addition to the food category for which it is applicable, the micro-organisms, their toxins, metabolites, the sampling plan, the limits, the analytical reference method and the stage at which the criterion is applied. In the case of process hygiene criteria, an action in case of unsatisfactory results is added (EU, 2005b).

It is unusual for maximum limits to be linked to specific analytical methods, as the advancement of analytical techniques makes it more practical to set the conditions to be met by the methods of analysis, thus preventing legislation from becoming obsolete after a certain period of time. However, in the case of microbiological parameters, the influence of the analytical method is decisive for detecting or quantifying a microorganism and, therefore, each microbiological criterion laid down in Regulation (EC) No. 2073/2005 is accompanied by a standardised method in accordance with an ISO standard (EU, 2005b).

We should also mention Regulation (EU) No. 2019/627 (EU, 2019b), which, while setting limit values for total volatile basic nitrogen in certain categories of fishery products, this being a quality criterion, may have an impact on the safety and security of the product. This determination shall be conducted where the organoleptic examination raises doubts about the freshness of the fishery products.

Regarding contamination by parasites, the legislation does not establish a specific numerical limit. For example, for *Trichinella*, Regulation (EU) 2015/1375 (EU, 2015) applicable, which states that samples shall be taken for the detection of *Trichinella*, which may be positive or negative. For their part, Regulation (EC) No. 853/2004 (EU, 2004) indicates, as regards fishery products, food business operators must ensure that fishery products have been subjected to a visual examination in order to detect visible parasites before being placed on the market. Fishery products that are obviously contaminated with parasites must not be placed on the market for human consumption.

**Table 1.** Microbiological criteria established by Regulation (EC) No. 2073/2005

| Food safety criteria                                                                                                                                                                                                                                                                              | Process hygiene criteria                                                                                                                                                                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Microorganisms                                                                                                                                                                                                                                                                                    | Microorganisms                                                                                                                                                                                                           |
| <i>Cronobacter</i> spp.<br><i>E. coli</i><br>Shiga toxin-producing <i>E. coli</i> (STEC) 0157, 026, 0111, 0103, 0145, 0104:H4<br>Staphylococcal enterotoxins<br>Histamine<br><i>Listeria monocytogenes</i><br><i>Salmonella</i><br><i>Salmonella</i> Typhimurium<br><i>Salmonella</i> Enteritidis | <i>Bacillus cereus</i> (presumed)<br><i>Campylobacter</i> spp.<br><i>E. coli</i><br><i>Enterobacteriaceae</i><br>Coagulase-positive Staphylococci<br>Aerobic colony count<br><i>Salmonella</i><br><i>Salmonella</i> spp. |
| Food groups                                                                                                                                                                                                                                                                                       | Food groups                                                                                                                                                                                                              |
| Ready-to-eat food<br>Dried infant formulae, follow-on formulae and dried dietary foods for special medical purposes for infants under 6 months of age<br>Meat and by products<br>Fishery products<br>Vegetables, fruit and vegetable products<br>Milk and dairy products<br>Egg products          | Meat and by products<br>Milk and dairy products<br>Egg products<br>Fishery products<br>Vegetables, fruit and vegetable products                                                                                          |

**Source:** (UE, 2005b).

#### 4.5 Maximum limits for radiological contaminants

Some nuclear accidents like Chernobyl (1986) and Fukushima (2011) released radioactive material into the atmosphere that contaminated food and feed in several countries. This has led to measures to ensure food safety of those products marketed in the EU.

Thus, Regulation (Euratom) 2016/52 (EU, 2016c) entered into force in 2016, which regulates a system laying down maximum tolerances of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, allowing maximum permitted levels of radioactive contamination regarding products to be placed on the market in order to protect the health of the population. This includes both products produced in the EU and those imported from third countries. Or, in other words, any food or feed that does not meet the maximum tolerances set by the European Commission could not be marketed within the EU.

Implementing Regulations (EU) No. 2020/1158 (EU, 2020b) and 2021/1533 (EU, 2021b) impose special import conditions for food and feed from the territories affected by the Chernobyl and Fukushima nuclear accidents, respectively. While only radioactive contamination in terms of caesium-137 should be controlled for foodstuffs that may still be affected by the Chernobyl accident, the sum of caesium-134 and caesium-137 should be verified for foodstuffs from Japan. This is due to the physical half-life of caesium-134, approximately 2 years, thus having passed a sufficiently safe period since the Chernobyl accident to guarantee its half-life.

Thus, in the event of an emergency or radiological accident and following a risk assessment, the European Commission will set maximum levels of radioactive contamination for different categories

of food. In this regard, a distinction must be made between primary and secondary foods, as well as those intended for infants, dairy products or liquid foods.

In duly substantiated cases, any EU Member State may, subject to authorisation, set temporary derogations from those maximum tolerances established for food and feed consumed on its territory (EU, 2016c).

At the national level we must also mention Royal Decree 3/2023 (BOE, 2023) which establishes the sanitary criteria for the quality of water for human consumption. It includes maximum limits for radiological parameters (radon, tritium, total alpha activity, beta rest activity and indicative dose ( $\Sigma$  radionuclides)).

## 5. *Codex Alimentarius* standards

The *Codex Alimentarius* is a compilation of standards, codes of conduct, guidelines and recommendations of the *Codex Alimentarius* Commission. The *Codex Alimentarius* Commission is an intergovernmental organisation of scientific nature that contributes to the harmonisation of food legislation, with the aim of improving safety in the food chain and the marketing of food, taking into account the interests of consumers (FAO, 1999).

This *Codex Alimentarius* Commission is not a legislative body, it only provides recommendations, meaning that the *Codex* is not binding on member countries. As an example, the EU is a member of the *Codex*, however, its main legislative body is the European Commission, and although when creating a new standard, it usually follows the *Codex recommendations*, European legislation prevails over the *Codex*. In this way, the European regulation could be stricter, thus differing from the *Codex*.

Among the standards published by the *Codex*, we can highlight for their relevance in this work the CX/MRL 2-2018 standard (Codex, 2018) relating to MRL and recommendations on risk management for residues of veterinary medicines in food, or the general standard CXS 193-1995 (Codex, 1995), for contaminants and toxins present in food and feed.

## 6. Databases of maximum limits on food

### 6.1 Pesticide residue databases

14 Maximum Residue Limits (MRL) for pesticides databases were identified (Table 2).

**Table 2.** Databases of Maximum Residue Limits for pesticides

| Databases                             | Organism                                                               | Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Reference                |
|---------------------------------------|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Pesticides Database Search            | <i>Codex alimentarius</i>                                              | Language: English<br>Search by: alphabetical listing (299 approx.), search by (pesticide, functional class (15), product (not working), product code                                                                                                                                                                                                                                                                                                                                             | (Codex database A, 2022) |
| EU Pesticides Database                | European Commission                                                    | Language: English<br>Search by: active substance, herbicide antidote and synergistic substances (1471 in total. Substance type, status, legislation, country and by seeker), food product (311 in total. Food group, subgroup, specific product, others and by search) and by pesticide residue (653 in total. Food, legislation, footnote, annexes and by search engine)<br>Other: Products that have an emergency authorisation can also be searched (3482). Search parameters can be combined | (European Union, 2022)   |
| Maximum Residue Level Search          | Health and Safety Executive (HSE)<br>Private company<br>United Kingdom | Language: English<br>Search by: residue/active substance (99 approx.), search list and by product name/code (314 approx.)<br>Others: Search parameters can be combined. Multiple pesticides can be selected at once (up to 5). HSE occupational risk prevention company                                                                                                                                                                                                                          | (HSE, 2022)              |
| Homologa                              | Private company<br>France                                              | Payment required                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | (Homologa, 2022)         |
| Maximum Residue Limits Search         | Government of<br>Canada                                                | Language: English and French<br>Search by: pesticide (approx. 327), food (approx. 846), crop, crop subgroup and concrete product<br>Others: several pesticides or foods can be selected at the same time                                                                                                                                                                                                                                                                                         | (Canada, 2022)           |
| BC Global                             | Bryant Christie Inc. (BCI)<br>United States                            | Language: English<br>Search by: countries (140), food categories (875), pesticides (1000)<br>Other: indicates regulation details, possibility of comparing limits, notifications by mail if there are changes, possibility of sending doubts, free basic account, payment account (\$3095)                                                                                                                                                                                                       | (BCI, 2022)              |
| Northwest Horticultural Council (NHC) | Private company<br>United States                                       | Language: English<br>Search by: list of countries (59), list of pesticides (trade name and active ingredient)<br>Others: only indicate the limits for pears, apples and cherries. Very incomplete                                                                                                                                                                                                                                                                                                | (NHC, 2022)              |
| National Standard Consultation        | State Phytosanitary Service<br>Costa Rica                              | Language: Spanish<br>Search by: pesticide, functional class, food, MRL<br>Others: search parameters can be combined                                                                                                                                                                                                                                                                                                                                                                              | (Costa Rica, 2022)       |

**Table 2.** Databases of Maximum Residue Limits for pesticides

| Databases                                                             | Organism                                                                   | Details                                                                                                                                                                                                                                                                                                      | Reference            |
|-----------------------------------------------------------------------|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Maximum Residue Limits (MRLs). List of Agricultural Chemicals in Food | The Japan Food Chemical Research Foundation                                | Language: Japanese and English<br>Search by: parameter of interest in alphabetical order: (approx. 831), pesticides, veterinary medicinal products and food (crop, animal product and tissue/fishery product, processed foods, mineral waters, alphabetical order)<br>Other: same database as for pesticides | (Japan, 2022)        |
| MRLs in pesticides                                                    | Ministry of Food and Drug Safety South Korea                               | Language: Korean and English<br>Search by: pesticide (760 approx.), food (640 approx.)<br>Others: once the search has been performed for one of the two parameters, a list of all the other parameters that it may contain/have appears, with a search bar to delimit it                                     | (South Korea, 2022a) |
| Hong Kong Pesticide MRLs Database                                     | Centre for Food Safety Hong Kong                                           | Language: English<br>Search by: pesticide (360 approx.), food (122 approx.)<br>Others: search parameters can be combined                                                                                                                                                                                     | (Hong Kong, 2022)    |
| Pesticide Residue in Food                                             | Department of Agriculture of the Ministry of Agriculture and Food Malaysia | Language: English<br>Search by: alphabetical listing of pesticides (124 approx.), functional class, food (75)<br>Other: next to each entry indicates the number of items it contains                                                                                                                         | (Malaysia, 2022)     |
| MPI pesticide maximum residue limit database                          | Ministry for Primary Industries (MPI) New Zealand                          | Language: English<br>Search by: country (23), pesticide (313 approx.), food (56)<br>Others: at least two parameters must be selected in order to be able to search. It is the only free database that collects the limits of several countries                                                               | (New Zealand, 2022)  |
| Agri-Intel                                                            | Private company South Africa                                               | Payment required                                                                                                                                                                                                                                                                                             | (Agri-Intel, 2022)   |

The **Codex Alimentarius** (Codex database A, 2022) has developed a pesticide database that allows access to its numerical regulations in relation to MRL. This database allows access to information by searching the pesticide residue, its functional class or the food. However, the search criteria are not combinable, i.e. the user must choose one. The information given includes the maximum permitted amount of the substance, the year of adoption and notes with supplementary information. The database indicates, by symbols, whether the raw material is at or near the analytical determination limit, whether the MRL allows a post-harvest treatment of the product, and whether the MRL or Maximum Foreign Residue Limit (MFRL) is temporary, independent of the Acceptable Daily Intake (ADI), until the required information has been provided and evaluated. In addition, it has a glossary of terms for a greater understanding of the data, available in several languages: English, Chinese or Spanish, among others.

One of the most comprehensive pesticide databases, of the 14 databases identified, both by the number of substances collected and by the information included, is that of the **European Union** (European Union, 2022), which contains information on maximum limits for 1471 active substances, 311 foodstuffs and 653 pesticide residues. The database, which is in English, allows the search by any of these 3 categories:

- Search by active substance: it can be done by writing the name of the substance in the search engine, or filtering by a series of parameters, such as the type of substance, the status (if the active substance is approved, not approved, not yet implemented at EU level, or pending), the legislation that regulates it or the country in which they are authorised. A single parameter can be selected or several can be combined. Once the search has been made using the filters, the substance of interest can be selected from the list provided, or the name can be typed into the search box. The list indicates the name of the active substance, whether it is approved, and the duration of the authorisation. Once an active substance is selected, its data sheet provides information on the applicable legislation, the date of approval and expiry of the approval, the Member State that requested its approval, a PDF file with the substance report, a list of all the EU countries in which it is authorised, a link redirecting the user to another page where the MRL are indicated for each foodstuff authorised for use, and toxicological information of interest. The search page for active substance also allows downloading an Excel file with all the information of the 1471 substances.
- Search by food: the search can be done in the search engine, by either the name or the code of the product. The list of food products is organized in a tree arrangement, with 4 categories: group (e.g. berries and small fruits), subgroup (grapes), main product (table grapes), and others. When selecting a specific product, its file indicates the rest of the products in which the same MRL apply. Below is a list with all authorised pesticide residues in that food and their MRL. When one is selected, it indicates the applicable legislation and in which annex of Regulation (EC) No. 396/2005 is included. All this information can also be downloaded in Excel format.
- Search by pesticide residue: As in the previous two cases, the name of the pesticide can be written directly in the search engine, or the search can be narrowed down using a series of filters, which can be combined. The search filters include the type of food, the legislation that applies to it, the notes of interest, and the annexes in which it is contained within Regulation (EC) No. 396/2005 (EU, 2005a). As in the previous cases, all this information can be downloaded in Excel format.

This database also allows searching for emergency authorisations for specific substances. This search can be performed by keyword, by country where the use has been authorised, by active substance, crop in which it has been authorised, and period of validity of the authorisation. The authorisation form for each substance can be downloaded in PDF or Excel formats.

At European level, it is also worth highlighting the database of the **Health and Safety Executive** (HSE) (United Kingdom, 2022) that includes the limits that are applicable in the United Kingdom, currently in line with those that are applicable in the EU.

In the Americas, several countries have developed databases on maximum contaminant limits and other parameters of health interest, such as Canada (Canada, 2022), the United States (BCI, 2022) or Costa Rica (Costa Rica, 2022), the latter being in Spanish.

The **Ministry of Health of Canada** has a database of the MRL established by the Canadian Pest Control Products Act (Pest Control Products Act). In this case, the user must select the chemical and food product to know the MRL and when it was adopted (Canada, 2022). The search can be done both in English and in French.

In the **United States**, the foreign service of the Department of Agriculture (USDA, United States Department of Agriculture. Foreign Agricultural Service) uses a database maintained by a service external to the Department (BCI, 2022). This service includes 4 types of maximum limit databases: for pesticides, veterinary medicines, contaminants and additives, both in the United States and in the EU, as well as in more than 140 countries and those established in the *Codex*. In order to access the databases, it is necessary to have an account, which can be free or premium. The free subscription only allows access to the databases of pesticides and drugs for veterinary use, with only the MRL applicable within the United States being visible. The Premium account provides more comprehensive information about MRL allowed both in the United States and other countries. Like this one, other databases such as **Homologa** (French) or **Agri-Intel** (South African), require payment for their use. The **Northwest Horticultural Council** (NHC) database was also studied. It includes only limits for pears, apples and cherries, resulting, therefore, very limited.

The **Department of Food Safety of the Ministry of Primary Industries of New Zealand** (MPI) presents through a database the MRL allowed for pesticides used in fruits and vegetables both nationally and internationally, including more than 20 countries, the EU and *Codex* (New Zealand, 2022). This is the only free database that allows searching the maximum limits of substances by country, which is a clear advantage when making imports and exports. However, the database is not as complete as others, as it does not collect all the pesticides or all the limits collected by the countries in their own databases or legislation.

In Asia, several countries have developed databases that include MRL for pesticides. The **Japanese Food Chemical Research Foundation** (JFCRF) (Japan, 2022) registers MRL of agricultural chemicals that may persist in food. This includes residues of pesticides and veterinary medicines in a single database. The information can be obtained through two types of search engines, one depending on the type of residue, and the other according to the food category, the search can be made both in English and in Japanese. For its part, the **Food Safety Agency of South Korea** (South Korea, 2022a) provides two separate databases: the pesticide database and the veterinary drugs database (South Korea, 2022b), both with the same search options, in Korean or in English. In addition, the **Hong Kong Centre for Food Safety** (Hong Kong, 2022) offers a database with the MRL for pesticides covered by its regulations. It is possible to search by name of the pesticide and/or by the type of food. The **Department of Agriculture of the Ministry of Agriculture and Food of Malaysia** (Malaysia, 2022) has also developed a database, through which it is possible to search for pesticide residues, functional class or food involved. The entire database is in English.

## 6.2 Residue limit databases for veterinary medicinal products

Among the 6 databases relating to residue limits of medicines for veterinary use identified (Table 3), the one that stands out for containing more search parameters is the **database of the Spanish Agency of Drugs and Medical Devices** (AEMPS, 2022), being in Spanish. The structure of this database is identical to the Annex to Regulation (EU) No 37/2010 (EU, 2010), a table with 7 columns including; pharmacologically active substance, marker residue, animal species, MRL, target tissue, other provisions and therapeutic classification. In the database search engine, any keyword belonging to one of the parameters in the table can be inserted, and the tables containing the keyword will become highlighted in yellow, allowing their easy identification. This database, on the other hand, does not eliminate the ones not containing the selected word, nor does it lead to the exact point in the highlighted tables, making the search more complicated than in other databases, such as that of the **Japan Food Chemical Research Foundation** (JFCRF) (Japan, 2022), of Japan or that of the **Ministry of Food and Drug Safety of South Korea** (South Korea, 2022b), whose search system is more intuitive and easier to use, presenting no language problems, since both databases allow searches in English, and the results can be also exported in Excel format. However, the number of active substances contained in the AEMPS database is higher (approximately 645) than in all the others, despite the fact that the Japanese database has the maximum limits of about 831 substances, since it compiles the limits for pesticides and veterinary drugs in the same database. The AEMPS database also contains links to specific regulatory changes. Prohibited substances are also included at the end of the table. The latest update of this database includes the latest amendment to Regulation (EU) No. 37/2010.

At this point, it is worth mentioning again the database of residues of medicines for veterinary use used by the foreign service of the United States **Department of Agriculture** (United States Department of Agriculture. Foreign Agricultural Service), maintained by a service outside the Department (BCI, 2022). This database includes more than 400 residue limits for veterinary medicines from more than 85 different countries, allowing comparisons between them. However, the free subscription only allows searches of the limits regulated in the United States.

With regard to international organizations, both the *Codex Alimentarius* and the Food and Agriculture Organization of the United Nations (FAO) maintain databases on veterinary drugs. In the case of the **Codex database** (Codex database B, 2022) the search can be performed by veterinary medicinal product, functional class and animal species involved, while the FAO **database** (FAO database, 2022) allows the search by medicinal product, functional class, ADI and MRL.

**Table 3.** Residue Limit Databases for Veterinary Medicinal Products

| Databases                 | Organism                  | Details                                                                                                                                                                            | Reference                |
|---------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| Veterinary Drugs Database | <i>Codex Alimentarius</i> | Language: English<br>Search by: veterinary medicinal product (79 approx.), functional class (15), animal species (18)<br>Other: also indicates the tissue and the year of adoption | (Codex database B, 2022) |

**Table 3.** Residue Limit Databases for Veterinary Medicinal Products

| Databases                                                             | Organism                                                      | Details                                                                                                                                                                                                                                                                                                                                                      | Reference            |
|-----------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Residues of some veterinary drugs in foods and animals                | Food and Agriculture Organization of the United Nations (FAO) | Language: English<br>Search by: veterinary medicine, functional class, ADI and MRL<br>Others: Search parameters can be combined. Provides information on: last evaluation, summary of the evaluation, JECFA meeting where it was approved and product data sheet                                                                                             | (FAO, 2022)          |
| MRL Maximum Residue Limits                                            | Spanish Agency for Medicines and Medical Devices (AEMPS)      | Language: Spanish<br>Search by: pharmacologically active substances (approx. 645), marker residues, animal species, MRL, tissues involved, other provisions and therapeutic classification<br>Other: database in table format. Search engine where to enter any keyword for these parameters. The boxes containing the keyword will be highlighted in yellow | (AEMPS, 2022)        |
| BC Global                                                             | Bryant Christie INC. (BCI) United States                      | Language: English<br>Search by: countries (85), food categories, veterinary drugs (400)<br>Other: indicates regulation details, possibility to compare limits, notifications by mail if there are changes, possibility of sending inquiries, free basic account, paid account \$2595                                                                         | (BCI, 2022)          |
| Maximum Residue Limits (MRLs). List of Agricultural Chemicals in Food | The Japan Food Chemical Research Foundation                   | Language: Japanese and English<br>Search by: parameter of interest in alphabetical order: (approx. 831), pesticides, veterinary medicinal products and food (crop, animal product and tissue/fishery product, processed foods, mineral waters, alphabetical order)<br>Other: same database as for pesticides                                                 | (Japan, 2022)        |
| MRLs in veterinary drugs                                              | Ministry of Food and Drug Safety South Korea                  | Language: Korean and English<br>Search by: veterinary medicine: (300 approx.) and food (230 approx.)                                                                                                                                                                                                                                                         | (South Korea, 2022b) |

### 6.3 Databases of contaminants (chemical, microbiological and radiological)

As for contaminant databases, only 2 were identified (Table 4), with the **TOTALIM database** (AESAN, 2022b), developed by AESAN, standing out for its relevance. It is in Spanish. This database includes not only maximum limits of chemical contaminants, but also microbiological and radiological contaminants, as well as parameters of health interest such as the residues of contaminants in materials in contact with food, being the only database found that collects this information. The database has instructions explaining how it works and giving an example of how to perform a search. Different search criteria can be applied and also can be combined to further narrow down the result. The search can be by parameter (292), type of parameter (microbiological, chemical or radiological), parameter group (25), particular food involved (255), food groups (21), or legislation that applies

(national or European). When a search is performed, the number of results found and a table with the data (search parameters, maximum limits, and remarks included in the legal document) for all of them is displayed. In addition, this database also allows exporting the search results in PDF format.

The other database of contaminants that was identified was that of **BC Global** (BCI, 2022) which, as discussed above, has developed 4 databases, of pesticides, veterinary medicines, contaminants and additives. The results obtained through the free subscription are extremely restricted. However, payment-required accounts group the maximum limits of a large number of countries, making it easier to verify different legislative compliance in exports. These payment-required accounts have several advantages, such as indicating if and when the limits will expire, if they are scheduled to be modified, as well as enabling notifications to be sent by e-mail if there are changes in the limit values, in addition to the possibility of sending queries regarding the interpretation of the data. Knowing the maximum limits of other countries is also of interest because if during official control activities, the competent authorities confirm the presence of substances whose limits are not legislated, it is possible to look up the limits of a country that does have them to estimate the severity of the situation.

**Table 4.** Databases of maximum limits of contaminants

| Database  | Organization                                 | Details                                                                                                                                                                                                                                              | Reference      |
|-----------|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| TOTALIM   | Spanish Agency for Food Safety and Nutrition | Language: Spanish. Search by: parameter (292 approx.), type of parameter (microbiological, chemical, radiological), parameter group (25), food (255 approx.), food group (21) and legislation (national/European)                                    | (AESAN, 2022b) |
| BC Global | Bryant Christie INC. (BCI) United States     | Language: English. Search by: countries (95), food categories and contaminants (80) Other: indicates details of regulation, possibility of comparing limits, notifications by mail if there are changes, possibility of sending queries. Paid \$3095 | (BCI, 2022)    |

## 7. Example of a search of the maximum limits databases: ethylene oxide in sesame seeds

By way of example of the usefulness of these databases, the maximum limit of ethylene oxide residues in sesame seeds has been searched (Table 5). When reviewing the report of the EU alert system, RASFF (Rapid Alert System for Food and Feed), and the Spanish, SCIRI (Rapid Information Exchange System), of 2020 (RASFF, 2020) (SCIRI, 2020) it was found that most of the alerts produced that year relating to chemical hazards were due to the presence of plant protection products, highlighting the case of ethylene oxide in sesame seeds from India, which led to a health alert that forced the withdrawal of large numbers of products containing them both in Europe and Spain. It should be noted that in the EU, ethylene oxide is a prohibited substance in plant protection products, while its use is authorised in the United States and Canada (in Canada, the status has expired on December 31, 2022, being in force at the time of the alert).

**Table 5.** Results of the search for ethylene oxide in sesame seeds in various databases

| Databases                                                                                                                                   | MRL                   |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| European Union (European Union, 2022)                                                                                                       | 0.05 mg/kg            |
| United Kingdom (United Kingdom, 2022)                                                                                                       | 0.05 mg/kg            |
| United States (BCI, 2022)                                                                                                                   | 7 mg/kg               |
| Canada (Canada, 2022)                                                                                                                       | 7 mg/kg               |
| Other: Japan (2022), South Korea (2022a), Hong Kong (2022), Malaysia (2022), Costa Rica (2022), New Zealand (2022), Codex database A (2022) | No limits are listed. |

The limit of 0.05 mg/kg in both the EU and the UK corresponds to the limit of analytical detection. If a substance is not authorised in the EU, its residues must also be evaluated, setting values that are completely safe for the consumer. The evaluation of this same active substance in another region of the world with its particular climatic characteristics, application systems or agricultural practices may result in the authorisation of its use in those third countries (EFSA, 2022a). Foods that comply with these MRL can be legally marketed without a reason prohibiting their placement on the market, thus avoiding conflicts in the food trade with third countries (AESAN, 2022a). This procedure, known as “import tolerance”, is covered by Regulation (EC) No. 396/2005 (EU, 2005a).

In the other countries where ethylene oxide does not appear in the databases, it has not been possible to determine whether it is because its use is not legislated, or if it is not allowed and, unlike in the EU, a detection limit is not included. It has not been confirmed whether this product is authorised in India and at what levels. Of the only two databases that collected the limits of several countries, one of them, BC Global, only included the maximum limits in the United States in the free account, and the other, from New Zealand, did not include ethylene oxide among the pesticides that could be searched.

## Conclusions

In conclusion, according to the study conducted of all the databases of Maximum Residue Limits for pesticides, residues of veterinary medicinal products and contaminants, the most complete in each category are:

- **Pesticides:** The database of the European Commission, which allows the search by active substance, food product, pesticide residue, or by emergency authorisations and provides information on the MRL, the legislation that is applicable, the duration of each authorisation, whether the substances are approved or not, the files of each substance, the EU countries where they are approved and the toxicological information of interest. In addition, the database allows exporting the data to an Excel file. It is in English.
- **Medicinal products for veterinary use:** The AEMPS database includes the highest number of substances, however, its search system, although simple, is not a database itself but a table, since it only highlights the results in yellow, so it is the user who then has to search for the highlighted boxes that meet the search criteria. It is in Spanish.

- **Contaminants:** The AESAN TOLALIM database has been the only public database found in this category. In addition, it is the only one that also includes data relating to the limits of microorganisms, residues of contaminants in materials in contact with food and radiological contamination. Another advantage is that your data can be exported to PDF format. It is in Spanish.

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