Report

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QTM 13: Reporting of micro-organism pesticides

Supply of statistical services in statistical methodology Lot 1: Methodological support

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Abbreviations

CFU	Colony Forming Units
EC	European Commission
EU	European Union
MS	Member State(s)
NSI	National Statistical Office
PPP	Plant Protection Product

1 Introduction

The original purpose of agricultural statistics was to monitor the Common Agricultural Policy's main objectives, such as the production and supply of agricultural products and income in the farming sector. However, in recent decades the agricultural sector has significantly changed. A focus on agricultural practices that would benefit the climate and environment together with sectorial legislations has put a higher emphasis on the need for agri-environmental statistics. To achieve a sustainable use of pesticides, statistics on pesticide sales (since 2011) and use (since 2010) are collected.

Regulation (EC) 1185/2009 on pesticide statistics establishes the reporting requirements for data on pesticides to be accomplished by the Member States. As per the Regulation's Annex I, Section 3, the reporting unit shall be kilogram of active substances. However, many countries have reported that a number of active substances of biological origin cannot be measured in kg, and that they encounter problems in reporting their pesticide sales data. These active substances are found mainly in the Categories of Products "Fungicides of microbiological or botanical origin" (code F06) and "Insecticides of microbiological or botanical origin" (code I05), defined in Annex III of the Regulation.

The main challenge of correctly reporting biological fungicides and insecticides lies in the fact that they are sold in various forms and concentrations. The most common measuring units are "Toxicity equivalents" or "CFU" (colony forming units), which are legally not compliant and cannot be aggregated in the way required by the Regulation. It is complex to calculate quantities of micro-organisms in kilograms and not methodologically reasonable since micro-organisms are not equivalent to chemical substances. However, the Regulation still requires reporting in kg.

An analysis of available methods at Member State (MS) level has been undertaken to clarify the situation and find out if a common methodology could be recommended to countries. This study explores how the pesticides which are micro-organisms are reported in agricultural statistics and identifies possible good practices applicable in various EU MS.

2 Current situation

There is no agreed EU-definition of "bio-pesticides". The concept generally includes certain types of active substances derived from natural materials, such as animals, plants, bacteria and viruses. They include micro-organisms that control pests (microbial pesticides), naturally-occurring substances that control pests (biochemical pesticides), and pesticide substances produced by plants containing added genetic material (plant-incorporated protectants). Bio-pesticides are employed in agricultural use for the purposes of insect control, disease control, weed control, nematode control and plant physiology and productivity.

Based on the current legislation [Regulation (EC) 1185/2009 Annex I, Section 3] the quantities of active substances sold must be reported in kilograms. The quantity of active substances is usually calculated based on sales of plant protection products nationally reported by companies, but the weights of active substances do not reflect the differences between strains (for bacteria or fungi) or isolates (for viruses) and manufacturers.

The technical grade of a given microbial active substance contains a proportion of biologically active units, e.g. cells, spores or inclusion bodies and their number or concentration varies depending on the identity of the microbial and the manufacturing process. Manufacturers specify the content of biologically active units in different ways, while the methods are specific to the microbial species and formulation. Reporting countries apply different approaches to deal with this situation. The difficulties in reporting quantities of micro-organisms in kilograms have been already conveyed by the experts in different Member States. It is necessary to find a way to convert these other units to the one required by the Regulation, in order to have an acceptable and comparable data set at EU level.

3 Collection of information

3.1 Approach and means

The work started with the collection of information on how Member States (MS) deal with the target to report statistics on biological fungicides and insecticides in kg. The purpose was to identify best practice methods in order to find out if a common method for converting available units into kg could be recommended for implementation in the EU MS and other reporting countries.

Desk research was carried out to analyse publicly available information on the reporting methods on micro-organism pesticides in EU MS. The first step of the desk research was a revision of the information provided by Eurostat (e.g. minutes of the Working Group on pesticides statistics, quality reports from national authorities in EU MS). The desk research task continued with exploring the information available on the websites of several national institutions and authorities (e.g. national statistical institutes, public institutes for research, departments for environment or agriculture, etc.).

The desk research concluded with an inventory of legislative acts (EU regulations, etc.), documents and papers on pesticides related policies, and the measuring of micro-organisms quantities and conversion factors. However, the information publicly available on the webpages of the targeted institutions proved to be general in nature, and although related to pesticides sales or use, they did not specifically address the micro-organisms. Therefore, the desk research was followed by direct contacts (by email or phone) with selected institutions. The selection of the institutions (and respectively countries) approached was done based on the content found on their website or in the quality reports.

The countries presenting more detailed methodological information, or those who mentioned problems or challenges related to biological pesticides, were contacted first. A request for information was sent to these countries, to inquire about the detailed methodology they use for the reporting statistics on biological fungicides and insecticides in kg, or the conversion of micro-organisms in kg. If a country reported that a methodology was in place, the country was asked to provide examples of this calculation. Table 1 below lists the institutions that have been contacted.

Table 1: List of countries that have been directly contacted and related administration

Country	Administration
Belgium	Attaché Agréation des Pesticides/Attaché Erkenning Pesticiden
Cyprus	NSI Cyprus
Czechia	NSI Czechia
Denmark	Miljø- og Fødevareministeriet

Country	Administration
Estonia	Statistics Estonia
France	Bureau des statistiques végétales et animales of the Ministry of Agriculture and food
Finland	Natural Resources Institute Finland (Luke)
Germany	Department Plant Protection Products Federal Office of Consumer Protection and Food Safety (BVL)
Greece	Head of Farm Structure Statistics Section Agriculture, Livestock, Fisheries & Environmental Statistics Division ELSTAT
Ireland	Pesticide Controls Division Department of Agriculture, Food & the Marine
Italy	ISTAT - National Institute of statistics
Latvia	Central Statistical Bureau of Latvia
Luxembourg	STATEC
Malta	Environment, Transport and Agriculture Statistics of Malta
Netherlands	Statistician Pesticides Team Environment (SLO) Statistics Netherlands
Poland	Główny Urząd Statystyczny, Departament Rolnictwa
Portugal	Department of Economic Statistics Agriculture and Environment Statistics Service
Romania	NSI Romania
Slovak Republic	Cross-sectional Statistics Department, Business Statistics Directorate, of the Statistical office of Slovak Republic
Slovenia	Statistical Office of the Republic of Slovenia
Spain	INE Spain

However, part of the information collected through direct contacts was too general to allow further analysis. Some documents provided by the institutions described the environmental impact of pesticides and the risk

for human health, but they were not necessarily related to the use of biological active substances in agriculture. Some institutions/countries declared that they don't have a methodology for the calculation or the conversion of micro-organisms in kg (see chapter 4).

No information was collected and analysed from the following EU countries: Austria, Bulgaria, Croatia, Hungary, Lithuania, Sweden, the United Kingdom, or from the other reporting countries Iceland, Norway and Switzerland.

4 Results of the exercise of information collection

The collection of information was followed by the analysis of the methodologies being collected. If a respondent provided only general information and no detailed information on the applied methodology, the information was not used further. A second contact was established only in few cases.

The relevant information analysed for the current study is described below.

4.1 Background documentation reviewed

- **European Commission** website (https://ec.europa.eu/food/plant/pesticides): The website contains definitions and descriptions of Pesticides, Plant Protection Products and Active substance. The regulations on pesticides and plant protection control are available. The pesticides database involves the list of approved and non-approved active substances, the products and the residues. Further information is related to the sustainable use of pesticides, active substances approval, maximum residue levels and REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues.

- **Regulation (EC) No 1185/2009** of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides, which is the legal basis for the collection of statistics. The Regulation requires that each Member State collects statistics on active substances in plant protection products placed on the market, and use of active substances in agriculture.

- **Eurostat**: Minutes of the Working Group on "Agriculture and environment – pesticides statistics" that took place in Luxembourg in 2013. The document illustrates the legal framework and related aspects, the transmission format of statistics on pesticides, the question related to confidentiality of data and quality reports and underlined the existent difficulties related to collection and report of the statistics on this topic.

- **Eurostat**: Quality reports of different countries, including the description of methodologies for data collection, validation and compilation, data relevance, completeness, accuracy, coherence and reliability. The information available differs from one MS to another: in some cases they are very detailed in other case they are more general or poor. Regarding the questions related to the task, in general, there is a methodology for the conversion of products amounts into active substances amounts.

4.2 Information reviewed - by country

This section presents an overview of the relevant information collected (i.e. relevant for statistics related to micro-organisms), that has been analysed for drawing the conclusions formulated at the end of the report. The countries are grouped according to the experts' interpretation on the responses provided.

4.2.1 Countries that convert the active substance concentration/kg of product to get the kg of active substance

- **Czechia**: Statistics on pesticide sales include micro-organisms used as pesticides. The calculations are carried out in the same way as when the amount of active ingredients in chemical pesticides is calculated. The quality report mentions that the amount of product is converted into amount of active substances by CISTA (Central Institute for Supervising and Testing in Agriculture). No further methodology for conversion is provided.

- **Denmark**: The concentrations of micro-organisms used as pesticides are given as g/L in the database of the NSI. Based on the concentration it is possible to calculate the amount of micro-organisms in the same way as the amount of active ingredients in chemical pesticides is calculated.

- **Ireland**: Direct contact with the responsible of pesticide statistics in Ireland clarified that micro-organisms are recorded when they are encountered in a survey. The application rate of product containing the micro-organism applied is recorded. Based on the concentration as per the product label the calculation is a rate of active/product applied.

- **Malta**: The responsible for pesticides statistics from the department of Environment, Transport and Agriculture, Statistics of Malta, confirmed that Malta collects and measures micro-organisms used as pesticides. But there is just one product that is imported and sold on the local market under this description; and, being identifiable, its sale by the relative importer is strictly not published and treated as confidential.

  The responsible governmental authority from which NSI Malta gets the list of authorised products states that the product contains a specific amount of weight per kilogram of this active substance. Therefore, the formula/measurement described below to calculate the correct amount used during each calendar year is applied:

  Units of pesticide sold by the importer multiplied by the weight in grams of the active substance per kilogram divided by 1000 to convert into kilograms.

- **Poland**: The responsible for pesticides statistics of Główny Urząd Statystyczny, Departament Rolnictwa declared that different units are converted into kg for reporting to Eurostat. For micro-organisms, in each case in which it is possible to come to some source data (like a label), a

calculation is performed. If needed, the distributors or producers are contacted to clarify. In detail, the information used for the calculation of pesticides is derived from the 'Polish pesticides register database', where the active substance of pesticides is deposited. Three calculations are performed on traditional pesticides:

- For the conversion of liquid pesticides – if the amount of pesticide used was 100 litres and the content of active substance is 100 g/litre, is derived that 100g * 100 litres of active substance.
- For the conversion of solid pesticides – if the amount of pesticide used was 100 kilograms and the content of active substance is 100 g/kg, is derived 100g/1000 * 100 = 10 kg of active substance.
- For concentrations in percentage – for pesticides in kilograms there is information about the concentration of active substance contained; e.g. if the amount of pesticide used was 100 kg and the content of active substance is 10% , is derived 10% * 100 kg of active substance (i.e. in kilograms is 10/100 * 100 = 10 kg of active substance).

For pesticides which are containing microorganisms the same calculations are performed, but mostly the information of the product is the commonly used basis for the calculation. As an example: a product called ASPERELLO T34 BIOCONTROL contains active substance Trichoderma asperellum T34 in concentration of 12%, meaning that this product contains 120 g/kg of active substance.

- **Slovenia**: The information gathered from the Administration for Food Safety, Veterinary Sector and Plant Protection concerning the micro-organisms revealed that the concentration of micro-organisms (in grams) per kg of the product for each PPP is available in the authorisation of the micro-organism. Based on this ratio, the algorithm in the application transforms the quantity of sold products into the quantity of micro-organisms.

- **Slovak Republic**: The responsible for statistics on pesticides from the Cross-sectional Statistics Department, Business Statistics Directorate of the Statistical office of Slovak Republic stated that the different units and all pesticides which are expressed in weight units (g/kg, or g/l) are compared to each other. The calculation is performed based on the information provided by the authorisation holders.

Table 2: Calculation examples performed by the Slovak Republic

Name of the plant protection product	Active substance	Content of active substance listed on the label	Expression in g/l
TRICHOMIL	Trichoderma harzianum Riafai	1.108spores.g-1	8.1 g/l
POLYVERSUM	Pythium oligandrum Drechsler	≥ 1 x 1060ospores .g-1	175 g/kg

Name of the plant protection product	Active substance	Content of active substance listed on the label	Expression in g/l
	– oospores		
MADEX	Cydia pomonella Granulovirus (CpGV)	3 x 1013 virus particles.l-1	230 g/l
MADEX TOP	Cydia pomonella Granulovirus (CpGV)	3 x 1013 virus particles.l-1	230 g/l
CARPOVIRUSINE	Cydia pomonella Granulosis Virus M (CpGV-M)	3 x 1013 virus particles.l-1	909 g/l
BIOBIT XL	Bacillus thuringiensis subsp. Kurstaki	10600.000 mj/mg	192.5 g/l
Serenade Aso	Bacillus subtilis str. QST 713	1,040 x 1012 CFU.l-1	13.96 g/l

- **Spain:** The Spanish Ministry of Agriculture, Fisheries and Feed clarified that the holders of authorised products send their sales data in kilograms or in litres, and a conversion is performed. For simplification, it is considered that 1 litre = 1 kilogram. For example, if one firm declares 100 Kg of the plant protection product Pombal 80wg, which contains 80% of the active substance Fosetil-Al, the value reported in statistics is 80 kg of Fosetil-Al.

  The composition of the pesticide products is obtained from the register of phytosanitary products of the Ministry of Agriculture, Fisheries and Feed. Regarding the micro-organisms, the procedure is similar in terms of the percentage of micro-organisms in the product.

4.2.2 Countries which do not seem to base their calculations on concentration of active substance

- **Greece**: Greece clarified that litres are converted into kilograms at a 1:1 ratio, based on the consideration that this is a reasonable approximation since water is the solvent often used for liquid pesticides. Sales that are reported to use using other measure units (Pieces - canisters, boxes, etc.) are excluded from the calculations. There is no differentiation between the treatment of sales data related to micro-organisms used as pesticides and sales data related to other pesticides.

4.2.3 Countries seeking a solution for reporting information on micro-organisms

- **Belgium**: After the examination of the information available on the Eurostat web-pages related to quality reports, the responsible of pesticides statistics and the responsible for the survey on

pesticides for seed treatment in Belgium were contacted. The information received shows that, for sale statistics, the authorisation holders are supposed to report to the authorities, the sale volumes either in kg (for solids) or in litres (liquid and gas) of product. These quantities are converted into kg of active substance using the following formula:

kg AS =(kg product x content AS in %) x 100 for solids and
kg AS =(L product x content AS in g/L) x 1000 for liquids

Both for sale and use statistics there is an issue with "bio-pesticides". For such products, quantities are often expressed in units (traps – pieces, sticks, ampoules, number of pieces) and it is difficult or even impossible to convert into kg of active substances.

Belgium experts declared that, for micro-organisms, when the concentration in a certain product is in the unit "CFU", the conversion into kg of active substance is impossible. So far, there is no solution for this kind of products.

- **Germany**: The information publicly available on the web-pages of relevant institutions was not sufficient to understand the methodology that was followed. Therefore, the desk research was complemented by a direct contact with the responsible of statistics on pesticides, who clarified in more in detail the information/methodology in the presentation on "Reporting sales of biological substances", at the Eurostat Working Group on Agro-Environmental Indicators in 2013.

  For most substances of biological origin which are equivalent to chemical substances in terms of reporting units (e.g. pheromones, fermentation products, plant extracts…) the information can be reported in kg. However, this is not possible for the products containing substances from micro-organisms which are non-equivalent to chemicals. Two commercial products with the same micro-organism and identical concentration of biologically active units may differ in active substance content.

  Therefore, kg may not be a meaningful unit to report sales of microbial active substances (micro-organisms), because no universally accepted consistent unit exists for different micro-organism types. Accordingly, Germany proposed an alternative calculation, which converts the amount of sales of microbial active substance into a "minimum area treated". In addition to the active substance content in kg, the active substance content is also reported in a biological unit. There is a variety of possible units which depend on the nature of the product: IU, CFU, concentration of virus particles, etc. These units are not interchangeable or comparable, so they are reported in the most meaningful way.

  The following formula was proposed:

  Amount of product sold [kg or L]/ maximum application rate [kg or L]/ha

Considering the assumptions that the most common use is only one application per year with maximum application rate on the same area is done.

Some examples of calculation are also provided:

Example 1: insecticide for spraying in field crops or forestry

Product: Dipel ES;
Active substance: Bacillus thuringiensis subspecies kurstaki;
(Active substance content: 33,2 g/L (1800 IU/mg));
Amount of product sold: 20.000 L;
Maximum application rate of product (from PPP register): 3 L/ha;
Potentially treated area: 20.000 L / 3 L/ha = 6667 ha;
Add up all ha-values for products with the same micro-organism.

Example 2: fungicide for seed treatment

Product: Cerall;
Active substance: Pseudomonas chlororaphis strain MA 342;
(Active substance content: 4 * 1012 CFU/L);
Amount of product sold: 2000;
Maximum application rate of product (from PPP register);
1 L / dt seeds and max. 2 dt seeds/ha: max. 2 L/ha;
Potentially treated area: 2000 L / 2 L/ha = 1000 ha;
Add up all ha-values for products with the same micro-organism.

4.2.4 Countries that receive information directly in Kg

- **Portugal:** From the information available in the quality report, by 1st April each year1, all data relating to the amount sold in the previous year, expressed in kilograms and broken down by PPP and active substance. Statistics Portugal metadata system integrates and provides the terms and definitions of the concepts used for statistical purposes on the national statistical system. The following definitions were provided:

  - Phytopharmaceutical products - substances used to protect plants or plant products against harmful organisms or prevent their action, e.g. acaricides, insecticides, fungicides, herbicides, etc.

[1] All data relating to the amount sold in the previous year, is reported to the DGAV (Direção-Geral de Alimentação e Veterinária)by each authorisation holder of a PPP as per the Decree-Law n.º 145/2015 of 31 July.

- Active substance - substance or micro-organism which carries out a general or specific action on harmful organisms, plants, and / or their parts or products.

The direct contact did not add more information on the procedures or methods applied for calculations.

4.2.5 Countries without information on pesticides based on micro-organisms

- **Cyprus**: The responsible expert of pesticides statistics was directly contacted by mail and declared that no micro-organisms that are used as pesticides are measured. Both surveys (Pesticide sales and Pesticide use in agriculture) measure the quantities of the active substances contained in the pesticides using the following formula:

  The quantity of sold active substance = The quantity of sold pesticide x Content of active substance in the respective preparation.

- **France**: The responsible for statistics on pesticides from the Bureau des statistiques végétales et animales of the Ministry of Agriculture and Food declared that all quantities are provided directly in kg. Micro-organisms are not measured.

- **Italy**: The analysis on what is available on the website of the Italian National Institute of Statistics allows downloading the information related to different types of data that could be useful for a general overview of pesticides usage at regional or national level, but there is no information on the methodologies for calculation or the data collection. Therefore, the responsible for pesticides statistics was contacted by phone. It was confirmed that there is no information about the methodologies of calculation applied by individual producers. As regards micro-organisms, no information is available.

- **Latvia**: The information available from the Central Statistical Bureau of Latvia which contains tables with results of a survey and data gathered on the use of pesticides in orchards, vegetable and potato areas, greenhouse crops, as well as in maize areas was examined. Active substances of pesticides include micro-organisms in Latvia, but there is no specific information about micro-organisms and their measurement. Direct contact with a responsible of pesticides statistics clarified that micro-organisms are not measured due to the conversion issues. Micro-organisms were used only in greenhouses and in a very small volume.

- **Netherlands**: Limited information on how Statistics Netherlands compiles the statistics on pesticides is available on the link of Wageningen University. Other links also provide the possibility to analyse interactive graphs with information on sales of chemical pesticides in agriculture, active substances and costs of crop protection, environmental aspects and use of active substance per crop measured in kg/ha per year or type of active substance. There is no information about

formulas or measurement conversion in terms of micro-organisms.

- **Romania**: The templates of specific questionnaires used for data collection on pesticides and of the document "Overview on pesticides used in Romania" drafted by Medium et sanitas association and the Institute of Public Health Bucharest were analysed. The calculation of micro-organisms or their measurement is not mentioned. After direct contact by mail the responsible for survey on pesticides declared that Romania does not measure micro-organisms used as pesticides. Documentation on micro-organisms used as pesticides is not available.

5 Identification of good practices

The analysis of the information collected shows that, currently, there is no common methodology used for the calculation of the quantity of active substances in pesticides containing micro-organisms by all Member States. All the cases analysed are quite heterogeneous. Different formulas are applied, that are established subject to the unit of measure in which the substance is expressed or the form of the substances, i.e. solid or liquids. The question of how to measure micro-organisms is still sensitive and just few countries deal with it.

The analysis showed the information needed for the possible conversion.

Example 1: Slovak Republic

Based on the practice in the Slovak Republic, the following data / information are needed to allow for a conversion:

- Name of the plant protection product;
- Active substance;
- Content of active substance listed on the label;
- Expression in g/l.

The sources of these information/data in the Slovak Republic are the authorisation holders and labels of products.

In terms of the content of micro-organisms on the labels of the products, the information provided by the Slovak Republic is more detailed, mentioning the possible unit of measure, which can be expressed in CFU units or in number of spores, virus particles etc. The example of conversion they provided could be applicable in other countries, but it depends if other countries have the possibilities to have data on microorganisms that must be expressed in one of the units they mentioned

Example 2: Germany

Based on the practice in Germany, the following data / information are needed to allow for a conversion:

- Product;
- Active substance;
- Active substance content;
- Amount of product sold;
- Maximum application rate of product;
- Potentially treated area.

The sources of these information/data in Germany are the PPP register and labels.

Example 3: Poland

Based on the practice in Poland, the following data / information are needed to allow for a conversion:

- Product;

- Active substance;
- Content of active substance listed on the label;
- Expression in g/l or concentration in percentage.

The sources of these information/data in Poland is the Polish pesticides register database.

The heterogeneity of the methodologies may also be due to the lack of a concrete definition of micro-organisms (bio-pesticides), also considering that in some cases the problem related to them has not been correctly identified by the contacted institutions.

6 Methodology to guide Member States in conversion calculation

Due to the various ways to deal with micro-organisms used as pesticides it is mandatory to implement a very basic procedure to build on.

Following the example of the Slovak Republic, **the first step** would be to gather a basic set of data that would allow calculating reliable results. The collection of information on the pesticides which are using micro-organisms could be done through contacts with the authorisation holders. Based on the knowledge of the ingredients of a product, basic calculations can be performed in combination with the sales/use statistics.

As the quantities must be reported in kg, from the available information the calculation should imply different steps:

1. Taking into account if it is necessary to convert liquids to solids (some of the MS provided examples of calculation);
2. Converting plant protection products to active substance based on concentration in product, using the possible formulas suggested by some of the Member States;
3. Converting microorganisms to kg of active substance.

7 Conclusions and recommendations

The information collected and analysed shows that there is no common or similar methodology that countries could apply for reporting micro-organism pesticides in kg. Many of the countries that have been contacted declared that for products such as micro-organisms quantities are often expressed in different units (traps – pieces, sticks, ampoules, number of pieces) and it is difficult or impossible to convert into kg of active substances.

The situation among countries is very heterogeneous. Only few countries have defined a method to report micro-organisms in pesticides and use a conversion formula to transform the available quantities in kg based on the amount or the concentration of active substance. However, some of them have formulas not directly related to micro-organisms, but only to quantity of pesticides or active substance in general, as for example Belgium, Finland and Malta.

Germany provided an interesting example for the calculation of micro-organisms. However, the solution they propose is not immediately applicable because the result in not expressed in kg as requested by the EU Regulation.

In other cases (i.e. Denmark, Ireland, Slovenia and Czechia) calculations of micro-organisms are performed, but the methodology is not complete or clear.

Other countries (France, Italy, Latvia, Netherlands, Romania, and Cyprus) declared that they don't deal with this calculation or at the moment they have no information about it. Furthermore, many of the publicly available documents being analysed in relation to pesticides do not mention micro-organisms at all.

Given that several institutions/countries stated that there is no adequate method for reporting this kind of pesticides in kg, the Regulation should provide that a different unit is used. That is in line with the German example to achieve a higher quality in reporting using the most meaningful unit. It is not necessary to drop the reporting in kg completely for this kind of products, but an additional measuring unit can be implemented to increase the usability and comparability of this reports. A more sufficient measuring unit like CFU, toxicity equivalents or similar can be defined for different products.