REPORT

RAPORTTI

Disinfectants in primary production of food of animal origin

Turvallisuus- ja kemikaalivirasto

tukes

Disinfectants in primary production of food of animal origin

Contents

1 Introduction

The Ministry of Agriculture and Forestry granted the Finnish Safety and Chemicals Agency (Tukes) funding for a project entitled “Biocidal products in animal hygiene in food and feed facilities”. A key objective of the project was to identify and examine the use of biocides in primary production. During the project, biocidal products used in primary production of food of animal origin were specified as the main focus of the study. Due to the extent of the topic, biocides used in other types of food production and food premises, as well as issues related to insect and rodent control, were excluded from the scope of the project. This project report describes the interfaces between the application of biocides regulations and several other regulations, the roles of different authorities, and the interfaces between the responsibilities of different bodies that supervise compliance with the regulations.

This report compiles information necessary for different authorities and business operators that place on the market and use disinfectant biocidal products. The project has produced information material for various operators and identified further measures to ensure the implementation of the requirements of the biocides legislation in the coming years.

The project has been implemented by Senior Officers Oskari Hanninen, Hannu Mattila, Timo Nieminen and Sari Penttinen, as well as Leading Specialist Tiina Tuusa and Head of Unit Paula Haapasola. Comments on the draft version of this report were made by experts from the Ministry of Agriculture and Forestry and the Finnish Food Authority.

2 Background

A key principle of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (Biocidal Products Regulation) is that biocidal products and the active substances they contain must be authorised by the authority for their intended use. In Finland, the Finnish Safety and Chemicals Agency (Tukes) is the authorisation authority for biocides. The implementation of the Biocidal Products Regulation proceeds in stages. The authorisation procedure is currently applied to veterinary hygiene products (product type 3) and disinfectants for food and feed areas (product type 4). In addition to the product regulation under the Biocidal Products Regulation, the use of certain biocides is regulated by other regulations.

Biocidal product authorisation decisions authorise the placing on the market and use of these products. The decisions take a stance on the health and environmental risks arising from the use of the products, as well as on the suitability and effectiveness of the products for various uses and conditions. Products belonging to biocidal product types 3 and 4 were not nationally authorised before, so the biocidal authorities have not previously been familiar with the use environments and industry of the products.

Chemicals legislation is very broad and, in particular, companies that place biocidal products on the market and users of these products must acquire new skills and continuously update their knowledge to comply with the requirements of the Biocidal Products Regulation. In practice, during the transitional period of the Biocidal Products Regulation, products are transferred within the scope of the authorisation procedures one by one because the deadline for applying for product authorisations is linked to the approval of the individual active substances contained in the products. The processing of authorisation applications takes a long time and causes a delay in the entry of products in the registers of approved products. With the authorisation procedures, products may be subject to new conditions of use and restrictions that differ from previous practices.

According to the Biocidal Products Regulation, companies manufacturing biocides or their representatives must apply for a product authorisation in each member state and specify the uses of the product included in the authorisation in detail. In practice, this may result in a situation in which a use that would be critical in animal disease elimination, for example, is not applied for in Finland, especially if the use of the biocide is of minor economic significance for the manufacturer or marketer. In such cases, use under the Biocidal Products Regulation may require special measures such as deviations from the normal authorisation procedure.

Biocidal products of product types 3 and 4 are used in animal, feed and food production to combat food-borne pathogens and animal diseases. This report focuses on the uses in primary production of food of animal origin and feeding stuffs on farms. Regarding feeding stuffs, the report examines the use of disinfectants in their primary production, and especially on animal farms, but not the use of biocides in their manufacture of feeding stuffs, for example.

3 Objectives of the project

The main objectives of the project were to gain a picture of the situation regarding the authorisation procedures for biocidal product types 3 and 4 and increase dialogue and communication between the biocidal authorities, food chain operators and the supervisory authorities. This would ensure that the biocidal product authorisation authority had at its disposal the information necessary for making authorisation decisions on the uses and needs of biocidal products in Finland. The development of communication aims to ensure that operators in the food chain (e.g. end users and distributors of biocides) and the supervisory authorities receive information and can take into account the regulations and any restrictions on the use of biocides arising from the authorisation decisions. Increased knowledge about the biocides legislation enables companies and users of biocides to comply with the regulations and adapt their activities in the event that a product that has previously been used is prohibited, for example.

The aim of the project was also to identify and collect information about uses of biocides that were critical to the primary production of food of animal origin, food hygiene and primary production in the feed industry. This information helps ensure that approved biocidal products will be available for these uses in the future. The aim is also to ensure that the obligations of the Biocidal Products Regulation can be observed in the control of animal diseases and the maintenance of food hygiene.

The concrete objectives of the project were defined as:

- the compiling of information about the use of biocides in primary production of food of animal origin and feeding stuffs;
- the identification of legislative interfaces;
- the identification of different uses of biocides and the current practices related to these uses, as well as any Finnish specificities;
- the identification of the environmental and health risks associated with the use of biocides and the necessary risk management measures;
- the discussion and exchange of information with primary production operators in the animal production and feed industry, as well as with the authorities, and identification of operators at which information about chemicals legislation should be targeted (e.g. wholesale distributors marketing biocides, the supervisory authorities);
- the identification and anticipation of changes resulting from biocidal product authorisation procedures in terms of product availability and use restrictions;
- the development of guidelines and information material for different operators.

4 Biocides legislation

The EU Biocidal Products Regulation (528/2012) is a complex and extensive legislative package concerning the placing on the market and use of biocidal products. Biocidal products are used for protecting humans, animals, materials or articles against harmful organisms such as pests or micro-organisms with the active substances in the biocidal product. The basic principle of the regulation is that a biocidal product may only be placed on the market if it has been authorised. Prior to the authorisation of a biocidal product, the active substances it contains must have been approved for biocidal use.

A biocidal product is a substance or, more generally, a mixture containing the active substance(s) and co-formulants, which are used to formulate the active substance into a form suitable for use. The product can be a solution, a suspension, a paste or a tablet. A biocidal active substance is a substance that has a destructive or repellent effect on harmful organisms. A substance can be a single chemical substance or microbe, or an in-situ generated active substance produced from starting materials. The active substance is formulated for use as a biocidal product, which is usually a mixture of several substances.

Biocidal products are classified in four main groups, which are divided into a total of 22 product types. The main groups are disinfectants, preservatives, pest control and other biocidal products. In accordance with the Biocidal Products Regulation, the product types of disinfectants are described in Appendix 2 to this report.

Biocidal products are also subject to other chemicals legislation such as the Regulation on Classification, Labelling and Packaging of Chemicals ((EC) No 1272/2008, CLP Regulation).

The regulation of biocides has interfaces with several other regulations. When considering whether a particular product falls within the scope of biocidal regulation, decisive factors are the use of the product, marketing claims, and the fact that the product contains a biocidal active substance.

The Chemicals Act obligates Tukes to maintain an advisory service related to biocides and other chemical regulations. The advisory service is specifically aimed at supporting business operators in issues related to compliance with the complex legislation.

4.1 Authorisation of biocidal products and approval of active substances

The authorisation procedure for biocides is a two-step process: the active substance must first be approved at the level of the European Union, and only then can products containing it be submitted for national or Union authorisation. Approval is based on an extensive risk assessment, which examines factors such as the properties of the substance and the environmental and health risks. When a biocidal active substance is approved, its implementing regulation is published in the Official Journal of the European Union. The annex to the regulation indicates the date of approval of the active substance and the product type to be approved. The approval date is the deadline by which products containing that active substance on the market must be authorised unless they also contain another active substance whose risk assessment is ongoing. The period between the date of publication of the regulation and the date of approval of the active substance is around 1 to 1.5 years to ensure applicants for product authorisations have sufficient time to compile their material and submit their applications. The deadline for applying for authorisation concerns applications for authorisation from the reference member state, mutual authorisation from other member states or Union authorisation.

The approval of an active substance may be subject to specific conditions, which must be observed when making authorisation decisions concerning products containing that active substance. Such specific conditions may be related to restricting use to professional users only, or certain conditions of use to protect the environment or health.

If no application for authorising a product is submitted to the member state or the European Chemicals Agency (ECHA) by the deadline, the product on the market may be sold for a further 180 days, and the use of the existing biocidal product may continue for up to 365 days from the date of approval of the active substance. If a product application is submitted before the date of approval of the active substance, the sale and use of the product on the market may continue for the product type in question until the processing of the application is completed. Even if the active substance has been approved for use in a certain product type, a product application may also result in a prohibition of the product because the approval of the active substance does not include an assessment of the effectiveness and safety of all possible uses.

Biocidal product applications must include extensive research data, including product efficacy studies. The data requirements are described in Annex III to the Biocidal Products Regulation. The applicant must also be allowed to refer to studies on the active substance, i.e. they must hold a letter of access (LoA) which may be provided by an approved active substance supplier listed in Article 95 list. Under the Biocidal Products Regulation, products can only be approved for the product types for which the active substance has been approved. For example, disinfectants belong to product types 1 to 5, whose descriptions can be found in Appendix 2 to this report. In addition, products can only be approved for the uses for which they have been applied. In the application, the applicant must demonstrate the safety of the product for humans, animals (if necessary) and the environment, as well as its efficacy, according to the intended use. Appendix 3 to this report includes an example of the description of a single use of a disinfectant provided in the summary of product characteristics approved as part of the product authorisation.

Biocidal products must be authorised nationally in each member state where it is planned they will be used, or they must be approved under Union authorisation. Applications for authorisation under the Biocidal Products Regulation are submitted via the Register for Biocidal Products (R4BP) maintained by the ECHA. If a company is planning to submit a product authorisation application for assessment in Finland, it should contact Tukes at least one year before submitting the application.

The time it takes to process authorisation applications varies between countries. Typically, product applications take several years to process. Delays in processing are often caused by incomplete application materials.

Biocidal product authorisation can be applied for an individual biocidal product or product family. A product family refers to a group of biocidal products that have the same use and contain the same active substances. The concentration of active substances may vary only so little that it does not affect the risk posed by the products or their effectiveness in their intended use.

For all disinfectants, it is possible to apply for so-called Union authorisation, which is an EU-wide authorisation. The condition is that the conditions of use of the product are similar in all EU countries.

National authorisation means that the product is authorised in one country. An authorisation application for a product is submitted to one member state (the reference member state), and a mutual authorisation may be applied for from other member states. In principle, a mutual recognition is granted under the same conditions as the authorisation granted by the reference member state, but the Biocidal Products Regulation provides for some exceptions.

Information about nationally authorised biocidal products can be found in the KemiDigi database maintained by Tukes. Products authorised by the Union can be found in the register maintained by the European Chemicals Agency (ECHA). Detailed instructions for using the KemiDigi biocides register and the ECHA's biocidal products database can be found in the following guide (in Finnish): Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (valtioneuvosto.fi) (Chapter 5 on information sources for biocides supervision).

4.2 Safer biocidal products

4.2.1 Candidates for substitution and comparative assessment

The Biocidal Products Regulation contains criteria for active substances that are candidates for substitution. The purpose is to ensure that these substances are phased out and replaced with safer active substances over time. The criteria are based on the intrinsic hazardous properties of the substances.

An active substance is considered a candidate for substitution if any of the following criteria for exclusion are met:

- the substance is classified as a respiratory sensitiser
- the toxicological reference values of the substance are significantly lower than those of the majority of the approved active substances of the same type of product and use
- the substance meets two of the criteria for being persistent, bio-accumulative and toxic (PBT)
- the substance raises concerns about human or animal health and the environment, even when very restrictive risk management measures are taken
- the substance contains a significant proportion of non-active isomers or impurities

If the active substance is found to meet the criteria for a candidate for substitution in the assessment, this will be mentioned in the conclusions drawn from the assessment of the substance. In such cases, the European Chemicals Agency will launch a public consultation. Active substances that are candidates for substitution and products containing them are authorised for a shorter period than normal. When an active substance is considered a candidate for substitution, products containing that active substance will be subject to a comparative assessment at the time of authorisation and will only be authorised if safer alternatives for the corresponding use do not exist. For example, glutaraldehyde and formaldehyde are candidates for substitution.

4.2.2 Simplified authorisation procedure

The aim of the simplified authorisation procedure is to encourage the use of biocidal products that are less harmful to the environment and to human and animal health.

Biocidal products may be granted national authorisation through a simplified procedure if they contain active substances listed in Annex I to the Biocidal Products Regulation and meet the other criteria laid down in the regulation. Authorised products may be placed on the market in other countries through a notification procedure. Substances listed in Annex I include certain food additives such as lactic acid or benzoic acid used in low concentrations in products.

4.3 Timetables for the authorisation of active substances and product authorisation applications

For product type 3, 26 active substances have so far been authorised, and a further 24 active substances are under assessment (Figure 1). For example the following active substances have been authorised: iodine and PVP iodine, burnt and slaked lime, active chlorine released from sodium hypochlorite, formaldehyde, glutaraldehyde, peracetic acid, and hydrogen peroxide (Appendix 5). A prohibition decision has been taken for six active substances. More active substances have been included in the assessment, but the assessment has not been completed for some, and they can no longer be used. These chemicals appear on the ECHA's active substance register lists.

The following biocidal active substances are currently used on the Finnish market in products authorised

under the Biocidal Products Regulation: iodine and PVP iodine, lactic acid (simplified authorisation procedure), l(+)-lactic acid, hydrogen peroxide and peracetic acid. The following active substances are also used in products of product type 3 authorised in other countries: benzoic acid; dolomitic lime; calcium dihydroxide; chlorocresol; and active chlorine released from sodium hypochlorite.

The processing of product applications may take several years. For example, for products whose active substance is active chlorine released from sodium hypochlorite, the product authorisation needed to be applied for by 1 January 2019. At the end of 2023, only France had granted national authorisations.

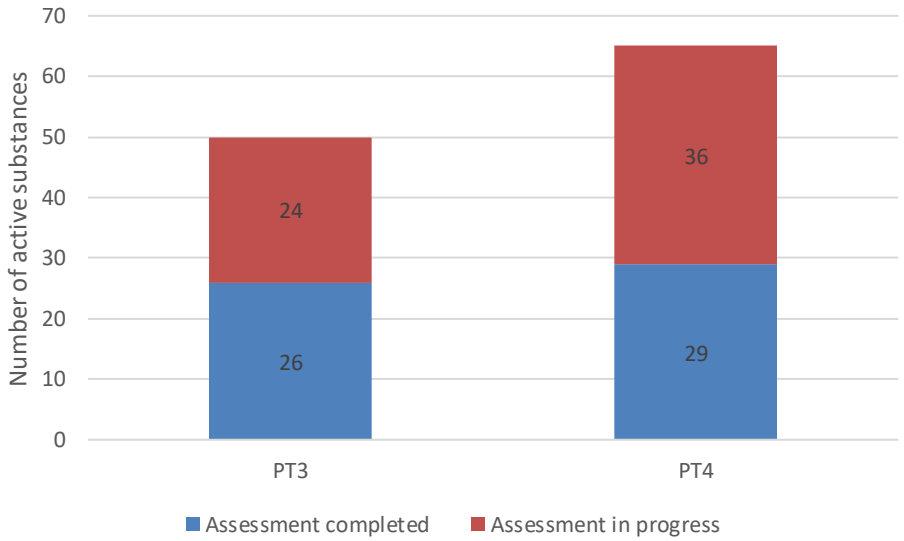

Figure 1. Current assessment situation of active substances for product types 3 and 4

There are several products on the market whose active substance is a quaternary ammonium compound, DDAC or ADBAC/BKC. The application period for the biocidal product authorisation for these products depends on whether the same product is intended not only for product type 3 or 4 use but also for product type 2 use, i.e. general surface disinfection. If the DDAC product is also intended for product type 2 use and contains no other active substances that are still under assessment, the product authorisation must be applied for by 1 February 2024. The application period for ADBAC/BKC product type 2 is 1 July 2025 in the draft Decree. There are many products containing this active substance on the market, and the timetable therefore concerns many manufacturers. If the DDAC product is only intended for product type 3 and 4 use, the authorisation needed to be applied for by 1 November 2022.

For product type 4, 29 active substances have so far been authorised, and a further 36 active substances are under assessment (Figure 1). Active substances authorised for use in product type 4 but not in product type 3 include decanoic and octanoic acid, propanol, and ozone produced from oxygen (Appendix 6).

Biocidal products authorised for product type 4 under the Biocidal Products Regulation have the following biocidal active substances on the Finnish market (as of September 2023): isopropanol and propanol; active chlorine released from sodium hypochlorite; (+)-tartaric acid and sodium benzoate (simplified authorisation procedure); lactic acid (simplified authorisation procedure); L(+)-lactic acid; peracetic acid; and hydrogen peroxide.

As the review programme for existing active substances progresses, an increasing number of biocidal products in use will need to be authorised in accordance with the regulation. Companies placing products on the market must check the authorisation status of their biocidal products trough the biocidal product registers. In addition, they must actively monitor the authorisation status of active substances, and when active substances are authorised, and application deadlines published, they must decide whether they intend

to apply for product authorisation. If no application is submitted by the deadline, all sales of the product must be stopped after 180 days.

Due to the complexity of biocides regulations, Tukes maintains a chemicals helpdesk service which answers questions concerning biocides, as well as the REACH and CLP Regulations.

4.4 Disinfectants on the market

During the current legislative transitional period, many biocidal products on our market intended for product type 3 use do not yet require a product authorisation in accordance with the Biocidal Products Regulation. If a product contains a biocidal active substance whose EU-level assessment is not complete, the product cannot and does not yet need to be authorised. A detailed description of how to identify whether a disinfectant is authorised can be found in Appendix 4 to this report. However, most biocidal products are subject to a chemical notification and can be found in the KemiDigi chemical products register. The KemiDigi chemical product register currently contains around 200 products with different trade names for which product type 3 has also been reported as the use code. Some products are also intended for other product-type uses (Table 1).

For comparison, in October 2023, only 17 authorised products of product type 3 were found in the KemiDigi biocides register for which the authorisation procedure under the Biocidal Products Regulation had been successfully completed. In addition, products that have received Union authorisation can be sold in Finland, but their information can only be found in the ECHA's Register for Biocidal Products.

Table 1. Chemical notifications for products of product types 3 and 4.

	Product type 3	**Product type 4**
Number of products	200	240
Number of companies	32	43
Notifications per company	1–72	1–100
Active substances	e.g. various chlorine compounds, quaternary ammonium compounds, iodine, peracetic acid, glutaraldehyde and hydrogen peroxide	e.g. various chlorine compounds, quaternary ammonium compounds, hydrogen peroxide, diamine, peracetic acid, glutaraldehyde and lactic acid

For product type 4, the situation is the same. At this stage, a large number of biocidal products on our market intended for product type 4 use do not yet require product authorisation in accordance with the Biocidal Products Regulation. The KemiDigi chemical product register currently contains around 240 products with different trade names for which product type 4 has also been reported as the use code (Table 1). Some products are also intended for other product-type uses, usually those of product types 2 and 3.

4.5 Exceptional use of biocidal products

The placing on the market and use of biocidal products require that the biocidal product has national authorisation or mutual authorisation in Finland, or Union authorisation that applies throughout the EU.

However, according to Article 55(1) of the Biocidal Products Regulation, Tukes may exceptionally permit the making available on the market or the limited and controlled use of a biocidal product, even if the product is not authorised or does not meet the conditions for authorisation. Such an exception may be permitted for a

maximum period of 180 days. The granting of the exception is subject to the condition that the measure has been demonstrated to be necessary due to a risk to public health, animal health or the environment that cannot be countered by other means.

When granting an exception, Tukes is obligated to immediately inform the competent authorities of other countries and the Commission of its actions and the justification for them.

If it is necessary to extend the exception, Tukes may make a request to the Commission to be allowed to extend the exception for a maximum of 550 days and to provide justification. The Commission will adopt the decision by means of an implementing act.

4.5.1 Examples of exceptional uses previously permitted by Tukes

4.5.1.1 Buffered iodine product for fish roe disinfection

Animal health legislation requires the disinfection of salmonid roe when roe is moved from sea areas to inland water areas, from inland wild fish to aquaculture facilities and between aquaculture facilities. In addition, roe disinfection is recommended whenever it is taken from wild fish and delivered to a facility or transferred from one facility to another. Buffered iodine is suitable for roe disinfection because it keeps the roe alive. When exceptional authorisation was applied for the iodine product from Tukes, no suitable product existed on the Finnish market. Based on the application, Tukes exceptionally permitted the limited and controlled use of the iodine product for a fixed period of 6 months to ensure animal health. After the deadline, the company that had applied for the exceptional authorisation applied for a recognition of the product authorisation in sequence from Tukes. This was possible because the product had previously been granted biocidal product authorisations for roe disinfection in several EU member states. In this case, authorisation of exceptional use was necessary because the manufacturer of the product had not applied for authorisation in Finland, and the domestic sellers of the product had been unaware that a product authorisation was required.

4.5.1.2 Sodium hydroxide for eradicating the IHN disease in fish in a recirculation aquaculture facility

Infectious haematopoietic necrosis (IHN) in salmonids was found in a recirculation aquaculture facility used for farming rainbow trout. IHN is a disease affecting salmonids caused by a virus. According to animal health legislation, IHN is an animal disease that is controlled in Finland and will be eradicated by the animal health authorities (e.g. the Finnish Food Authority).

In a recirculation aquaculture facility, fish are farmed indoors in tanks. Water from the tanks is recycled back into the tanks through biological and mechanical cleaning equipment. It is a large facility with many different pipelines that cannot be cleaned of the virus solely mechanically.

When choosing a suitable disinfectant, it was necessary to take into account factors such as the location of the facility to be cleaned, its conditions and various materials, the equipment available, the availability of substances, the amounts used and the user, and environmental safety related to the substances. According to an assessment by the Finnish Food Authority, products containing authorised biocidal active substances were unsuitable to be used for this purpose.

The Finnish Food Authority was aware that sodium hydroxide had previously been used to disinfect recirculation aquaculture facilities in other countries. Sodium hydroxide disinfection is carried out by raising the pH of the water circulating in the facility to 11–12.

However, sodium hydroxide is not included in the review programme for existing biocidal active substances and is not currently being assessed for any product type. The use of sodium hydroxide to disinfect the

recirculation aquaculture facility required that the Finnish Food Authority applied for exceptional authorisation, which Tukes granted for a period of 6 months based on the risk to animal health.

The exceptional use of sodium hydroxide as a disinfectant has been permitted in various EU member states on several occasions. From this, it can be interpreted that sodium hydroxide is needed as a disinfectant for uses in which it cannot be substituted by other active substances. If no authorisation is applied to use sodium hydroxide as an active substance, authorisations of exceptional use must also be applied for in the future.

5 Interfaces between the Biocidal Products Regulation and other regulations

5.1 Feed legislation

In feed legislation, only a few references are made to biocides. Annex III to Regulation (EC) No 767/2009 on the placing on the market and use of feed mentions a prohibition of using wood or sawdust treated with biocides for animal nutrition. In turn, the Feed Hygiene Regulation (EC 183/2005) lays down general provisions on feed industry operators' record-keeping obligations concerning the use of biocides, and decrees of the Ministry of Agriculture and Forestry (Mmma 1266/2020 and Mmma 71/2022) lay down more detailed provisions on these. The record-keeping obligation applies to both primary production of feeding stuffs (feed production) and feeding stuff manufacturing (industrial production). In the case of the Feed Additives Regulation (EC 1831/2003), it has been noted that the demarcation of substances used in the treatment of animal drinking water should be clarified, and that it should be explicitly stated that products authorised as biocides cannot be used in the treatment of animal drinking water.

Animal farm supervision (supervision of primary production operators in the feed industry) under feed legislation is carried out by the Centres for Economic Development, Transport and the Environment (the area of responsibility of business and industry) under the guidance of the Finnish Food Authority. The activities of other feed industry operators (other than those in primary production, such as feed factories) are supervised by the Finnish Food Authority.

Article 2(5) of the Biocidal Products Regulation states that the Regulation does not apply to feed. However, the guideline (CA-Dec13-Doc.11.3 – Final.rev1) specifies that this only applies to unmodified products; if feed is *marketed as* a biocidal product (e.g. as an attractant), it is subject to the requirements of the Biocidal Products Regulation. Article 69(1) of the Biocidal Products Regulation states that a biocidal product that can be mistaken for feed must be packaged to minimise the likelihood of error. Under Article 19(1)(b) of the Biocidal Products Regulation, when biocidal products are authorised, it must also be assessed that the use of products such as disinfectants leaves no residues in the feed that will have an impact on animal health.

5.2 Food legislation

Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs (General Food Hygiene Regulation) mentions that biocides must be used appropriately in the production of food of plant origin (Annex I, point 5h). It also provides for the obligation of primary production operators to keep records (Annex I, point 9(a)). These requirements are described in more detail in section 6.2.1.

Article 2(5) of the Biocidal Products Regulation states that the Regulation does not apply to foodstuffs used as repellents or attractants, or to the processing aids referred to in the Food Additives Regulation (EC 1333/2008). For example, depending on the application, ozone can be either a processing aid (cleaning

vegetables with ozonised water) or a biocidal product (disinfecting surfaces in food processing facilities).

If food *is marketed* as a repellent or attractant, the product is considered a biocidal product and is subject to the requirements of the Biocidal Products Regulation (guideline CA-Dec13-Doc.11.3 – Final.rev1). In 2019, some substances used in food were added to Annex I of the Biocidal Products Regulation (vinegar, yeast, egg powder, honey, D-fructose, cheese, concentrated apple juice). The substances in Annex I are biocidal active substances that can be used in biocidal products for which authorisation is applied under the simplified procedure (Article 25 of the Biocidal Products Regulation).

Article 69(1) of the Biocidal Products Regulation states that a biocidal product that can be mistaken for food or drink must be packaged to minimise the likelihood of error, and where such products are available to the public, they must contain ingredients that make the products unpleasant to consume and, in particular, unattractive to children.

When approving biocidal products, it must also be assessed that the use of products such as disinfectants does not leave residues in food that will affect human health (Article 19 (1)(b) of the Biocidal Products Regulation).

5.3 Residue legislation

In accordance with Article 19(1) of the Biocidal Products Regulation, where necessary, maximum residue limits (MRLs) must be established for food and feed with respect to the active substances contained in biocidal products.

In general, the use of biocidal products does not directly expose farm animals or fodder plants to the active substances the products contain. In the framework of the interim procedure currently in force, it has been agreed that the need to establish MRLs will only be considered in the risk assessments of active substances used as disinfectants for product types 2, 3, 4 and 5 (see Table 1 for descriptions of these product types), insecticides and repellents (product types 18 and 19) and antifouling agents (product type 21)[12]. If an MRL has already been established for an active substance under legislation on plant protection products (PPP) or veterinary medicinal products (VMP), it is used in the risk assessments of biocides. When products are authorised under the Biocidal Products Regulation, it is possible that some uses of product type 3 will be restricted or further specified in the instructions for use due to MRL exceedances. For example, the authorised uses of products containing chlorocresol may change as a result of residue assessments. In their meetings, the Commission and the competent authorities are currently (autumn 2023) discussing how to proceed with the authorisation of a biocidal product if, based on the risk assessment, there is no concern about dietary exposure, but the existing MRL (e.g. a default of 0.01 mg/kg) is nevertheless exceeded.

Detectable traces of chlorate have been found in foodstuffs. Chlorate was previously used in plant protection products, and a very low default maximum limit was used in this context. Current residues are mainly due to the use of chlorine-based disinfectants in the processing of food and drinking water, resulting in by-products that often exceed the default value for chlorate. Pursuant to Regulation (EC) No 396/2005 on maximum residue levels, Regulation (EU) No 2020/749 on temporary MRLs for chlorate was adopted, taking the use of legitimately treated drinking water in food processing into account. Based on the collected prevalence data and risk assessment, maximum levels have been set at such a level that food industry operators can apply the most effective measures preventing and reducing the presence of chlorate in food to protect public health, while taking the microbiological safety of food into account.

[1] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/e0d28b0a-31d7-44dd-85bf-cd887bdc724a/details

[2] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/6a496a32-8ed4-4806-87f6-40902cda7143/details

5.4 Organic production legislation

Based on Article 24 of the new Organic Production Regulation (EU) No 2018/848, the use of certain disinfectants included in the lists of products and substances allowed in organic production may be permitted in organic production.

Under Implementing Regulation (EU) No 2021/1165, until the end of 2023, the use of the lists contained in the previous Organic Regulation (EC) No 889/2008 is permitted until the new lists are ready (provided, however, that the products comply with the Biocidal Products Regulation). Annex IV, point (D) to Regulation (EU) No 2021/1165 also contains a list of products and active substances that may not be used as biocidal products in organic production.

5.5 Veterinary Medicinal Products Regulation

The revised Veterinary Medicinal Products Regulation (EU) No 2019/6, which has been applied since 28 January 2022, states in Recital 80 that experience in advertising veterinary medicinal products has shown that it is necessary to highlight the difference between feed and biocidal products on the one hand and veterinary medicinal products on the other, as this difference is often misrepresented in advertising. According to Article 3, if a veterinary medicinal product also falls within the scope of the Biocidal Products Regulation (or the Feed Additives Regulation (EC) No 1831/2003), the Veterinary Medicinal Products Regulation shall apply in the event of a conflict. By means of implementing acts, the Commission may also adopt decisions on whether a specific product or product type is to be considered a veterinary medicinal product. In matters of scope, a product-specific statement will therefore be requested from the Finnish Medicines Agency (Fimea) concerning the application of the veterinary medicines legislation.

The Biocidal Products Regulation does not apply to veterinary medicinal products (Article 2(2)).

5.6 Detergents Regulation

The Detergents Regulation (EU) No 648/2004 does not exclude detergents from the scope of the Biocidal Products Regulation. Products may be classified as both detergents and biocidal products. If a product contains a certain amount of a biocidal active substance, and its purpose is to limit algae growth, for example, it is also a biocidal product, and it must be authorised in accordance with the Biocidal Products Regulation, even if it is only marketed as a detergent. This interpretation has been confirmed for one detergent by a Commission Implementing Decision (EU 2022/146[3]).

The Detergents Regulation is being revised, and the proposal presented in the summer of 2023 contains new requirements for detergents containing micro-organisms. Detergents containing micro-organisms mean detergents to which one or more micro-organisms have been intentionally added, either on its own or as part of a detergent. One of the requirements is that any claims made by a manufacturer about the effects of the micro-organisms contained in a product must be substantiated by third-party testing. The product description or other product brochures must not claim or imply that the detergent has an antimicrobial or disinfectant effect unless the detergent complies with the requirements of the Biocidal Products Regulation. The micro-organism used must also be an active substance authorised in accordance with the Biocidal Products Regulation.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022D0146.

5.7 Food contact materials

Materials and articles that come into direct or indirect contact with food are called food contact materials (FCM). These may include packaging materials, food handling equipment or various surfaces that come into contact with food. Food contact materials are regulated by Regulation (EC) No 1935/2004 and more detailed EU and national legislation adopted under it. For example, biocides are identified in the Plastics Regulation (EU) No 10/2011, and a so-called temporary list of biocides has been introduced, including biocides in FCM use that are being assessed by member states within the framework of biocides legislation. The Plastics Regulation is being revised to include a clearer link between biocides legislation and FCM legislation.

The Biocidal Products Regulation excludes processing aids from its scope, but they refer to food or feed additives. Article 19 of the Biocidal Products Regulation, which concerns the conditions for the authorisation of products, stipulates that when granting authorisation, it is necessary to ensure, in accordance with Regulation (EC) No 1935/2004, specific migration limits or residue limits for materials in contact with food. The approval decisions concerning active substances include a special condition for active substances of product type 4, according to which these active substances cannot be used in food contact materials unless a specific migration limit has been set, or it has been judged to be unnecessary.

Biocides are used in food contact materials to provide an antimicrobial effect. For example, in primary production, the packaging of berries is covered by FCM regulations. Biocides can also be used in the aseptic packaging of food. Products intended to be incorporated in materials that may come into contact with food are included in product type 4 of biocidal products. Biocidal products intended for these uses must have either national or Union authorisation, or during the transitional period of the Biocidal Products Regulation, the active substance contained in the product must be included in product type 4 in the review programme for biocidal active substances. For example, if an antibacterial plastic container or article for food preparation is placed on the market, only biocides that meet the conditions described above may be used in its manufacture. The container or article is an article treated with a biocide which must be labelled in accordance with Article 58 of the Biocidal Products Regulation, including information about the biocidal active substance and biocidal property, and accompanied by appropriate instructions for use and precautions.

5.8 Animal diseases

Provisions on combating animal diseases are laid down in the Animal Health Law (EU 2016/429) and the EU regulations issued on its basis, as well as in the national Animal Diseases Act (76/2021) and the regulations issued on its basis. The animal health authority is responsible for the eradication of animal diseases that are controlled under certain legislation, such as African swine fever and highly pathogenic avian influenza. Veterinarians provide guidance on the control of other diseases. The attending veterinarian provides instructions for the treatment and prevention of diseases in animal facilities, including the prevention of udder and foot diseases.

Veterinary medicinal products are excluded from the scope of the Biocidal Products Regulation because they are regulated by other Community legislation, as well as by the national Act on the Medication of Animals (387/2014). However, the interface between these regulations must be clarified repeatedly on a case-by-case basis. Disinfectant biocides and other cleaning agents are used to prevent the spread of infectious animal diseases. Biocidal products authorised for appropriate use in product type 3 or products with active substances included in the EU risk assessment programme for biocidal product type 3 may be used for veterinary hygiene and the disinfection of animal facilities. In some cases, biocidal products of product types 2 or 4 may also be used.

6 Supervision of biocidal products in different legislative areas

The primary production of food of animal origin is subject to an extensive network of regulations under which the authorities issue permits and conduct supervision. The powers of the authorities are defined separately in each piece of substantive legislation, including the Environmental Protection Act, the Chemicals Act, and national food and feed legislation. Appendix 4 to this report lists the authorities related to the primary production of food of animal origin and their powers.

6.1 Market surveillance of disinfectants

In Finland, Tukes supervises compliance with the Chemicals Act and regulations issued on its basis, as well as with EU chemicals legislation such as the Biocidal Products and CLP Regulations. The supervision of biocides promotes compliance with the legislation on biocidal products through advice, guidance and the means of supervision provided for in the Market Surveillance Act.

The market surveillance of biocidal products targets issues such as active substances, authorisation, labelling and marketing. Tukes conducts supervision on a risk basis, which means that it targets supervision where it brings the greatest benefits for public health and the environment. Tukes is a member of the European Chemicals Agency's supervisory forum for biocides and cooperates with other Nordic countries (Nordic Enforcement Group, NEG), which strive to promote the consistency of supervision in different EU/EEA countries.

6.2 Supervision of disinfectants in primary production

6.2.1 Agricultural and feed production

Operators are obligated to keep records of the use of disinfectants in agricultural and feed production, including organic production (General Food Hygiene Regulation (EC) No 852/2004, Feed Hygiene Regulation (EC) No 183/2005, Organic Production Regulation (EU) No 2018/848). When plant production uses disinfectants that may come into contact with organic or in-conversion products, the substances must be substances and products approved for this purpose in organic production (Organic plant production – Finnish Food Authority).

According to the General Food Hygiene Regulation (EC) No 852/2004, food industry operators producing or harvesting plant products must keep records on the use of biocides. In relation to the use of biocidal products such as disinfectants, plant production farms must keep records on the name, quantity and period of use of the substance (8. Common requirements for plant and mushroom production – Finnish Food Authority).

According to the Feed Act (1263/2020) and its amendment (18/2022), the Feed Act also applies to the supervision of the Feed Hygiene Regulation (EC) No 183/2005, the General Food Hygiene Regulation (EC) No 852/2004 and the Organic Production Regulation (EU) No 2018/848 concerning feed, feed industry operations and feed supervision. The Centres for Economic Development, Transport and the Environment (the area of responsibility of business and industry) supervise the record-keeping obligation concerning the use of disinfectants in feed production.

The supervision of feed on farms comprises the supervision of compliance with feed legislation, as well as with conditionality on farms that have applied for agricultural subsidies. According to the Decree on the Pursuit of Activities in the Feed Sector (1266/2020), primary production operators in the feed industry must keep a record of the use of biocides: the biocides used and their quantities and periods of use. In practice, the records concern disinfectants used to disinfect surfaces in contact with feeding stuffs, such as warehouse structures or feeding equipment, to ensure feed safety. Biocides must not be introduced in feed. The record-keeping requirement may also be fulfilled by retaining the receipts for the purchase and/or sale of

disinfectants or other similar documents if these provide the information required above. Under the amendment (71/2022) of the Decree on the Pursuit of Activities in the Feed Sector, records must be kept of biocides for at least one year, but in practice, records must be kept for at least three years due to the supervision of permanent neglect of conditionality (Conditionality guide 2023 – Finnish Food Authority). On farms, the supervising authority checks that records have been kept of the use of disinfectants, and that they are properly stored and handled separately from animal feed and facilities (Supervision of cross-compliance for feed hygiene). Chapter 7 of the Feed Act provides for administrative coercive measures and sanctions in the event of non-compliance with the Feed Act or European Union legislation on feeding stuffs.

6.2.2 Milk production

Milk production is regulated by the General Food Hygiene Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for on the hygiene of foodstuffs.

Biocides used in milk production include teat dips for the disinfection of udders (product type 3) and disinfectants for milking equipment (product type 4). The regulation laying down specific hygiene rules for food of animal origin provides for the use of teat dips as follows: *teat dips and sprays shall only be used after they have been approved or registered in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.* The above provision is reflected in the supervision guidelines of the Finnish Food Authority (4. Specific requirements for milk production– Finnish Food Authority) as follows: *Only approved or registered teat dips and sprays (products legally marketed in the EU) should be used*. The Biocidal Products Regulation (EU) No 528/2012 replaced the Biocidal Products Directive 98/8/EC on 1 September 2013. Appendix 4 to this report briefly describes the conditions under which disinfectants such as teat dips are allowedfor use in accordance with the Biocidal Products Regulation. They must either have product authorisation or meet the requirements of the transitional legislation. The supervision guidelines also state that teat dips must be used so that they do not leave residues in the milk, and the manufacturer's instructions must be followed. In addition, the supervision guidelines give the following instructions on the handling of dangerous substances such as disinfectants: disinfectants should be stored in places intended for them, away from animals, and preferably in their original packaging.

The supervisory authority is the municipal food control authority.

6.3 Supervision of the conditions of disinfectants

The Centres for Economic Development, Transport and the Environment (the responsibility area of the environment) and the municipal environmental protection authority supervise compliance with the terms and conditions set for the use of biocidal products authorised in accordance with the Biocidal Products Regulation (section 11 of the Chemicals Act). The supervision of conditions is carried out in connection with the supervision of activities under the Environmental Protection Act, and it is related to the operators' obligation to ensure the prevention and control of environmental damage in the use and storage of chemicals. The municipal environmental protection authority also supervises the use of disinfectants in operations that are not subject to permit or notification under the Environmental Protection Act.

For example, the supervisor checks that disinfectants are used and stored in animal houses in a manner approved in the disinfectant authorisation. If an inspection reveals deficiencies in the use of the disinfectant that need to be addressed by administrative means, procedures described in the Chemicals Act are usually followed. In principle, using a product in violation of the instructions for use is a violation of the Chemicals Act. In the event that the violation is so severe that it causes or may cause a risk of environmental pollution,

the use of procedures described in the Environmental Protection Act must also always be considered. Disinfectants allowed under the transitional provisions are supervised like other chemicals.

Examples of the application of the Chemicals Act and the Environmental Protection Act in violations related to biocidal products can be found in Table 4 (p. 36) and Appendix 4 of the Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (in Finnish) (valtioneuvosto.fi). The bans and orders of the supervisory authority and their enforcement are provided for in sections 46 and 47 of the Chemicals Act. The penalty for a chemical violation is provided for in section 59 of the Chemicals Act. Sections 179, 175 and 176 of the Environmental Protection Act provide for the powers of the supervisory authority regarding the rectification of a violation or negligence and the remediation of substantial pollution of a water body and damage to nature, and section 184 provides for the reinforcement of a prohibition or order.

7 Instructions for the use of disinfectant products

The instructions for use, summaries of product characteristics and safety data sheets are the most important instructions for the use of disinfectants for end users. Disinfectants authorised under the transitional provisions (see Appendices 5 and 6: Active substances under assessment) are not subject to product authorisation but are subject to other general obligations concerning the placing on the market of chemicals. The instructions for use of these products are the responsibility of the manufacturer/importer/distributor.

The summary of product characteristics is part of the authorisation decision for products authorised under the Biocidal Products Regulation and includes instructions for use. The key information of the summary of product characteristics is also presented on the sales packaging of the product. Tukes inspects the sales packaging of nationally authorised products, but those of products with Union authorisation are not inspected. The approved dosage and other instructions for use, as well as risk management measures, can always be found in the summary of product characteristics. If the product packaging does not comply with the instructions for use in the summary of product characteristics, please report it directly to Tukes market surveillance using the supervision form. The summaries of product characteristics of national authorisations can be found in KemiDigi and the ECHA Register for Biocidal Products, but the summaries of product characteristics of Union authorisations can only be found in the ECHA register. Detailed instructions for using these registers can be found in the following guide (in Finnish): Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (valtioneuvosto.fi) (Chapter 5 on information sources for biocides supervision).

Safety data sheets are the responsibility of the manufacturer/importer/distributor.

The Animal Health ETT association has also created its disinfection instructions for primary producers, and the Finnish Food Authority refers to these instructions on its website. The association's instructions are freely available for download on its website. As a project, Tukes commented on the instructions that the association updated in the summer of 2023, focusing on the perspective of the Biocidal Products Regulation.

Guidelines on disinfection are also published in professional journals such as *KMVET*. The authors are experts in their field but may be unaware of the restrictions imposed by the Biocidal Products Regulation on the use of products. Tukes may increase awareness of the Biocidal Products Regulation by presenting the regulation in key professional journals such as *KMVET*.

8 Uses of disinfectants in primary production of food of animal origin

The Biocidal Products Regulation divides disinfectants into product types 1 to 5 (Annex 2), all of which are or can be used in animal production. Appendix 2 provides descriptions of the product types of disinfectants and examples of their use in the primary production of food of animal origin. The same product may be approved for use in several product types such as product types 2, 3 and 4. This report focuses on the uses of product types 3 and 4, as they are specific to the production of food of animal origin, and their authorisation procedures are of topical interest. Other product types of disinfectants are mainly used outside the primary production of food of animal origin, so problems with their use are usually not specifically related to animal production.

The disinfection of surfaces in animal facilities is probably the most common use of product type 3. Disinfectants are usually applied to cleaned surfaces by spraying or foaming. Common active substances include peracetic acid, glutaraldehyde, quaternary ammonium compounds, sodium hypochlorite and trihydrogen pentapotassium di(peroxomonosulfate) di(sulphate), or KMPS. Disinfectants can also be applied to surfaces indirectly via air as an aerosol. Hydrogen peroxide in particular is suitable for this purpose.

Boots used in production facilities must be disinfected when necessary. Disinfectants are typically either sprayed on the outside of boots or poured into tanks through which boot users walk. Product type 3 is used for the disinfection of boots in animal production facilities. Buildings used for animal production may also have rooms used only by workers, and the products used for their disinfection fall under product type 2.

Figure 2. The disinfection of the outside of transport equipment for live animals is considered to fall under product type 3, while the disinfection of the inside of the cabins of transport equipment is considered product type 2 use. (Image: Animal Health ETT)

A special machinery case is feed transport vehicles, which must be disinfected regularly. Products used for the disinfection of the cargo compartment of feed transport trucks fall under product type 4.

The disinfection of vehicles from the outside probably falls under the same product type as the disinfection of other machinery from the outside.

Animal houses may also have uses that fall under product type 4. These include the disinfection of feed storage surfaces, as well as milking equipment and farm tanks on dairy farms. Products of product type 4 may not be used for product type 3 uses unless they are also authorised for product type 3.

The disinfection of equipment intended for the distribution of drinking water to animals may be carried out using products of product type 4 if necessary. The disinfection of drinking water for animals, which is not covered by this report, falls under product type 5. For example, in warm broiler halls, a biofilm may accumulate in the water piping, which may be prevented by adding a disinfectant to the water. Although it is not intended to disinfect drinking water as such, it is still product type 5 because animals drink treated water.

The eradication of disease is a special case of disinfection in production facilities. It is carried out to eradicate a pathogen found in a production facility that is considered to be sufficiently harmful. In this case, the production facility and its surroundings are disinfected as thoroughly as possible. Depending on the disease, the eradication can be carried out either by a private operator or by the authority. According to the Finnish Food Authority's website, *"the animal health authority is responsible for the eradication of an animal disease detected in a facility in situations in which the animal disease is one to be controlled by official measures. In this case, a regional veterinarian is responsible for planning the measures to be taken, with the help of a municipal veterinarian, and the animal health authority concludes agreements with the operator implementing the measures. As a rule, the costs of the measures that are the responsibility of the animal health authority are paid for from state funds*." Disease eradications may involve untypical uses such as disinfecting the surroundings of the animal house. Such uses may be problematic if disinfectant manufacturers have not included them in their product applications. This issue is discussed more extensively in the "Identified problems" report section.

Figure 3. Products used for the disinfection of ventilation ducts fall under product type 2. (Image: Animal Health ETT)

8.1 Poultry

Poultry production is carried out as batch rearing, in which the rearing facility is always cleaned and disinfected before a new rearing batch (washing between batches). Producers disinfect their facilities themselves or buy it as an outsourced service. Washing between batches may also include the disinfection of the drinking water line using products of product type 4.

Poultry hatching eggs from which day-old chicks hatch must be disinfected with products of product type 3 authorised for the purpose before they are dispatched from the facility that produces them.

Figure 4. A broiler house that has been washed before the arrival of a new batch of broilers. *(Image: Animal Health ETT)*

8.2 Cattle

Teat dips are routinely used in milk production to prevent mastitis from milking. Iodine compounds or lactic acid are commonly used as active substances.

The cloths used for cleaning teats in connection with milking can be washed with a disinfectant detergent, which falls under product type 3 based on its use.

The aim of hoof bath products is to maintain hoof health by destroying pathogens causing hoof diseases. Animals walk through a bath containing the product. Hoof bath products may be biocides or veterinary medicinal products, depending on the exact use. Hoof bath products are discussed in more detail in the section on copper sulphate in this report. Quaternary ammonium compounds are also used in hoof baths.

The products used to disinfect milking equipment and farm tanks fall under product type 4. Sodium hypochlorite and peracetic acid are commonly used as active substances.

8.3 Fish farming

Water may be disinfected to destroy fish pathogens and parasites, especially in recirculation aquaculture facilities. The active substances used for the disinfection include ozone and hydrogen peroxide released from sodium percarbonate. The disinfection of a recirculation aquaculture facility to eradicate a disease is

discussed in more detail in section 4.5 of the report on the exceptional use of biocidal products.

Animal health legislation requires the disinfection of salmonid roe when roe is moved from sea areas to inland water areas, from inland wild fish to aquaculture facilities and between aquaculture facilities. In addition, roe disinfection is recommended whenever it is taken from wild fish and delivered to a facility or transferred from one facility to another.

Formalin, or an aqueous solution of formaldehyde, is used on fish farms, and in such cases, it must be considered whether it is for veterinary medicinal use or biocidal use. The latter use is no longer permitted because no authorisation has been applied for a product containing formaldehyde for such use, at least not in the Finnish market.

In September 2023, the Standing Committee on Biocides adopted a decision on the demarcation and inclusion in product type 3 of the Procalx product, which contains calcium oxide as an active substance and is intended for the control of the salmon louse (*Lepeophtheirus salmonis*). The decision concludes that the control of parasitic forms living without the host in water could be biocidal, but as the parasite in question is an arthropod, the use is not disinfection and falls under biocidal product group 18 (insecticides, acaricides and products to control other arthropods).

In connection with an application concerning the active substance, Tukes has asked Fimea whether the use of hydrogen peroxide released from sodium percarbonate against fish parasites (the salmon louse and *Ichthyophthirius multifiliis*, which causes white spot disease) in water can be non-medicinal. According to Fimea, the mentioned uses were non-medicinal, but this statement cannot be generalised to concern the use of hydrogen peroxide released from sodium percarbonate against fish parasites in general. At the time of writing, it is unclear whether biocidal treatment of water to destroy a salmon parasite (flatworm), for example, is considered disinfection falling under product type 3 or a control falling under product type 16 (Molluscicides, vermicides and products to control other invertebrates).

8.4 Beekeeping

Bees are subject to several bacterial diseases that may require disinfectants to control them. For example, acetic acid vaporisation and sodium hydroxide are used for disinfection. Sodium hydroxide has not been authorised as an active substance for product type 3, so its use requires an exception granted by Tukes. Acetic acid falls within the simplified authorisation procedure under the Biocidal Products Regulation, but the concentration must be limited so that the product does not receive a hazard classification. Glacial acetic acid should therefore not be sold or used for disinfection purposes, as authorisation to use it as an active substance has not been applied for. Based on online searches, it appears that glacial acetic acid is used and marketed for disinfection purposes in beekeeping.

9 Identified issues

9.1 Knowledge of the Biocidal Products Regulation among industry operators

In Finland, disinfectant products were not subject to prior approval before the entry into force of the EU Biocidal Products Regulation in 2012. Although the Biocidal Products Regulation has been in force for more than 10 years, its effects on many end users have only become apparent in recent years as common disinfectant products have become subject to prior approval. The regulation is therefore not yet well known among operators in the sector. This project aims to increase awareness, especially among the authorities.

9.2 Difficulty of identifying allowed products

Due to the transitional period for the implementation of the Biocidal Products Regulation, new biocidal products continue to become subject to prior approval. Product authorisations restrict the use of the product to authorised, relatively well-defined uses. It may therefore be difficult to determine which products are allowed for the intended use. The situation is also constantly changing, meaning, for example, that a previously authorised product may become unauthorised as a result of the completion of the active substance assessment, without any specific information being delivered to the end users. Appendix 4 to this report briefly describes the conditions under which a disinfectant product is allowedfor use in the primary production of food of animal origin. To help identify authorised products, Tukes has prepared a detailed guide for the authorities, which can be found in the "Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products" publication (Ministry of the Environment publications 2022:7) (Chapter 4.2 on biocidal products authorised for use). The guide is also suitable for operators who use biocidal products in their operations.

9.3 Essential uses for which there is no authorised product

Prior approval of biocidal products may lead to situations in which there is no authorised suitable product for a particular use, as no applicant has submitted an authorisation application for that use. This can happen especially in cases in which the intended use is not commercially significant. However, even a rarer use may prove very necessary in the eradication of diseases, for example. A certain use may be quite common in Finland, but it is not included in the product applications because it is rare elsewhere in Europe. At the initiative of end users, a product authorisation holder may add additional uses to its product authorisation by means of amendment applications. The informing of authorisation holders remains the responsibility of end users, and authorisation holders are not obligated to add additional uses. In the case of essential uses, an exemption from the requirements of the Biocidal Products Regulation can also be applied for (see section 4.5 on the exceptional use of biocidal products). However, an exception can only be permitted for a limited period. If the need for use is permanent, and the authorisation holder is unwilling to add it to its product authorisation, other types of solutions are required.

Other types of necessary products that are missing from the market are products that have been granted national authorisation for their intended use in some EU countries, but not in Finland. Finland is a fairly small market, so the problem is relatively common. In such cases, the best solution is to find a party that is ready to apply for mutual recognition of the product authorisation in sequence from Tukes. Typically, the applicant is an authorisation holder in other countries, but the applicant may also be a domestic company interested in importing.

Even if the required use has been approved for the product, authorised use may also be hindered by use-specific restrictions, which concern factors such as the method of application, dilution for use or outdoor use. Restrictions are imposed if the safety or effectiveness of the method of use has not been demonstrated. However, this does not directly mean that the excluded uses cause an unacceptable risk or lack of efficacy. It may only mean that the applicant has not mentioned all the necessary uses in the product application, in which case their health and environmental risks or efficacy have not been assessed. If a necessary use is excluded from approved use, end users should inform the authorisation holder, who may choose to submit an application for the necessary change.

A special case of use-specific restrictions is the restriction of the use of surface disinfectants to the disinfection of non-porous surfaces. The restriction comes from efficacy tests that limit the suitability of the tests to the porosity of the test surfaces. Generally, applicants only request tests on non-porous surfaces, and the uses of product authorisations are limited accordingly. If the use is limited to non-porous surfaces, the disinfection of concrete surfaces, for example, is not an approved use.

Different sections of this report include some essential uses for which authorised products have not been identified at the time of writing. As a possible follow-up, a more systematic means of collecting these uses and contributing to most effectively making them known to the authorisation holders could be created.

9.3.1 Lime

Burnt and hydrated lime are inexpensive disinfectants that are widely used to disinfect animal houses, manure, feed storages, machinery and topsoil in situations such as the eradication of animal diseases. Burnt and hydrated lime are both approved as active substances for product types 2 and 3. However, approval has not been sought for product type 4, so it is not permitted to use these substances for feed storage disinfection. Only lime products authorised as disinfectants may be used for product types 2 and 3. The situation has therefore changed since any suitable lime product could be used for disinfection. Uses should also comply with product authorisations. At the time of writing, there are therefore no lime products on the Finnish market that are authorised for the disinfection of machinery, emptied slurry trolley tanks or the bottoms of fish ponds. It is possible that at the request of a sufficiently influential party, an authorisation holder of approved products could submit an amendment application to add uses to product types 2 and 3, but there is no obligation for the authorisation holder to do this. While awaiting more comprehensive product applications, it is possible to apply for authorisation of an exceptional use of lime products for a fixed period. However, this procedure cannot be used to authorise the regular use of lime products. The remaining alternative is the use of substitute products.

The disinfection of feed storages or the surfaces of feed transport equipment requires an application to authorise the active substance for product type 4, which is a considerably more laborious and expensive procedure than adding uses to existing product authorisations. However, it is presumably much easier to find substitutes for the disinfection of feed storages and the surfaces of feed transport equipment than for most other current uses of lime.

Figure 5. Pens after lime treatment (Image: Animal Health ETT)

9.4 Use contrary to instructions for use

Many disinfectants are used in primary production that, by their nature, may also be suitable for uses for which they are not marketed. An example is the use of the Virkon S product to disinfect the skin of animals. Applying a commonly available disinfectant to new uses is attractive from end users' perspective, as they can avoid purchasing a separate product. However, in terms of the implementation of the Biocidal Products Regulation, this is problematic, and the aim of any future projects could be to increase information so that at least veterinarians would be aware that use that does not comply with the instructions for use is contrary to the Biocidal Products Regulation.

9.5 Demarcation between product types

As described in section 4.1 (Authorisation of biocidal products and approval of active substances) and Appendix 4 of the report, product types are of great practical importance for the prior approval of biocidal products and the identification of products authorised for an intended use. However, the demarcation of product types is not always unambiguous. The aim is to create a uniform interpretation of borderline cases within the Union, but each borderline case must be solved individually.

For end users, borderline cases are a problem, especially if the active substance of a suitable product is not approved for both product types under which the intended use can be considered to fall. In primary production, the typical borderline case is between product types 2 and 3. The Biocidal Products Regulation defines the disinfectants for surfaces and materials of product type 3 as follows:

"Products used to disinfect the materials and surfaces associated with the housing or transport of animals."

The definition could be interpreted as limiting product type 3 to uses in animal facilities only. However, in the product assessment, it is appropriate to also classify other uses outside animal facilities as falling under product type 3 if the conditions of use are essentially similar to those in animal facilities. An example of such use is the disinfection of animal transport vehicles from the outside, which has been considered to fall under product type 3. Manure disinfection is also classified as falling under product type 3, even if the disinfection does not take place in animal houses. At the time of writing, it is unclear whether the disinfection of the topsoil or pavements (concrete, gravel, asphalt) in the vicinity of animal houses falls under product type 2 or 3 in cases such as eradicating animal diseases. In connection with a product approval (Union authorisation), it has been outlined that the disinfection of the topsoil in a corral falls under product type 3.

The disinfection of machinery may be necessary to prevent the spread of pathogens when the machinery is moved between facilities. The disinfection of machinery is a special use that has not been considered in product applications or in the interpretation manuals of the Biocidal Products Regulation when writing this report. Supposedly, the disinfection of machinery from the outside falls under product type 2, although the use is very similar to the disinfection of animal transport vehicles from the outside, which has been considered to fall under product type 3.

In general, it can be stated that if an animal facility has premises intended only for employees, the products used to disinfect these premises fall under product type 2. Product type 2 also includes the disinfection of ventilation ducts in animal houses.

The treatment of fish culture water with a biocidal product to eradicate fish parasites may be a biocidal or medicinal use, depending on the exact intended use. However, biocidal treatment may be considered as pest control instead of disinfection, at least if the target organism is an arthropod such as salmon louse (see section 8.3).

Tukes takes the initiative to promote common EU interpretations in borderline product-type cases.

9.6 Authorisation of alcohols as active substances for product type 3 has not been applied for

No application has been submitted to authorise alcohols (ethanol, propanol, isopropanol) as active substances for product type 3. However, these are needed in frost and in general for disinfecting electrical equipment. At least part of the electrical equipment of animal houses and animal transport vehicles is such that their disinfection can be considered to fall under product type 2 (see Demarcation between product types). However, there are also likely to be uses that clearly fall under product type 3 for which alcohols are needed. Alternative products should be found for these, or an exceptional use should be sought.

9.7 Veterinary medicine or biocidal product?

Based on the Biocidal Products Regulation, product type 3 includes "products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with an anti-microbial function".

According to the Veterinary Medicinal Products Regulation, a veterinary medicinal product means any substance or combination of substances intended to treat or prevent an animal's disease.

However, it may be difficult to determine whether products used for the skin disinfection of healthy animals are primarily intended for disease prevention. In Finland, Finnish Medicines Agency's (Fimea) task is to decide whether a product is considered a medicine in Finland. The classification is made product specifically based on an assessment of the effect and the intended use.

Tukes actively strives to bring borderline cases that have come to its knowledge to Fimea for resolution.

9.7.1 Copper sulphate as active substance in hoof baths

In Finland, copper sulphate is the most commonly used active substance in hoof baths. Copper sulphate is used in hoof baths for the treatment and prevention of skin infections in hoofs. According to Fimea, such use can be considered medicinal. However, hoof bath products can also be used biocidally. The demarcation between biocidal and medicinal use is unclear if the animal is without clinical symptoms.

The biocidal use of copper sulphate in hoof baths is not allowed because no application has been submitted to authorise the substance as an active substance for product type 3. However, copper sulphate preparations were sold and marketed for biocidal use as late as August 2023. Allowed hoof bath products containing other active substances are on the market in Finland, but none of their product assessments were completed by August 2023.

Within the framework of this project, Tukes has addressed issues related to the use of copper sulphate in hoof baths with the Finnish Food Authority. As a result of the cooperation, Tukes sent a call for evidence to Fimea. In its statement, Fimea pointed out that based on Article 4 (1) of the Veterinary Medicinal Products Regulation (EU) No 2019/6, a veterinary medicinal product means a substance/product that is specifically marketed for the treatment/prevention of a disease, and/or that is specifically intended (by the manufacturer) to restore, repair or modify vital functions. Even if the end use by the end user/veterinarian is medicinal, Fimea cannot authorise the chemical if it is not a veterinary medicinal product in accordance with the Veterinary Medicinal Products Regulation. According to Fimea, if copper sulphate exists only as a chemical or active substance, the Finnish Food Authority is the competent authority to guide the practices related to extemporaneous prescribing.

Within the framework of this project, Tukes investigated which of the hoof bath products on the market were allowed. Tukes also intervenes in the sale and marketing of copper sulphate products for biocidal use.

9.8 Insufficient expertise of companies carrying out disinfection

Animal producers often outsource large-scale disinfections of their production facilities to smaller specialised companies that may lack knowledge of chemical legislation or of the conditions for product approval. As a follow-up to the project, information or supervision targeted at these companies could be considered. However, identifying the companies is challenging because there is no specific register for them.

9.9 Fragmentation of the disinfectant market

Disinfectants are sold to primary producers by travelling sales representatives from relatively small companies. To promote the implementation of the Biocidal Products Regulation, it is important to target information and possibly supervision at these operators.

10 Information and communication

As the implementation of the Biocidal Products Regulation progresses, and product types 3 and 4 become subject to authorisation procedures, it is more important than before to reach out to business operators and supervisory authorities related to primary production. Decisions are made annually on the approval, prohibition or restriction of active substances, new products are also approved for the market, and on the other hand, products are withdrawn from the market. It is therefore important to find effective communication channels and ways through which Tukes as an authorising authority can regularly provide up-to-date information and at the same time, guide operators to seek information smoothly from Tukes's and the European Chemicals Agency's sources of information.

As a biocides authorising authority, Tukes needs information about the biocidal products and disinfection practices used in primary production. This information is used to assess the risks associated with the use of the products, as well as important uses. Often Tukes obtains information about the diverse uses of disinfectants in primary production through the enquiries made in its advisory service. Making the advisory service familiar to businesses and the public authorities is one of the concrete goals of communication.

As authorities, close cooperation between Tukes and the Finnish Food Authority will be necessary in the future, including in challenging questions related to the interpretation of legislative interfaces.

The project identified industry associations and other operators that could serve as channels for communicating information to users of disinfectants in primary production. The project also launched cooperation with Animal Health ETT, and the guidelines provided by the association were reviewed and updated if necessary. This work is described in more detail in section 10.2.

10.1 Information providers for disinfectant users

The challenge of communication is to reach the right target group. This project identified operators that could help target information and communication at users of disinfectants in primary production.

Information provider	**Description of activities**
Animal Health ETT	The association promotes the health and welfare of production animals by coordinating national animal healthcare and guiding the import of animal material and feed. These activities are used to manage animal disease risks and create a basis for the safety

	of domestic food of animal origin. The association's members are dairy, slaughterhouse and egg packing companies.
Siipikarjaliitto	Siipikarjaliitto is a central organisation for the poultry industry, acting as a link between the organisations and producers in the industry and the authorities. The organisation provides its members with advice, communication, training and lecturing.
Käytännön Maamies	A professional magazine for farmers published 12 times a year.
KMVET	A sister publication of *Käytännön Maamies* focusing on the health of Finnish farm animals.
Valio	Provides guidelines and sells disinfectants to its producers.
A-tuottajat	Provides guidelines and sells disinfectants to its producers.
Finnish Food Authority	Provides information to veterinarians and feed supervisors at ELY Centres.
Finnish Sheep Breeders Association	An association focusing on sheep breeding lobbying and information. Publishes the *Lammas ja vuohi* magazine for its members. The magazine includes veterinary columns whose topics are occasionally related to biocides. In 2021–2022, these have included the biosafety of farms, production hygiene and sheep drinking water.
Suomen Sikayrittäjät ry	A national lobbying association for pig keeping.
Regional State Administrative Agencies	Provide information to supervisory veterinarians in their region.
Maaseudun Tulevaisuus	A newspaper published three times a week.
Nauta magazine	A magazine for dairy and meat farms.
Arla	Could help disseminate information to producers.
HKScan	Could help disseminate information to producers.
Suomen Hippos ry	A national central organisation for trotting and horse breeding.
Suomen Kalankasvattajaliitto ry	A nationwide fish farmers' lobbying organisation.
Maitoyrittäjät ry	An association representing the interests of the dairy industry. Provides information and training to its members.
Faba	A specialist shop in the field of livestock raising, breeding and health. Sells disinfectants, among other products.

10.2 Comments on Animal Health ETT's guidelines

Animal Health ETT is an association with national and international activities, whose mission is to promote the health and welfare of production animals and manage disease risks in the imports of animal material and feed. The association provides various guidelines on topics such as:

- Cleaning and disinfection of animal transport equipment
- Washing and disinfection between batches on poultry farms
- Cleaning and disinfection of slurry trolleys
- Cleaning and disinfection of machinery
- Cleaning and disinfection of calf farms

The guidelines include instructions on cleaning, washing and disinfection. Products suitable for disinfection are grouped under different active substances and mentioned by name. In the spring of 2023, Tukes reviewed the guidelines and commented on the situation of the products from the perspective of the implementation of the Biocidal Products Regulation and the current information contained in KemiDigi. Some of the products are not available anymore, and a likely reason for this is that product authorisations under the Biocidal Products Regulation should have been applied for the products. The guidelines will also need to be updated in the future because some products are discontinued by the manufacturers, and new ones are introduced to replace them.

11 Proposals for further action

As the authorisation authority for biocides, Tukes identified the following needs and objectives for further action following this project:

1. During the project, the cooperation between Tukes and the Finnish Food Authority has intensified significantly, which has increased the awareness of the authorities, especially regarding the legislation of their areas of responsibility and the close connections between them. Cooperation with the Finnish Food Authority will be continued by mutually providing information on the progress of the implementation of the Biocidal Products Regulation and its effects on primary production operators. To ensure cooperation, a meeting or another joint event will be held at least once a year.

2. In the coming years, the resources of Tukes market surveillance will be allocated to the supervision of disinfectants in primary production on a project basis, and the results of these projects will be disseminated.

3. Cooperation with the responsible parties and experts at the Finnish Food Authority and the Ministry of Agriculture and Forestry will be continued by providing information about the progress of legislative projects. If necessary, comments on EU-level draft regulations will be prepared together to ensure that the interface between primary production and feed regulations is considered in biocidal regulations as much as possible.

4. Investigations will be carried out into other EU countries' interpretations of the interfaces between biocidal and other regulations, as well as how different types of products are classified in the product types described in the Biocidal Products Regulation. Efforts will be made to promote common interpretations among EU countries in borderline product-type cases.

5. An annual plan will be drawn up to systematically inform business operators in the industry about the obligations of the Biocidal Products Regulations. The most effective means and channels of

communication with other public authorities will be identified, using cooperation with industry associations.

6. Cooperation with industry associations will be developed in activities such as the preparation and updating of guidelines for primary production operators.

7. Cooperation with veterinarians will be developed, and communication channels will be identified to provide up-to-date information.

8. Veterinarians and producers will be provided with information about the changes brought about by biocides legislation in agricultural trade journals and through the information channels used by the Finnish Food Authority.

9. The advisory service activities of Tukes will be promoted among industry associations, supervisory authorities, and companies that market and import biocides in primary production.

10. A separate follow-up project will be implemented aimed at raising awareness of Tukes and biocides legislation among operators in the fish farming sector. It has been found that various chemicals are used for biocidal purposes in fish farming, but awareness of biocidal legislation and its requirements is poor among operators in the industry. The industry guidelines also contain outdated information that does not take the requirements of the Biocidal Products Regulation into account.

12 Appendices

Appendix 1. Terms used in the report

Primary production	Primary food production refers to the first stage of food production. Primary production includes milk production, egg production, meat farming, fishing and fish farming, vegetable, fruit, grain and mushrooms farming, primary production of feed, honey production, gathering of wild berries and mushrooms, and hunting.
Making available on the market	The supply of a biocidal product or treated article for distribution or use in the course of a business, whether in return for payment or free of charge.
Biocidal active substance	A substance (or micro-organism) that has an effect on harmful organisms.
Biocidal product	A substance or mixture containing (or generating) one or more active substances, the purpose of which is to destroy, deter, render harmless, prevent the action of, or limit the occurrence of harmful organisms by any means other than mere physical or mechanical action. A treated article is a biocidal product if its primary purpose is to act as a biocide.
Biocidal product family	A group of biocidal products of similar composition (with certain exceptions) used in the same way, with the same active substance, and with similar risks and efficacy.
Food premises	Food premises are any buildings, or part thereof, or any other outdoor or indoor space in which food intended for sale or otherwise disposed of is prepared, stored, transported, marketed, served or otherwise handled. Online grocery stores are also considered food premises. However, food premises does not refer to a primary production site.
National authorisation	Authorisation by the competent authority of a member state to make a biocidal product (or biocidal product family) available on the market and use it in its territory or part of its territory.
Treated article	A treated article means any substance, mixture or article that has been treated with or intentionally incorporates one or more biocidal product.
Authorisation holder	A person established in the European Union who is responsible for placing a biocidal product on the market in a particular member state or the Union, and who is specified in the authorisation.
Placing on the market	The placing of a biocidal product or treated article on the market for the first time.
Union authorisation	Authorisation by the Commission to make a biocidal product (or a biocidal product family) available on the market and use it within the Union or part of its territory.
Product type, PT (product type)	One of the 22 product types listed in Annex V to the Biocidal Products Regulation and belonging to four main groups: Main group 1: Disinfectants Main group 2: Preservatives Main group 3: Pest control Main group 4: Other biocidal products

Summary of product characteristics	The appendix to a biocidal product authorisation decision adopted based on the Biocidal Products Regulation, which summarises the key elements of the risk assessment of the biocidal product and describes the approved instructions for use and risk management measures.
Processing aid	A substance added to foods during preparation to give them certain properties, such as yeast added to bread.
Reference member state	The EU member state chosen by an applicant, which is responsible for the assessment of the application.

Appendix 2. Product types of biocidal products

The product types of disinfectants (1–5), as well as examples of the use of products falling under these product types in primary production of food of animal origin. These product types do not include cleaning agents that do not have a deliberate biocidal effect, including washing liquids and powders and similar types of products. This report only deals with products of product types 3 and 4.

Product group	**Product-type description in the Biocidal Products Regulation (Annex V to Regulation (EU) No 528/2012)**	**Examples of use**
1. Human hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.	hand disinfection
2. Disinfectants and algaecides not intended for direct application to humans or animals	Products used for the disinfection of surfaces, materials, equipment and furniture that do not come into direct contact with food or feeding stuffs. Usage area include, inter alia, swimming pools, aquariums, bathing and other waters, air-conditioning systems, and walls and floors in private, public, industrial and in other areas for professional activities. Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil. Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials. Products used for incorporation in textiles, tissues, masks, paints and other articles or materials with the purpose of producing treated articles with disinfecting properties.	disinfection of surfaces in premises for human (non-animal) use only disinfection of cabins of transport equipment from the inside

3. Veterinary hygiene	Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products, or with an anti-microbial function. Products used to disinfect the materials and surfaces associated with the housing or transport of animals.	disinfection of animal houses disinfection of teats and hooves disinfection of boots disinfection of the cargo compartment and external surfaces of animal transport vehicles disinfection of manure
4. Food and feed area	Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals. Products used to impregnate materials which may come into contact with food.	disinfection of milking equipment and farm tanks disinfection of feed storage surfaces disinfection of feeding vessels and feed handling equipment disinfection of the cargo compartment of feed transport trucks disinfection of drinking water dispensers for animals

5. Drinking water	Products used for the disinfection of drinking water for both humans and animals.	disinfection of drinking water for animals

Appendix 3. Example of the authorised use of a biocidal product

Examples of authorised uses of biocidal products can be seen in summary of product characteristics (SPC) documents available at the ECHA webpage (https://echa.europa.eu/information-on-chemicals/biocidal-products).

Appendix 4. Public authorities and their powers

The authorities involved in the operation of primary production of food of animal origin and their powers.

Area of responsibility (legislative area)	**Public authority and its powers**	**Reference list including links to instructions, supervision plans, websites of the authorities, etc.**
Environmental permit (Environmental Protection Act (527/2014), Environmental Protection Degree (713/2014))	Environmental permit authorities include the **Regional State Administrative Agency (the area of responsibility of environmental permits)** and the **municipal environmental protection authority**. Their division of powers, as well as the permit requirements, are described in the Environmental Protection Act and Decree on Environmental Protection. Depending on the scale of the operations, animal houses, fish farming, and the manufacture and production of food and feed may require an environmental permit. Smaller animal houses are subject to notification, as is the manufacture and production of food and feed if their waste water is discharged to a waste water treatment plant subject to an environmental permit. The application for an environmental permit includes a list of chemicals in which the operator indicates all the chemicals used in its operations, including disinfectants. The environmental permit authorities do not check whether disinfectants are subject to permit or suitable for the activity indicated in the application, and the responsibility for these lies with the operator. Environmental permits do not lay down permit regulations for the implementation of disinfection of animal houses or feed production/storage facilities. Instead, permit regulations are issued for the discharge of waste and washing water. For example: “Slurry and waste and washing water from animal houses must be used as fertiliser in the field. Slurry and washing water may also be delivered to a facility	Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (valtioneuvosto.fi)

	that holds an environmental permit if a valid delivery contract is presented to the supervisory authority prior to the delivery." Or: "The washing and toilet waters of the old and new breeding facility must be discharged into the sewage system in accordance with the application. The washing of manure transport and spreading equipment must be carried out on a sealed base so that the washing waters are collected and discharged into the sewage system." The permit regulations of environmental permits do not generally take a specific stand on whether washing water, waste water or manure/slurry contains disinfectants or their decomposition products.	
Authorisation of biocidal products (Biocidal Products Regulation (EU) No 528/2012)	**Tukes (Biocides Unit)** grants national authorisations for biocidal products. Tukes may grant an exception for a biocidal product or use that does not meet the conditions for authorisation laid down in the Biocidal Products Regulation if such a measure is necessary due to a risk to public health, animal health or the environment that cannot be contained by other means. The **European Commission** grants Union authorisations for biocidal products throughout the European Union.	
Allowed disinfectants and their supervision (Biocidal Products Regulation (EU) No 528/2012)	Allowed disinfectants include nationally authorised products in Finland, as well as products that have Union authorisation that does not include an exception regarding Finland. Allowed disinfectants also include products which contain biocidal active substances whose assessment for the product type required for use is still in progress, or for which a product application under the Biocidal Products Regulation is pending after approval of the active substance for the product type in question. For example, the above means animal houses may be disinfected using products containing an active substance that is under assessment for product type 3. If the assessment of the active substance contained in the product has been completed, it is permitted to use the product	Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (valtioneuvosto.fi)

	if an authorisation application for the product is pending for product type 3. Correspondingly, the disinfection of feed premises and feed processing falls under product type 4. The use of these disinfectants therefore does not require prior approval during the transition period. **Tukes (Chemical Products Unit)** and **the environmental protection authorities** which supervise the conditions of biocides supervise biocidal products that may be on the market and should be authorised. Tukes's supervisory measures target the distributors/importers of products, and the environmental protection authorities' measures focus on the operators.	
Market surveillance of disinfectants (Chemicals Act (599/2013))	**Tukes (Chemical Products Unit**) market surveillance targets issues such as the active substances of disinfectants, authorisation requirements, labelling and packaging, as well as marketing.	Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (valtioneuvosto.fi)
Supervision of the conditions of disinfectants (Chemicals Act 599/2013)	**The Centre for Economic Development, Transport and the Environment (the environmental responsibility area)** and the **municipal environmental protection authority** supervise permits issued under the Biocidal Products Regulation in connection with their supervision of facilities in accordance with the Environmental Protection Act. The municipal environmental protection authority also supervises the use of disinfectants in operations that are not subject to permit or notification under the Environmental Protection Act. The Centre for Economic Development, Transport and the Environment (the responsibility area of the environmental) guides the municipal environmental protection authority in the above supervision activities.	Guide to the Environmental Protection Authority on Surveillance of Conditions Concerning Biocidal Products (valtioneuvosto.fi) Handling and storage of chemicals on farms:Instructions for the environmental protection authority (valtioneuvosto.fi)

Obligation to keep records of disinfectants in primary production of feed and its supervision (General Food Hygiene Regulation (EC) No 852/2004, Organic Production Regulation (EU) No 2018/848, Feed Hygiene Regulation (EC) No 183/2005, Feed Act (1263/2020) and its amendment (18/2022))	Operators are obligated to keep records of the use of disinfectants in agricultural and feed production, including organic production. According to the Feed Act (1263/2020) and its amendment (18/2022), the Feed Act also applies to the supervision of the General Food Hygiene Regulation (EC) No 852/2004 and the Organic Production Regulation (EU) No 2018/848 concerning feed, feed industry operations and feed supervision. **The Centre for Economic Development, Transport and the Environment (the area of responsibility of business and industry)** supervises the obligation to keep records of the use of disinfectants in feed production.	Conditionality guide 2023 – Finnish Food Authority Record-keeping requirements for agricultural production, 2022 – Finnish Food Authority Supervision of cross-compliance for feed hygiene
Prevention and control of animal diseases (Regulation on transmissible animal diseases and amending and repealing certain acts in the area of animal health, “Animal Health Law”, (EU) No 2016/429, Animal Diseases Act (76/2021))	The Ministry of Agriculture and Forestry is responsible for managing the control of animal diseases. As a central government authority, the Finnish Food Authority plans, directs, develops and supervises the control of animal diseases. The official veterinarian is the competent animal health authority in its jurisdiction.	Controlling animal diseases – Finnish Food Authority
Feed and feed industry operators (EU legislation – Finnish Food Authority) National legislation – Finnish Food Authority)	The Finnish Food Authority ensures the quality of feed by monitoring, inspecting and analysing imported, domestically manufactured and marketed feeds. In addition, the Finnish Food Authority supervises feed industry operators through inspection visits. The purpose of the supervision of the feed chain is to ensure that feeding stuffs are safe and fit for purpose, and that they comply with the legal requirements. Supervision is carried out in accordance with an annual supervision plan.	Feeds and feed business operators – Finnish Food Authority

Ensuring of food safety (food legislation)	In the administrative sector of the Ministry of Agriculture and Forestry, the Finnish Food Authority leads, directs and develops the ensuring of the safety and quality of the food chain. The supervision is based on a national multiannual supervision plan (VASU) for the Finnish food chain, which provides a detailed description of the entire supervision chain. The competent supervisory authority, i.e. the supervisor, is usually the **municipal officeholder.**	National multiannual supervision plan for the food chain for 2021–2024 – Finnish Food Authority Ensuring food safety – Finnish Food Authority

Appendix 5. Active substances for product type 3

Approved active substances for product type 3 (PT3)

Finnish name of the biocide	English name of the biocide	EC number	CAS number	Approved under regulation	Start of approval	Approval end date
Bentsoehappo	Benzoic acid	200-618-2	65-85-0	(EU) 1035/2013	01/07/2015	30/06/2025
Polyvinyylipyrrolidiinijodi	Polyvinylpyrrolidone iodine	607-771-8	25655-41-8	(EU) 94/2014	01/09/2015	31/08/2025
Jodi	Iodine	231-442-4	7553-56-2	(EU) 94/2014	01/09/2015	31/08/2025
Glutaraali (glutaarialdehydi)	Glutaral (glutaraldehyde)	203-856-5	111-30-8	(EU) 2015/1759	01/10/2016	30/09/2026
Vetyperoksidi	Hydrogen peroxide	231-765-0	7722-84-1	(EU) 2015/1730	01/02/2017	31/01/2027
PHMB(1600;1.8)	polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1,600 and a mean polydispersity (PDI) of 4.7 of 1.8 (PHMB(1,600;1.8))	608-042-7	27083-27-8	(EU) 2016/125	01/07/2017	30/06/2024
Peretikkahappo	Peracetic acid	201-186-8	79-21-0	(EU) 2016/672	01/10/2017	30/09/2027
Bifenyyli-2-oli	Biphenyl-2-ol	201-993-5	90-43-7	(EU) 2016/1084	01/01/2018	31/12/2027
Bacillus amyloliquefaciens, kanta ISB06	*Bacillus amyloliquefaciens*	-	-	(EU) 2016/1085	01/01/2018	31/12/2027
Amiinit, N-C10-16-alkyylitrimetyleenidi-, reaktiotuotteet kloorietikkahapon kanssa (amfolyytti 20))	Amines, N-C10-16-alkyl methylenedi-, reaction products with chloroacetic acid	-	139734-65-9	(EU) 2016/1083	01/01/2018	31/12/2027
Kalsiummagnesiumtetrahydroksidi/kalsiummagnesiumhydroksidi / sammutettu dolomiittinen kalkki	Calcium magnesium tetrahydroxide/calcium magnesium hydroxide/hydrated dolomitic lime	254-454-1	39445-23-3	(EU) 2016/1933	01/05/2018	30/04/2028
Kalsiummagnesiumoksidi/dolomiittikalkki	Calcium magnesium oxide/dolomitic lime	253-425-0	37247-91-9	(EU) 2016/1932	01/05/2018	30/04/2028
Kalsiumoksidi/kalkki / poltettu kalkki / sammuttamaton kalkki	Calcium oxide	215-138-9	1305-78-8	(EU) 2016/1936	01/05/2018	30/04/2028

Kalsiumdihydroksidi/kalsiumhydroksidi / sammutettu kalkki	Calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime	215-137-3	1305-62-0	(EU) 2016/1935	01/05/2018	30/04/2028
Klorokresoli	Chlorocresol	200-431-6	59-50-7	(EU) 2016/1930	01/05/2018	30/04/2028
Kalsiumhypokloriitista vapautunut aktiivinen kloori	Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3	(EU) 2017/1274	01/01/2019	31/12/2028
Natriumhypokloriitista vapautunut aktiivinen kloori	Active chlorine released from sodium hypochlorite	231-668-3	7681-52-9	(EU) 2017/1273	01/01/2019	31/12/2028
Tetra-asetyylietyleenidiamiinista (TAED) ja natrium-perkarbonaatista tuotettu peretikkahappo	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate	-	-	(EU) 2017/1276	01/01/2019	31/12/2028
L-(+)-maitohappo	L-(+)-lactic acid	201-196-2	79-33-4	(EU) 2017/2002	01/05/2019	30/04/2029
Formaldehydi	Formaldehyde	200-001-8	50-00-0	(EU) 2020/1763	01/02/2022	31/01/2025
Peretikkahapon (PAA) ja peroksioktaanihapon (POOA) reaktiomassa	Reaction mass of peracetic acid and peroxyoctanoic acid	-	-	(EU) 2020/1771	01/04/2022	31/03/2032
Hypokloorihapokkeesta vapautunut aktiivinen kloori	Active chlorine released from hypochlorous acid	-	-	(EU) 2021/347	01/07/2022	30/06/2032
Natriumkloridista elektrolyysillä tuotettu aktiivinen kloori	Active chlorine generated from sodium chloride by electrolysis	-	-	(EU) 2021/345	01/07/2022	30/06/2032
Didekyylidimetyyliammoniumkloridi (DDAC)	Didecyldimethylammonium chloride	230-525-2	7173-51-5	(EU) 2021/1045	01/11/2022	31/10/2032
Alkyyli-(C12-16)-dimetyylibentsyyliammoniumkloridi (ADBAC/BKC (C12-C16))	Alkyl (C12-16) dimethylbenzyl ammonium chloride	270-325-2	68424-85-1	(EU) 2021/1063	01/11/2022	31/10/2032
Muurahaishappo	Formic acid	200-579-1	64-18-6	(EU) 2023/2643	01/11/2024	31/10/2034

Active substances under assessment for product type 3 (PT3)

Finnish name of the biocide	English name of the biocide	EC number	CAS number
Natriumkloridista ja pentakalium-bis(peroksimonosulfaatti)bis(sulfaatista) tuotettu aktiivinen kloori	Active chlorine generated from sodium chloride and pentapotassium bis(peroxymonosulphate) bis(sulphate)	-	-
Alkyyli-(C12-18))-dimetyylibentsyyliammoniumkloridi (ADBAC (C12-18))	Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18))	269-919-4	68391-01-5
Alkyyli-(C12- C14)-dimetyyli(etyylibentsyyli)ammoniumkloridi (ADEBAC (C12-C14))	Alkyl (C12-C14) dimethyl(ethylbenzyl)ammonium chloride (ADEBAC (C12-C14))	287-090-7	85409-23-0
Alkyyli-(C12-C14)-dimetyylibentsyyliammoniumkloridi (ADBAC (C12-C14))	Alkyl (C12-C14) dimethylbenzylammonium chloride (ADBAC (C12-C14))	287-089-1	85409-22-9
Klooridioksidi	Chlorine dioxide	233-162-8	10049-04-4
Natriumkloriitista happoa lisäämällä tuotettu klooridioksidi	Chlorine dioxide generated from sodium chlorite by acidification	-	10049-04-4
Natriumkloriitista elektrolyysillä tuotettu klooridioksidi	Chlorine dioxide generated from sodium chlorite by electrolysis	-	-
Natriumkloriitista hapettamalla tuotettu klooridioksidi	Chlorine dioxide generated from sodium chlorite by oxidation	-	10049-04-4
Syanamidi	Cyanamide	206-992-3	420-04-2
D-glukonihappo, yhdiste N,N'-bis(4-kloorifenyyli)-3,12-di-imino-2,4,11,13-tetra-atsatetradekaanidiamidiinin kanssa (2:1) (CHDG)	D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (CHDG)	242-354-0	18472-51-0
Didekyylidimetyyliammoniumkloridi (DDAC (C8-10))	Didecyldimethylammonium chloride (DDAC (C8-10))	270-331-5	68424-95-3
Ilmasta tai vedestä tuotetut vapaat radikaalit	Free radicals generated in situ from ambient air or water	-	-
Glykolihappo	Glycolic acid	201-180-5	79-14-1
Glyoksaali	Glyoxal	203-474-9	107-22-2
Natriumperkarbonaatista vapautunut vetyperoksidi	Hydrogen peroxide released from sodium percarbonate	-	-
N-(3-aminopropyyli)-N-dodekyylipropaani-1,3-diamiini (diamiini)	N-(3-aminopropyl) -N-dodecylpropane-1,3-diamine	219-145-8	2372-82-9
Pentakaliumbis(peroksimonosulfaatti)bis(sulfaatti) (KPMS)	Pentapotassium bis(peroxymonosulphate) bis(sulphate)	274-778-7	70693-62-8

Salisyylihappo	Salicylic acid	200-712-3	69-72-7
Hopeanitraatti	Silver nitrate	231-853-9	7761-88-8
Natriumdikloori-isosyanuraattidihydraatti	Sodium dichloroisocyanurate dihydrate	220-767-7	51580-86-0
Symkloseeni	Symclosene	201-782-8	87-90-1
Tosyyliklooriamidinatrium (klooriamiini T)	Tosylchloramide sodium (tosylchloramide sodium – chloramin T)	204-854-7	127-65-1
Trokloseeninatrium	Troclosene sodium	220-767-7	2893-78-9

Appendix 6. Active substances for product type 4

Approved active substances for product type 4 (PT4)

Finnish name of the biocide	English name of the biocide	EC number	CAS number	Approved under regulation	Start of approval	Approval end date
Bromietikkahappo	Bromoacetic acid	201-175-8	79-08-3	(EU) 1032/2013	01/07/2015	30/06/2025
Bentsoehappo	Benzoic acid	200-618-2	65-85-0	(EU) 1035/2013	01/07/2015	30/06/2025
Polyvinyylipyrrolidiinijodi	Polyvinylpyrrolidone iodine	607-771-8	25655-41-8	(EU) 94/2014	01/09/2015	31/08/2025
Jodi	Iodine	231-442-4	7553-56-2	(EU) 94/2014	01/09/2015	31/08/2025
Dekaanihappo	Decanoic acid	206-376-4	334-48-5	(EU) 90/2014	01/09/2015	31/08/2025
Oktaanihappo	Octanoic acid	204-677-5	124-07-2	(EU) 93/2014	01/09/2015	31/08/2025
Propan-2-oli	Propan-2-ol	200-661-7	67-63-0	(EU) 2015/407	01/07/2016	30/06/2026
Glutaraali (glutaarialdehydi)	Glutaral (glutaraldehyde)	203-856-5	111-30-8	(EU) 2015/1759	01/10/2016	30/09/2026
5-kloori-2-(4- kloorifenoksi)-fenoli (DCPP)	5-chloro-2-(4-chlorphenoxy)phenol (DCPP)	429-290-0	3380-30-1	(EU) 2015/1727	01/12/2016	30/11/2026
Vetyperoksidi	Hydrogen peroxide	231-765-0	7722-84-1	(EU) 2015/1730	01/02/2017	31/01/2027
PHMB(1600;1.8)	polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1,600 and a mean polydispersity (PDI) of 1.8 (PHMB(1,600;1.8))	608-042-7	27083-27-8	(EU) 2016/125	01/07/2017	30/06/2024
Peretikkahappo	Peracetic acid	201-186-8	79-21-0	(EU) 2016/672	01/10/2017	30/09/2027
Bifenyyli-2-oli	Biphenyl-2-ol	201-993-5	90-43-7	(EU) 2016/1084	01/01/2018	31/12/2027
5-kloori-2-metyyli-2hisotiatsol-3-onin ja 2-metyyli-2h-isotiatsol3-onin (3:1) reaktiomassa C(M)IT/MIT (3:1)	Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (mixture of CMIT/MIT)	-	55965-84-9	(EU) 2016/131	01/07/2017	30/06/2026

Amiinit, N-C10-16-alkyylitrimetyleenidi-, reaktiotuotteet kloorietikkahapon kanssa (amfolyytti 20))	Amines, N-C10-16-alkyl methylenedi-, reaction products with chloroacetic acid	-	139734-65-9	(EU) 2016/1083	01/01/2018	31/12/2027
Kalsiumhypokloriitista vapautunut aktiivinen kloori	Active chlorine released from calcium hypochlorite	231-908-7	7778-54-3	(EU) 2017/1274	01/01/2019	31/12/2028
Natriumhypokloriitista vapautunut aktiivinen kloori	Active chlorine released from sodium hypochlorite	231-668-3	7681-52-9	(EU) 2017/1273	01/01/2019	31/12/2028
Tetra-asetyylietyleenidiamiinista (TAED) ja natrium-perkarbonaatista tuotettu peretikkahappo	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate	-	-	(EU) 2017/1276	01/01/2019	31/12/2028
Propan-1-oli	Propan-1-ol	200-746-9	71-23-8	(EU) 2017/2001	01/05/2019	30/04/2029
L-(+)-maitohappo	L-(+)-lactic acid	201-196-2	79-33-4	(EU) 2017/2002	01/05/2019	30/04/2029
PHMB (1415;4.7)	polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1,415 and a mean polydispersity (PDI) of 4.7 (PHMB(1,415;4.7))	-	1802181–67-4	(EU) 2018/613	01/11/2019	31/19/2026
Peretikkahapon (PAA) ja peroksioktaanihapon (POOA) reaktiomassa	Reaction mass of peracetic acid and peroxyoctanoic acid	-	-	(EU) 2020/1771	01/04/2022	31/03/2032
Hypokloorihapokkeesta vapautunut aktiivinen kloori	Active chlorine released from hypochlorous acid	-	-	(EU) 2021/347	01/07/2022	30/06/2032
Natriumkloridista elektrolyysillä tuotettu aktiivinen kloori	Active chlorine generated from sodium chloride by electrolysis	-	-	(EU) 2021/345	01/07/2022	30/06/2032

Didekyylidimetyyliammoniumkloridi (DDAC)	Didecyldimethylammonium chloride	230-525-2	7173-51-5	(EU) 2021/1045	01/11/2022	31/10/2032
Hapesta tuotettu otsoni	Ozone generated from oxygen	-	-	(EU) 2023/1078	01/07/2024	30/06/2034
N,N-didekyyli-N-(2-hydroksietyyli)-Nmetyyliammoniumpropionaatin ja N,Ndidekyyli-N-(2-(2-hydroksietoksi) etyyli)-Nmetyyliammoniumpropionaatin ja N,Ndidekyyli-N-(2-(2-(2-hydroksietoksi)etoksi)etyyli)-Nmetyyliammoniumpropionaatin reaktiomassa (DMPAP)	Reaction mass of N,Ndidecyl-N-(2-hydroxyethyl)-Nmethylammonium propionate and N,Ndidecyl-N-(2-(2-hydroxyethoxy) ethyl)-Nmethylammonium propionate and N, Ndidecyl-N-(2-(2-hydroxyethoxy)ethoxy)ethyl)-N-methylammonium propionate ('DMPAP')	-	-	(EU) 2023/2089	01/02/2025	31/01/2035
Muurahaishappo	Formic acid	200-579-1	64-18-6	(EU) 2023/2643	01/11/2024	31/10/2034

Active substances under assessment for product type 4 (PT4)

Finnish name of the biocide	English name of the biocide	EC number	CAS number
2-fenoksietanoli	2-phenoxyethanol	204-589-7	122-99-6
Natriumkloridista ja pentakalium-bis(peroksimonosulfaatti)bis(sulfaatista) tuotettu aktiivinen kloori	Active chlorine generated from sodium chloride and pentapotassium bis(peroxymonosulphate) bis(sulphate)	-	-
Natrium-N-kloorisulfamaatista tuotettu aktiivinen kloori	Active chlorine generated from sodium N-chlorosulphamate	-	-
Alkyyli-(C12-18))-dimetyylibentsyyliammoniumkloridi (ADBAC (C12-18))	Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18))	269-919-4	68391-01-5

Alkyyli-(C12- C14)-dimetyyli(etyylibentsyyli)ammoniumkloridi (ADEBAC (C12-C14))	Alkyl (C12-C14) dimethyl(ethylbenzyl)ammonium chloride (ADEBAC (C12-C14))	287-090-7	85409-23-0
Alkyyli-(C12-C14)-dimetyylibentsyyliammoniumkloridi (ADBAC (C12-C14))	Alkyl (C12-C14) dimethylbenzylammonium chloride (ADBAC (C12-C14))	287-089-1	85409-22-9
Klooridioksidi	Chlorine dioxide	233-162-8	10049-04-4
Natriumkloriitista happoa lisäämällä tuotettu klooridioksidi	Chlorine dioxide generated from sodium chlorite by acidification	-	-
Natriumkloriitista elektrolyysillä tuotettu klooridioksidi	Chlorine dioxide generated from sodium chlorite by electrolysis	-	-
Natriumkloriitista hapettamalla tuotettu klooridioksidi	Chlorine dioxide generated from sodium chlorite by oxidation	-	-
Tetraklooridekaoksidikompleksista (TCDO) happoa lisäämällä tuotettu klooridioksidi	Chlorine dioxide generated from tetrachlorodecaoxide complex (TCDO) by acidification	-	-
Didekyylidimetyyliammoniumkloridi (DDAC (C8-10))	Didecyldimethylammonium chloride (DDAC (C8-10))	270-331-5	68424-95-3
Dinatriumperoksodisulfaatti	Disodium peroxodisulphate/sodium persulphate	231-892-1	7775-27-1
Etanoli	Ethanol	200-578-6	64-17-5
Ilmasta tai vedestä tuotetut vapaat radikaalit	Free radicals generated in situ from ambient air or water	-	-
Glykolihappo	Glycolic acid	201-180-5	79-14-1
Glyoksaali	Glyoxal	203-474-9	107-22-2
N-(3-aminopropyyli)-N-dodekyylipropaani-1,3-diamiini (diamiini)	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (diamine)	219-145-8	2372-82-9
Pentakaliumbis(peroksimonosulfaatti)bis(sulfaatti) (KPMS)	Pentapotassium bis(peroxymonosulphate) bis(sulphate)	274-778-7	70693-62-8
Muurahaishaposta ja vetyperoksidista tuotettu permuurahaishappo	Performic acid generated from formic acid and hydrogen peroxide	-	-

Kvaternaariset ammoniumyhdisteet, bentsyyli-C12-18 -alkyylidimetyyli, suolat 1,2-bentsisotiatsol-3(2H)-oni-1,1-dioksidin kanssa (1:1) (ADBAS)	Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, salts with 1,2-benzisothiazol-3(2H)-one 1,1-dioxide	273-545-7	68989-01-5
Reaktiotuotteet: glutamiinihappo ja N-(C12-C14-alkyyli)propyleenidiamiini (glukopotamiini)	Reaction products of: glutamic acid and N-(C12-C14-alkyl)propylenediamine (glucoprotamin)	403-950-8	164907-72-6
Salisyylihappo	Salicylic acid	200-712-3	69-72-7
Hopea	Silver	231-131-3	7440-22-4
Hopeaboorifosfaattilasi	Silver borophosphate glass	-	-
Hopeakloridi	Silver chloride	232-033-3	7783-90-6
Hopeanitraatti	Silver nitrate	231-853-9	7761-88-8
Hopeafosfaattilasi	Silver phosphate glass	608-534-1	308069-39-8
Hopeafosfoboraattilasi	Silver phosphoborate glass	-	-
Natriumdikloori-isosyanuraattidihydraatti	Sodium dichloroisocyanurate dihydrate	220-767-7	51580-86-0
Symkloseeni	Symclosene	201-782-8	87-90-1
Tosyyliklooriamidinatrium (klooriamiini T)	Tosylchloramide sodium (tosylchloramide sodium – chloramin T)	204-854-7	127-65-1
Trokloseeninatrium	Troclosene sodium	220-767-7	2893-78-9