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Synthetic Pyrethroids and Water Quality

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J. Lahr et al.

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Synopsis

Synthetic pyrethroids and water quality

Synthetic pyrethroids are chemicals that kill insects and parasites. They are used in crop protection products, in biocides (such as home aerosols and ant bait boxes), and in medication for people and animals (such as flea collars). Synthetic pyrethroids can enter the water in several ways.

Synthetic pyrethroids are a problem for the quality of surface water. They are very toxic to the organisms that live in water. The safe concentrations of these substances for the environment are very low, but low concentrations are difficult to measure in water, so their levels in surface water are therefore often unclear. If these substances are found, the quantities are often higher than the standard.

In addition, there are different laws with different standards for these substances. As a result, the concentration may comply with one law, but not with another. The permitted concentrations when admitting plant protection products and biocides are generally less strict than the general standards for the quality of surface water. As a result, water quality standards can be exceeded, even though the substance does meet the requirements for approval. A solution to this could be to compare all national and European laws for these substances and determine one safe concentration.

It is known that three of the synthetic pyrethroids (deltamethrin, esfenvalerate and lambda-cyhalothrin) cause 90 percent of the effects on water quality, while they only account for 0.1 percent of use. This concerns all crop protection products for crops grown in the open air. Less use of these synthetic pyrethroids will therefore greatly improve water quality in the Netherlands. In any case, RIVM recommends using more environmentally friendly alternatives to these substances whenever possible.

This research summarises what is known from various studies about the sale of synthetic pyrethroids, how much is emitted, how they behave in the environment, their toxicity and their presence in surface waters and sewage treatment plants in the Netherlands. With this knowledge, the government, water managers, manufacturers and users of these substances can continue to work on measures to improve water quality.

Keywords: synthetic pyrethroids, plant protection products, biocides, veterinary medicinal products, human medicines, water quality, surface water

Publiekssamenvatting

Synthetische pyrethroïden en waterkwaliteit

Synthetische pyrethroïden zijn chemische stoffen die insecten en parasieten doden. Ze worden gebruikt in gewasbeschermingsmiddelen, in biociden (zoals spuitbussen voor in huis en mierenlokdozen), en in medicijnen voor mensen en dieren (zoals vlooienbanden). Synthetische pyrethroïden kunnen op verschillende manieren in het water terechtkomen.

Synthetische pyrethroïden zijn een probleem voor de kwaliteit van het oppervlaktewater. Ze zijn erg giftig voor de organismen die in water leven. De veilige concentraties van deze stoffen voor het milieu zijn erg laag maar lage concentraties zijn moeilijk om in water te meten. Daarom is vaak niet duidelijk hoeveel ervan in oppervlaktewater zit. Als deze stoffen wel worden gevonden, zijn de hoeveelheden vaak hoger dan de norm.

Daarbij komt dat er voor deze stoffen verschillende wetten bestaan met verschillende normen. Hierdoor kan de concentratie voor de ene wet voldoen, maar voor een andere niet. De toegestane concentraties bij de toelating van gewasbeschermingsmiddelen en biociden zijn in het algemeen minder streng dan de algemene normen voor de kwaliteit van oppervlaktewater. Hierdoor kunnen de normen voor de waterkwaliteit worden overschreden, terwijl de stof wel aan eisen voldoet om toegelaten te worden. Een oplossing hiervoor kan zijn om alle nationale en Europese wetten voor deze stoffen naast elkaar te leggen en daar één veilige concentratie voor te bepalen.

Bekend is dat drie van de synthetische pyrethroïden (deltamethrin, esfenvaleraat en lambda-cyhalothrin) 90 procent van de effecten op de waterkwaliteit veroorzaken terwijl ze maar 0,1 procent van het gebruik vormen. Het gaat hier om alle gewasbeschermingsmiddelen voor gewassen die in de open lucht worden geteeld. Minder gebruik van deze synthetische pyrethroïden verbetert de waterkwaliteit in Nederland dus sterk. Het RIVM beveelt in ieder geval aan om waar mogelijk milieuvriendelijker alternatieven voor deze stoffen te gebruiken.

Dit onderzoek vat uit verschillende studies samen wat bekend is over de verkoop van synthetische pyrethroïden, hoeveel ervan wordt uitgestoten, hoe ze zich in het milieu gedragen, hun giftigheid en hun aanwezigheid in oppervlaktewateren en rioolwaterzuiveringsinstallaties in Nederland. Met deze kennis kunnen de overheid, waterbeheerders, fabrikanten en gebruikers van deze stoffen verder werken aan maatregelen om de waterkwaliteit te verbeteren.

Kernwoorden: synthetische pyrethroïden, gewasbeschermingsmiddelen, biociden, diergeneesmiddelen, medicijnen, waterkwaliteit, oppervlaktewater

Contents

Summary

Synthetic pyrethroids are a group of chemically related compounds used as pesticides and pharmaceuticals. They are the man-made versions of natural pyrethroid insecticides derived from *Chrysanthemum* flowers. The synthetic pyrethroids share similar properties such as a tendency to adsorb to particles, sediments and animal tissues. They are also toxic to aquatic invertebrates and fish at low concentrations.

A recent model study showed that three synthetic pyrethroids, deltamethrin, esfenvalerate and lambda-cyhalothrin, are responsible for 90% of the total environmental impact in Dutch surface waters by plant protection products used in open cultivation. Moreover, most synthetic pyrethroids are difficult to measure in water at the level of their environmental quality standards. Most synthetic pyrethroids are therefore ‘non-evaluable’. Because of their high potential impact in waters and their non-evaluability, synthetic pyrethroids are considered as problematic substances in water quality management. Fewer environmental emissions to surface waters would result in a significant improvement of chemical and probably also the ecological water quality.

In this report we present relevant information about synthetic pyrethroids as background for water managers and other stakeholders and in order to provide some outlook to possible measures to reduce the environmental impact of these substances. The report does not include an in-depth analysis of the available scientific literature. The information is based on mostly publicly available information from the Netherlands and a few selected scientific reviews.

At present, 21 synthetic pyrethroid substances are allowed for different types of use in the European Union, 14 of which are on the market in the Netherlands in plant protection products (PPP), in biocidal products, and in veterinary or human medicinal products (VMP, HMP).

National sales figures for individual synthetic pyrethroids in PPP were fairly constant during the past 10 years, amounting to 8,000-15,000 kg per year. Data for VMP could only be obtained as ranges, but indicate a total sale of several tons per year during the past years. The estimated yearly use of permethrin as a HMP is at least 360 kg (prescribed use only) and showed a threefold increase over the past years, probably because it is increasingly used against scabies.

There are no sales figures for biocides in the Netherlands. We have however obtained total yearly sales data of synthetic pyrethroids in Belgium, which are fairly stable over the past years with nearly 16,000 kg per year. This might give an impression of the situation in the Netherlands. Somewhat higher sales numbers may be expected on the basis of population size, but will likely be in the same order of magnitude. Summing up these figures, we estimate a total yearly sales for synthetic pyrethroids of least 30,000 kg per year.

An unknown amount of biocides enters the Netherlands in the form of treated articles (e.g. impregnated wood, clothes, carpets and rugs), which may also contribute to emissions to surface water.

Different emission routes of synthetic pyrethroids to water bodies exist depending on the type of compound and its use. They may enter surface waters directly by spray drift upon treatment of crops, but they can also reach surface water via waste water treatment plants after use as biocides (for example indoor insecticidal sprays), veterinary medicines (such as in flea collars) or human medicines (cream against scabies).

Just like the sales figures, estimated emissions of synthetic pyrethroid compounds from PPP to surface waters in the Netherlands have been fairly constant in recent years. The increase of permethrin as HMP against scabies is likely to result in increased emissions to waste water. Due to effective removal, emissions to surface water of synthetic pyrethroids by waste water treatment plants are relatively low. Emission estimates for biocides and VMP are not available which severely hampers a proper evaluation of their contribution to the total environmental impact of synthetic pyrethroids.

Eight of the 21 synthetic pyrethroids allowed for use in Europe are assigned as ‘Candidate for Substitution’ (CfS), meeting two of the three criteria for Persistence, Bioaccumulation and Toxicity (PBT). Among these are esfenvalerate and lambda-cyhalothrin, two of the three compounds that prompted this study. All synthetic pyrethroids meet the T-criterion because of their high toxicity to aquatic organisms.

Because of their common mode of action, cumulative effects may also occur when different synthetic pyrethroids are simultaneously present. However, mixture toxicity is not included in the derivation and compliance check of environmental quality standards for surface water in the context of the Water Framework Directive (WFD-EQS). For authorisation decisions, mixture toxicity of multiple substances is taken into account, but only when substances are part of the same formulated product or in case of tank mixes when the use of another product is prescribed on the label.

The authorisation criteria for most synthetic pyrethroids used in PPP are orders of magnitude higher than the WFD-EQS for surface water. Authorisation criteria for synthetic pyrethroids used in biocides are also higher than WFD-EQS, but differences are smaller than for PPP. In the case of synthetic pyrethroids that are used in both PPP and biocides, authorisation criteria for biocides are significantly lower than for PPP.

These differences between regulatory thresholds are the consequence of regulatory frameworks having different protection goals, different methods, and different ways of collecting and using scientific data. The imbalance between authorisation criteria and WFD-EQS for synthetic pyrethroids leads to different insights into their effects on surface water quality and hampers a consistent approach towards minimising the impact of these problematic substances.

For most synthetic pyrethroids, limits of quantification are also orders of magnitude higher than their respective WFD-EQS. Therefore, when synthetic pyrethroids are incidentally observed in national surface water they usually exceed the EQS. Recent improvements in analytical methods have resulted in lower quantification limits. However, such dedicated analyses are not yet routinely used in the Netherlands.

The study in the present report does not contain an in-depth analysis of the sources of the synthetic pyrethroids detected. However, an analysis of positive observations indicates an association between concentrations of synthetic pyrethroids in surface waters and certain crops. It should be noted, however, that results are likely influenced by the design of the monitoring network, and are only indicative.

Existing measures to reduce the environmental impact of synthetic pyrethroids include Emission Reduction Plans by the manufacturers and measures in the framework of Integrated Pest Management, such as using alternative methods of pest control or more environmentally friendly insecticides. In addition, for deltamethrin and esfenvalerate measures have been taken to prevent the use of different products with the same active substance on the same field within a certain period of time.

The following recommendations are given on the basis of this study:

- Whenever possible, replace the use of synthetic pyrethroids with alternatives that have less impact on the environment.
- Further develop the approach of ‘one substance, one assessment’ in regulatory frameworks.
- Develop a framework to monitor yearly sales and emissions of active substances in biocides in the Netherlands and make data publicly available, as well as those of veterinary and human pharmaceuticals.
- Investigate the import of articles treated with pesticides and assess possible emissions to the environment.
- Update surface water quality standards of relevant synthetic pyrethroids when new information is available.
- Include mixture effects of products with synthetic pyrethroids at authorisation on the market and in regulatory frameworks.
- Evaluate the role of sediments and suspended matter for the environmental fate and effects of synthetic pyrethroids in more detail and include this in risk assessment and WFD compliance check.
- Conduct a pilot study of the estimated concentrations at authorisation in order to assess to what extent future exceedance of surface water quality standards can be foreseen at the authorisation stage.
- Conduct a feasibility study to monitor synthetic pyrethroids in aquatic biota as an alternative or complement to surface water monitoring.

1 Introduction

1.1 Reason for the study

In 2019 the Dutch government issued an interim evaluation of its policy plan for 2013-2023 on plant protection called 'Gezonde Groei, Duurzame Oogst'[1] (Healthy Growth, Sustainable Yield; acronym: GGDO). The overall results were published by Tiktak et al. (2019) and the evaluation of the environmental impact by Verschoor et al. (2019). Two main methods were used for the evaluation of the environmental impact of plant protection products (PPP) in surface waters, (1) monitoring data for surface waters from the National Monitoring Network of Plant Protection Products (LM-GBM[2]), and (2) environmental modelling using the Dutch Pesticide Risk Indicator (NMI[3]), version 4.

The NMI calculations showed a large impact of three synthetic pyrethroids on surface water quality. For the years 2012 and 2016, deltamethrin, lambda-cyhalothrin and esfenvalerate were responsible for approximately 90% of the total environmental burden in surface waters caused by PPP used in open cultivation in the Netherlands (Verschoor et al., 2019). The total burden increased for all three substances from 2012 to 2016. These substances represented 0.1% of the total usage of all plant protection products in kilograms active substance (a.s.) in these years.

Despite the fact that the three pyrethroids were jointly estimated to have such a great relative impact in Dutch surface waters, the same result cannot be fully substantiated on the basis of monitoring in surface waters. This is due to the fact that the three substances cannot be analysed at the very low levels at which they exhibit their toxic effects. The limit of quantification (LoQ) for most synthetic pyrethroids is higher than their respective Environmental Quality Standard (EQS) in surface water. Therefore they cannot be evaluated with respect to their impact on water quality. Almost all synthetic pyrethroid substances used in the Netherlands are non-evaluable at the level of the EQS (more on this in Chapter 6), but there are more so-called non-evaluable PPP that occur in surface waters.

In a follow-up study Van der Zaan et al. (2021) studied improved analysis methods for surface waters for 52 non-evaluable substances of the LM-GBM. The improvements included e.g. larger extraction volumes and sophisticated detection methods. As a result of the more advanced methods, more than half of the initially non-evaluable substances included in their study became evaluable. However, this was not the case for the four synthetic pyrethroids (deltamethrin, lambda-cyhalothrin, esfenvalerate and cypermethrin) studied by Van der Zaan et al. (2021).

[1] https://open.overheid.nl/documenten/ronl-archief-aaa2dc4c-64ac-4f50-a1eb-f521d4d03350/pdf
[2] https://unievanwaterschappen.nl/publicaties/factsheet-landelijk-meetnet-gewasbeschermingsmiddelen-land-en-tuinbouw-februari-2021/
[3] https://www.pesticidemodels.eu/nmi/home

The non-evaluability of several synthetic pyrethroids was again demonstrated in a recent study in surface waters at recreational sites and in natural areas in the Netherlands (Natuur & Milieu, 2023; Visser et al., 2023). According to this study, the likelihood of detecting toxic substances in these water has not decreased between 2014 and 2021. Similarly, the likelihood of exceeding water quality standards has not decreased over this period.

As a consequence of their presumed high environmental impact in surface waters and their limited measurability, synthetic pyrethroids are currently seen as problematic substances for water quality in the Netherlands.

1.2 Aim and scope of the study

The finding that, according to the model calculations, three synthetic pyrethroid substances are responsible of 90% of the total environmental impact in Dutch surface waters by PPP active substances used in open cultivation, could represent 'low-hanging fruit'. A significant improvement in water quality can possibly be realised by tackling these compounds. This could contribute to the achievement of the WFD targets in 2027.

It is not a coincidence when three substances from the same chemical group of insecticides are responsible for such a large portion of the environmental impact. Therefore, in this report we analyse and describe the cause why synthetic pyrethroids in particular are problem substances for water quality in terms of the use and chemical and toxic properties of these compounds.

Because different synthetic pyrethroids have similar properties, it was decided to collect and summarise the existing knowledge about all synthetic pyrethroids that are used in the Netherlands as active substance in authorised plant protection products, biocides, veterinary pharmaceuticals and/or human medicines. These types of use may all result in emissions to the aquatic environment.

The information presented in this report serves as background information for policy makers, water managers, manufacturers and users of synthetic pyrethroids. It provides an outlook to possible measures to reduce the environmental impact of these substances. The report does not include an in-depth analysis of the available scientific literature. It merely describes what is known about synthetic pyrethroids and the consequences for surface water quality and water management based on mostly publicly available information and a few selected scientific reviews.

The study focusses on synthetic pyrethroids allowed in the EU and in the Netherlands, since the compounds that triggered this study belong to that group. Natural pyrethroids were not included because there are no data on their occurrence in surface waters, nor on modelled environmental impact. Finally, we do not specifically address synthetic pyrethroids that enter the Netherlands from neighbouring countries via rivers and streams. However, where we report measurements of synthetic pyrethroids in surface waters, such as in Chapter 6, it is possible that some of it may be attributed to sources outside the Netherlands.

1.3 Reader's guide

After this introductory section the report consecutively sets out to describe:

- The history and general characteristics of synthetic pyrethroids (Chapter 2),
- The authorisation of products based on synthetic pyrethroids (Chapter 3),
- Their emission routes to surface waters and their environmental behaviour (Chapter 4),
- Environmental effects and regulatory thresholds such as EQS (Chapter 5),
- Their occurrence in surface waters and sewage treatment plant water (Chapter 6),
- The possibilities for risk mitigation such as Emission Reduction Plans and using alternative PPP (Chapter 7).

The findings of the study are discussed in the various chapters. The report ends with separate sections containing conclusions (Chapter 8) and recommendations (Chapter 9).

2 History and characteristics of synthetic pyrethroids

Pyrethroids are fast-acting insecticides, with a so-called 'knock-down' effect, that are toxic to pest organisms at low doses/concentrations. They act on the nervous system of animals and disrupt the sodium channels in neurons by delaying the closure of the channel. This results in multiple action potentials firing in the nerve and causes neurological disruption (Maund et al., 2012; Singh et al., 2022; Ahamad & Kumar, 2023).

Pyrethroids exist as naturally occurring compounds and synthetic varieties. The former has been known since the 17th century when the insecticidal properties of wild *Chrysanthemum* flowers (formerly *Pyrethrum*) were discovered (Katsuda, 2012; Aznar-Alemany & Eljarrat, 2020a; Singh et al., 2022). These pyrethrins were extracted from dried flower heads and are still used. In the 20th century pyrethrin analogues were developed to make them more chemically stable. These are called synthetic pyrethroids. The relative photostability of synthetic pyrethroids allowed them to be used more easily outdoors such as in agriculture and for the control of vector organisms that spread diseases.

Synthetic pyrethroids have a high selectivity towards insects, i.e., their acute toxicity to pest organisms is much stronger than to mammals. Because of this, they were considered relatively safe for use by humans, and preferred over other less selective groups of insecticides such as organophosphates, carbamates and organochlorine compounds (Katsuda, 2012). However, recent studies in mammals report carcinogenic, neurotoxic and immunosuppressive properties, effects on lymphoid cells, the liver and the kidneys, and a potential for reproductive toxicity (Aznar-Alemany & Eljarrat, 2020a; Zhu et al., 2020). Synthetic pyrethroids are also very toxic to aquatic invertebrates and fish (Katsuda, 2012; Maund et al., 2012; Giddings et al., 2019; Ranatunga et al., 2023).

Synthetic pyrethroids were also considered to break down relatively quickly in the environment, mainly through photodegradation by light and biodegradation by organisms (Demoute, 1989). They are ‘hydrophobic’ or ‘lipophilic’, i.e., they have a high affinity for fat and bind to organic matter, suspended matter and sediment (Maund et al., 2012) where they may persist longer (Méjanelle et al, 2022). It was previously claimed that bioaccumulation in biota was limited by metabolisation (Maund et al., 2012). However, it is mentioned in the literature that the high toxicity of synthetic pyrethroids to fish is partly due to high gill absorption and slow hydrolytic detoxification (Yang et al., 2014). Moreover, evidence of their bioaccumulation in wildlife and humans has been reported in several studies reviewed by Aznar-Alemany & Eljarrat (2020b).

Synthetic pyrethroids are classified into two groups according to their toxicity and physical properties, namely Class I and Class II. Class I induce tremors and have no cyano group in the alcohol moiety. Class II induce seizures and do contain an alpha-cyano group in the molecule

(Maund et al., 2012; Gajendiran & Abraham, 2018; Singh et al., 2022; Ahamad & Kumar, 2023). See Appendix 1 for more information on these two classes of synthetic pyrethroids. Table 1 in Chapter 3 indicates to which class the synthetic pyrethroids further discussed in this report belong.

Most synthetic pyrethroids present different (stereo)isomers with different environmental metabolism (Katagi, 2012), biological activity and toxicity (Aznar-Alemany & Eljarrat, 2020a; Zhu et al., 2020). The insecticidal effect of pyrethroids in insecticidal products may be enhanced by adding piperonyl butoxide (PBO) or other compounds (e.g. Singh et al, 2022). Piperonyl butoxide inhibits enzymes that break down pyrethroids in the body such as in the liver.

3 Authorisation and use of synthetic pyrethroids in the Netherlands

3.1 Regulatory frameworks

Synthetic pyrethroids are used as pesticide for agricultural and non-agricultural use, and in human and veterinary pharmaceuticals. In the following sections we give a brief overview of the regulatory frameworks for these respective use categories.

3.1.1 Pesticides

Pesticidal products are designed to control harmful organisms. Pesticides for agricultural use are called 'plant protection products' (PPP) as the aim of these products is to protect crops, plants or plant products against plagues and pests. Pesticides that are used in non-agricultural applications are called 'biocides'. This also applies to pesticides that are used on farms, as long as they are not used to protect crops. Examples are disinfectants for milking parlours or insecticides to kill flies in stables. When an insecticide is used to treat animals, it is regulated as a pharmaceutical (see section 3.1.2).

For placing PPP or biocidal products on the Dutch market, manufacturers or importers need an authorisation (license) from the Board for the authorisation of plant protection products and biocides ('College voor de toelating van gewasbeschermingsmiddelen en biociden', Ctgb), which is the Competent Authority in the Netherlands. Authorisation is regulated by European law prescribing that all products must be evaluated regarding efficacy, and safety for men, animals and the environment. European legal acts are Regulation (EC) 1107/2009 for PPP[4], and Regulation (EU) 528/2012 for biocidal products[5]. The process consists of a two-step procedure: European approval of active substances and national authorisation of products.

3.1.1.1 European approval of active substances

PPP and biocidal products may only contain active substances that are approved at a European level. To get this approval, manufacturers must submit a dossier with information about efficacy, physical-chemical properties, environmental fate and behaviour, and potential effects on human health and non-target organisms. A risk assessment should be performed in which predicted exposure is compared with safe values (also called risk limits) for workers, the general population, and the environment. For European approval efficacy is evaluated and at least one safe use has to be demonstrated.

Approval is granted for 10 years, after which re-evaluation is needed and renewal may follow for another 15 years. For active substances that meet the criteria for exclusion or substitution (see section 3.1.1.3), the

[4] REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
[5] REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products

maximum approval period is five or seven years, and renewal can be granted for a period not exceeding seven years.

For PPP, the European Food Safety Authority (EFSA) is responsible for scientific advice to risk managers and the European Commission. Decisions on biocides approval are based on opinions of the Biocidal Products Committee at the European Chemicals Agency (ECHA).

3.1.1.2 National authorisation of products

Once an active substance is approved at the European level, the manufacturer or importer may seek authorisation in a European member state to place products with the active substance on the market. Authorisation can be sought for other uses than evaluated during the European approval process of the active substance. If a product is effective and safe, authorisation is granted, mostly for a 10-year period, after which renewal can be requested.

The risk assessment procedure for PPP and biocidal products is regulated in the European regulations mentioned in section 3.1.1. European law also regulates the combined authorisation of PPP in member states belonging to the same regional zone and the mutual recognition of authorisations among European member states, although there is some room for country-specific requirements. Not all biocidal active substances have yet been evaluated at a European level. Active substances for which approval is in progress may be used in biocidal products until a decision is made about approval or non-approval. Such products still need to be authorised by Ctgb pending European approval of the active substances.

More information on European active substances approval and national product authorisation can be found on the website of Ctgb and in the authorisations database ('Toelatingendatabank'[6]).

3.1.1.3 Criteria for exclusion and substitution

Active substances cannot be approved when meeting one of the exclusion criteria. This refers to substance that are classified as carcinogenic, mutagenic or reprotoxic (CMR) category 1A or 1B according to Regulation (EC) 1272/2008[7], endocrine disruptors, substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). Exceptions to these exclusion criteria are possible to a very limited extent. For PPP this involves situations in which a severe threat to plant health cannot be controlled in any other way. Such exceptions are not applicable to mutagenic, PBT- or vPvB substances. Exceptions for biocides are possible when there is a negligible risk from exposure (e.g. use in closed systems), when it is shown by evidence that the active substance is essential to prevent or control a serious danger to human or animal health or the environment, or when non-approval would lead to a disproportionate negative impact on society.

[6] https://toelatingen.ctgb.nl/en/authorisations
[7] REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Active substances are identified as 'Candidate for Substitution'(CfS) when two out of three PBT-criteria are met, i.e., when a substance is PB, PT or BT[8]. The substitution criterion is applicable to both PPP and biocides. Annex II of Regulation 1107/2009 lists some additional criteria for PPP, i.e., a relatively low Acceptable Daily Intake (ADI), Acute Reference Dose (ArfD) or Acceptable Operator Exposure Level (AOEL) for humans, a significant proportion of non-active isomers, or "reasons for concern linked to the nature of the critical effects (such as developmental neurotoxic or immunotoxic effects) which, in combination with the use/exposure patterns, amount to situations of use that could still cause concern, for example, high potential of risk to groundwater; even with very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones)" (Annex II, point 4). At the time of writing, eight synthetic pyrethroids allowed for use in the Netherlands are identified as CfS, among which esfenvalerate and lambda-cyhalothrin, which prompted this study (see further section 4.3).

3.1.2 *Pharmaceuticals*

Pharmaceuticals are officially referred to in legislation as 'medicinal products for human use' and 'medicinal products for veterinary use', abbreviated as HMP and VMP, respectively. VMP and HMP can get a market authorisation on a national or European level, but contrary to PPP and biocides there is no centralised European approval for *active substances* prior to product authorisation.

The body of European Union legislation in the pharmaceutical sector is compiled in Volume 1 and Volume 5 of the publication 'The rules governing medicinal products in the European Union'[9]. The basic legislation is supported by a series of guidelines that are published in other volumes of these Rules[10]. To obtain market authorisation, the manufacturer should submit a registration dossier with information on efficacy, risks and quality of the pharmaceutical.

Certain types of pharmaceuticals are subject to a centralised authorisation procedure. Such European market authorisations are granted by the European Medicines Agency (EMA), based on evaluations by the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP). National dossiers are evaluated by the Netherlands' Medicines Evaluation Board ('College ter Beoordeling van Geneesmiddelen', CBG) which issues national licenses. The website of CBG gives information on pharmaceuticals that are authorised for use in the Netherlands[11].

Since 2006, an environmental risk assessment addressing environmental fate and ecotoxicological effects has been included in the authorisation procedure for pharmaceuticals, and PBT-characteristics of the active substance are evaluated as well. The environmental risk assessment may consist of a simple screening, or a more elaborate assessment based on experimental data. A decision scheme and trigger

[8] By definition, active substances that meet the exclusion criteria but are approved by exception, are also CfS
[9] EudraLex - Volume 5 (europa.eu)
[10] https://health.ec.europa.eu/medicinal-products/eudralex_en
[11] https://www.cbg-meb.nl/

values are used to determine whether or not an extended assessment is needed. Products may thus be authorised without further environmental risk assessment. This applies to e.g. products for pets, or products with a low predicted environmental concentration.

The role of the environmental risk assessment in the authorisation differs between human and veterinary pharmaceuticals. A VMP will not be authorised when the active substance is identified as PBT. For non-PBT substances, the environmental impact is part of a risk-benefit analysis which may lead to non-authorisation or inclusion of risk mitigation measures in the use instructions. For HMP, however, environmental risks are not included in the risk-benefit analysis, but environmental impact may be reason to propose risk mitigation measures.

3.2 Approved substances, authorised products and uses

Table 1 presents an overview of synthetic pyrethroids that are allowed in Europe for use either in PPP, biocides, HMP or VMP. European approval of active substances is only applicable to plant protection products (PPP) and biocides. Table 1 shows also the number of products authorised on the Dutch market for each of the synthetic pyrethroids (status 28-08-2023). Synthetic pyrethroids that are not approved as PPP or biocide are not shown unless there is a use as HMP or VMP. Respective product groups are discussed in the following sections.

Please note that for three biocidal active substances the initial application for European approval is in progress. As indicated in section 3.1.1.2, national authorisations of products containing such active substances may still be in place until a decision is made about approval or non-approval.

3.2.1 Pesticides

Table 1 shows that 17 synthetic pyrethroids have a European approval for use as active substance in PPP and/or biocidal products. For three substances the biocidal approval procedure is in progress. For one substance (flumethrin) there is no approval as active substance in PPP and/or biocidal products, nor is a biocidal approval procedure in progress for this substance. However there are VMP with this substance making a total of 21 synthetic pyrethroids which could potentially be marketed in the Netherlands. Of these 21 active substances, 14 are indeed on the Dutch market, 2 solely for use in PPP, 6 solely as biocide and 2 solely in VMP. Four active substances are approved for multiple uses. Permethrin has the highest number of products, followed by tetramethrin and deltamethrin, but this is not necessarily associated with the use volume (see section 3.3).

In addition, there are seven approved substances without any national Dutch product authorisations. Because these substances are approved in Europe, manufacturers may submit an authorisation request for products based on these active substances in The Netherlands.

Information on the use of pesticides is given in sections 3.2.1.1 and 3.2.1.2.

Table 1 Overview of European approval status of synthetic pyrethroids and number of authorised products in the Netherlands. European approval of active substances is only applicable to plant protection products (PPP) and biocides, market authorisation of human or veterinary medicinal products (HMP, VMP) is done at product level. X = not approved, √ = approved, empty cell = no application for approval/no authorisation. Status August 2023.

Name	CAS	Pyrethroid class	European approval (active substances)		NL authorisation (products)			
			PPP	**biocide**	**PPP**	**biocide**	**HMP**	**VMP**
1R-trans-phenothrin	26046-85-5	I		√		13		
alfa-cypermethrin	67375-30-8	II	X	√		2		
cyfluthrin (beta-cyfluthrin)	68359-37-5	II	X	√				
cypermethrin	52315-07-8	II	√	√	2			1
cyphenothrin	39515-40-7	II		√				
deltamethrin	52918-63-5	II	√	√	12	15		17
d-tetramethrin	1166-46-7	I		initial application for approval in progress				
epsilon-momfluorothrin	1065124-65-3	II		√				
esfenvalerate	66230-04-4	II	√		2			
etofenprox	80844-07-1	I	√	√				
flumethrin	69770-45-2	II						8
gamma-cyhalothrin	76703-62-3	II	√					
imiprothrin	72963-72-5	I		√				
lambda-cyhalothrin	91465-08-6	II	√	√	10	3		
metofluthrin	240494-71-7	I		√		1		
permethrin	52645-53-1	I	X	√		84	3	54
prallethrin	23031-36-9	I		initial application for approval in progress		19		
tau-fluvalinate	102851-06-9	II	√					1
tefluthrin	79538-32-2	I	√		3			
tetramethrin	7696-12-0	I	X	initial application for approval in progress		34		
transfluthrin	118712-89-3	I		√		16		

3.2.1.1 Use as plant protection product

Synthetic pyrethroids in authorised PPP may be used on arable land, in vegetables and fruit, in horticulture, and cultivation of grass, herbs and mushrooms. They are used against many different insects, among which beetles, butterflies, caterpillars, lice and other invertebrates such as millipedes. Products may be applied outdoors and in greenhouses by spraying crops. PPP with cypermethrin, esfenvalerate and tefluthrin are only authorised for professional use, PPP with deltamethrin and lambda-cyhalothrin may also be used by non-professionals, e.g. in ornamentals, fruit and vegetable gardens. PPP with cypermethrin are currently only authorised for soil treatment and in-house post-harvest storage treatment, while PPP with tefluthrin are only authorised for seed treatment and in-furrow granule treatment.

3.2.1.2 Biocidal use

Biocides are classified into 22 product types (PTs), divided into four main groups: disinfectants, preservatives, pest control and other. All Dutch authorised biocidal products with synthetic pyrethroids belong to PT18 and are used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction. These products may be used against all kinds of insects, such as flies, moths, beetles, ants and wasps. Products may be authorised for professional use, such as anti-fly treatment in stables, but also for non-professional use in sprays, bait boxes and gels.

One of the synthetic pyrethroids, permethrin, also has authorisations in the Netherlands for use in PT8, for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. These products are intended to be used against woodworm, i.e., larvae of wood-eating beetles such as the longhorn beetle. Products with permethrin may be applied by dipping, spraying, or rolling for preventive and curative treatment, and may be used by professionals and non-professionals. Two other synthetic pyrethroids from Table 1, cypermethrin and etofenprox, are also approved in Europe for both PT8 and PT18, but there are currently no national authorisations in the Netherlands for biocides based on these active substances.

3.2.2 Pharmaceuticals

3.2.2.1 Use as veterinary medicinal products

Five synthetic pyrethroids are allowed for use in VMP. These products are mainly anti-parasitic products with permethrin or deltamethrin for treatment of cats and dogs against fleas and lice. These products for pets are often applied as a solution or spray on the animal, as collar or as shampoo. They are regulated as VMP because the purpose of treatment is animal health. Products that are intended to fight fleas in cat- or dog beds or on rugs are regulated as biocides. Apart from these uses for pets, some products with deltamethrin, cypermethrin and permethrin are authorised for use against flies, ticks and lice on cattle, sheep and lambs. These products are usually applied as a solution on the animals’ fur. Fluvalinate and flumethrin are authorised for varroa mite treatment in bee culture by means of strips that are placed in the beehive.

3.2.2.2 Use as human medicinal product

Permethrin is the only synthetic pyrethroid that is allowed to be used as HMP. It is applied against *Pediculosis pubis* and scabies. *Pediculosis pubis* (pubic lice; 'schaamluis' in Dutch) is a sexually transmitted disease caused by the parasite *Phthirus pubis*. Scabies ('schurft' in Dutch) is a contageous skin infection caused by the mite *Sarcoptes scabiei var hominis*. Scabies has been receiving media attention because of its increasing incidence, in particular, among teenagers and students[12]. Permethrin is applied as cream or gel.

3.3 Use volumes and sales data

3.3.1 Plant protection products

Figure 1 provides an overview of the annual sales from 2010 to 2020 of four active substances for which products are authorised as PPP in the Netherlands. The sales data concern only the use as PPP for professional use and range from 8,000 to 15,000 kg per year in total for these four compounds. For a fifth active substance, cypermethrin, no sales data are available (or it was not sold during the years included in Figure 1). Esfenvalerate and tefluthrin are only authorised as PPP, so for these compounds yearly sales represent the total use. Deltamethrin and lambda-cyhalothrin, however, are also marketed as biocide.

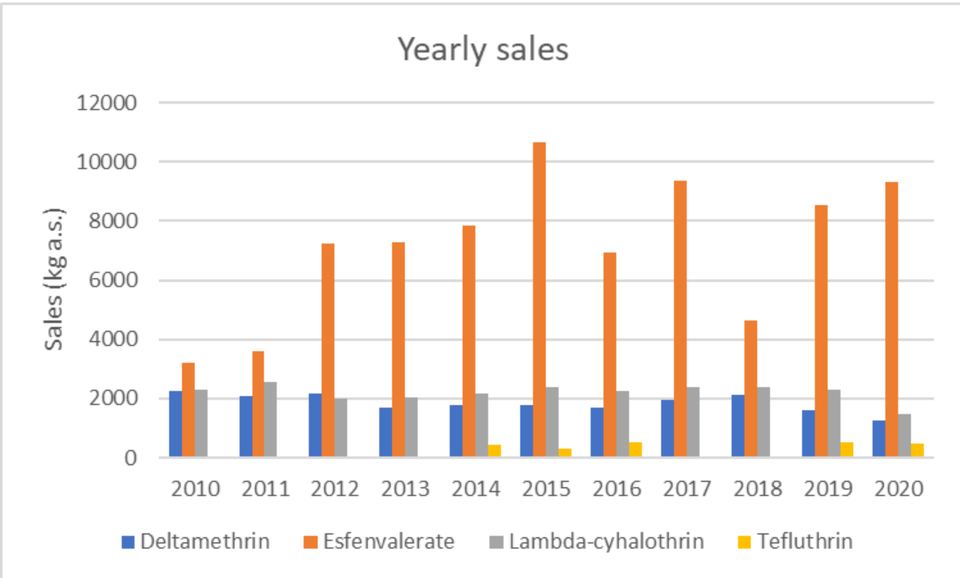

Figure 1 Yearly sales of four synthetic pyrethroids from authorised PPP in the Netherlands (in kg active substance). Sales data represent only the professional use. Source: [Afzetgegevens gewasbeschermingsmiddelen in Nederland | Publicatie | Rijksoverheid.nl](#).

3.3.2 Biocides

Data on sale and/or use of biocides in the Netherlands are not available. As an alternative, we received the total yearly sales data of synthetic pyrethroids in Belgium, see Table 2.

[12] https://www.nivel.nl/nl/nivel-zorgregistraties-eerste-lijn/actuele-weekcijfers-aandoeningen-surveillance

Table 2 Sales of biocides for professional and non-professional use in Belgium (kg active substance per year). Source: Federal Public Service (FPS) Health, Food Chain Safety and Environment.

	2018	**2019**	**2020**	**2021**	**2022**
Total synthetic pyrethroids	19,826	15,526	18,315	18,293	15,836

The sales data of the total synthetic pyrethroids in Belgium include the following synthetic pyrethroids of authorised biocidal products in Belgium: permethrin, cypermethrin, alpha-cypermethrin, deltamethrin, tetramethrin, cyfluthrin, empenthrin, cyphenothrin, 1R-trans phenothrin, esbiothrin, d-phenothrin, transfluthrin, prallethrin and lambda-cyhalothrin. Biocides based on the synthetic pyrethroids empenthrin, esbiothrin and d-phenothrin are no longer sold in Belgium because these substances are no longer permitted to be used in biocides (not approved).

Based on the populations differences between Belgium (11.5 million) and the Netherlands (17.5 million) we might expect larger sales volumes for biocides in the Netherlands, assuming that use habits are similar for both countries.

Please note that products imported from outside the EU may have been treated with biocides in the country of origin, e.g. impregnated clothes, carpets and rugs. The active substances used in these 'treated articles' should have European approval, but the products used for treatment need not to be authorised in the receiving member state. This implies that an unknown amount of biocides enters the Netherlands in the form of treated articles, which may contribute to emissions to surface water.

3.3.3 *Veterinary medicinal products*

Table 3 shows the annual sales figures of four synthetic pyrethroids in VMP (prescriptions only). No sales data are known for tau-fluvalinate. This substance is only contained in strips for Varroa mite control in beehives, and we do not expect any relevant emissions to the aquatic environment from this use. The sales of deltamethrin as a VMP are 100-500 kg per year, compared to ca. 1,000-2,000 kg per year in plant protection products. Since sales data could only be obtained as ranges, exact figures cannot be given. However, summing up the geometric means of the ranges per compound leads to an estimated total yearly sales volume of ~2,700 kg.

Table 3 Sales of veterinary medicines in the Netherlands (kg active substance per year). Source: FIDIN.

Active substance	**2017**	**2018 and 2019**	**2020**	**2021 and 2022**
Cypermethrin	0	<10	10-100	0
Deltamethrin	100-500	100-500	100-500	100-500
Flumethrin	100-500	100-500	100-500	100-500
Permethrin	1,000-5,000	1,000-5,000	1,000-5,000	1,000-5,000

3.3.4 *Human medicinal products*

Figures on the use of permethrin in the Netherlands as HMP can be found in the GIP database[13]. This database contains use data for prescription medicines in the Netherlands. Between 2018 and 2022, the number of users increased from over 29,000 to over 78,000. Over the same period the number of dispenses (‘uitgiftes’ in Dutch) increased more than threefold from nearly 42,000 to over 129,000 per year with a total of defined daily doses (DDD) rising from 2.2 to 7.2 million.

The definition of the DDD is not straightforward for creams or gels. Assuming a dose of 30 g cream for whole body treatment and a concentration of 50 mg permethrin per g cream, Moermond et al. (2020) calculated a DDD of 1500 mg active substance, and arrived at a total use of 3.3 tonnes permethrin in 2018 (2.2 million DDD x 1,500 mg a.s.). However, this would lead to an unrealistic high amount of cream issued per user and per dispense. It is more likely that the DDD corresponds with the strength of the cream and should be 50 mg active substance. In that case, the prescribed use in 2022 equals 362 kg permethrin.

As a cross check, we calculated the number of packagings issued per user and dispense. With a concentration of 50 mg a.s./g and a packaging size of 30 g, the revised total use of ~360 kg permethrin in 2022 corresponds with 3 tubes per user and 1.9 tubes per dispense event. This is realistic given the fact that patients have to apply skin treatment twice. Alternatively, assuming that two 30 g tubes with 50 mg a.s./g are issued per dispense, 129,020 dispenses in 2023 correspond with 387 kg permethrin.

It should be noted that these calculations only involve prescribed use. Permethrin is also freely available at pharmacies and drugstores without prescription, also referred to as ‘over the counter’ (OTC) use, and this is not included in these numbers. In addition, the number of patients with scabies continues to increase. This means that 360-390 kg is an underestimate of the actual use of permethrin as HMP.

[13] GIPdatabank.nl

4 Emission routes and environmental behaviour

4.1 Emission Routes

The way synthetic pyrethroids end up in surface water depends on how they are used. When it comes to environmental emissions, we usually distinguish between indirect and direct emissions. With indirect emissions a substance enters the environment after waste water treatment, which can be an on-site treatment or a municipal waste water treatment plant (WWTP). In the case of direct emissions, a substance ends up in the environment without any purification step in between, for example if a plant protection product blows over while spraying a field (drift) or it ends up in the ditch via drainage water. Table 4 summarises the potential emission routes to surface water for the synthetic pyrethroids that have products authorised in the Netherlands.

Table 4 Potential emission routes of synthetic pyrethroids used as plant protection products (PPP), biocides, or human and veterinary medicinal products (HMP, VMP).

Type of product	Route	Via	Examples*
PPP	direct	drift, drainage and leaching, run-off	spraying of arable fields and grasslands
	indirect	after on-site treatment or via municipal WWTP	discharge of waste water after application in greenhouses
biocide	direct	drainage after leaching from manure	use in stables
	indirect	sewage and WWTP	release from treated materials such as wood, carpets, dog beds or clothing
VMP	direct	rinsing from coat; leaching from faeces	treated dog that swims; cattle walking in the rain
	indirect	sewage and WWTP	washing of treated animals; washing of textiles that have been in contact with treated animals
HMP	indirect	sewage and WWTP	showering after skin treatment
	direct	rinsing from skin	swimming after skin treatment (not likely)

*based on e.g. Lahr et al. (2019), Monforts et al. (2021), Wezenbeek et al. (2021), Baas et al. (2022), Wenneker et al. (2022), Kools et al. (2023), Toolbox Emissiebeperking[14], Wezenbeek & Komen (2023).

[14] Toolbox Emissiebeperking (toolboxwater.nl)

4.2 Environmental fate and behaviour

This section gives a brief generic overview of the environmental behaviour of synthetic pyrethroids, although it is noted that properties may differ between individual substances. A full overview of fate and behaviour characteristics is not within the scope of this report. For substance-specific information the reader is referred to the European approval documents and associated lists of endpoints which are available via EFSA and ECHA.

Once released in the environment, synthetic pyrethroids are subject to various environmental processes. Originally they were thought to be very easily degraded in the environment (Demoute, 1989). However, at present, according to e.g. Méjanelle et al. (2022), they are recognised as a threat to nontarget species and ecosystem health and "their quasi constant emissions in urban and agricultural area (*sic*) may compensate for their degradation, therefore sustaining the occurrence and behaviour of some individual synthetic pyrethroids as 'quasi persistent organic pollutants". Note that this is not the same as a conclusion about persistence in a regulatory sense. See further section 4.3.

In the environment, depending on the environmental circumstances, synthetic pyrethroids are removed by photolysis (by light), hydrolysis (reaction with water) and or biodegradation (by microbes). Hydrolysis is stronger in alkaline environments than at acid or neutral pH values. Photolysis depends on the presence of (ultraviolet) light. Note that synthetic pyrethroids are specifically chemically altered in comparison to natural pyrethroids in order to make them environmentally stable enough for outdoor use in agriculture (Katsuda, 2012; Zhu et al., 2020). The photodegradation products of some synthetic pyrethroids such as cypermethrin may also be persistent and toxic (Zhu et al., 2020).

Due to their lipophilicity, most synthetic pyrethroids have a high affinity for organic matter. Once entering surface water, they are rapidly removed from the water phase, ending up in suspended particles or in the sediment (Katagi, 2012). The lipophilic properties of synthetic pyrethroids also mean that they are easily taken up by living matter such as in plants and aquatic organisms, i.e., they may bioaccumulate (also see section 4.3 and section 6.3). In these organisms, depending on the properties of the molecule and the organisms, they are further metabolised.

Synthetic pyrethroids have a low vapour pressure and do not have long residence times in air (Katagi, 2012). They may, however, be found in rain water (Katagi, 2012) and might be transported over longer distances following application (Méjanelle et al., 2022).

4.3 Persistence, Bioaccumulation and Toxicity (PBT)

Table 5 provides a summary of the conclusions regarding persistence (P), bioaccumulation (B) and toxicity (T) taken from European and national assessments of PPP and biocides, where available (see table footnotes). The criteria for PBT/vP/vB are laid down in Section 1 of Annex XIII to the REACH Regulation, but there are differences in the interpretation between regulatory frameworks. The table only presents active substances that are approved in Europe or for which the approval is in progress. Active substances without authorised products in the Netherlands are indicated with an asterisk.

Table 5 Summary of conclusions on PBT-properties of synthetic pyrethroids with a European approval (or approval in progress). P/vP = (very) persistent; B/vB = (very) bioaccumulative; T = toxic; CfS = Candidate for Substitution; Y = Yes, N = No, pot = potentially meeting criterion. PFAS = polyfluoroalkyl substance. Grey background: indicative assessment based on dossier data.

Name		**P**	**B**	**T**	**vP**	**vB**	**PBT**	**CfS**	**PFAS**	**Source[#]**
1R-trans-phenothrin		Y	N	Y	N	N	N	Y	N	CA/ECHA
alfa-cypermethrin		N	N	Y	N	N	N	N	N	CA/ECHA
cyfluthrin (beta-cyfluthrin)*		N	N	Y	N	N	N	N	N	CA/ECHA
cypermethrin		N	N	Y	N	N	N	N Y[a]	N	CA/ECHA EU PPP
cyphenothrin*	cis	Y	N	Y	N	N	N	N		CA/ECHA
	trans	N	N	Y	N	N	N			
deltamethrin		pot	N	Y	N	N	N	N N	N	CA/ECHA EU PPP
d-tetramethrin*		no dossier data available								
epsilon-momfluorothrin*		N	N	Y	N	N	N	N	N	CA/ECHA
esfenvalerate		N	Y	Y	N	N	N	Y	N	EU PPP
etofenprox*		N	Y	Y	N	N	N	Y	N	CA/ECHA
flumethrin		no dossier data available								
gamma-cyhalothrin*		N	Y[b]	Y	N	N	N	Y[c]	Y	EU PPP
imiprothrin*		N	N	Y	N	N	N	N	N	CA/ECHA
lambda-cyhalothrin		N	Y	Y	N	N	N	Y Y	Y	CA/ECHA EU PPP
metofluthrin		[d]	N	Y	[d]	N	N	N	N	CA/ECHA
permethrin		Y	N	Y	N	N	N	Y	N	CA/ECHA
prallethrin		N	N	Y	N	N	N	N	N	Ctgb[e]
tau-fluvalinate		needs attention, T fulfilled, B borderline						N	Y	EU PPP
tefluthrin		needs attention (Smit & Keijzers, 2022)						N	Y	EU PPP
tetramethrin		N	N	Y	N	N	N	N	N	Ctgb[f]
transfluthrin		[g]	N	Y	[g]	N	N	N	N	CA/ECHA

*: active substances without authorised products in the Netherlands

#: CA = Information of the Competent Authority meeting on approved active substances with regard to certain exclusion/substitution criteria[15]; ECHA = European approval documents for biocides; EU PPP = European Pesticides Database, based on Regulations (EU) 2015/408 and 540/2011, Part E; Ctgb = Ctgb decisions
a: significant proportion of non-active isomers, see Regulation (EU) 2021/2049
b: bioconcentration factor (BCF) in PPP dossier based on read across with lambda-cyhalothrin
c: low ARfD/AOEL, see Regulation (EU) 2020/1295
d: inconclusive
e: based on information from authorisation decision for registered product 14480 N and draft European biocides dossier
f: based on authorisation decision for registered product 8214N and internal evaluation by RIVM
g: metabolites (potentially) meeting criterion

[15] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/7149b88b-d49c-4f42-ae76-0e37f1aeafb0/details

The information on the status as Candidate for Substitution (CfS; see also 3.1.1.3) as presented in Table 5 is based on official documentation. For approved biocides, the PBT-conclusions are included in the assessment reports on the ECHA website. For esfenvalerate, the identification as BT-substance is included in Regulation (EU) 2015/2047. For other PPP, however, the available EFSA conclusions do not include formal documentation on the individual PBT-criteria and overall conclusions were therefore taken from the European Commission's Pesticides Database. For gamma-cyhalothrin (CfS because of human toxicity), tau-fluvalinate and tefluthrin (not CfS) the information on individual PBT-aspects in Table 5 is based on a quick scan of the List of Endpoints by RIVM. For d-tetramethrin and flumethrin, no dossier data could be retrieved. Note that the information in the table should not be considered as a formal PBT-assessment, the actual status should be checked in the appropriate sources.

From Table 5 it is clear that all synthetic pyrethroids meet the criterion for toxicity, this is because the No Observed Effect Concentration (NOEC) or 10% Effect Concentrations (EC_{10}) for aquatic organisms is lower than the trigger of 0.10 mg/L. The majority of approved substances does not meet the triggers for persistence and bioaccumulation. Of the five synthetic pyrethroids currently with authorised PPP in the Netherlands, cypermethrin, esfenvalerate, and lambda-cyhalothrin are assigned as CfS. For cypermethrin, this is due to a significant proportion of non-active isomers, while for the other two compounds the CfS-status is based on their B and T-status[16].

Four of the 21 pyrethroids listed in Table 5 are meeting the OECD definition[17] of PFAS. Two of those PFAS-pyrethroids, gamma-cyhalothrin and lambda-cyhalothrin are Candidates for Substitution, which means that during authorisation of PPP and biocides alternatives should be considered. The other two PFAS-pyrethroids are tau-fluvalinate and tefluthrin, which are not CfS at the moment. This means that there is presently no incentive to consider alternatives. For more information about PFAS in pesticides, see chapter 5 in Komen & Wezenbeek (2022)[18].

In summary, eight of the 21 synthetic pyrethroids allowed for use in Europe are assigned as 'Candidate for Substitution' (CfS), mostly due to meeting two of the PBT-criteria. Among these are esfenvalerate and lambda-cyhalothrin, two of the three compounds that prompted this study. All synthetic pyrethroids meet the T-criterion because of their high toxicity to aquatic organisms.

[16] Note that a recent Dutch report incorrectly states that the CfS-status of cypermethrin and esfenvalerate is withdrawn (Natuur & Milieu, 2023). These compounds were removed from the first list of CfS in Regulation (EC) 2015/408 because they were included in the list of CfS in Part E of Regulation 540/2011, making their appearance in the former regulation obsolete, see also https://food.ec.europa.eu/plants/pesticides/approval-active-substances_en
[17] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf
[18] Tau-fluvinate is incorrectly missing in table 7 of Komen & Wezenbeek (2022).

4.4 Emissions to surface water – plant protection products

4.4.1 Emission registration

Figure 2 presents the estimated yearly emissions of PPP to surface water according to the Dutch Emission Registration[19]. Data are presented for three substances for which products are authorised in the Netherlands (deltamethrin, esfenvalerate, lambda-cyhalothrin). The emissions shown for these three compounds are almost entirely due to drift into surface waters and not to drainage or to use in greenhouses (surface runoff is not included in the model calculations). Data for cypermethrin and tefluthrin are not available.

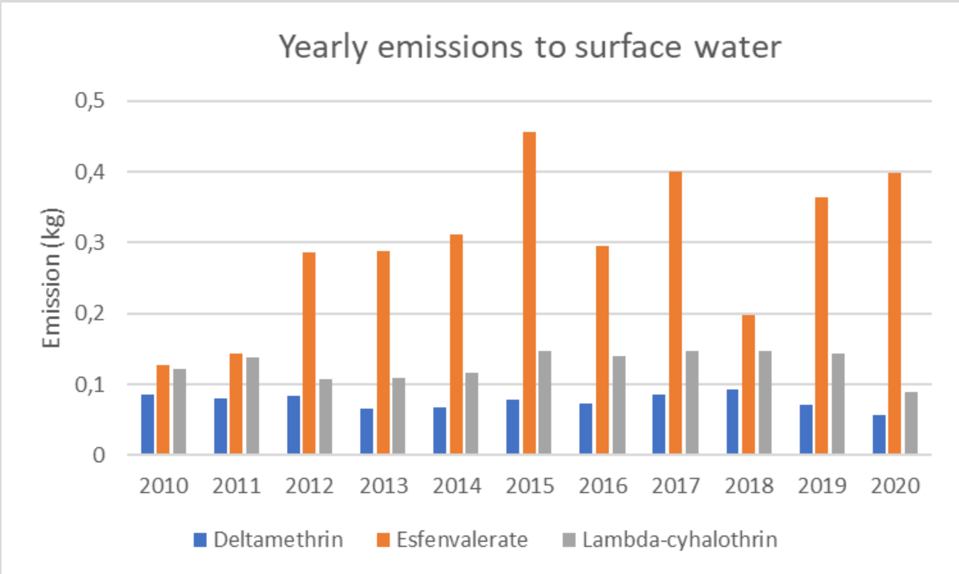

Figure 2 Estimated total annual national emissions to surface water of synthetic pyrethroids sold as plant protection products for professional use in the Netherlands. Based on the source data of the Emission Registration[20], estimates based on the NMI4 model[21].

4.4.2 Calculations with the national Environmental Indicator (NMI)

For three synthetic pyrethroids used in plant protection, the relative contribution of different crop systems to their usage, emissions to surface water and impact was obtained according to NMI estimations for 2016. Figures with the results are shown in Appendix 2.

For deltamethrin more than 80% of the usage is in four crop types: arable fields, flower bulbs, nurseries, and flowers under glass. The emissions and estimated environmental impact in surface water, however, is attributed to its use in arable fields, flower bulbs and nurseries only.

For esfenvalerate the usage, emissions to surface waters and the impact in surface waters originates almost entirely from application in arable fields and flower bulbs.

[19] https://www.emissieregistratie.nl/
[20] https://www.emissieregistratie.nl/
[21] https://legacy.emissieregistratie.nl/erpubliek/documenten/06%20Water/01%20Factsheets/Bestrijdingsmiddelengebruik%20bij%20landbouwkundige%20toepassingen.pdf

For lambda-cyhalothrin usage, emissions, and impact can largely be attributed to its use in arable fields, flower bulbs and vegetables grown in the field.

4.5 Emissions to surface water – other products

4.5.1 Biocides

There is no registration in the Netherlands of sales or use volumes of biocides. In the absence of adequate data, it is not possible to estimate emissions, like for PPP in the Emission Registration. In addition, current monitoring programs are not specifically targeted to biocide use (Wezenbeek et al., 2021; see also Chapter 6).

The environmental risk assessment procedure for European approval and national authorisation does include emission estimates. Initial release of substances from biocidal products (or treated materials) to the environment are estimated using Emission Scenario Documents (ESD) and Technical Agreements on Biocides (TAB). Using the estimated emissions, predicted environmental concentrations (PEC) are derived for the local receiving surface water.

The European assessment reports for active substance approval on the public ECHA website may thus give an indication of the environmental concentrations to be expected. It should be noted, however, that the environmental risk assessment of biocides is based on generalised scenarios and models that are developed to support harmonised regulatory decision making across Europe. In the absence of (prospective) sales data, assumptions are made on the market share of a certain insecticide as compared to alternative substances. Aggregated use of the same active substance for different products and uses is only taken into account to a limited extent. Moreover, the European assessments do not necessarily include the products and uses currently authorised on the Dutch market. Collecting emission estimates and PECs would therefore require that individual national authorisation reports from Ctgb are consulted. This is a major effort that is outside the scope of the present report, but it may be considered to run a pilot on selected active substances.

4.5.2 Veterinary medicinal products

Baas et al. (2022) collated existing knowledge on anti-parasitic drugs and water quality in the Netherlands, including some synthetic pyrethroids. They state that knowledge is lacking on emissions of VMP and if their use leads to increased risks for the aquatic environment, but indicate that unwanted effects are to be expected when these substances enter the environment. Similar conclusions were drawn earlier by Lahr et al. (2019) and Montforts et al. (2021) in their overviews on environmental aspects of VMP.

Reversed calculations for deltamethrin and permethrin indicate that emissions of <10% of the sales volume to surface water would be sufficient to exceed the environmental risk limit or EQS (Montforts et al., 2021; Kools et al., 2023). This estimation is based on highly generalised assumptions about use, removal in the WWTP and dilution into surface water, and is thus subject to uncertainty. Still, additional information on excretion by pets and emissions by e.g. washing of dogs, indicate that 10% emission of the total use volume is realistic (Kools et al., 2023). This implies that emissions of VMP may potentially lead to exceedance of water quality standards, at least on a local scale. However, like for biocides, there are no monitoring programs specifically focused on the use of VMP, and it is not possible to relate water quality data to the use as VMP (Lahr et al., 2019; see also Chapter 6).

4.5.3 *Human medicinal products*

For HMP in principle the same applies as for biocides and VMP: it is difficult to make emission estimates for specific substances, in particular when a substance is also used for other purposes. Moermond et al. (2020) estimated that the use of permethrin as HMP resulted in a yearly emission to surface water of 1260 kg, based on a yearly use of 3.3 tonnes in 2018, 95% loss after application and a default 60% removal efficiency from waste water.

As explained in section 3.3.4, the estimated use of 3.3 tonnes is likely based on a misinterpretation of the defined daily dose (DDD). New calculations result in an estimated use of 360-390 kg in 2022 (prescribed use only). Excretion was potentially underestimated in Moermond et al. (2020) because an excretion percentage of ≥99% may be assumed based on dermal absorption of c. 0,5-1%[22] mentioned in the SmPC (Summary of Product Characteristics) for permethrin. If all residual permethrin is discharged to the sewer upon showering, this would imply that at least 360 kg permethrin is discharged to the sewer.

Measurements in influent and effluent of waste water treatment plants indicate that removal efficiency of permethrin is close to 100% (see section 6.2.3). Assuming 95% removal efficiency as a realistic worst case, the yearly emission to surface water resulting from prescribed use is estimated as ~20 kg. It should be noted that this does not include OTC use without prescription, neither direct emissions to surface water upon swimming. However, it is not considered likely that after scabies treatment people will go out swimming without showering first to remove the cream.

[22] https://www.geneesmiddeleninformatiebank.nl/smpc/h131403_smpc.pdf

5 Environmental effects and regulatory thresholds

5.1 Ecotoxicity of synthetic pyrethroids

Synthetic pyrethroids are designed to control insects, mites and other invertebrate pest organisms. Therefore, it can be expected that taxonomically related water organisms are sensitive as well. Indeed, it has been demonstrated in many laboratory and field studies that synthetic pyrethroids are highly and acutely toxic to aquatic arthropods. Fish, molluscs and amphibians appear to be sensitive as well (e.g. Maund et al., 2011; Giddings et al., 2019; Zhu et al., 2020; Ranatunga et al., 2023).

Based on a large dataset with ecotoxicity studies with synthetic pyrethroids, Giddings et al. (2019) conclude that the ecotoxicity profiles of synthetic pyrethroids are reasonably consistent, when looking at the relative sensitivity of different taxonomic groups. Overall, crustaceans and insects are most sensitive, followed by fish, amphibians and molluscs, although data for the latter two groups are scarce. Effects on aquatic invertebrates such as crustaceans often occur at concentrations far below 1 µg/L, i.e., in the low ng/L or even pg/L range (Maund et al, 2011; Giddings et al., 2019; Ranatunga et al., 2023).

It is recognised that sediment is part of the aquatic ecosystem and the impact on sediment inhabiting species may be an important aspect because of the affinity of synthetic pyrethroids for organic matter, suspended particles and sediments. Although regulatory testing of biocides and PPP involves studies with sediment-dwelling organisms, there still is limited information on the sediment-based toxicity of synthetic pyrethroids (Ranatunga et al., 2023). Nonetheless, based on a meta-analysis of >800 literature studies with monitoring data from >2500 sites in 73 countries, Stehle & Schulz (2015) showed that sediment thresholds may be exceeded in a large proportion of cases. Méjanelle et al. (2020) state about synthetic pyrethroids that “their residual occurrence in sediments is presently recognised as a threat to diversity of sediment-dwelling invertebrates and also as the cause of a decrease of diversity in aquatic environments at a global scale”. However, monitoring of synthetic pyrethroids in suspended matter or sediment is not performed on a regular basis in the Netherlands, and it is not possible to make a comparison between actual exposure and effect values. Therefore, the information in this chapter is focused on the water phase.

The next sections give an overview of the regulatory thresholds for synthetic pyrethroids in surface water, and discuss the differences between regulatory frameworks. Lastly, two points of attention are raised and discussed, namely differences between dissolved and total concentrations and mixture effects.

5.2 Authorisation criteria and water quality standards

5.2.1 Overview of existing authorisation criteria and water quality standards

For synthetic pyrethroids with European approval or approval in progress (status 28-08-2023), Figure 3 gives a graphical display of the current authorisation criteria ('toelatingscriteria') for PPP and biocides, and water quality standards as derived in the context of European and national water quality policy. The figure shows four different values, where available:

- Regulatory Acceptable Concentration (RAC) for PPP,
- Predicted No Effect Concentration (PNEC) used as authorisation criterion for biocides,
- European Water Framework Directive (WFD) standard for chronic exposure (annual average environmental quality standard; AA-EQS), and
- Netherlands' national water quality standard (AA-EQS or formerly derived Maximum Permissible Concentration, MPC; some of these are indicative values).

The WFD also uses the Maximum Acceptable Concentration EQS. The MAC-EQS is based on short-term toxicity data and intended to assess the acute effects of short term exposure peaks. The MAC-EQS is less relevant in the context of this comparison, but is used in Chapter 6 for comparison with monitoring data.

Underlying data and their sources can be found in Appendix 3. Bifenthrin does not have a European approval, but is added to the table since the European Commission proposed to list it as a priority substance under the WFD[23], based on a comparison of monitoring data with the proposed EQS. It should be noted that the use of bifenthrin-based biocidal products in the Netherlands has expired; detection in surface water is a result of historical use as wood preservative.

PNECs used for the authorisation of pharmaceuticals are not included in the overview because they are not derived, nor documented in a centralised way and may differ depending on the product and dossier submitted. To retrieve these PNECs, authorisation dossiers would have to be checked separately, which was not feasible in the context of this report. In the context of the European PREMIER project[24], efforts are currently made to collect and publish PNECs for HMP in a public database which will include the values used for authorisation.

Figure 3 clearly shows that there are large differences in acceptable concentrations between frameworks. There are various reasons for this, which is further explained in the next sections.

[23] https://environment.ec.europa.eu/publications/proposal-amending-water-directives_en
[24] https://imi-premier.eu/

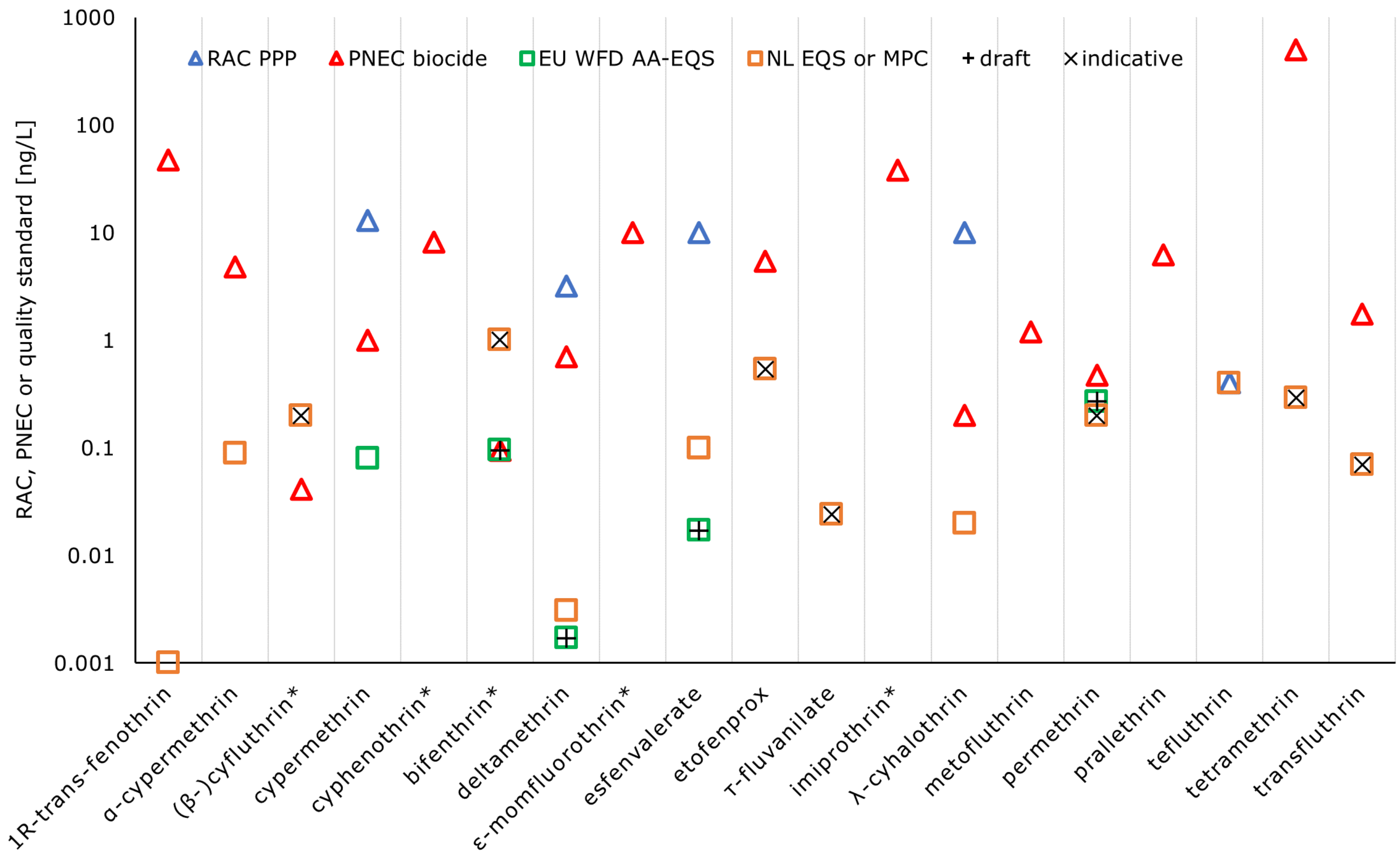

Figure 3 Overview of existing authorisation criteria for synthetic pyrethroids in plant protection products (RAC PPP, blue triangle) and biocides (PNEC, red triangle), European water quality standards (WFD AA-EQS, green square) and national water quality standards (NL EQS or MPC, orange square). Draft European WFD-EQS are indicated with a plus-sign, formerly derived (indicative) Maximum Permissible Concentrations (MPC) with a cross. The Y-axis gives the values in ng/L on a logarithmic scale, distance between two lines is a factor of 10 difference. Active substances without authorised products in the Netherlands are indicated with an asterisk. Data from Appendix 3.

5.2.2 *Differences between authorisation criteria and EQS*

Authorisation criteria for PPP, biocides and pharmaceuticals (RAC, PNEC), and surface water quality standards (EQS, MPC) represent concentrations of a substance in surface water below which unacceptable ecotoxicological effects are not expected. They are derived using experimental data on the effects of active substances on water organisms such as water fleas, fish, algae, and aquatic insects.

Assessment factors are applied to extrapolate the results of these tests to concentrations that ensure protection of the ecosystem. The choice of the assessment factor depends on the duration of the tests, and the taxa and number of species tested. The assessment factor should be sufficient to cover residual uncertainty in the effects assessment.

Despite this shared principle of extrapolating experimental ecotoxicity data to safe concentrations for the ecosystem, there are large differences between frameworks, as the data in Figure 3 clearly show. This does not come as a surprise, since differences between frameworks have been evaluated in earlier studies (e.g. Brock et al., 2011; Smit et al., 2013; Van Dijk et al., 2021).

For those compounds for which a comparison can be made, PPP-RACs are orders of magnitude higher than EU or national water quality standards, while the biocides-PNEC is in between. The most obvious case is deltamethrin, for which the PPP-RAC is a factor of ~1,900 higher than the proposed WFD-EQS. For esfenvalerate and cypermethrin the differences amount to 590 and 163, respectively. The exception is tefluthrin, for which the PPP-RAC and the Dutch indicative water quality standard are the same. For the same substances, the biocide-PNEC is a factor of 4.6 to 50 lower than the PPP-RAC. The difference between the biocides-PNEC and WFD-EQS ranges from a factor of ~74 for permethrin to ~400 for deltamethrin.

Differences with formerly derived (indicative) MPC (crossed orange symbols in Figure 3) should be considered with care since data collection and methodology are outdated. However, experience with recent evaluations shows that updated EQS will not necessarily be more in line with authorisation criteria, although they do provide a better scientific basis to draw conclusions on water quality.

The observed differences are in accordance with Van Dijk et al. (2021) who compared lower tier regulatory thresholds of 65 substances evaluated in multiple frameworks, and showed that thresholds between those frameworks differed by a factor of 1 to 5,625, with a median difference of 3.6. Differences are partly explained by the fact that frameworks use different datasets, which is due to differences in data access and/or the time of derivation. For instance, some of the national quality standards were derived decades ago when access to European PPP evaluations was not possible and an indicative MPC was derived from limited acute ecotoxicity data. However, there are also more fundamental differences between frameworks concerning the evaluation and use of underlying studies and how data are processed and used.

When considering the methodology used for derivation of environmental risk limits, a distinction can be made between biocides, pharmaceuticals and WFD water quality standards on the one hand, and PPP on the other hand. The first group builds on guidance developed under the European legislation for industrial chemicals (REACH) and preceding legislation, while guidance for PPP has been developed separately using a different approach. An in-depth analysis of the PPP and WFD frameworks was made about 10 years ago and is illustrated with case studies (Brock et al., 2011; Smit et al., 2013). Although methodological changes have been implemented in both frameworks since then, the overall picture is still valid. More recent discussions on the differences between regulatory frameworks can be found in Gustavsson et al.(2017) and Van Dijk et al. (2021). In the following sections we briefly summarise some of the main aspects.

5.2.2.1 Biocides, pharmaceuticals, water quality standards

The aquatic effects assessment for authorisation of biocides and pharmaceuticals, and methods for derivation of European and national water quality standards are all based on the guidance for risk assessment of industrial chemicals as developed by the European Chemicals Agency (ECHA) in the context of REACH[25]. As a result there are many common elements in the derivation of a PNEC for biocides and pharmaceuticals, and European and national EQS for surface water, but Figure 3 shows clear differences as well. As mentioned in section 5.2.2, this may be partly explained from differences in data access, which is explained below.

Active substance approval of biocides and pharmaceuticals is mainly based on industry studies performed by laboratories that are specialised in performing standard tests for regulatory purposes. There is also an option to include open literature. However, systematic literature searches and evaluation of potentially relevant open literature are not included by default in the industry submissions, at least this is not apparent from the public versions of the approval reports. Dossier studies cannot be accessed for other purposes without permission of the owner, and publicly available regulatory documents for biocides generally only mention the key data used for PNEC-derivation without full details. It should be noted that the European risk assessment reports for PPP, made available by EFSA, generally include extensive study summaries, which enables their use for EQS derivation if the level of detail is sufficient. In general, the use of regulatory data for other purposes is thus easier for PPP than for biocides. Depending on individual agreements, industry parties may also be willing to share data for European or national EQS-derivation, but this is not a general obligation.

Due to limited access to regulatory data, there is a tendency that derivation of EQS for biocides is based on open literature, leading to differences in underlying datasets. This is especially true for substances that are subject of intensive scientific research for which more open literature studies are available. Besides, EQS derivation focuses on data for active substances rather than products, because it is anticipated that

[25] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

the formulated product will not be present in its original form after entering the environment. Instead, authorisation criteria for PPP may be based on studies with formulated products, especially in case of a higher tier assessment.

Taken together, these aspects may all contribute to a situation in which datasets for the same substance differ between regulatory frameworks. This will potentially lead to different outcomes even when methods are basically comparable, which is illustrated by comparing the biocides-PNEC with the WFD-EQS. In addition it has to be noted that even with the same method and same studies, differences may occur because individual experts may have different opinions on the reliability and relevance of individual studies. In this context, several initiatives have been raised to develop guidance for the evaluation of ecotoxicity studies (Moermond et al., 2016; Lahr et al., 2023). Finally, there may be differences among experts as to whether residual uncertainty is sufficiently covered, and different assessment factors may be proposed.

5.2.2.2 Plant protection products

The approval and authorisation of PPP uses specific methods developed by the European Food Safety Authority (EFSA), which differ from those for biocides, pharmaceuticals, and water quality standards in a number of aspects. The main difference is that PPP authorisation follows a tiered approach, in which primary producers, invertebrates and fish are evaluated separately and acute and chronic RACs are derived per taxonomic group. For those taxa that do not pass the first tier, a refined 'higher tier' assessment can be performed by testing additional species from the sensitive taxa and taking the geometric mean or using statistical extrapolation for that particular species group. Another option is to perform mesocosm experiments (EFSA, 2013).

In the other frameworks (biocides, pharmaceuticals, WFD), data for different trophic levels and taxonomic groups are combined into one dataset and an assessment factor is applied to the lowest value. A refined effects assessment is usually performed taking all species into account rather than focusing on a specific species group, e.g. in line with the REACH-guidance, statistical extrapolation requires a prescribed set of different taxa and is not performed to fish or arthropods separately. Geometric mean values from different tests are only calculated for the same species, and not for different species within a taxon (ECHA, 2008; EC, 2018).

The 1st tier PPP assessment is related to the maximum predicted exposure concentration for a specific application. Options for refinement include modified exposure tests in the lab which mimic the application pattern of a PPP, and semi-field studies simulating the effects in an edge-of-field ditch after PPP application. According to EFSA (2013) short-term effects may be accepted in the approval of PPP under certain conditions if potential for population recovery within an ecologically relevant time period is demonstrated considering the appropriate exposure profile. The other frameworks use effect values in a generic way to derive safe values for aquatic ecosystems for long term exposure, or short term peak exposure, without acceptance of any effects. According to information from Ctgb, recovery is generally not included anymore in the risk assessment for PPP, although it may be considered in certain cases. The PPP-RACs for deltamethrin, esfenvalerate and lambda-cyhalothrin are based on semi-field experiments, but we could not check in detail if recovery was taken into account.

Van Dijk et al. (2021) conclude that assessment factors used for the PPP first-tier RAC are generally lower than for other frameworks, which can be explained by the different assessment schemes. In addition, the use of different approaches and dedicated studies in higher tier PPP risk assessment may lead to further divergence between frameworks. Semi-field studies may give valuable information on the risks for sensitive species groups in edge-of-field waters resulting from a particular PPP-application, but are hardly transferable to other exposure situations, such as emissions of biocides via sewage treatment plants. Modified exposure studies and mesocosm experiments submitted for PPP risk assessment are, therefore, often not considered suitable for PNEC or EQS derivation. The data for synthetic pyrethroids confirm this conclusion. As indicated above, the RACs for deltamethrin, esfenvalerate and lambda-cyhalothrin are based on semi-field studies, whereas the biocides-PNECs and water quality standards are based on single-species laboratory data.

5.2.3 Dissolved or total concentrations

Another point of attention is that European and national WFD-standards are legally considered as total concentrations, without filtration to remove suspended matter, whereas from a scientific point of view they are considered as dissolved concentrations. This is related to the incorrect interpretation of effect values in previous versions of the European WFD-guidance (Lepper, 2005; EC, 2011). The updated version of 2018 explicitly states that derived quality standards are expressed as dissolved concentrations. This is because bound chemicals are less bioavailable, and uptake and effects are associated with the dissolved fraction. Standard laboratory toxicity and bioconcentration tests contain low levels of total organic carbon (TOC) in the test system, and the resulting EQS therefore refers to dissolved concentrations (EC, 2018).

According to the WFD-guidance it follows that compliance assessment should ideally be based on the sampling and analysis of the dissolved fraction in the water column, similar to the way the PNEC is used under REACH (EC, 2018). In line with this, the opinions of the SCHEER (Scientific Committee on Health, Environmental and Emerging Risks)[26] on the draft EQS for priority substances recalculated the proposed EQS to total concentrations. The difference in interpretation regarding dissolved or total concentrations leads to the situation that for bifenthrin the biocides-PNEC and the draft WFD-EQS of 0.095 ng/L are based on the same study with the same assessment factor, but are compared with either dissolved (biocides) or total (WFD) environmental concentrations.

Measuring concentrations in unfiltered samples potentially overestimates the dissolved concentration, since extraction and analysis include the

[26] SCHEER - Opinions (europa.eu)

fraction that is bound to suspended matter. This may become an issue for synthetic pyrethroids that strongly bind to organic matter (log K_{oc} 5 or higher). In this case, monitoring of total concentrations may result in false positives, because ecotoxicological effects for organisms in the water phase can generally be attributed to dissolved concentrations. It should be noted, however, that actual suspended matter concentrations in the field may be variable. Moreover, for strongly sorbing and relatively toxic substances like deltamethrin it is very hard to adequately measure dissolved concentrations in aquatic ecotoxicity tests and it is difficult to establish whether the ecotoxicological effects assessment and proposed EQS really represent dissolved concentrations. In case of non-compliance with the WFD-EQS, it is advised to consider if correction for the actual suspended matter concentration is applicable and would change the conclusion. Biota measurements may be helpful to increase insight into the bioavailability of dissolved synthetic pyrethroids to aquatic organisms (see also section 6.3).

5.2.4 Mixture effects

Water quality standards are derived for single substances and do not take account of mixture effects. The same holds in general for the authorisation of PPP and biocides, although mixture toxicity is taken into account when substances are part of the same formulated product or when for tank mixes the use of another product is prescribed on the label. The absence of a mixture assessment has been recognised since long as a serious omission of chemicals legislation (e.g. Syberg et al., 2009; Kortenkamp et al., 2019). In view of the common mode of action of synthetic pyrethroids it would be advisable to consider mixture toxicity, because otherwise the environmental risks are likely underestimated. The EQS-dossiers prepared in the context of revision of the WFD refer to three options:

1. A pragmatic and simple way would be to sum-up risk quotients, i.e., to calculate the sum of the ratios between predicted or measured concentrations and the PNEC or EQS. This option is in accordance with the methods of Backhaus et al. (2013) for biocides. However, for a number of compounds analytical methods are not adequate to detect them at the level of the PNEC or EQS, and for these non-evaluable substances it is not possible to derive risk quotients at all (see also section 6.1.1).
2. Another option is to consider the derivation of an EQS for the group of synthetic pyrethroids as a whole. This may be done by considering the relative potency of individual synthetic pyrethroids as compared to a reference toxicant. The data of Giddings et al. (2019; see section 5.1) may be further explored for this purpose.
3. A third option could be to use effect based methods (EBM), but it is indicated that it is difficult to select an EBM that specifically detects the presence of synthetic pyrethroids in water (Napierska et al., 2018). The recent review of Ahamad & Kumar (2023) suggests that specific biosensors may be available, but reported detection limits would probably still be too high to detect synthetic pyrethroids at concentrations relevant for aquatic risk assessment.

Another issue which is relevant in the context of mixture toxicity, is the use of piperonyl butoxide (PBO) in products with synthetic (and natural) pyrethroids. PBO is used in PPP to enhance the effectiveness by inhibition of cytochrome P450 activity, thereby slowing down insecticide degradation and prolonging the effective time of the active substance. Existing PNEC and EQS values, however, are based solely on data for the active substances, and these might be underprotective when in surface water residues of PBO are present in combination with synthetic pyrethroids.

Authorised biocidal products in the Netherlands with PBO only concern combinations with the pyrethrins and chrysanthemum extracts, there are no authorisations for biocides with a combination of PBO and synthetic pyrethroids. For PPP there are four authorised products with a combination of synthetic pyrethroids and PBO. These products with cypermethrin or deltamethrin are used for treatment of cereals in storage and cereal storage places. In theory, this application should not lead to emissions to surface water, although runoff from properties cannot be excluded. In 2020-2021, PBO was detected in 6 out of c. 11,000 surface water samples in concentrations between 0.18 and 0.4 µg/L (Keijzers & Postma, 2023). It is not possible to draw conclusions on whether this is associated with natural or synthetic pyrethroids, nor whether this is due to biocidal or agricultural use.

It is recognised that implementing mixture toxicity requires a change in some fundamental starting points of regulatory risk assessment, as current authorisation procedures are based on the assessment of individual products for specific uses. However, achievements of EFSA in the context of human risk assessment of PPP show that progress can be made.[27]

[27] see Chemical mixtures | EFSA (europa.eu)

6 Monitoring data from the Netherlands

In this chapter, different data sources will be compared to gain a better understanding of the occurrence of synthetic pyrethroids in waters and some of the routes of synthetic pyrethroids to the aquatic environment.

6.1 Surface water

To assess the occurrence of synthetic pyrethroids in surface water, data from the 'Pesticide Atlas' (Atlas bestrijdingsmiddelen in oppervlaktewater[28]) are used. The 'Pesticide Atlas' includes all surface water monitoring data for pesticides for the Netherlands, including the WFD-monitoring locations (413 locations), the 'National monitoring network for plant protection products' (Landelijk Meetnet Gewasbeschermingsmiddelen[29], 106 locations) and the drinking water intake points (9 locations). The measured concentrations are evaluated against the different EQS and RAC[30].

It should be noted that monitoring of pesticides of surface waters in the Netherlands has historically been focused on PPP. The monitoring locations covered in the Pesticide Atlas are therefore strongly associated with crop protection.

6.1.1 Comparison with water quality standards and authorisation criteria

Available data from 2010 to 2021 for synthetic pyrethroids were compiled and compared with existing water quality standards and authorisation criteria per substance, per location. These comparisons are called compliance checks. However, these are not formal compliance checks conducted for WFD reporting purposes. The total dataset comprised of in total 1,266 monitoring locations and 84,016 comparisons. A summary of the evaluated data for every substance is provided in Appendix 4.

Figure 4 presents the comparison of monitoring data with the AA-EQS and MAC-EQS. For the AA-EQS the annual average per location per year is used and for the MAC-EQS the yearly maximum concentration per location. As can be seen, most samples (>90%) are non-evaluable, meaning that it is often not possible to determine whether the standard is exceeded or not. The remaining subset of measurements reveals concentrations that mostly surpass the EQS by more than 5-fold. Although not a formal compliance check, this is indicative of substantial non-compliance. Because it is slightly more evaluable, esfenvalerate exhibits the highest incidence of exceeding the EQS. Note that for deltamethrin and esfenvalerate, the future EQS as proposed by the European Commission for the revision of the WFD is even lower than the current national EQS (see section 5.2.1, Figure 3 and Appendix 3, Table A3.1). This will initially lead to more non-evaluable measurements, but with improved analytical methods potentially also to more frequent and higher exceedances in the future.

[28] Atlas bestrijdingsmiddelen in oppervlaktewater, https://www.bestrijdingsmiddelenatlas.nl/
[29] Landelijk meetnet gewasbeschermingsmiddelen land- en tuinbouw 2020 - Unie van Waterschappen
[30] https://www.bestrijdingsmiddelenatlas.nl/toelichtingen/berekeningenbewerking

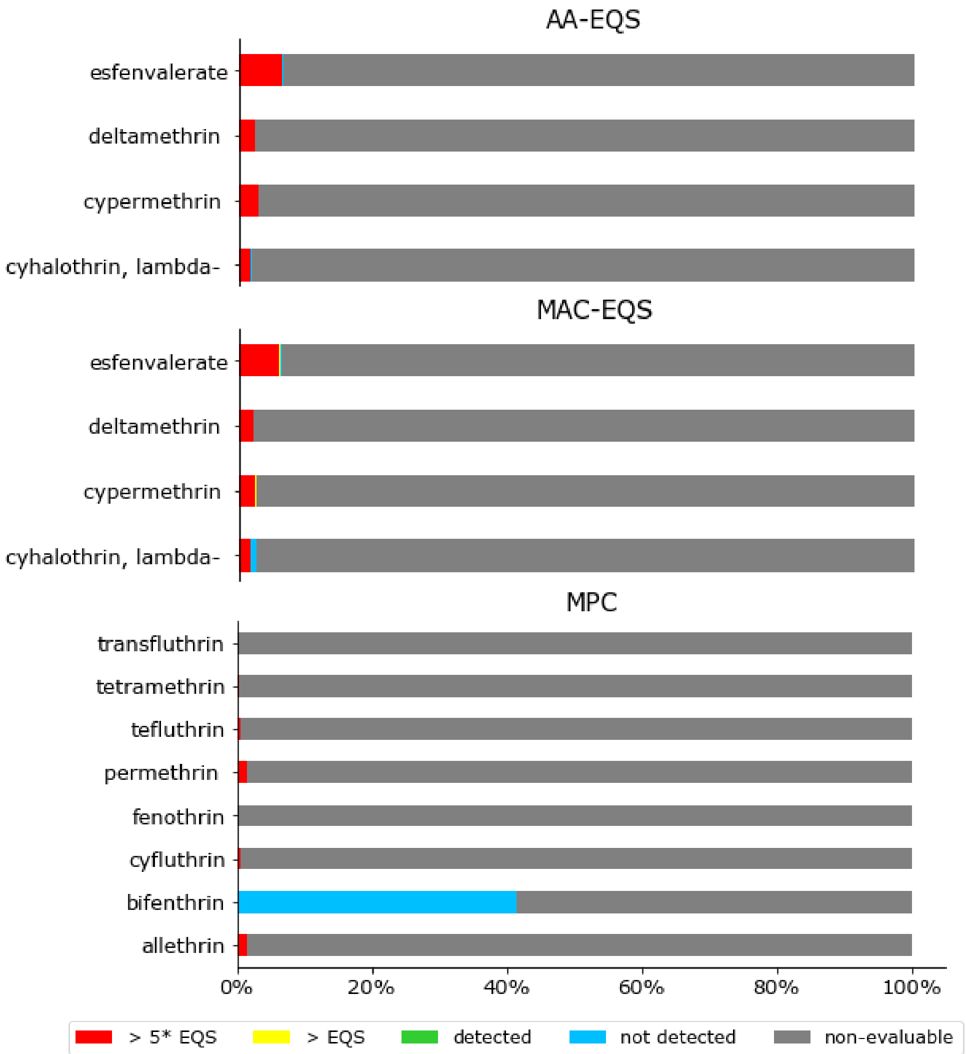

Figure 4 Comparison of monitoring data for active substances authorised as PPP in surface water in the Netherlands with the AA-EQS, MAC-EQS and MPC. The X-axis represents the percentage of the total number of compliance checks with the EQS or MPC per location for 2010-2021. Red: >5 times EQS or MPC; yellow: >EQS/MPC; green: detected, <EQS/MPC; blue: not detected and LoQ <EQS/MPC; grey: non-evaluable, not detected and LoQ>EQS/MPC. Bifenthrin and allethrin have been measured but have presently no authorised products in the Netherlands.

In case of substances without an EQS, previously derived (indicative) Maximum Permissible Concentrations (MPC) serve as the current surface water quality standard in the Netherlands. Similar to what is observed for substances with an EQS, most data for these substances fall into the non-evaluable category (Figure 4). This implies that the data do not provide sufficient information to ascertain compliance with the standard. Bifenthrin stands out as a relative exception, allowing testing against the MPC for 43% of the measurements (more in section 6.1.3). However, note that the AA-EQS for bifenthrin as proposed by the European Commission is about 10 times lower than the current MPC (see Appendix 3, Table A3.1), which may again reduce the evaluability for this substance in the future. Bifenthrin is no longer approved as active substance for biocide or PPP use, but it is included in the evaluation because measurements are available and the substance is a candidate WFD priority substance.

Additionally, permethrin and allethrin exceed the MPC for 1.5% of all the compliance checks and 100% of the evaluable compliance checks. For permethrin, the proposed AA-EQS is slightly higher than the current MPC and the number of exceedances may decrease also considering the fact that the AA-EQS is compared with the annual average concentration instead of the 90^{th} percentile as was done for the MPC. It is anticipated, however, that most measurements will remain non-evaluable. Allethrin (and d-allethrin) is no longer approved as active substance for biocide or PPP use, but it is included here because monitoring data are available and it is detected. According to the Ctgb database[31] the last biocidal products, mostly repellents against mosquitos, were discontinued in 1998

6.1.2 *Comparison with authorisation criteria*

Figure 5 presents the comparison of monitoring data with the authorisation criteria for PPP and biocides[32]. For this purpose the 90^{th} percentile concentration per location per year was used. Please note that several synthetic pyrethroids are used both as PPP and biocides.

The authorisation criteria for PPP for esfenvalerate and deltamethrin are exceeded more than 5-fold at 1.3 and 1.6% of all measurements, and 16 and 1.9% of the evaluable measurements respectively. Although authorisation criteria are less strict than the EQS, still 25% of the measurements of lambda-cyhalothrin and 89% of deltamethrin are non-evaluable using the analytical methods used by water managers for routine monitoring.

Compared with the authorisation criteria for biocides, permethrin, deltamethrin and lambda-cyhalothrin exceed the criteria at around 2% of the locations, but are largely non-evaluable for this criterion. For this criterion, tetramethrin is the exception. It has a relatively high RAC (see Figure 3). It is fully evaluable and was not detected in any of the measurements evaluated here.

[31] https://toelatingen.ctgb.nl/nl/authorisations
[32] Note that this comparison is based on the data available in 2021. Meanwhile, the pesticide atlas includes monitoring data for 2022 and authorisation criteria may have been updated as well.

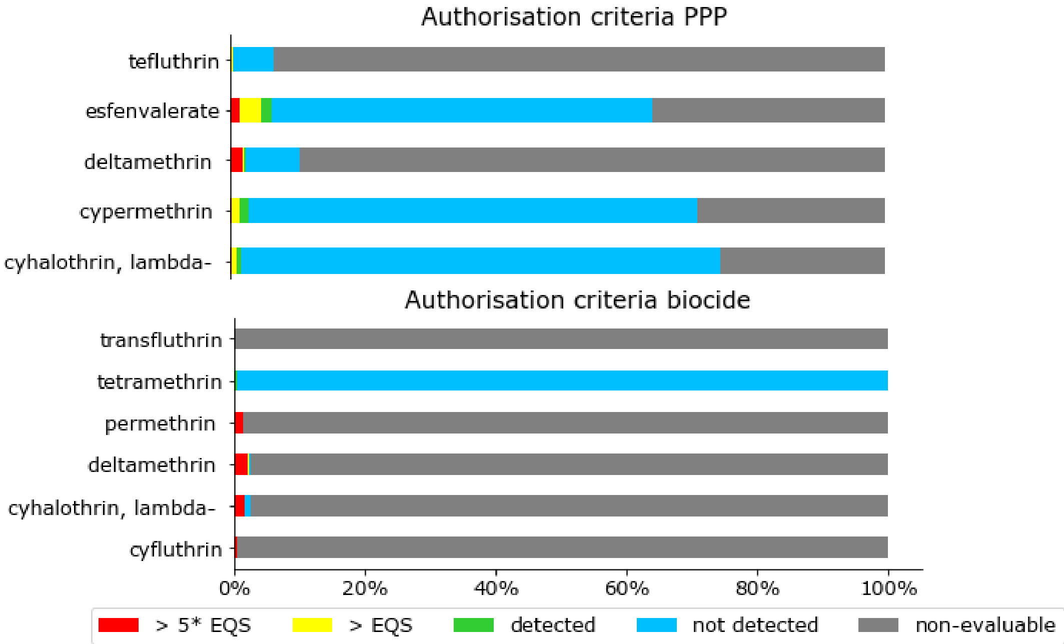

Figure 5 Comparison of monitoring data in surface water for active substances in authorised PPP and biocides with their respective authorisation criteria (PPP-RAC and biocides-PNEC). The X-axis represents the percentage of compliance checks with the authorisation criteria per location for 2010-2021 using the 90th percentile concentration. Red: >5 times PPP-RAC or biocides-PNEC; yellow: >PPP-RAC or biocides-PNEC; green: detected and <PPP-RAC or biocides-PNEC; blue: not detected and <PPP-RAC or biocides-PNEC; grey: non-evaluable, not detected and LoQ>PPP-RAC or biocides-PNEC.

6.1.3 *Quantification limits and evaluability*

From the previous paragraph it is clear that analytical methods for synthetic pyrethroids presently used for routine monitoring in the Netherlands are insufficient for detection at the level of most water quality standards.

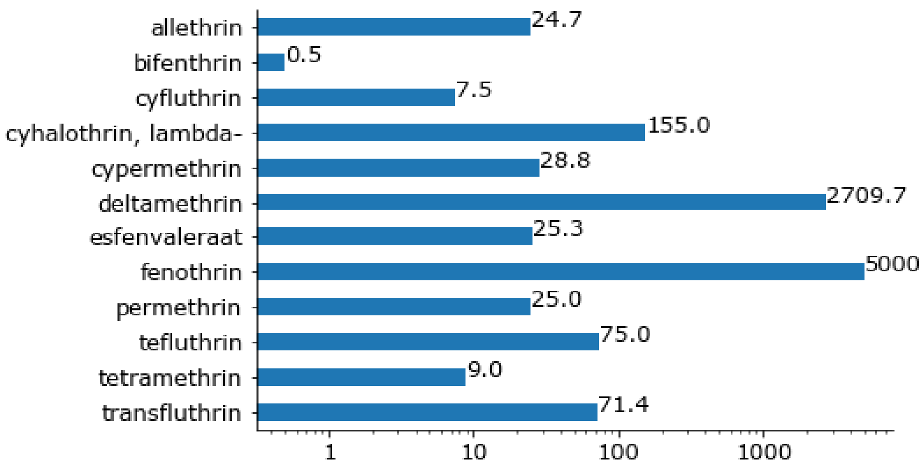

Figure 6 Ratio between average LoQ and EQS or MPC on a logarithmic scale in 2021 (source: Bestrijdingsmiddelenatlas). The ranges of these LoQs are not available.

Figure 6 shows the ratio between the average LoQ and the EQS or MPC for 2021. Phenothrin and deltamethrin show the highest discrepancy with a ratio of 5,000 and 2,710, respectively, mostly due to the much lower EQS/MPC rather than analytical techniques. This means that concentration of deltamethrin must be higher than 2710 times the EQS to be detected.

The exception is bifenthrin. The LoQ for bifenthrin improved over the last years and has been lower than the current MPC since 5 years (Figure 7). However, this substance may become less evaluable again in the future because of a lower proposed AA-EQS (see section 6.1.1).

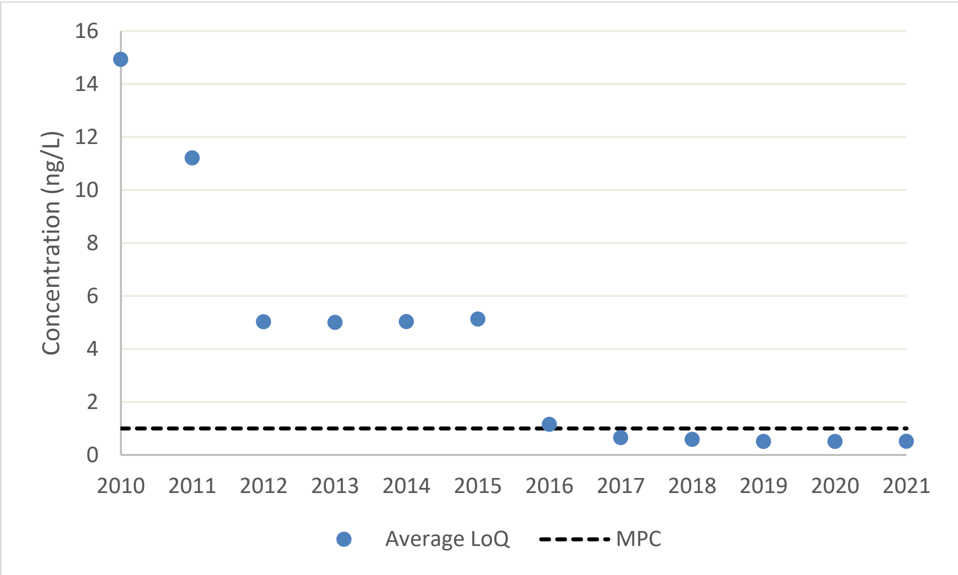

Figure 7 Limit of Quantification of bifenthrin in the 'Bestrijdingsmiddelenatlas' from 2010 to 2021 (blue dots) and MPC (dotted line).

In more recent measurements conducted in 2022 by the Directorate General for Public Works and Water Management ('Rijkswaterstaat') significant advancement have been made in lowering the LoQs for both lambda-cyhalothrin and deltamethrin (personal comment C. Hogendoorn, Rijkswaterstaat, the Netherlands). This was done by extracting a greater volume of surface water. Specifically, the LoQ for deltamethrin has been reduced from 0.01 to 0.002 µg/L while the LoQ for lambda-cyhalothrin has been reduced from 0.004 to 0.001 µg/L (information received from Rijkswaterstaat). Despite these advancements, it is important to note that the LoQs, while improved, still remain substantially higher than the AA-EQS for lambda-cyhalothrin and deltamethrin, by 50 and 645 times respectively.

There are more recent publications that achieve lower LoQs for synthetic pyrethroids in water. Rösch et al. (2019) for example reached LoQs ranging from 12.5 to 125 pg/L and applied their method successfully to Swiss surface waters to detect various synthetic pyrethroids at concentrations below the EQS of the WFD, including deltamethrin, esfenvalerate and lambda-cyhalothrin. Such methods, however, are currently not used in routine monitoring in the Netherlands because they require specific methods for sample treatment and/or detection.

It should be noted that some of the water quality standards are outdated. This holds in particular for the indicative MPCs. However, it has been shown for several compounds that updating the water quality standards with recent ecotoxicity data according to current methods will not necessarily lead to higher values. In contrast, recently proposed EQS for bifenthrin, deltamethrin and esfenvalerate are lower than existing water quality standards. Considering the toxicity to aquatic organisms, newly derived water quality standards will remain in the low ng/L range.

6.1.4 Correlation of substances with crops

The Pesticide Atlas also calculates the correlation of substances to different kinds of land use. For this, publicly available data on land use and crops is used[33]. This correlation analysis allows for the identification of significant associations between the five synthetic pyrethroids authorised as PPP and different crops. The results for 2019-2021 (Table 6) reveal that concentrations of esfenvalerate, deltamethrin, and lambda-cyhalothrin exhibit a highly significant correlation ($P < 0.001$) with cultivation of sugar beets, grains, and potatoes. Additionally, deltamethrin concentrations show a highly significant relationship with asparagus. Concentrations of each of these three substances also show significant correlations with other crops[34]. The pesticide cypermethrin demonstrates a strong correlation with catch crops, urban areas, and other crops (see Table 6). Tefluthrin concentrations, on the other hand, display a significant correlation ($0.01 < P < 0.05$) with grains only. These findings shed light on the varying degrees of connection between the occurrence and concentrations of specific pesticides in surface waters and distinct agricultural or other practices.

It is important to exercise caution when interpreting the results of these correlations, as limited knowledge of pesticides, land use, and methodologies employed may lead to misinterpretation. The analysis is also based on only the measurements that exceed the LoQ. Furthermore, it should be noted that the results may not fully represent the current situation due to evolving policies and actions. While the significant correlations between pesticide concentrations and specific land use in Table 6 may suggest a relationship, they should be viewed as indicative for further investigation into potential causes of pesticide presence in surface water. Please note that correlation of concentrations with land use types indicates that there is emission from these land use types, but does not necessarily also indicate a risk.

[33] https://www.bestrijdingsmiddelenatlas.nl/toelichtingen/koppeling
[34] The category 'other crops' refers to smaller crops that cannot easily be placed in the other categories, such as herbs buckwheat, quinoa, alfalfa and hops. The full list of crops can be found via this link.

*Table 6 Correlation of concentrations of synthetic pyrethroid active substances in Dutch surface waters with land use for 2019-2021. *** = P<0.001, ** = P<0.01 and * = P<0.05. Source: Bestrijdingsmiddelenatlas.*

Substance	**Land use (crops)**
Esfenvalerate	Sugar beets, grains, and potatoes*** Legumes** Catch crops, greenhouse*
Deltamethrin	Sugar beets, grains, leek, potatoes, and asparagus, other crops*** Legumes, strawberries** Catch crops, maize*
Cyhalothrin, lambda-	Sugar beets, grains, potatoes, other crops*** Asparagus, legumes, leek** Maize, catch crops, strawberries*
Cypermethrin	Catch crops, urban areas, other crops*** Greenhouse*
Tefluthrin	Grains*

6.1.5 Spatial distribution of PPP

Due to the high number of non-evaluable samples, the spatial distribution of the three synthetic pyrethroids that are most used in authorised PPP does not exhibit clear patterns. Only esfenvalerate, which has the highest number of evaluable measurements of these PPP, shows a somewhat discernible spatial pattern (Figure 8; maps for deltamethrin and lambda-cyhalothrin shown in Appendix 5). Most of the observations and exceedances of the AA-EQS and RAC of esfenvalerate seem to occur in the province of South Holland.

Nevertheless, it is crucial to exercise caution when interpreting these findings as definitive conclusions cannot be drawn based on the available data. But note that the earlier correlation analysis with land use did provide valuable insights, indicating a correlation between esfenvalerate concentrations and potatoes, grains and sugar beets, and also legumes catch crops and greenhouses. These correlations suggest potential associations between esfenvalerate use and these specific crops. To establish a more comprehensive understanding of the relationship between esfenvalerate and agricultural practices, as well as its spatial distribution, a larger number of evaluable measurements would be required.

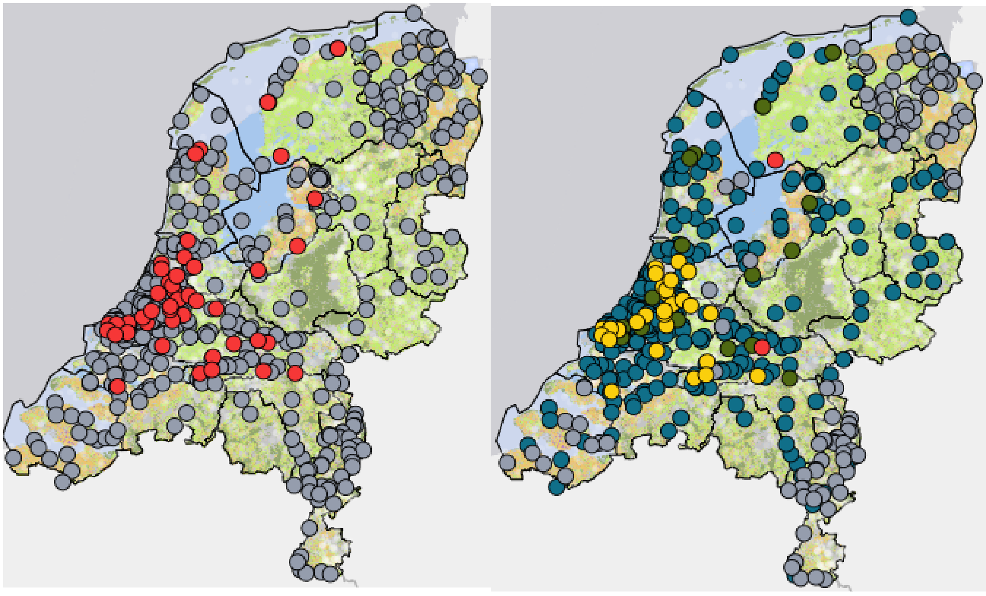

Figure 8 Exceedance for esfenvalerate for the national AA-EQS in the Netherlands (0.00019 µg/L) (left) and the authorisation criterion (RAC) for PPP (0.01 µg/L) (right) in 2021. Red: >5 times EQS or RAC; yellow: >EQS or RAC; green: detected and <EQS or RAC; blue: not detected, but <EQS or RAC; grey: non-evaluable, LoQ > EQS or RAC. Note that the draft European AA-EQS for esfenvalerate is about a factor of 10 lower than the current national AA-EQS.

Figure 8 also clearly demonstrates the strong contrast between comparing concentrations of esfenvalerate with the AA-EQS and the authorisation criterion for PPP (RAC). Unlike the AA-EQS, which lacks any measurements between the standard and the LoQ, the much higher authorisation criterion results in more evaluable locations (grey locations turn into coloured locations). A considerable proportion of the locations exhibit esfenvalerate levels below the RAC (green or blue). Note that the draft European AA-EQS for esfenvalerate is about a factor of 10 lower than the current national AA-EQS. Nonetheless, 4.5% of locations exceed the RAC and 35.6% of locations remain non-evaluable.

6.2 Wastewater treatment plants

For the use of synthetic pyrethroids by the general public, it is assumed that emissions to surface water primarily occur indirectly via wastewater (see Table 4). To address this route, available measurements from the WATSON database were used. The WATSON database[35] includes all measurements for in- and effluents of wastewater treatment plants (WWTPs) in The Netherlands. It provides data on the influent and effluent volumes per year per WWTP, and it calculates the removal efficiency, when simultaneous measurements are available for influent and effluent.

Note that for these measurements of synthetic pyrethroids in influent and effluent, no distinction can be made between consumer use as biocides, VMP or HMP as the source.

[35] https://data.emissieregistratie.nl/watson

6.2.1 *Influent*

Permethrin was found to be highly prevalent in the influent of WWTPs (Table 7), with an average concentration of 0.2953 µg/L and 100% detection frequency whenever analysed. When reported separately, the isomer trans-permethrin was also identified, although at a lower average concentration of 0.0437 µg/L and 15% occurence.

Other synthetic pyrethroids in the analyses, such as tetramethrin, alfa-cypermethrin, allethrin, bifenthrin, cyfluthrin, cypermethrin, fenpropathrin, and lambda-cyhalothrin, were not quantified in any of the samples. This could indicate either analytical difficulties or their absence. For allethrin and fenpropathrin the latter is likely the case since these compounds are not or no longer approved as pesticide or pharmaceutical in Europe.

Esfenvalerate and deltamethrin, while present in the influent in 2% and 5% of the samples, exhibited relatively low average concentrations of 0.004688 µg/L and 0.002177 µg/L respectively.

*Table 7 Measurements of synthetic pyrethroids in influent of Dutch WWTPs for 2010-2018. Concentrations are in µg/L. * = no products authorised in the Netherlands at the time of writing, ** = substances without European approval.*

Substance	**Measurements**	**> LoQ**	**% >LoQ**	**Average conc.**
alfa-cypermethrin	27	0	0%	0
allethrin**	15	0	0%	0
bifenthrin**	15	0	0%	0
cyfluthrin*	15	0	0%	0
cypermethrin	15	0	0%	0
deltamethrin	62	3	5%	0.002177
esfenvalerate	64	1	2%	0.004688
fenpropathrin**	15	0	0%	0
lambda-cyhalothrin	42	0	0%	0
permethrin	15	15	100%	0.2953
trans-permethrin#	27	4	15%	0.0437
tetramethrin*	15	0	0%	0

#: not approved as such, but part of the isomeric mixture permethrin

6.2.2 *Effluent*

In the case of effluent (Table 8), the analysis revealed that only two substances were quantified in the measured samples, and at very low frequencies. Tetramethrin and permethrin were quantified in only one instance each (2%). All other substances under investigation were not quantified in any of the measured effluent samples. It is important to note that while the LoQ for these measurements is not publicly disclosed in the Watson database, a similar phenomenon as in surface water measurements could be inferred, where substances are not quantified but can potentially be present at concentrations below the LoQ.

*Table 8 Measurements for effluent of Dutch WWTPs for 2010-2018. Concentrations are in µg/L. * = no products authorised in the Netherlands at the time of writing, ** = substances without European approval.*

Substance	Measurements	> LoQ	% >LoQ	Average
alfa-cypermethrin	73	0	0%	0
allethrin**	61	0	0%	0
bifenthrin**	71	0	0%	0
cyfluthrin*	67	0	0%	0
cyhalothrin	6	0	0%	0
cypermethrin	133	0	0%	0
deltamethrin	240	0	0%	0
esfenvalerate	188	0	0%	0
fenpropathrin**	67	0	0%	0
lambda-cyhalothrin	184	0	0%	0
permethrin	65	1	2%	7.692E-05
cis-permethrin[#]	30	0	0%	0
trans-permethrin[#]	61	0	0%	0
tefluthrin	16	0	0%	0
tetramethrin**	61	1	2%	8.197E-05

#: not approved as such, but part of the isomeric mixture permethrin

6.2.3 *Removal*

The limited occurrence of synthetic pyrethroids in both influent and effluent poses challenges in calculating the removal efficiency. Out of the 876 measurements conducted for all substances where both influent and effluent were analysed, only 20 measurements revealed concentrations higher than the limit of quantification (LoQ). These 20 measurements pertained to influent samples without detectable concentrations in the corresponding effluent. As a result, a removal efficiency of ~100% was achieved for deltamethrin, permethrin, trans-permethrin and esfenvalerate. The reliability of these findings, however, is compromised due to the scarcity of measurement data. Still, based on the relatively high lipophilicity of synthetic pyrethroids in general (section 4.2) it is expected that most synthetic pyrethroids will be removed from wastewater by sorption to sludge. For less persistent synthetic pyrethroids it is possible that biodegradation contributes to removal in the WWTP as well.

Despite their removal in the WWTP, persistent or potentially persistent synthetic pyrethroids like deltamethrin may remain present in the resulting sewage sludge. At present, sewage sludge in the Netherlands is disposed of by incineration or by storage in designated depots. However, numerous initiatives are employed to investigate sustainable use of sludge for e.g. energy production or reclaiming resources. It should be noted that the presence of chemicals such as synthetic pyrethroids may be an issue when sludge is used for other purposes.

6.3 Occurrence in biota

As indicated in section 4.3, the majority of substances does not meet the formal regulatory triggers for being B/vB. However, bioaccumulation in wildlife and humans has been reported in several studies reviewed by Aznar-Alemany & Eljarrat (2020b). These authors cite several studies on detection of synthetic pyrethroids in livers of Franciscana dolphins from urban and agricultural areas along the Brazilian coast with detection frequencies of 80% and higher for a number of individual compounds. Similar observations were made by Aznar-Alemany et al. (2017) for the Mediterranean coast in southern Spain. Bioaccumulation of synthetic pyrethroids such as bifenthrin, cyhalothrin and permethrin was also detected in wild fish (Corcellas et al., 2015; Xie et al., 2022).

We are not aware of monitoring data of synthetic pyrethroids in aquatic biota from Dutch surface waters, and it is difficult to translate the findings from the literature to the Netherlands without knowledge on how the use and emission of synthetic pyrethroids in the study areas relate to the Dutch situation. Permethrin has been detected in Dutch songbirds (see references in Wezenbeek & Komen, 2023), but it is unclear if there is a relationship with exposure via the aquatic compartment.

In general, dietary risks for humans are not expected and the EQS dossiers for synthetic pyrethroids prepared in the context of the WFD indicate that water quality standards for direct ecotoxicity are protective for predators and humans. Still, in view of the challenges associated with the analytical determination of synthetic pyrethroids in surface water, it may be worthwhile to consider measuring synthetic pyrethroids in aquatic biota (including sediment organisms) as an indication of exposure. Biota concentrations could be useful as an alternative assessment method for non-evaluable substances for which detection limits in water are higher than the water quality standard.

7 Risk mitigation and alternatives to PPP

Since a several decades, many measures have been introduced to reduce the environmental impact of pesticides resulting from agricultural use. In this chapter two ways of dealing specifically with synthetic pyrethroids are described and discussed, emission reduction plans (ERPs) for PPP and substitution of the substances. To our knowledge, the concept of ERP is unique for PPP. Similar activities to systematically address emission reduction for biocides or VMP are not employed. This is most likely due to the fact that there is no insight into the extent to which these uses contribute to the environmental impact of synthetic pyrethroids. For HMP, there is an extensive policy approach to reduce residues in water[36], but no specific actions are defined for permethrin. Therefore, this chapter is mainly focusing on PPP, although the identification and evaluation of alternatives for Candidates for Substitution (CfS) is relevant for biocides as well.

7.1 Emission reduction plans for PPP

Emission reduction plans (ERPs) have been used in the Netherlands since 2013 as one of the tools to address water quality problems related to the use of PPP[37]. An ERP may be drafted by the authorisation holder if based on monitoring data there is a plausible connection between exceedance of the environmental quality standard and the use of a product. In the ERP, the authorisation holder records measures to reduce the emissions of plant protection products to surface water (e.g. Tiktak et al., 2019). The causal analysis is performed according to an agreed protocol (De Werd & Kruijne, 2013), using data from the national monitoring network for PPP as recorded in the Pesticide Atlas (see section 6.1). The ERP is a non-legal and non-mandatory instrument intended as a safety net and it is drawn per active substance. The actual plans are confidential but summaries are publicly available. More information can be obtained via the Toolbox Water[38].

Measures in an ERP may for instance consist of voluntary tightening the authorisation, for example by restrictions on the label, taking extra emission reducing measures and improving compliance through better information (Tiktak et al., 2019). Basis for ERPs are the water quality standards (European WFD-EQS or national equivalents) and not the generally less stringent authorisation criteria (RACs). ERPs thus help to achieve the goals of the WFD. However, ERPs are a non-legal instrument and cannot be enforced.

Currently there are ERPs in place for deltamethrin, esfenvalerate and (alpha)cypermethrin. Summaries of these ERPs are published online at the website of the Toolbox Water. The summaries are undated, without authors and varying in detail.

[36] Ketenaanpak medicijnresten uit water | Beleidsnota | Rijksoverheid.nl
[37] see National Action Plan Crop Protection available via Geactualiseerd nationaal actieplan duurzaam gebruik gewasbeschermingsmiddelen 2022 t/m 2025 | Kamerstuk | Rijksoverheid.nl
[38] Emissiereductieplan – Toolbox Emissiebeperking (toolboxwater.nl)

The ERP for cypermethrin is in place since 2017 (personal comment D. Kalf, Rijkswaterstaat, the Netherlands). The summary mentions that there are not many PPP based on cypermethrin on the market in the Netherlands. The possible cause of EQS exceedances in surface waters may be its use in rape seed and spray drift. As a pilot the sale of the relevant product with cypermethrin was put on hold in 2016 and 2017 with an evaluation of the effect due in 2018. The results of this measure are not described in the summary, but the registration of this particular product has expired at the end of 2022. Two other products are still authorised as PPP, one for soil treatment by granules in arable crops, vegetables and public areas, the other for post-harvest treatment of stored cereals and for treatment of storage areas.

There is an ERP for esfenvalerate since c. 2018 (pers. comm. D. Kalf). Several causes for the exceedance of EQS by esfenvalerate are discussed in the summary, notably its use a biocide, spray drift from agricultural applications and yard runoff. The actions taken by the producer include stopping support of the use of esfenvalerate as a biocide, recommending more strict drift reducing techniques on the label, modification of the application rate in order to reduce contamination of surface waters, and employing yard scans. These measures were planned for the re-registration of products based on esfenvalerate in the Netherlands that was foreseen for 2019. As the procedure for European renewal of the active substance is still ongoing, re-registration of products has not started yet.

The ERP for deltamethrin, finally, has been established in 2019 (pers. comm. D. Kalf). Although deltamethrin is also used as a biocide and non-professionally, the analysis of its exceedances of the EQS in surface waters focussed on its (professional) use in agriculture. Spray drift and residual flows from horticulture in greenhouses were identified as the most plausible causes. No specific measures are proposed specifically for deltamethrin but the summary mentions two broader developments, i.e., the availability of better drift reduction techniques and the establishment of collective purification plants for waste water from greenhouse horticulture. Together with better analysis methods for deltamethrin it is proposed to evaluate the situation again with monitoring results for 2021-2023.

For evaluating the results of the ERPs, the yearly reports on the website of the Pesticide Atlas are used (pers. comm. D. Kalf). These reports[39] contain the percentage of monitoring sites over a three year period where the AA-EQS, MAC-EQS or MPC of monitored active substances are exceeded. For the present report these percentages were collected for cypermethrin (including alpha-cypermethrin), deltamethrin and esfenvalerate for the years 2010-2021. The results are shown in Figure 9.

The percentage of exceedance of the EQS for all three synthetic pyrethroids first increases from 2011-2013 onwards but is later reduced. Because of the use of three year time periods for evaluation and the simultaneous and ongoing introduction of other risk mitigating measures

[39] https://www.bestrijdingsmiddelenatlas.nl/samenvattingen

than ERPs from legal and regulatory requirements, it cannot be established with certainty if the reductions observed are due entirely or in part to the ERPs. The percentage exceedance of EQS for cypermethrin and deltamethrin is decreasing up to 2019-2021 and drops below 2% of the monitoring sites. The introduction of the ERP for deltamethrin in 2019 may be too recent to observe an effect. The reduction in the percentage exceedance for esfenvalerate seems to stall from 2017-2019 onwards and it may even increase to over 5% in 2019-2021.

It is important to note here that the percentages of exceedance of the EQS in Figure 9 may represent a significant underestimation of the real exceedances because the LoQ of all three compounds is well above the EQS and substances are non-evaluable (see Figure 4), and because the monitoring strategy is based on grab samples and not continuous sampling.

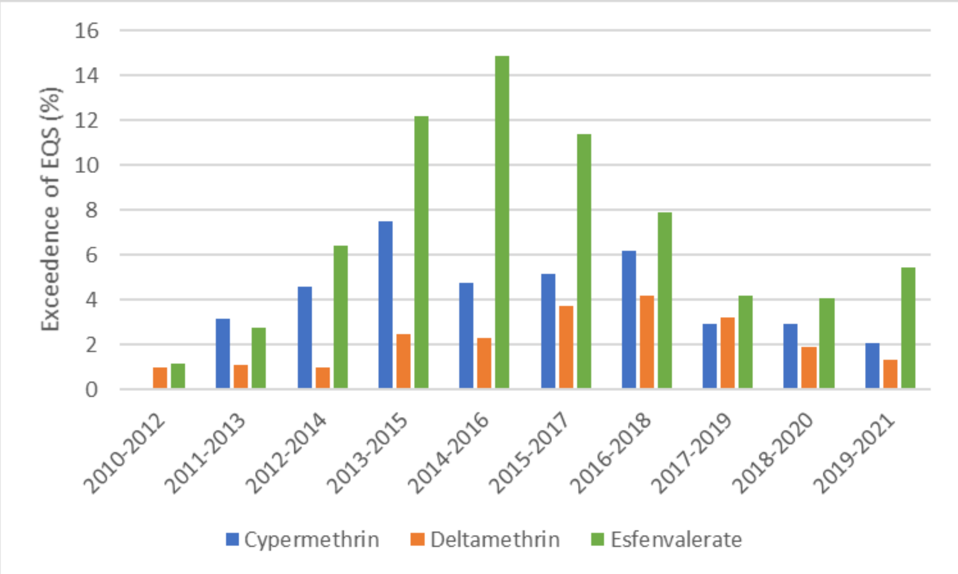

*Figure 9 Degree of exceedance of Environmental Quality Standards (AA-EQS, MAC-EQS or MPC; see section 5.2.1 for an explanation). The percentage is calculated as n/Ntotal*100%, where n= number of monitoring stations with exceedance and Ntotal= total number of monitoring stations). Cypermethrin= alpha-cypermethrin + cypermethrin.*

Regarding deltamethrin and esfenvalerate, it is also worthwhile to note that Ctgb has taken measures to prevent the use of different products with the same active substance on the same field within a certain period of time ('gestapeld gebruik' in Dutch). The measures were issued in 2021 and will be evaluated three years after implementation[40].

7.2 Alternatives

As indicated in section 3.1.1.3 and section 4.3, a number of synthetic pyrethroids is identified as Candidate for Substitution (CfS) under the European PPP and biocides regulation. When a substance is identified as CfS, the Netherlands Food and Consumer Safety Authority (NVWA)

[40] Notitie Ctgb maatregelen tegen stapelen met gewasbeschermingsmiddelen | Collegebesluit | College voor de toelating van gewasbeschermingsmiddelen en biociden

makes an inventory of alternatives, after which Ctgb performs a comparative assessment including non-chemical alternatives.
When the concept of CfS was introduced in the PPP regulation, it was predicted that the comparative assessment of alternatives would pose an enormous challenge to the Competent Authorities (Faust et al., 2014). A recent evaluation indicates that the number of CfS has remained unchanged, suggesting that progressive replacement by less hazardous alternatives has not been achieved so far (Robin & Marchand, 2023). Based on experience during the past years, Ctgb recently concluded that the comparative assessment in its present form is impracticable and not effective and published the intention to adapt its methodology for comparative assessments as from 2024. The modified methodology aims to speed up the assessment by introducing a working procedure for the unambiguous and transparent identification of significantly safer alternatives[41].

Another way of reducing or eliminating the impact of synthetic pyrethroids is by using alternative methods of pest control or alternative insecticides. The Netherlands Food and Consumer Safety Authority (NVWA, 2023) has recently released a study on alternatives for the synthetic pyrethroids deltamethrin, esfenvalerate and lambda-cyhalothrin for professional use. The outcome of the study was an extensive list of measures in the framework of Integrated Pest Management (IPM) and of both biological and chemical alternatives for the three synthetic pyrethroids for various crop-pest combinations. Measures to prevent (damage by) pests are proposed as a first option in IPM approaches. Non-chemical alternatives such as biological agents are the second option. These are often considered more environmentally friendly than many chemical alternatives. Only when previous options have not resulted in sufficient control of a pest, the option of using chemical insecticides may be considered.

The alternatives mentioned by the NVWA (2023) for the three synthetic pyrethroids include some substances which are CfS. These are clearly marked in the report. The NVWA states that substitution of the synthetic pyrethroids in their study with (other) CfS is undesirable. Esfenvalerate and lambda-cyhalothrin are already CfS themselves.

Indeed, care should be taken not to substitute harmful insecticides with insecticides with the same behaviour in the environment and the same undesired toxic properties, so-called ‘regrettable substitution’. The NVWA lists two other synthetic pyrethroids as alternatives for deltamethrin, esfenvalerate and lambda-cyhalothrin, i.e., tefluthrin and cypermethrin (a CfS).

Our study shows that most of the synthetic pyrethroids evaluated have more or less the same properties, i.e., they are somewhat persistent in the environment, they often bioaccumulate and they are all extremely toxic to aquatic organisms. In addition, they are mostly non-evaluable because of analytical limitations. Substitution of synthetic pyrethroids with other synthetic pyrethroids will therefore not lead to less impact in surface waters.

[41] Beleidsregel vergelijkende evaluatie gewasbeschermingsmiddelen | Beleidsnota | College voor de toelating van gewasbeschermingsmiddelen en biociden (ctgb.nl)

Natural pyrethroids, pyrethrins, are also listed as alternatives to synthetic pyrethroids in some cases. It would be worthwhile to establish if these are more environmentally friendly than synthetic pyrethroids, considering both their environmental behaviour and toxicological effects. Several current uses of pyrethrins against flying insects involve combinations with piperonyl butoxide to enhance their efficacy (see Chapter 2 and section 5.2.4) which should be considered as well when evaluating implications for water quality as a result of widespread use of pyrethrins as an alternative.

8 Conclusions

The most important conclusions from the study, drawn from the results and discussions in the previous chapters, are given below.

Authorisation & sales

- At present 21 synthetic pyrethroids are allowed as active substances for different types of use (biocides, PPP, VMP and HMP) in the European Union.
- In the Netherlands, 5 synthetic pyrethroid compounds are used in authorised plant protection products (PPP), 9 in biocidal products, 5 in veterinary medicinal products (VMP) and 1 in a human medicinal product (HMP). In total 14 different synthetic pyrethroid active substances are used in marketed products in the Netherlands.
- National sales figures for individual synthetic pyrethroids in PPP (professional use only) are fairly constant in recent years, ranging from 8,000-15,000 kg. Data for VMP (prescriptions only) could only be obtained as ranges, but indicate a total sale of several tons per year during the past years. Use of permethrin as HMP (prescriptions only) showed a threefold increase over the past years as a result of increased scabies incidence and is estimated to be at least 360 kg per year. The contribution of non-professional use of PPP and non-prescribed use of VMP and HMP is unknown.
- There are no sales figures for biocides in the Netherlands. Sales data of synthetic pyrethroids in biocides in Belgium (professional plus non-professional use) have been fairly constant in recent years (i.e., the order of magnitude), varying between 15,000 and 20,000 kg over the past years.
- Taking the available information together, we estimate the total sales for synthetic pyrethroids in the Netherlands for all uses to be least 30,000 kg per year.

Emissions

- Different emission routes of synthetic pyrethroids to water bodies exist depending on the type of compound and its use. They may for example enter surface waters directly by spray drift upon treatment of crops, but can also reach surface water indirectly via waste water treatment plants after use as biocides (e.g. indoor insecticidal spray), veterinary medicines (e.g. flea collars) or human medicines (cream against scabies).
- Just like the sales figures, estimated emissions of synthetic pyrethroid compounds from PPP to surface waters in the Netherlands have been fairly constant in recent years.
- Emission estimates for biocides and VMP are not available. The increase of permethrin as HMP against scabies is likely to result in increased emissions to waste water. However, emissions to surface water will likely remain relatively low, because the substance is effectively removed in waste water treatment plants.

Environmental behaviour & toxicity

- Synthetic pyrethroids have in common that they strongly absorb to suspended matter and sediments. They ultimately disappear from water in different ways and at different speeds by means of photodegradation, hydrolysis and/or biodegradation.
- Synthetic pyrethroids are generally very toxic to aquatic organisms, and mixture effects may occur in the environment because of their common mode of action.
- Eight of the 21 synthetic pyrethroids allowed in Europe for use in PPP, biocides, VMP and HMP and included in this study are assigned as 'Candidate for Substitution' (CfS), mostly due to meeting two of the three criteria for Persistence, Bioaccumulation and Toxicity (PBT). Among these are esfenvalerate and lambda-cyhalothrin that prompted this study. All synthetic pyrethroids meet the T-criterion because of their high toxicity for aquatic organisms.

Regulatory thresholds

- For five synthetic pyrethroids that are allowed for use as PPP in the Netherlands, European or national chronic surface water quality standards are set in line with the methodology of the European Water Framework Directive (WFD). In four cases, the authorisation criteria are orders of magnitude higher than these surface water quality standards, with differences ranging from a factor of 163 (cypermethrin) to almost 1,900 (deltamethrin). There is no difference for tefluthrin (factor is 1).
- Authorisation criteria for biocides are also higher than WFD chronic surface water quality standards, but differences are smaller than for PPP, ranging from a factor of 1.74 (permethrin) to 400 (deltamethrin).
- For the three synthetic pyrethroids with authorisations for both PPP and biocides, authorisation criteria for biocides are a factor of 4.6 to 50 lower than for PPP.
- Differences between regulatory frameworks result from differences in methodology and data availability.
- From a scientific point of view, the WFD standards represent dissolved concentrations. Monitoring and compliance check is performed with total concentrations, including the adsorbed fraction, which may be not or only partially bioavailable. This may potentially lead to an overestimation of exceedance of the standards.
- Mixture toxicity is not included in the derivation and compliance check of WFD standards, and only to a limited extent in authorisation decisions (i.e, in case of formulated mixtures and tank mixes).

Occurrence in surface waters, WWTPs and biota

- Synthetic pyrethroids are difficult to analyse at the low concentrations needed to evaluate the WFD quality standards, and therefore at present they are mostly non-evaluable. Differences between the limits of quantification and chronic water quality standards vary from 7.5 (for cyfluthrin) to 2,700 for deltamethrin and even 5,000 for phenothrin.

- When synthetic pyrethroids are incidentally observed in national surface water, they usually exceed the water quality standards.
- In sewage treatment plant influents, mainly permethrin was detected. It cannot be concluded, however, whether this results from use as biocide, VMP or HMP. The compound was hardly found in the effluent, indicative of at a high removal rate. In view of the substance characteristics, this is not necessarily due to degradation. Instead, the substance may end up in the sewage sludge because of sorption.
- Recent technical improvements in analytical methods have resulted in lower quantification limits in recent years. At present, however, such dedicated analyses are not yet routinely used in the Netherlands and at the time of publication of this report most measurements of synthetic pyrethroids in the Netherlands are still non-evaluable.
- In the Netherlands no field studies have been done on the bioaccumulation of synthetic pyrethroids in aquatic organisms such as fish. However, according to the literature they are often found in fish. Biota monitoring may therefore be used as an indication that synthetic pyrethroids do occur in surface waters and sediments.

Potential sources

- The study in the present report does not contain an in-depth analysis of the sources of the synthetic pyrethroids detected. When substances are authorised in only one framework (PPP, biocide, veterinary or human pharmaceuticals), the source of emissions to the environment may be straightforward, although several emission routes may exist even within one framework (e.g. for biocides used in different product types). When substances are authorised in multiple frameworks, the type of location may reveal more about the possible source(s). Of the 14 synthetic pyrethroids allowed for use in the Netherlands, four have authorisations in multiple frameworks (cypermethrin, deltamethrin, lambda-cyhalothrin and permethrin).
- An indicative correlation analysis with data from the Dutch Pesticide Atlas indicated a highly significant correlation between synthetic pyrethroids used in agriculture and their concentrations in surface waters. Crops for which the strongest correlation with measured concentrations were found were sugar beets, grains and potatoes.
- Calculations with the Dutch Environmental Indicator (NMI) showed that the emissions and impact of the three principal synthetic pyrethroids used in plant protection can be traced back to their use in the following coarse categories of crops, depending on the specific pyrethroid: arable fields, flower bulbs, flowers under glass, tree nurseries and outdoor vegetables.
- The detection of some synthetic pyrethroids in WWTP influent points at their use as biocides and/or pharmaceuticals as a source. Some of these compounds are also used in veterinary pharmaceuticals. For permethrin an additional important source may be its use against scabies in human pharmaceuticals.

Risk mitigation and alternatives

- Emission reduction plans (ERP) have been established for cypermethrin, deltamethrin and esfenvalerate used as PPP in the Netherlands. These are voluntary schemes conducted by pesticide manufacturers with measures to reduce the exceedance of WFD water quality standards in surface waters.
- Over the past years, the number of (measurable) exceedances of the EQS in surface waters has decreased to some degree. In the framework of the present study, it could not be established if this is a result of general risk reduction measures that have been introduced over these years, such as drift reduction techniques and buffer zones, or an effect of other measures proposed in the ERP.
- The Netherlands Food and Consumer Safety Authority (NVWA) has recently published alternatives for the professional use of deltamethrin, esfenvalerate and lambda-cyhalothrin as PPP. The alternatives include measures in the framework of Integrated Pest Management (IPM), low-risk pesticides such as biological agents and alternative active compounds.

9 Recommendations

Based on the findings and conclusions presented in this report, recommendations are made that may contribute to reducing the impact of synthetic pyrethroids on water quality. Some of the recommendations are generic and applicable to other active substances as well.

Improve consistency between regulatory frameworks

The overview of authorisation criteria and water quality standards for synthetic pyrethroids confirms that large differences exist between substance authorisation frameworks, even though they serve a common goal, to prevent unacceptable impact on human health and the environment The discrepancy between regulatory frameworks is one of the reasons for the European Commission to move towards 'one substance, one assessment'. Van Dijk et al. (2021) make a plea for a regular update and re-evaluation of registration and approval dossiers, harmonisation of protection goals and disclosure of industry data. Data sharing will certainly contribute to harmonisation, but there are also substantial methodological differences between frameworks that need to be addressed but will not be solved easily on short notice. This means that differences between authorisation criteria for PPP, biocides and pharmaceuticals, and water quality standards will likely persist for some time.

Apart from this, there is the fundamental issue of prospective risk assessments for PPP, biocides, and pharmaceuticals being carried out on a product-by-product basis using predicted environmental concentrations (PECs), whereas the WFD-water quality assessment focuses on measured concentrations resulting from all sources together. In order to check if future exceedance of WFD standards can be foreseen at the stage of product authorisation, PECs from national authorisation dossiers could be compared to these standards. For PPP and biocides, these dossiers are publicly available via the database of Ctgb. This approach could be tested in a limited pilot study for a selected number of synthetic pyrethroids that are used for different purposes. By including information from PPP and biocides, the relative importance of both types of use may become more clear. If such a pilot yields useful information, extension to VMP may be considered as well. Since the frameworks have different approaches, careful consideration is needed of the appropriate PECs and WFD-EQS to be used (e.g. initial or time weighted average, i.e., AA or MAC).

Establish more insight into use volumes and emissions

At present, only the sales (and emission) data of PPP for professional use are fully public. Use and emission data of HMP can be estimated but do not include over-the-counter use (see section 3.3.4). Sales ranges of prescribed VMP can be obtained for studies such as the present one, but emission estimates are lacking. Sales and emission data for biocides are not available. The only information we have is the total yearly sales data of synthetic pyrethroids in Belgium. For substances like synthetic pyrethroids that have multiple uses, the absence of reliable data on use volumes and emissions per substance category is an important knowledge gap. Clarifying the relative contribution of different uses may increase the effectiveness of measures in specific sectors of use, although a general emission reduction would be most favourable for protection of water quality . The ministry of IenW recently expressed the intention to start monitoring the sales of biocides in the Netherlands which will give a first impression. It is recommended to investigate actual use as well and to model emissions, because this will provide more relevant insight into sources. Data availability for VMP and HMP need to be improved especially regarding non-prescription drugs. Furthermore, dedicated environmental monitoring and modelling could elucidate which sources contribute most to the environmental load of synthetic pyrethroids in a certain region.

Avoid regrettable substitution

When substituting certain synthetic pyrethroids with other chemical insecticides, harmful insecticides should not be replaced with Candidates for Substitution or with other compounds with similar undesired properties, so-called 'regrettable substitution'. Since most synthetic pyrethroids share the same properties, substituting one synthetic pyrethroid with another would constitute such a regrettable substitution and almost certainly not lead to an improvement of surface water quality. Also, when replacing synthetic pyrethroids with natural pyrethroids it should also be established if these are not just as harmful.

Update water quality standards

National water quality standards for trans-phenothrin, tau-fluvalinate, permethrin, tetramethrin and transfluthrin were set long ago. It is likely that more and higher quality data have become available in the meantime which potentially lead to different values. Updated EQS will not necessarily be more in line with authorisation criteria, but will give a better basis to draw conclusions on water quality. It is therefore recommended to derive updated EQS for the mentioned substances. Tau-fluvalinate is not considered as a priority since it is only allowed for use in beehives from which environmental emissions to water are not likely.

Promote appropriate compliance check of WFD-EQS

It is important to promote at the European level that compliance checking of monitoring data according to the WFD is to be performed in an appropriate way, considering the difference between total and dissolved concentrations as explained in the current WFD-guidance. If ecotoxicological effect data and derived EQS are expressed as dissolved concentrations, they should be compared with measured dissolved concentrations after filtration. If monitoring data are expressed as total concentrations in non-filtered samples, the EQS should be expressed accordingly, e.g. by recalculation to total concentrations taking account of local suspended matter concentrations. It should be noted, however, that for the substances under consideration it is not fully clear if effect concentrations in the ecotoxicity tests underlying the EQS really concern dissolved concentrations.

Take account of mixture toxicity

In view of the common mode of action of synthetic pyrethroids, it is recommended to address the occurrence of mixture toxicity in the environment. Mixture effects may be included in water quality and risk assessments by adding-up risk quotients for individual compounds. Another option is to consider the derivation of an EQS for the group of synthetic pyrethroids as a whole by using information on relative potency.

Address knowledge gaps in environmental exposure

Some of the routes and environmental behaviour of synthetic pyrethroids are still less known. This is true for atmospheric transport of synthetic pyrethroids to surface waters, which warrants more study (see e.g. Méjanelle et al., 2022). Another knowledge gap is the presence of synthetic pyrethroids in surface water in relation to suspended matter and sediment (Méjanelle et al., 2022). In order to obtain more insight into the role of suspended matter in the Dutch aquatic environment, it would be worthwhile to analyse a series of samples containing synthetic pyrethroids before and after filtration.

Improve analytical methods

Although improvements have been made, it is a major challenge to detect synthetic pyrethroids in surface waters in the Netherlands at relevant regulatory levels. Until improved cost-efficient routine monitoring methods become available, this severely hampers regular compliance checking. Due to the large number of non-evaluable measurements, it is difficult to establish a plausible connection between exceedance of environmental quality standards and use. Such a connection is needed to initiate more voluntary and regulatory action. Measurements in biota may be used as an alternative to detect the presence of synthetic pyrethroids in surface waters. Such data may also be used for further risk assessment. It is recommended to perform a pilot and measure synthetic pyrethroids concentrations in samples that are collected within the context of the existing WFD biota monitoring network. Care should be taken, however, that samples are used from areas in which emissions of synthetic pyrethroids are likely.

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Appendix 1 Chemistry and classification of synthetic pyrethroids

According to Katagi (2012) “synthetic pyrethroids are basically carboxylic esters whose acid and/or alcohol moieties have geometrical isomerism and/or optically active center(s) in most cases". Synthetic pyrethroids are classified into two groups based on their toxicity and physical properties, namely Class I and Class II. Class I synthetic pyrethroids have a basic structure of a cyclopropane carboxylic acid ester. This basic structure is circled in Figure A1.1 using the synthetic pyrethroid 1R-trans-phenothrin as an example. The synthetic pyrethroids 1R-trans-phenothrin, bifenthrin, d-allethrin, d-tetramethrin, epsilon-momfluorothrin, imiprothrin, metofluthrin, permethrin, prallethrin, tefluthrin, tetramethrin and transfluthrin all belong to the class I synthetic pyrethroids. Class I synthetic pyrethroids, unlike class II synthetic pyrethroids, do not contain an alpha-cyano group (circled).

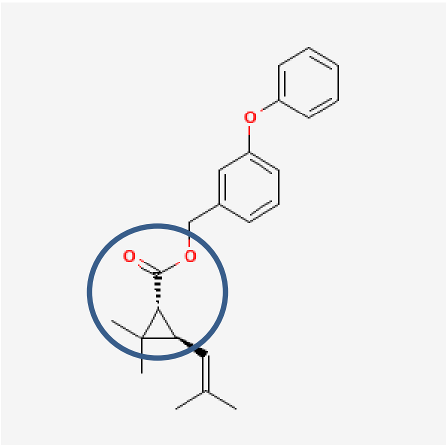


Figure A1.1 Structure of a class I synthetic pyrethroid (1R-trans-phenothrin)

Class II synthetic pyrethroids have alpha-cyano group. The synthetic pyrethroids alpha-cypermethrin, cyphenothrin, cyfluthrin, cypermethrin, deltamethrin, esfenvalerate, flumethrin, gamma-cyhalothrin, lambda-cyhalothrin, and tau-fluvalinate all belong to the class II synthetic pyrethroids. An example of a class II synthetic pyrethroid is shown in Figure A1.2, in which the alpha-cyano group is circled.

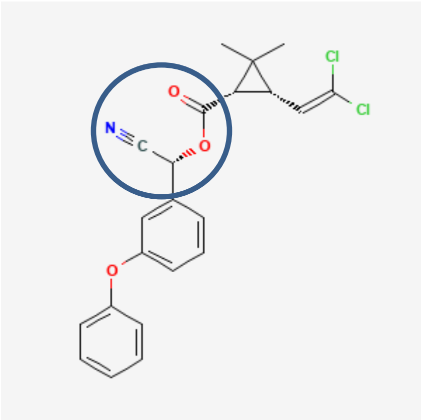


Figure A1.2 Structure of a class II synthetic pyrethroid (alpha-cypermethrin)

Like the class I synthetic pyrethroids, most class II synthetic pyrethroids contain a basic structure of a cyclopropane carboxylic acid ester. The class II synthetic pyrethroids esfenvalerate and tau-fluvalinate do contain a carboxylic acid ester with a cyano group at the alpha position, but do not contain the cyclopropane ring. The structural formulas of esfenvalerate and tau fluvalinate are shown in Figure A1.3.

RIVM attaches a great deal of importance to the accessibility of its products, but at present we cannot yet provide this figure in an accessible form. Also see www.rivm.nl/accessibility.

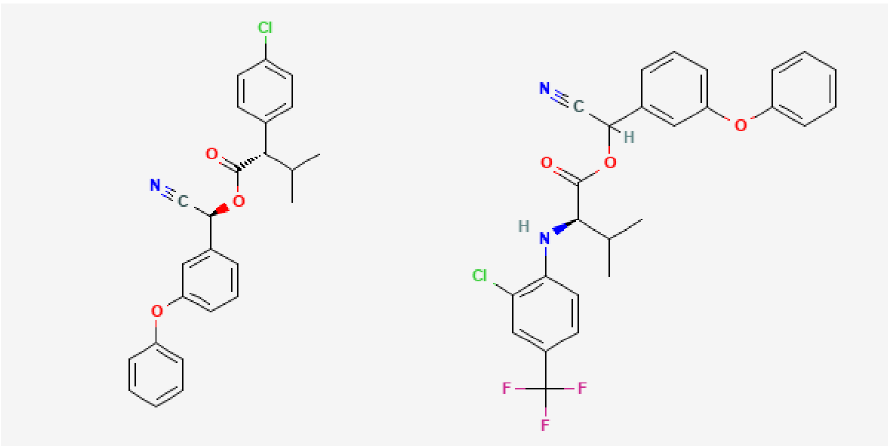


Figure A1.3 Structure of a class II synthetic pyrethroids esfenvalerate and tau-fluvalinate.

The synthetic pyrethroid etofenprox does not contain a basic structure of a cyclopropane carboxylic acid ester, nor an alpha-cyano group or cyclopropane ring. Nevertheless, based on a similar toxicity and mechanism of action, etofenprox is considered to belong to the group of synthetic pyrethroids (of class I as it has no cyano group). The structural formula of etofenprox is shown in Figure A1.4.

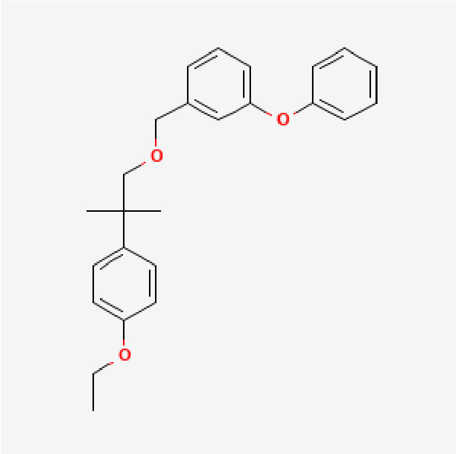
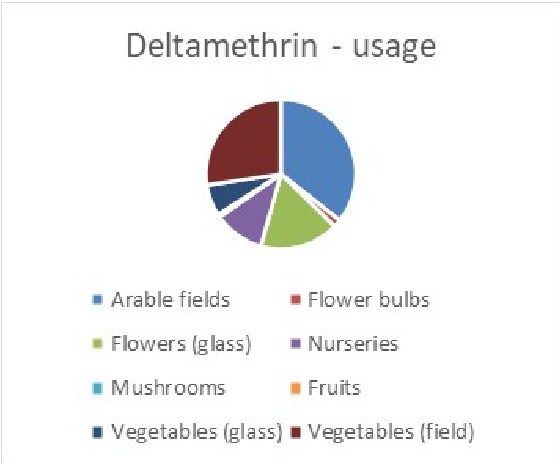
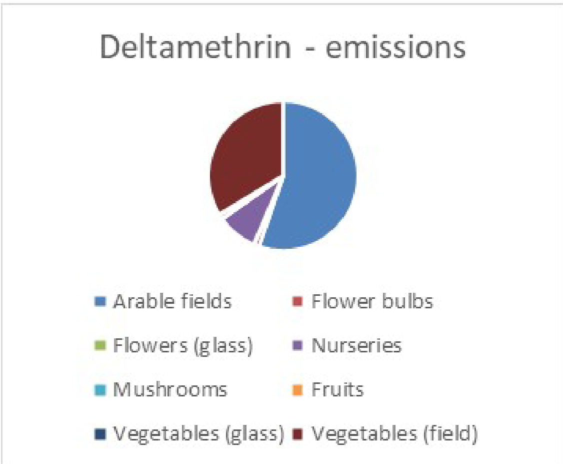


Figure A1.4 Structure of etofenprox

Appendix 2 Usage, emissions and impact in surface waters





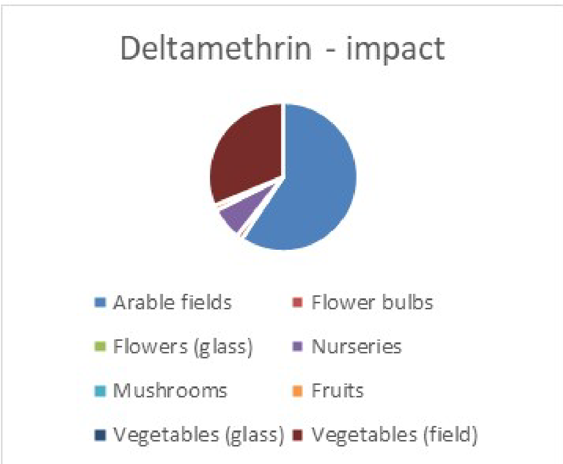
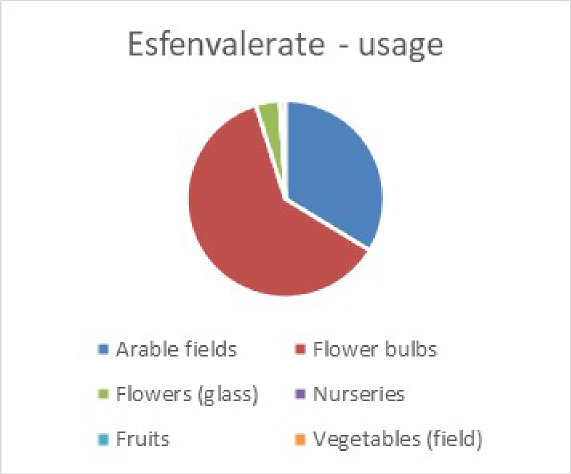
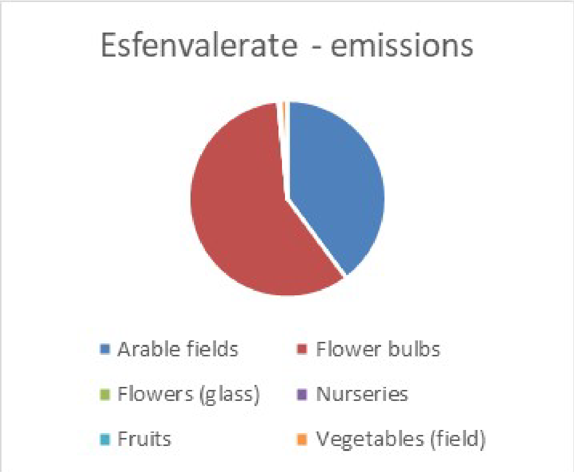


Figure A2.1 Relative contribution of different crop systems to the usage, emissions to surface water and impact in surface water of deltamethrin used in PPP according to model estimations for 2016 with the National Environmental Indicator (NMI).





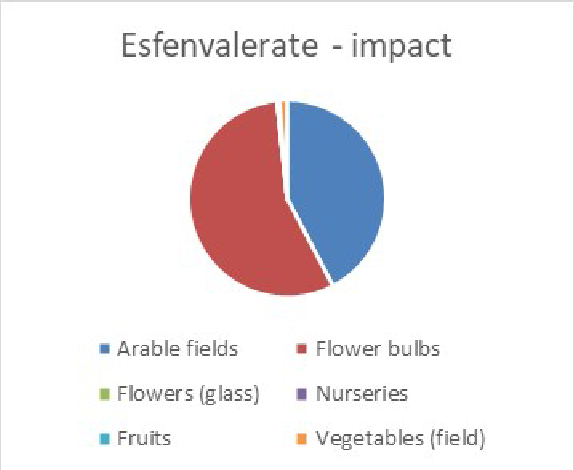
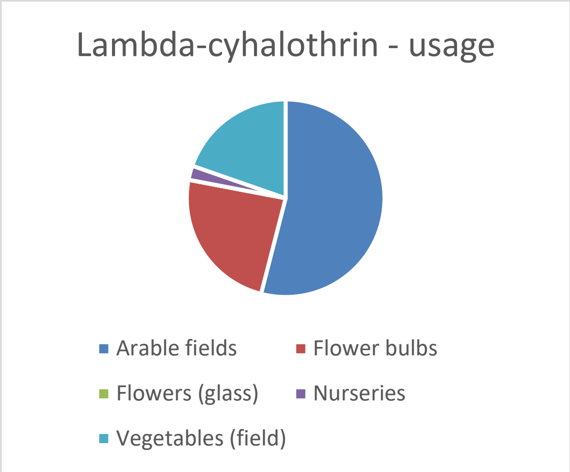
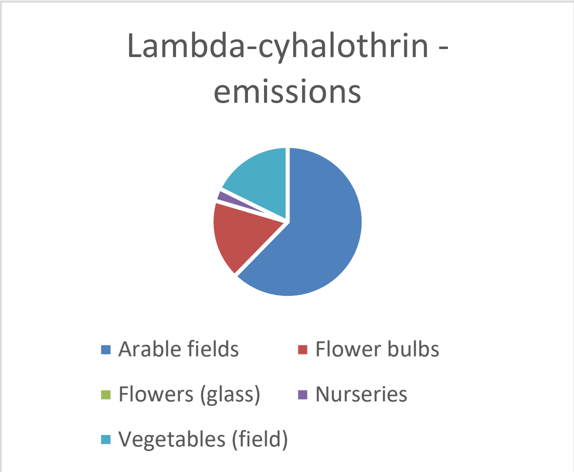


Figure A2.2 Relative contribution of different crop systems to the usage, emissions to surface water and impact in surface water of esfenvalerate used in PPP according to model estimations for 2016 with the National Environmental Indicator (NMI).





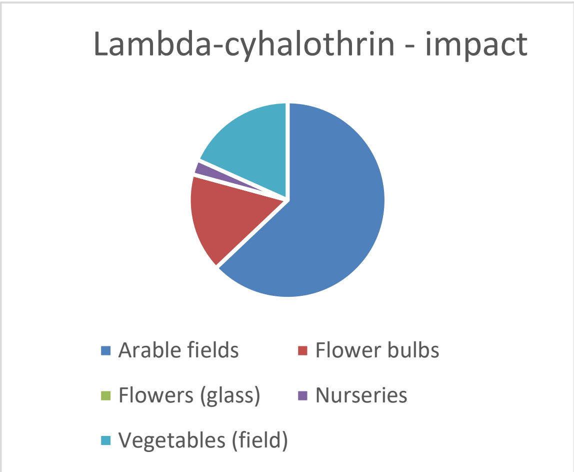


Figure A2.3 Relative contribution of different crop systems to the usage, emissions to surface water and impact in surface water of lambda-cyhalothrin used in PPP according to model estimations for 2016 with the National Environmental Indicator (NMI).

Appendix 3 Information on authorisation criteria and water quality standards

Data retrieval

Regulatory Acceptable Concentrations (RACs) for PPP were retrieved from the 'Pesticide Atlas' (Atlas Bestrijdingsmiddelen in Oppervlaktewater[42]). The lowest Predicted No Effect Concentrations (PNECs) for biocides were taken from the European approval dossiers at the website of the European Chemicals Agency (ECHA)[43], except for prallethrin and tetramethrin for which PNECs were retrieved from national authorisations via the database of the Netherlands' Competent Authority Ctgb[44].

Current European and national environmental quality standards for surface water (EQS) were retrieved from the RIVM website 'Risico's van Stoffen'[45]. Draft European EQS for bifenthrin, deltamethrin, esfenvalerate and permethrin are included in the proposal of the European Commission for amending the Water Framework Directive (WFD) and associated daughter directives (version 26 October 2022)[46]. European water quality standards are the Annual Average Environmental Quality Standard (AA-EQS) for chronic exposure and the Maximum Acceptable Concentration (MAC-EQS) for short term exposure peaks. National water quality standards are (indicative) AA- and MAC-EQS or formerly derived Maximum Permissible Concentrations (MPC). When comparing monitoring data with water quality standards, the AA-EQS is evaluated against the annual average concentration, while the MAC-EQS is evaluated against the yearly maximum concentration. The MPC is tested against the 90th percentile, as is the case for the authorisation criteria, the RAC (Regulatory Acceptable Concentration) for PPP and PNEC (predicted No Effect Concentration) for biocides.

[42] https://www.bestrijdingsmiddelenatlas.nl/atlas/1/1
[43] https://echa.europa.eu/information-on-chemicals
[44] https://toelatingen.ctgb.nl/nl/authorisations
[45] https://rvs.rivm.nl/
[46] Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy

Table A3.1 Overview of authorisation criteria for synthetic pyrethroids with a European approval (or in progress) as plant protection product (PPP) or biocide, and European and national water quality standards. All values in ng/L as dissolved concentrations, unless stated otherwise. Bifenthrin is no longer approved in Europe but is added because of its status as candidate priority substance under the WFD. Substances marked with an asterisk have no authorised products in the Netherlands at the time of writing. RACs for PPP are dependent on the predicted exposure profile, Predicted No Effect Concentrations (PNEC) biocides relate to chronic exposure. European water quality standards are the Annual Average Environmental Quality Standard (AA-EQS) for chronic exposure and the Maximum Acceptable Concentration (MAC-EQS) for short term exposure peaks. National water quality standards are (indicative) AA- and MAC-EQS or formerly derived Maximum Permissible Concentrations (MPC). Details on derivation are presented in Table A3.2.

Type	**Authorisation criteria [ng/L]**		**Surface water quality standards [ng/L]**					
Framework	**PPP**	**biocide**	**European EQS**			**National EQS**		
Substance	**RAC**	**PNEC**	**AA**	**MAC**	**Note**	**AA/MPC**	**MAC**	**Note**
1R-trans-phenothrin		47				0.001		indicative MPC for phenothrin
alfa-cypermethrin		4.8				0.09		
bifenthrin*		0.095	0.095	11	draft; total	1.0		indicative MPC
cyfluthrin (beta-cyfluthrin)*		0.041				0.2		indicative MPC
cyphenothrin*		8.1						
cypermethrin	13	1.0	0.08	0.60	total	see EU		
deltamethrin	3.2	0.70	0.0017	0.017	draft; total	0.0031	0.31	legal; total
d-tetramethrin*								
epsilon-momfluorothrin*		10						
esfenvalerate	10		0.017	8.5	draft; total	0.19	1.7	legal; total
etofenprox*		5.4				0.54		indicative MPC
flumethrin								
tau-fluvalinate						0.024		indicative MPC for fluvalinate
gamma-cyhalothrin*								
imiprothrin*		38						
lambda-cyhalothrin	10	0.20				0.020	0.47	legal; total
metofluthrin		1.2						
permethrin		0.47	0.27	2.5	draft; total	0.2 0.3		MPC; dissolved total
prallethrin		6.2						
tefluthrin	0.40					0.40	5.3	indicative; dissolved

Type	Authorisation criteria [ng/L]		Surface water quality standards [ng/L]					
Framework	PPP	biocide	European EQS			National EQS		
Substance	RAC	PNEC	AA	MAC	Note	AA/MPC	MAC	Note
						0.51	6.7	total
tetramethrin		500				0.29		indicative MPC
transfluthrin		1.75				0.070		indicative MPC

Table A3.2 Background of authorisation criteria and chronic water quality standards for synthetic pyrethroids with approval (in progress) for use in plant protection products (PPP) and biocides. Substances marked with an asterisk have no authorised products in the Netherlands at the time of writing. Bifenthrin is no longer approved in Europe, but included because of its status as candidate priority substance under the Water Framework Directive. RAC= Regulatory Acceptable Concentration; PNEC = Predicted No Effect Concentration; AF = assessment factor; NL= the Netherlands, EQS = environmental quality standard in line with WFD methods; MPC = formerly derived Maximum Permissible Concentration.

Name	Authorisation criterion [ng/L]				Chronic water quality standard [ng/L]			
	PPP RAC	key study, AF	biocide PNEC	key study, AF	NL EQS/MPC	key study, AF	EU EQS	key study, AF
1R-trans-phenothrin			47	chronic crustacean AF 10	0.001[a]	indicative MPC, source unknown		
alfa-cypermethrin			4.8	chronic insect AF 5	0.09	acute crustacean AF 100		
bifenthrin*			0.095	chronic crustacean AF 10	1.0	acute crustacean, AF 100	0.095	chronic crustacean, AF 10
cyfluthrin* (beta-cyfluthrin)*			0.041	chronic crustacean AF 10	0.2	indicative MPC, source unknown		
cypermethrin	13	geomean chronic fish AF 10	1.0	chronic fish AF 10	see EU		0.080	chronic crustacean AF 50

Name	Authorisation criterion [ng/L]				Chronic water quality standard [ng/L]			
	PPP RAC	key study, AF	biocide PNEC	key study, AF	NL EQS/MPC	key study, AF	EU EQS	key study, AF
cyphenothrin*			8.1	chronic crustacean AF 10				
deltamethrin	3.2	mesocosm	0.70	chronic insect AF 5	0.0031	acute crustacean AF 100	0.0017	acute crustacean AF 100
d-tetramethrin*								
epsilon-momfluorothrin*			10	chronic crustacean AF 50				
esfenvalerate	10	mesocosm			0.10 (dissolved 0.19 (total)	chronic fish AF 10	0.017	chronic crustacean, AF 10
etofenprox*			5.4	chronic crustacean AF 10	0.54	chronic crustacean AF 100 indicative		
gamma-cyhalothrin*								
imiprothrin*			38	acute fish AF 1000				
lambda-cyhalothrin	10	mesocosm	0.20	chronic crustacean AF 10	0.020	chronic crustacean AF 50		
metofluthrin			1.2	acute fish AF 100				
permethrin			0.47	chronic crustacean AF 10	0.20 (dissolved) 0.30 (total)	acute crustacean AF 100		

Name	**Authorisation criterion [ng/L]**				**Chronic water quality standard [ng/L]**			
	PPP RAC	**key study, AF**	**biocide PNEC**	**key study, AF**	**NL EQS/MPC**	**key study, AF**	**EU EQS**	**key study, AF**
prallethrin			6.2	acute crustacean AF 1000				
tau-fluvalinate					0.024[b]	indicative MPC source unknown		
tefluthrin	0.40	chronic fish AF 10			0.40	chronic fish AF 10 indicative		
tetramethrin			500	acute fish AF 10	0.29	indicative MPC source unknown		
transfluthrin			1.75	chronic crustacean AF 10	0.070	indicative MPC source unknown		

Appendix 4 Surface water monitoring data for 2010-2021

Table A4.1 Summary of the comparison of monitoring data with chronic water quality standards (MPC, AA-EQS), acute water quality standards (MAC-EQS), and authorisation criteria for plant protection products (PPP-RAC) and biocides (biocides-PNEC).

Substance	**Standard**	**Average # of locations per year**	**% > 5* EQS**	**% > EQS**	**% detected**	**% non-evaluable**	**% not detected**
allethrin	MPC	74	1.5	0	0	98.5	0
bifenthrin	MPC	54	0	0	0.2	58.7	41.2
cyfluthrin	MPC	159	0.4	0	0	99.6	0
cyfluthrin	PNEC biocide	159	0.4	0	0	99.6	0
cyhalothrin, lambda-	AA-EQS	1294	1.6	0	0	98.2	0.1
cyhalothrin, lambda-	MAC-EQS	1294	1.5	0.2	0	97.5	0.9
cyhalothrin, lambda-	RAC PPP	1294	0.1	0.8	0.7	25.3	73.1
cyhalothrin, lambda-	PNEC biocide	1294	1.5	0.1	0	97.5	0.9
cypermethrin	AA-EQS	1710	2.6	0	0	97.4	0
cypermethrin	MAC-EQS	1710	2.3	0.3	0	97.5	0
cypermethrin	RAC PPP	1710	0.1	1.1	1.4	28.9	68.5
deltamethrin	AA-EQS	1658	2.4	0	0	97.6	0
deltamethrin	MAC-EQS	1658	2.1	0	0	97.9	0.1
deltamethrin	RAC PPP	1658	1.7	0.4	0.2	89.4	8.3
deltamethrin	PNEC biocide	1658	2.1	0.3	0	97.6	0.1
esfenvalerate	AA-EQS	1177	6.3	0	0	93.6	0.1
esfenvalerate	MAC-EQS	1177	5.8	0.3	0	93.8	0.1
esfenvalerate	RAC PPP	1177	1.3	3.3	1.8	35.6	58.1
phenothrin	MPC	26	0	0	0	100.0	0
permethrin	MPC	515	1.4	0	0	98.6	0
permethrin	PNEC biocide	515	1.4	0	0	98.6	0
tefluthrin	MPC	108	0.5	0	0	99.5	0
tefluthrin	RAC PPP	108	0	0.3	0.2	93.6	6.0
tetramethrin	MPC	303	0.3	0	0	99.7	0

Substance	Standard	Average # of locations per year	% > 5* EQS	% > EQS	% detected	% non-evaluable	% not detected
tetramethrin	PNEC biocide	303	0	0	0.3	0	99.7
transfluthrin	MPC	53	0	0	0	100	0
transfluthrin	PNEC biocide	53	0	0	0	100	0

Appendix 5 Spatial distribution of AA-EQS and RAC exceedances of PPP

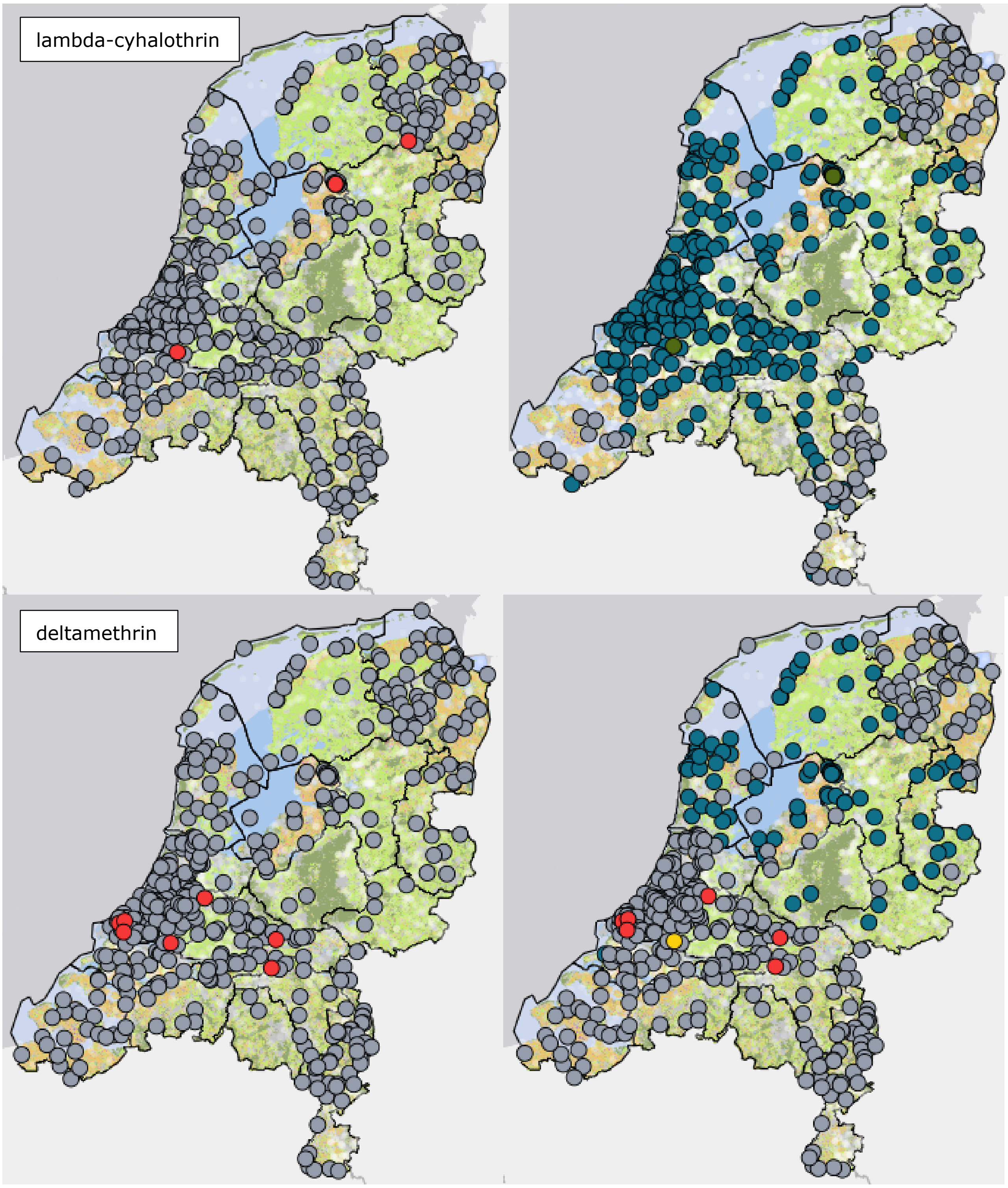


Figure A5.1 Spatial distribution of the exceedances of the AA-EQS (left map) and RAC for PPP (right map). Red: >5 times EQS/RAC; yellow: >EQS/RAC; green: detected and <EQS/RAC; blue: not detected and <EQS/RAC; grey: non-evaluable, not detected and LoQ>EQS/RAC.

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