Prospects and side effects of carbendazim, tebuconazole and propiconazole in film and construction material preservatives (PT7 and PT10)

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Summary

- *Report and summary*

This report describes the results of a study that was conducted on behalf of the Dutch Ministry of Infrastructure and Water Management (IandW). This ministry wants to use the results of this study as an input into EU decision-making on the reassessment of the approval of carbendazim and tebuconazole for PT7 and PT10 and propiconazole for PT7. The three active substances are all candidates for substitution.

There are two circumstances that raise specific research questions. First, no biocides based on these substances are authorised to be placed on the Dutch market, nor are there such biocides registered in the ECHA database as authorized under BPR conditions. Second, all three active substances are specifically relevant for Dutch surface water quality (carbendazim has even been flagged as a 'specific pollutant').

The research questions to be answered are therefore:

1. Will there be approval requests for these substances for PT7 and PT10, authorisations of biocides based on them, and/or biocides and articles treated with these biocides on the EU market?
2. To what extent do historical, current and future use of these substances and products for PT7 and PT10 contribute to the problems with surface water pollution and the occurrence of resistance?

This summary briefly outlines the results of the research.

- *Answers to research question 1*

Concerning the first research question it is concluded that there will be no requests for reapproval of carbendazim and tebuconazole for PT7 and PT10, nor for propiconazole for PT7. The original producers/suppliers will not apply for reapproval and have already removed the active substances from the EU market (mainly because the approvals of these substances have come with restrictions that seriously impacted their markets). The deadlines for requests for approval have meanwhile expired.

According to the producers/suppliers of these active substances, there are no more biocides based on these substances on the EU market. Such products could still be legitimately marketed under transitional law in certain Member States, but available data do not indicate that this is taking place.

As far as paints, adhesives and plaster with these ingredients are concerned, some historical stock may lead to incidental (and finite) use. The number of buildings and constructions that are treated with these paints, adhesives and plasters will rise no further. What remains is a historical leftover, that may nevertheless still leach for some time.

- *Answers to research question 2*

The extent to which carbendazim, tebuconazole and propiconazole in biocides for PT7 and PT10 and in articles treated with such biocides contribute to water pollution, appears to be marginal and historic. (High) concentrations of carbendazim in Dutch surface waters appear to be associated with historic emissions of this persistent substance. Use of carbendazim (and thiophanate-methyl, which has carbendazim as its metabolite) in the past, and of tebuconazole in the present, as active substances in plant protection products, seem to (have) contribute(d) mostly to the high concentrations of these substances in the environment. To a lesser extent, the same holds true for tebuconazole and propiconazole as active substances for wood conservation (PT8). Finally, the

conclusions on research question 1 add to the impression that the contribution of PT7 and PT10 applications to water pollution are and will be marginal.

Also, the contribution of these active substances for PT7 and PT10 to azole resistance can be expected to be marginal and historic, for largely the same reasons as were mentioned above. These substances have been applied in far lesser volumes (if at all) for PT7 and PT10 than for non-biocidal use in plant production products and for biocidal use in wood preservation (PT8), and possibly for even more widely dispersed and voluminous use in (and disposal of) pharmaceuticals (human and animal medicines) and cosmetics.

- *Policy implications*

The overall conclusion following from these answers is that there is hardly or no relevance of specific policy and/or legal activity with respect to the reassessment of the approvals of carbendazim, tebuconazole and propiconazole for PT7 and PT10 (and the related authorisations).

It may, however, be worthwhile to explore whether use of carbendazim in (imported) textiles could be a source of the higher concentrations in surface waters that are sometimes measured in urban areas. Possibly, this could be an (as it is called) 'overlooked source' of carbendazim.

Samenvatting

- *Rapport en samenvatting*

Dit rapport beschrijft de resultaten van onderzoek dat is uitgevoerd in opdracht van het Nederlandse Ministerie van Infrastructuur en Waterstaat (IenW). Het ministerie wil de resultaten van dit onderzoek gebruiken als input voor de EU-besluitvorming over de herbeoordeling van de goedkeuring van carbendazim en tebuconazool voor PT7 en PT10 en propiconazool voor PT7. De drie werkzame stoffen zijn ieder aangemerkt als kandidaat voor vervanging.

Er zijn twee omstandigheden die specifieke onderzoeksvragen oproepen. Ten eerste zijn er geen biociden op basis van deze stoffen toegelaten voor de Nederlandse markt, en zijn er ook geen biociden geregistreerd in de ECHA-database die onder BPR-voorwaarden zijn toegestaan voor de EU-markt. Ten tweede zijn alle drie de werkzame stoffen specifiek relevant voor de Nederlandse oppervlaktewaterkwaliteit (carbendazim is zelfs aangeduid als 'specifieke verontreinigende stof').

De te beantwoorden onderzoeksvragen zijn daarom:

1. Komen er (a) goedkeuringsaanvragen voor deze actieve stoffen voor PT7 en PT10, (b) toelatingsaanvragen van biociden op basis van deze stoffen en/of (c) artikelen die met deze biociden zijn behandeld op de EU-markt?
2. In hoeverre dragen historisch, huidig en toekomstig gebruik van deze stoffen en producten voor PT7 en PT10 bij aan problemen met oppervlaktewaterverontreiniging en het ontstaan van resistentie?

Deze samenvatting schetst kort de resultaten van het onderzoek.

- *Antwoorden op onderzoeksvraag 1*

Voor de eerste onderzoeksvraag wordt geconcludeerd dat er geen verzoeken zullen worden ingediend voor hergoedkeuring van carbendazim en tebuconazool voor PT7 en PT10, noch voor propiconazool voor PT7. De oorspronkelijke producenten/leveranciers zullen geen hergoedkeuring aanvragen en hebben de werkzame stoffen al van de EU-markt gehaald (voornamelijk omdat de goedkeuringen van deze stoffen gepaard gingen met beperkingen die hun markten ernstig hebben beïnvloed). De deadlines voor verzoeken om goedkeuring zijn inmiddels verstreken.

Volgens de producenten/leveranciers van deze werkzame stoffen zijn er geen biociden meer op basis van deze stoffen op de EU-markt. Dergelijke producten zouden in bepaalde lidstaten nog rechtmatig onder overgangsrecht op de markt kunnen worden gebracht, maar beschikbare gegevens geven niet aan dat dit gebeurt.

Wat betreft verf, lijm en pleister met deze ingrediënten, kan een historische voorraad leiden tot incidenteel (en eindig) gebruik. Het aantal gebouwen en constructies dat met deze verven, lijmen en pleisters is behandeld, zal niet verder toenemen. Wat overblijft is een historisch restant, dat desondanks nog wel enige tijd kan uitlogen.

- *Antwoorden op onderzoeksvraag 2*

De mate waarin carbendazim, tebuconazool en propiconazool in biociden voor PT7 en PT10 en in artikelen die met dergelijke biociden zijn behandeld, bijdragen aan watervervuiling, lijkt marginaal en historisch te zijn. (Hoge) concentraties carbendazim in Nederlandse oppervlaktewateren lijken verband te houden met historische emissies van deze persistente stof. Gebruik van carbendazim (en thiofanaat-methyl, dat carbendazim als metaboliet heeft) in het verleden, en van tebuconazool in het

heden, als werkzame stoffen in gewasbeschermingsmiddelen, lijken vooral bij te (hebben ge)dragen aan de hoge concentraties van deze stoffen in het milieu. In mindere mate geldt hetzelfde voor tebuconazool en propiconazool als werkzame stoffen voor houtconservering (PT8). Tot slot versterken de conclusies op onderzoeksvraag 1 de indruk dat de bijdrage van PT7- en PT10-toepassingen aan waterverontreiniging marginaal is en zal zijn.

Ook kan worden verwacht dat de bijdrage van deze werkzame stoffen voor PT7 en PT10 aan azolenresistentie marginaal en historisch zal zijn, grotendeels om dezelfde redenen als hierboven genoemd. Deze stoffen zijn in veel kleinere volumes toegepast voor PT7 en PT10 (als ze dat al zijn) dan voor niet-biocidaal gebruik in gewasbeschermingsmiddelen en voor biocidaal gebruik in houtconservering (PT8), en mogelijk voor nog breder verspreid en omvangrijker gebruik in (en wegwerp van) farmaceutische producten (medicijnen voor mens en dier) en cosmetica.

- *Beleidsimplicaties*

De algemene conclusie die uit deze antwoorden volgt, is dat er nauwelijks of geen relevantie is van specifiek beleid en/of juridische activiteiten met betrekking tot de herbeoordeling van de goedkeuringen van carbendazim, tebuconazool en propiconazool voor PT7 en PT10 (of de gerelateerde toelatingen).

Wel kan het nog de moeite waard zijn om te onderzoeken of het gebruik van carbendazim in (geïmporteerd) textiel een bron zou kunnen zijn van de hogere concentraties in oppervlaktewater die soms in stedelijke gebieden worden gemeten. Mogelijk zou dit een (zoals het wordt genoemd) 'over het hoofd geziene bron' van carbendazim kunnen zijn.

1. Introduction

1.1 Background to the study

General background

The Biocidal Products Regulation (BPR; EU/528/2012) prohibits the use in biocidal products of active substances with carcinogenic, mutagenic or reprotoxic (CMR), endocrine disrupting, PBT or vPvB[1] properties (Article 5(1)). Exceptions to that ban are only possible if the risk of use is demonstrably negligible, if the active substance is essential to prevent or control a serious danger to human or animal health or to the environment, or if non-approval of the active substance would have disproportionate negative impact on society when compared with the risk to human and animal health or the environment arising from the use of the substance (Article 5(2)).
The approval of active substances is reassessed at regular intervals, in addition to the fact that the European Commission can reconsider an approval at any time based on new information.

Carbendazim and tebuconazole have been approved as active substances for film preservation (PT7)[2] and construction material preservation (PT10)[2] in 2022[3] and 2015[4] respectively. Propiconazole has been approved as active substance for film preservation (PT7) in 2016.[5] Carbendazim and tebuconazole were approved in procedures that started before the BPR came into effect. According to the ECHA-database on biocides, all three substances are marked as candidates for substitution.[6]

The approvals of carbendazim, tebuconazole and propiconazole for PT7 and PT10 are scheduled for reassessment in respectively 2025, 2025 and 2026. The decision-making regarding reapproval or phasing out takes place in the Standing Committee on Biocidal Products (SCBP), which includes the Ministry of Infrastructure and Water Management (IandW) for the Netherlands. For its input into reassessments in the SCBP, IandW needs up-to-date insight into the use and replacement perspective of these substances for these PT's. It has therefore requested a report of the impact of reapproval or phasing out of these substances.

Specific circumstances for carbendazim, tebuconazole and propiconazole for PT7 and PT10

Several specific circumstances may have a special impact on the reassessment process for these substances. One of these circumstances is that although the three substances have been approved for PT7 and two of them also for PT10, at his moment (September 2024) no biocidal products for PT7 and PT10 based on these active substances are authorized to be placed on the Dutch market. Also, no such biocidal products are registered in the ECHA database, which implies that there are no authorizations under BPR conditions[7] for placing these products on the EU market. This raises

[1] PBT: persistent, bioaccumulative, toxic; vPvB: very persistent, very bioaccumulative
[2] PT7 and PT10: Product types 7 and 10. The BPR distinguishes 22 product types into 4 main groups. PT7 and PT10 are part of main group 2: preservatives. Product type 7 concerns products used for the preservation of films or coatings to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works. Product type 10 concerns products used for the preservation of masonry, composite materials, or other construction materials other than wood.
[3] Commission implementing regulation (EU) 2021/348 of 25 February 2021.
[4] Commission implementing regulation (EU) 1038/2013 of 24 October 2013.
[5] Commission implementing regulation (EU) 2015/1609 of 24 September 2015.
[6] Active substances are marked as 'candidate for substitution' following article 10 of the BPR. Article 10 makes mention of several grounds for considering an active substance a candidate for substitution, amongst which: 'it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2)' (article 10.1(a)).
[7] It is still possible that biocidal products based on active substances that have been approved under procedures that started before the BPR came into effect (and therefore on the basis of Directive 98/8/EC), are legitimately marketed in several Member States under transitional law.

questions about the future prospect of these substances and products on the EU market, and even on the relevance of a study to prepare for the oncoming reassessment process, if any such process will take place at all.

The other aspect concerns the specific relevance of these active substances for water quality and the development of resistance. In particular, carbendazim has been flagged as a 'specific pollutant' with relevance under the Water Framework Directive (2000/60/EC) (Osté et al., 2018). Furthermore, all three substances are associated with the development of resistance in fungi, including the 'azole resistance' that is currently attracting the attention of policy makers and medical professionals due to its increasing prevalence and impact. The question is therefore whether biocides for PT7 and 10 with these active substances (still) contribute to water pollution and resistance development – through either biocides or treated articles, through products that are either produced in or imported into the EU, and through use that is either legal and proper or otherwise – which would thus require (further) EU risk management measures.

In order to contribute to a thorough and careful preparation of the oncoming reassessment process, this report aims to answer these questions.

1.2 Purpose of the study and research questions

Given what has been written above, the purpose of this study is to examine the relevance of specific policy and/or legal activity with respect to the reassessment of the approvals of carbendazim, tebuconazole and propiconazole for PT7 and PT10 (and the related authorisations).

The research questions are:

1. Will there be any approval requests for these substances for PT7 and PT10, will there be authorisations of biocides based on them, and will there be such biocides and articles treated with these biocides on the EU market?
2. To what extent do historical, current and future use of these substances and products (biocides and treated articles) for PT7 and PT 10 contribute to the problems surrounding surface water pollution and the occurrence of resistance?

1.3 Approach of the study

The study has been carried out by means of desk research, interviews with stakeholders and consultations with experts.

The desk research consisted of:

- Studying public databases of approved substances and authorised biocides and underlying documents of ECHA (EU), the Board for the Authorisation of Plant Protection Products and Biocides (College voor de toelating van gewasbeschermingsmiddelen en biociden – Ctgb) (Netherlands), FOD Volksgezondheid (Belgium), Bundesanstalt für Arbeitsschutz und Arbeitsmedizin - BAuA (Bundesstelle für Chemikalien) (Germany) and Ministerio de Sanidad (Spain)
- Analysing websites with surface water quality data (in particular the 'atlas of pesticides', www.bestrijdingsmiddelenatlas.nl')
- Studying scientific literature

Interviews and consultations concerned:

- An interview and a series of exchanges via e-mail with the two sole producers of the three substances

- An interview with an independent expert in the field of biocides
- Consultations of three Dutch government organisations: Ctgb, the National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu – RIVM) and Rijkswaterstaat (RWS).

A list of sources is included in appendix 1 to this report.

1.4 Reading guide

The following chapter (2) contains general descriptions of the three substances: their functional and hazard properties, details of their approval, the authorised applications and requirements for treated articles, as well as market data for as far as available.

Chapter 3 deals with the first research question and describes for all three substances their prospects for PT7 and PT10 on the EU market.

Chapter 4 deals with the second research question and looks into the contribution of the historic, actual and future use of these three substances and the biocides and articles that are treated with them for PT7 and PT10, to both water pollution and the development of (azole) resistance.

In chapter 5 the final conclusions of the research are described.

Appendix 1 contains the list of sources that have been consulted for this study.

2. Properties, application and market data

2.1 Introduction

This chapter describes, mainly based on desk research:

- What is known about the functional and hazard properties of carbendazim, tebuconazole and propiconazole (section 2.2). This mainly concerns data of a natural scientific nature that have largely been known and established for a longer time. The description in this chapter is therefore largely based on the assessments of the evaluating competent authority and opinions of the Biocidal Product Committee (BPC);
- For which applications in PT7 and PT10 products containing carbendazim or tebuconazole and in PT7 containing propiconazole are authorised (section2.3). Current data on this are taken from the websites of ECHA and Ctgb (reference date September 2nd, 2024); and
- What else is known about the nature and size of the current market (section 2.4).

2.2 Properties

2.2.1 Functional properties

The substances studied are as follows:

- Carbendazim (CAS 10605-21-7)
- Tebuconazole (CAS 107534-96-3)
- Propiconazole (CAS 60207-90-1)

- *Carbendazim*

The use of carbendazim in product types 7 and 10 is as a fungicide in mainly paints and plaster. It reduces fungal growth through interacting with a non-DNA target (tubulin), affecting the spindle apparatus during mitosis, thereby inhibiting the development of the germ tubes, the formation of appressoria (by which it infects a host), and the growth of mycelia.[8,9]

- *Propiconazole and tebuconazole*

Tebuconazole and propiconazole are used in PT 7 and PT10 as fungicides in paints, adhesives and masonry and to prevent fungal infestation.[10,11] The mode of action of tebuconazole and propiconazole (and the triazole-group) is through the ergosterol biosynthesis: it inhibits the enzyme lanosterol 14-alpha-demethylase, thus halting the production of ergosterol. Ergosterol is the main sterol in the fungal cell membrane. Depletion of ergosterol thus damages the cell membrane, leading to fluidity of the membrane, halting growth and eventually resulting in cell death (Reinprecht et al., 2010).

[8] ECHA (2019). *Assessment Report Carbendazim Product-type 7 (Film Preservative) and 10 (Construction Material Preservative)*; November 2019, eCA: Germany.
[9] BPC (2019). *Opinion on the application for approval of the active substance: Carbendazim, Product type:7.* ECHA/BPC/234/2019. And BPC (2019). *Opinion on the application for approval of the active substance: Carbendazim, Product type:10.* ECHA/BPC/235/2019.
[10] ECHA (2013). *Assessment Report Tebuconazole Product-type 7 Film preservative*; September 2013, eCA: Denmark. And ECHA (2013). *Assessment Report Tebuconazole Product-type 10 Construction material preservative*; September 2013, eCA: Denmark.
[11] ECHA (2015). *Assessment Report Propiconazole Product-type 7 Film preservatives;* January 2015, eCA: Finland.

2.2.2 Hazardous properties for human health

All three substances are marked as candidates for substitution in accordance with Article 10(1) of Regulation (EU) No 528/2012, because of their (suspected) reprotoxicity and/or their PBT-properties (Persistent, Bioaccumulating, Toxic). None of the three compounds are classified as (suspected of) causing cancer or being genotoxic.

Humans may be exposed to the active substances during formulation of the end-use-products, during the application of the products by (automatic) spraying and brushing of indoor and outdoor surfaces, the sealing of joints (tebuconazole) and during the service life of treated indoor and outdoor surfaces. There is also the possibility of secondary exposure through inhalation or contact with the (wet) surface after application or ingestion of paint chips containing the biocide residue by small children.[9,10,11]

Table 1: Summary of hazardous properties for human health

Active substance	Hazard classifications in ECHA (C&L)
Carbendazim[12]	May cause genetic defects (Muta. 1B) May damage fertility, may damage the unborn child (Repr. 1B) May cause allergic skin reaction (sensitizer)
Tebuconazole[13]	Harmful if swallowed Suspected of damaging the unborn child (Repr. 2)
Propiconazole[14,15]	Harmful if swallowed May cause allergic skin reaction (sensitizer) May damage fertility, may damage the unborn child (Repr. 1B) Under assessment as Endocrine Disrupting (ED list)[16]

2.2.3 Hazardous properties for the environment

Carbendazim, propiconazole and tebuconazole during their use in PT7 and PT10, may be released into the environment during the formulation and storage of end-use-products, during the application of the products by (automatic) spraying and brushing of indoor and outdoor surfaces, the sealing of joints (tebuconazole) and during the service life of treated indoor and outdoor surfaces. Emissions to the environment are expected to end up in either the adjacent soil and ground- or surface water and/or in the sewer system and sewage treatment plants.[9] The active substances may then continue to contaminate the soil through application of sludge from sewage treatment plants. The environmental risk assessments of the three compounds expect most emissions to the environment through application and consequent leaching of the compounds during service-life in outdoor situations.[9,10,11]

[12] See: https://echa.europa.eu/nl/brief-profile/-/briefprofile/100.031.108.
[13] See: https://echa.europa.eu/nl/brief-profile/-/briefprofile/100.100.535.
[14] See: https://echa.europa.eu/nl/brief-profile/-/briefprofile/100.056.441.
[15] Swedish Chemicals Agency (2019). BPC-33: Minority opinion on BPC opinion on carbendazim in PT 7 and 10, reference B09-00388.
[16] Based on what is known about its precursor thiophanate methyl, carbendazim may be suspected to also fulfil the exclusion criterion on endocrine-disrupting properties.

Table 2: Summary of hazardous properties for the environment

Active substance	Classifications in ECHA (C&L), including PBT
Carbendazim[8,9]	Very toxic to aquatic life (acute) Very toxic to aquatic life with long-lasting effects (chronic) Persistent and toxic[3]
Tebuconazole[10]	Very toxic to aquatic life (acute) Very toxic to aquatic life with long-lasting effects (chronic) Very persistent and toxic[4]
Propiconazole[11]	Very toxic to aquatic life (acute) Very toxic to aquatic life with long-lasting effects (chronic) Very persistent[5]

All three compounds are not readily biodegradable in the environment and remain stable under diverse environmental conditions. They adhere to soil particles and thus accumulate locally in the environment. On the other hand, the three compounds have a low bioaccumulation potential, since they will be readily metabolized in organisms.

2.2.4 Resistance development

- *Propiconazole and tebuconazole*

A specific risk involved in the use of propiconazole and tebuconazole is the development of resistant fungi strains against these compounds. Azoles such as propiconazole and tebuconazole are a broad-spectrum class of antifungals that can be used on both human pathogenic fungi and plant pathogenic fungi (Burks et al., 2021). As stated in the Assessment Report of propiconazole (2015): *[it] is a normal phenomenon embodied in the natural process of the evolution of biological systems and all DMIs (demethylation inhibitors), including propiconazole, have a similar risk [for resistance development], although resistance factors may differ.*

Related compounds and metabolites of propiconazole and tebuconazole are also used in human healthcare. There are signs of the potential relation between the use of azoles such as propiconazole and tebuconazole and the reduced effectiveness in medical applications. Indeed: azole-resistant fungi strain *Aspergillus fumigatus* demonstrates the same mechanism of resistance in both the environment and the clinic, leading to increased research into the environmental occurrence of resistance and the implications for human health. Azole-resistant *A. fumigatus* strains have been found in the environment on every continent, except for Antarctica, with the highest number of reports from Europe (Assress et al., 2021; Burks et al., 2021).

Both ECHA and RIVM/Ctgb report the observation of azole-resistant fungi (*A. fumigatus*) in wood waste and in soil in The Netherlands and Great-Britain respectively (Wezenbeek & Komen, 2023).[17] Azole-resistant fungi have been found on several locations in the Netherlands (including flower bulb waste, green waste, and wood chip waste). Because of the possible consequences of infections with resistant fungi including the risks for human health, a European research project into azole resistance is underway (Wezenbeek & Komen, 2023).

- *Carbendazim*

Resistance to carbendazim in fungi is also an emerging issue. Carbendazim is part of the benzimidazole fungicide group, for which resistance has been found in many fungal species world-

[17] Biocidal Products Committee (2022). *Opinion on the application for approval of the active substance: Propiconazole Product type: 8;* ECHA/BPC/324/2022.

wide.[18] Benzimidazoles have been and are widely used because of their broad-spectrum activity against a very wide range of (fungal) diseases.

Resistance to benzimidazole fungicides occurs through another route than the azole-resistance. The mode of action of carbendazim and other benzimidazole fungicides is through binding of the beta-tubulin protein. The consequent mode of resistance is therefore through specific alterations in the binding sites of the beta-tubulin.[8]

The Fungicide Resistance Action Committee (FRAC), that maintains a list of resistance to fungicides, indicates that carbendazim, among others, poses a high risk of resistance.[18] This is due to the single single site mode of action, which causes an elevated potential for resistance.[9] The FRAC states that since commercialization of benzimidazoles, resistance to benzimidazoles has been reported in approximately 60 genera in over 115 species of fungi, globally. While the need for (environmental) monitoring and a resistance management strategy is underlined by EHCA[8] and the FRAC, insight into the present occurrence of benzimidazole resistance in the environment in either the Netherlands or Europe was not found in the literature.

2.3 Approved substances and authorized products

2.3.1 Approved active substances

The table below presents a summary of the conditions under which the active substances are approved for the EU market in their respective implementing regulations.

Table 3: Summary commission implementing regulations

Active substance	Approved PT	Period of approval	Conditions for authorization	Minimum degree of purity (w/w)
Carbendazim[3]	7 and 10	01-02-2022 to 31-01-2025[19]	Conditions for biocidal products Conditions for treated articles	99,0%
Tebuconazole[4]	7 and 10	01-07-2015 to 30-06-2025	Conditions for biocidal products	95,0%
Propiconazole[5]	7	01-12-2016 to 30-11-2026	Conditions for biocidal products Conditions for treated articles	96,0%

2.3.2 Authorized biocidal products

A biocidal product is a product with an active substance that is intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on harmful or undesired organisms.[20] In the case of PT7 and PT10, these products may either be the pure active substance or a formulation with high concentration of the active substance (e.g. 100% propiconazole) that is placed on the market to consequently be used in the formulation and production of a biocidal product or treated article (paints, adhesives or plaster) or it may be the ready-to-use formulated paints or plaster carrying the biocidal intent.

[18] See: https://www.frac.info/frac-teams/expert-fora/benzimidazoles/information.
[19] The approval period is 3 years. It is considerably shorter than the regular 10 years, the regulation states, because of its classification as a mutagen and reproductive toxicant.
[20] See: https://english.ctgb.nl/biocidal-products/frequently-asked-questions/pre-application-support/what-is-a-biocidal-product.

Table 4 below presents a summary of the use of biocidal products based on carbendazim, tebuconazole and propiconazole and the conditions under which the biocidal products may be authorized for the EU market. The number of authorized biocidal products is based on the Ctgb and ECHA databases, with reference date September 2nd, 2024.

Table 4: Summary of biocidal products

Active substance	PT	Type of product and typical use	Conditions on biocidal products from implementing regulation	Number of authorized biocidal products in NL
Carbendazim[8,9]	7	Paint, indoors	Outdoor use poses unacceptable risks for environment during service life. Biocidal products containing carbendazim shall therefore not be authorised for use in paints and plasters which are intended to be used outdoors	0
	10	Plaster, indoors		0
Tebuconazole[10]	7	Adhesive/sealant indoors (joints in kitchen, bathroom)	-	0
	10	Adhesive/sealant outdoors (joints in façade)	For use in PT10: sealant may not be used in vertical joints outdoors, unless risks can be reduced to an acceptable level, so to prevent risks to the soil compartment.	0
Propiconazole[11]	7	Paints or adhesives indoors (e.g. tile glue)	Labels and safety data sheets must indicate preventive measures for outdoor application. The aquatic compartment must be protected by not allowing outdoor application on mineral surfaces, unless risks can be reduced to an acceptable level	0

The active substances are either mixed as biocidal product (formulation) or they are incorporated directly into the respective end-product. The formulation is done in an industrial setting by professionals. The paint, adhesive or plaster is applied on surfaces, by brush, roller or spraying and this may be done by either professionals or non-professionals.[8,9,10,21]

2.3.3 Treated articles

Treated articles are substances, mixtures or articles that have been treated with a biocide or into which a biocide has been intentionally incorporated (impregnated wood, paint that is formulated with a preservative, anti-odour socks, antibacterial carpet, etc.).[22] Within the context of this research, the treated articles are paints, adhesives and plasters with the active substance in the formulation, but another primary goal than its biocidal activity. The difference between biocidal products and treated articles is that treated articles which primary goal is its biocidal activity, are classified as biocidal products.[22]

[21] BPC (2014). *Opinion on the application for approval of the active substance: Propiconazole, Product type:7* ECHA/BPC/33/2014.
[22] See: https://english.ctgb.nl/biocidal-products/application-process/type-of-product/treated-articles.

Depending on the requirements of the approval of the active substance, the label of the treated article must state the hazards and/or conditions, even when the treated article does not carry the biocidal claim.

- For carbendazim in PT7 and PT10: because of its hazardous properties as mutagen, reproductive toxicant and skin sensitizer, the regulation[3] requires treated articles to be appropriately labelled, indicating these hazards and that these products may not be used outdoors. Also, the paints and plaster with carbendazim may not be placed on the market for outdoor use, and this has to be indicated on the label of the treated article.
- For propiconazole in PT7: the label of treated articles must provide information on the presence of propiconazole in the mixture, its effect and any relevant instructions for use, including any precautions to be taken because of the biocidal products with which a treated article was treated or which it incorporates.[5] The last means that the label of each article containing propiconazole must state the measures to be taken to prevent emissions to soil and water compartments.

The regulation approving tebuconazole for the use in PT7 and PT10 does not require additional conditions concerning treated articles, before these can be placed on the market.[4]

2.4 Market data

2.4.1 Products, authorisations, and suppliers

On the reference date (September 2nd, 2024), there were zero biocidal products with either carbendazim, propiconazole or tebuconazole as an active substance authorised for the Dutch market for PT7 and/or PT10, based on the databases of Ctgb and ECHA. This results in no authorization holders in the Netherlands nor in the EU.

There is one supplier of the active substance for carbendazim for PT7 and PT10 (Arxada), one supplier for tebuconazole in PT7 and PT10 (Lanxess) and one supplier for propiconazole in PT7 (Lanxess).

Up to April 2023 one product containing propiconazole was allowed on the Dutch market[23], and by mutual approval also for a period on the Danish, Estonian and French market[24]. The authorization for this product is cancelled in all named countries.

2.4.2 Market volumes

An attempt was made to gain insight into the amount of carbendazim, tebuconazole and propiconazole as active substances for PT7 and PT10, as well as the quantities of relevant biocides for PT7 and PT10 on the Dutch (and EU) market.

Of course, there are several indications that the quantities of these substances and biocides on the Dutch market can be expected to be minimal. First and foremost, there is the beforementioned fact that there are no authorised products for PT7 and PT10 with these substances for the Dutch market. Nor are there biocidal products – authorised under BPR conditions – registered in the ECHA database.

Still, as mentioned in footnote 7, it is possible that biocidal products based on active substances that have been approved under procedures that started before the BPR came into effect are legitimately marketed in several other EU Member States under transitional law. This might be the case for

[23] See: https://toelatingen.ctgb.nl/nl/authorisations/16694.
[24] See: https://echa.europa.eu/nl/information-on-chemicals/biocidal-products/-/disbp/factsheet/NL-0017051-0000/authorisationid.

carbendazim an tebuconazole. Indeed, when looking at public databases of registered or notified biocides, several of such biocides come to the fore. Table 5 shows our findings from the Belgian, German and Spanish databases. As can be seen, there are indeed authorized and notified products for PT7 and PT10 with carbendazim and tebuconazole for the Belgian and German market (and seemingly, also products with propiconazole for PT7 for the German market).

Table 5: Registered/notified biocides for PT7 and PT10 based on carbendazim, tebuconazole and propiconazole in Belgium, Germany and Spain (reference date: 9 September 2024)

Country	PT	Carbendazim	Tebuconazole	Propiconazole
Belgium	7	4 (combined) registrations, valid until 31/12/24	No registrations for PT7	No registrations for PT7
	10	No registrations for PT10	1 registration for PT8 and PT10, valid until 31/12/2030	No approval
Germany	7	24 notifications for PT7, all valid until 31/1/2025	2 notifications for PT7, both valid until 30/6/2025	5 notifications for PT7, all valid until 30/6/2025. Two of them are cancelled, three are authorised pending an approval decision
	10	8 notifications for PT10, all valid until 31/1/2025	2 notifications for PT10, both valid until 30/6/2025	No approval
Spain	7	No products with carbendazim in database	No registrations for PT7 or PT10 (58 products in database, all PT08)	No registrations for PT7 (105 products in database, 1 for PT18, all others for PT08)
	10			No approval

Of course, the fact that there are product formulations that are authorized and notified for these markets, does not necessarily mean that these products are actually (still) on the market. One indication that they are hardly or not, is the declaration by the suppliers of the active substances in interviews for this study, that none of these products are at present available on the EU market (see further in next chapter), and that all the registrations are historical.

To find further substance to these claims, it was tried to find market data on amounts of traded active substances and biocides in the Netherlands and several other EU Member States. For the Netherlands, however, there are no public sources for these data, as they are not registered. Data on the amount of these substances for PT7 and PT10 applications on the European market can be obtained from Member States where the volumes of traded active substances and biocides are registered.

- One of those countries is Belgium. The market data that suppliers are obliged to provide – numbers and tonnages of active substances and products per year – are published on a website,[25] albeit only at the level of Product Groups and PTs. On request, specific data for 2018 until 2021 are currently[26] available. These are shown in table 6 below. The table shows that only products for PT7 with carbendazim were traded in Belgium. For all other active substances and PT7/10 applications the volumes were zero.
  Also, it should be noted that for now there are only publicly available data on traded volumes of carbendazim-based products until 2021. The EU approval of carbendazim as an active substance

[25] See: apps.health.belgium.be/files-dwh-ext/files/gau/index.html.
[26] In Belgium, registration started in 2018; After 3 years, figures at substance level become passively public.

for PT7 and PT10, which may have had serious impact on the market position of carbendazim (see next chapter), dates from 2022.

Table 6: Traded amounts of biocides for PT7 and PT10 (in kg's) in Belgium, based on carbendazim, tebuconazole and propiconazole (source: FOD Volksgezondheid)

Year	Carbendazim		Tebuconazole		Propiconazole
	PT7	PT10	PT7	PT10	PT7
2018	1150	0	0	0	0
2019	2940	0	0	0	0
2020	650	0	0	0	0
2021	5460	0	0	0	0

– Another Member State where volumes of traded active substances and biocides are registered is Croatia. The volumes that are traded on the Croatian market are shown in the table below.

Table 7: Traded amounts of biocides for PT7 and PT10 (in kg's) in Croatia, based on carbendazim, tebuconazole and propiconazole (source: Republic of Croatia, Ministry of Health)

Year	Carbendazim	Tebuconazole		Propiconazole
	PT7 / PT10	PT7	PT10	PT7
2018	9,6	0	0	0
2019	640	0	0	0
2020	860	0	0	0
2021	820	0	0	0
2022	7,5	0	0	0
2023	10	0	0	0

These data show that also in Croatia only products for PT7 and PT10 with carbendazim were traded (notably: 6 products for PT7 and 1 for PT10). For tebuconazole and propiconazole for PT7/10 applications the volumes were zero.

The Croatian data on trade in carbendazim show a significant drop in 2022 and 2023, which coincides with the ban on outdoor use of carbendazim based products and the withdrawal of the active substance from the EU market by the supplier. Indeed, the Croatian expert confirms that the carbendazim based products traded in 2022 and 2023 were based on stocks from previous years. They concern 2 products that were formulated in Croatia and were intended for indoor use. No products were imported into Croatia after 2021.

– Finally, in Germany market data are registered as well. They are however only for the use of the authorities and are not publicly available.

3. Prospects on the EU market

3.1 Introduction

As was described, at this moment (September 2024) no biocidal products for PT7 and PT10 based on carbendazim, tebuconazole or propiconazole are authorized to be placed on the Dutch market. Also, no such biocidal products are registered in the ECHA database, which implies that there are no authorizations under BPR conditions for placing these products on the EU market.

To understand if (and if so, what type of) legal or policy attention is required around these active substances, it is important to have insight into the future prospect of these substances and products on the EU market. This chapter therefore answers the questions whether there will be any approval requests for these substances for these PTs, whether there will be authorisation requests for biocides based on them, and whether there will be such biocides and articles treated with such biocides on the EU market.

These questions will be answered separately for each active substance in paragraphs 3.2 to 3.4, and for treated articles with biocides based on these substances in paragraph 3.5.

3.2 Carbendazim for PT7 and PT10

Specific aspects of the approval

In the past, carbendazim was an important active substance for use in plant protection products. However, per 2014 the approval for this use expired (with the period of grace expiring per 2016).[27] The approval of another relevant substance in plant protection, thiophanate-methyl, which has carbendazim as metabolite, expired in 2020 (period of grace expiring per 2021).[28]

As was described in the previous chapters, carbendazim has been approved as active substance for film preservation (PT7) and construction material preservation (PT10) in 2022, in a procedure that started before the BPR came into effect.

It can be noted that this approval did not come about as straightforward as is mostly the case for these substances. First, the opinions of the Biocidal Products Committee (BPC) were not unanimous. Next to the adopted BPC opinions on the applications for approval of the active substance carbendazim for PT7 and PT10,[9] a minority opinion was issued by the Swedish competent authority in which it argues that outdoors use of carbendazim-treated articles should be prohibited.[15] Next, in 2020 the European Parliament adopted a resolution on the draft Commission implementing regulation approving carbendazim for use in PT7 and PT10.[29] The resolution calls on the Commission, on the basis of legal and political arguments and 'in light of the unacceptable risks it poses to human health and the environment,' to withdraw its draft implementing regulation and to submit a new draft, proposing not to approve carbendazim as an active substance for use in biocidal products of product-types 7 and 10.

[27] See: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/506.
[28] See: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/807.
[29] European Parliament resolution of 26 November 2020 on the draft Commission implementing regulation approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 (D069099/01 — 2020/2852(RSP)).

In 2021 the Commission issued its final Implementing regulation approving carbendazim for use in PT7 and PT10 (per 2022)[3] with two specific elements:[30]

- The period of approval is set at three years. The most important reason given for this, is that – in the context of a potential renewal of approval – it should be examined at Union level as soon as possible whether the conditions of Article 5(2) of the BPR can be satisfied.
- Biocidal products containing carbendazim may not be authorised for use in paints and plasters which are intended to be used outdoors. Furthermore, paints and plasters treated with or incorporating carbendazim may not be allowed to be placed on the market for outdoor use. Lastly, paints and plasters treated with or incorporating carbendazim must be labelled to indicate that they are not to be used outdoors.

The applicant for the approval sought review by the European Court of Justice. However, the court decision,[31] which was issued in 2024, did not follow the applicant's arguments.

Market effects of the approval

The ban on the outdoors use of paints and plasters with carbendazim, appears to have effectively led to a complete removal of carbendazim-based products in PT7 and PT10 from the European market. According to the applicant/producer, the main use of carbendazim in PT7 and PT10 was for outdoors. For indoor use – which is a far smaller market than the market for outdoors – there are no carbendazim-based products, as other fungicides are better suited for this purpose.

As a consequence, the producer has stopped selling carbendazim and carbendazim-based biocides within the EU. Also, it can be expected that no other manufacturer or formulator of biocidal products is supplying carbendazim-based products, as the active substance is no longer available within the EU and as they are also bound to the same restriction (a ban for outdoor use).

The producer states that he will not apply for renewal of the approval of carbendazim for PT7 and PT10 (meanwhile the deadline for doing so has expired). So, according to the supplier: "Carbendazim is forever lost for the EU market."

According to an interviewed expert, also other circumstances – like the costs incurred by the fixed purity rate, the costs and lack of capacity for the required testing of endocrine disruption of non-target organisms, and the hard stop on data protection in 2025 – would have made a submission for renewal highly unlikely.

The interviewed expert states that paints and plasters with carbendazim were mostly used in the Eastern and Southern parts of Europe. This has also been stated in a contribution to the public consultation as part of the assessment of carbendazim in 2014.[9] The supplier of carbendazim says he has limited or no knowledge of where in the EU products with carbendazim were used. The carbendazim was sold to paint makers and they can sell their products anywhere in the EU.

Producers' note on sustainability and innovation

The producer of carbendazim stresses the high performance and effectiveness of the fungicide carbendazim and claims that it significantly contributes to the maintenance of infrastructure and thus to the sustainability goals of reduced use of resources, reduced emission of greenhouse gases and reduced waste.

[30] The interviewed producer of carbendazim points out that the regulators did not follow a 'one safe use' approach. According to this producer, with the (last minute) introduction of a restriction for outdoor use the opportunity was denied to introduce additional data at product authorisation level.
[31] Judgement of the General Court (Ninth Chamber), 17 January 2024 in Case T-297/21.

He goes on to say: "We must look for technologies that allow for safe use of biocides. An example: most of our dry film products now contain encapsulated biocides. This technology allows to use low concentrations, release into the façade and then the environment is highly controlled, there is no longer the initial burst release with first rainfall and there is safer handling by manufacturers and painters. Carbendazim is still on the market in the USA and Asia, and there we are selling this innovation. The EU has been denied this innovation because of the imposed restriction. One should hope that while striving for a non-toxic environment, we will at the same time strengthen the framework for innovation in the EU as well as the competitive position of its industry."

The essence of the current EU approval system (under BPR) is that active substances with specific hazard characteristics are phased-out, unless there are no alternatives and use of these substances is essential to society. This principle has also been introduced to steer innovation towards less hazardous alternatives. Carbendazim has been approved in a procedure that started before the BPR came into effect, but the shorter duration of the approval (3 years) was chosen with the explicit intention to allow as soon as possible for an examination whether the reasons for exemption of article 5.2 BPR (essential for society and no alternatives) apply. All in all, this means that EU approval procedure is based on other principles than the ones on which the producer relies.

3.3 Tebuconazole for PT7 and PT10

As was described in the previous chapters, tebuconazole has been approved as active substance for film preservation (PT7) and construction material preservation (PT10) in 2015, in a procedure that started before the BPR came into effect. The approval expires 30 June 2025.

The applicant of this approval has successfully applied for authorisations for tebuconazole-based biocidal products for PT7 and PT10. Authorisations can be found in German and Belgian databases, next to a few authorizations of tebuconazole-based biocidal products for PT7 and PT10 from other producers.

On our questions, the applicant/producer informed us that its authorised products are no longer on the market anymore, and that the entries in the databases are historical. Moreover, he states that, to his knowledge, tebuconazole is currently neither used for PT7 nor for PT10 in the EU. The company itself decided not to apply under BPR for a biocidal product, due to low market acceptance in PT7. Also, no other suppliers have submitted applications for authorisations of biocidal products, according to the applicant/producer.

The applicant/producer states that it will not apply for reapproval of tebuconazole for PT7 and PT10, as this in commercially not attractive. Meanwhile the deadline for doing so has expired. This implies that tebuconazole will only be available on the EU market of active substances for biocides for wood preservation (PT8). Current use and perspectives for substitution of tebuconazole in PT8 have been described in a separate report (Le Blansch and Groot, 2024).

3.4 Propiconazole for PT7

Propiconazole has been approved as active substance for film preservation (PT7) in 2016. The approval expires 30 November 2026.

From the database of the Dutch Ctgb it shows that only one propiconazole-based product has been authorized for PT7 for the Dutch market (authorization per 2021). Next to that, in 2016 an application

was done for mutual recognition to the competent authorities (CA's) of a number of Member States, including France, Sweden and Germany, with The Netherlands as reference Member State.

As is described in the Commission implementing decision 2022/2054, in 2020 the German CA objected to the risk mitigation measures for articles treated with this product as they were described in the draft authorisation issued by the Dutch authorities.[32] Germany considered that these risk mitigation measures could only be included in an authorisation of a biocidal product if they were referred to in the conditions of approval of the active substance. As this was not the case and, consequently, according to Germany, unacceptable effects on human health and the environment from the use of the biocidal product could not be properly addressed in the authorisation, the product should not be authorised. As no agreement on this objection was reached by the coordination group, in 2021 the Netherlands referred the unresolved objection to the Commission. In 2022 the Commission issued the implementing decision mentioned above, in which it confirms the German arguments, to the effect that there will be no mutual recognition, and that the Dutch authorisation is withdrawn in 2023.[33] In practical terms, the consequence of all this is that the approval of propiconazole as active substance for PT7 remains valid until 2026, but that it is close to impossible to obtain an authorisation for propiconazole-based biocides for PT7.

The applicant/producer states that it will not apply for reapproval of propiconazole for PT7. To this he adds that, since the reclassification of propiconazole in 2020, the role of the substance in PT7 has diminished steadily. This would imply that propiconazole will only be available on the EU market of active substances for biocides for wood preservation (PT8). Current use and perspectives for substitution of propiconazole in PT8 have been described in a separate report (Le Blansch and Groot, 2024).

3.5 Treated articles

The final question to be answered in this chapter, is whether there are and will be articles treated with biocides based carbendazim, tebuconazole and propiconazole on the EU market. Treated articles are paints or adhesives (PT7) and plaster or adhesives (PT10). Treated end-products can be (parts of) buildings and constructions.

- ***Paints/adhesives:*** at present, there appears to be hardly or no paint or adhesive with either of these three active substances for PT7 purposes on the EU market. Even though these products could be marketed legitimately under transitional law in some member states, the producers of these substances have withdrawn their biocidal products from the market, and the producer of carbendazim has even withdrawn the active substance from the EU market. Belgian and Croatian market data show that the traded amounts of tebuconazole and propiconazole for PT7 and PT10 purposes were zero over all the years reported. Only for carbendazim for PT7 the Belgian and Croatian data show that there has been trade going on. In Belgium these data concern a period before the approval of 2022 in which outdoor use was banned. In Croatia, after 2021 the traded volumes of carbendazim for PT7 drop significantly, and only concern stocks from previous years that were used to formulate products for indoor use.
  For the future, no reapproval of the three substances will be applied, which means that they will not be available for (legitimate) use in paints or adhesives. This concerns both paints and adhesives produced in, and imported into the EU. According to the interviewed expert, world trade of paints is dominated by producers of several renowned brands who attach great importance to compliance to EU standards, which means that there will be little or no imported paint or adhesives with these substances in the EU.

[32] Commission implementing regulation (EU) 2022/2054 of 21 October 2022.
[33] Ctgb, Besluit NL-0017051-000, d.d. 14 april 2023.

All in all, there may only be some historical stock of paints with these substances that may lead to some incidental (and finite) use.

- ***Plasters/adhesives***: The same holds true for plasters and adhesives for PT10: producers have withdrawn their products from the market, the producer of carbendazim has even withdrawn the active substance from the market. Belgian data show that trade of carbendazim and tebuconazole for PT10 has been zero over the years. In Croatia there has been one carbendazim-based product for PT10 on the market, but this has disappeared after 2021.
  Also here, no reapproval will be applied for these active substances for PT10, so they will not be available for (legitimate) use in plaster. It is not known to what extent (illegal) imports could still lead to plaster with carbendazim of tebuconazole being available on the EU market.
  Also for plaster, it can be expected that only some historical stock with these substances may lead to some incidental (and finite) use.

- ***Buildings and constructions:*** With the disappearance of paints and plasters with carbendazim, tebuconazole and propiconazole, the number of buildings and constructions that are treated with these paint and plasters will rise no further. What remains is a historical leftover, that may nevertheless still leach for some time.

4. Contribution to water pollution and resistance development

4.1 Introduction

All three substances – carbendazim, tebuconazole and propiconazole – have relevance for water quality and for the development of (azole) resistance. But to what extent do biocides and treated articles based on these substances (still) contribute to these issues, and thus require (further) EU risk management measures? In this chapter the question is answered to what extent historical, current and future use of these substances and products (biocides and treated articles) for PT7 and PT10 contributes to the problems surrounding surface water pollution and the occurrence of resistance.

The next paragraph (4.2) answers this question with respect to water pollution, the paragraph after that (4.3) deals with resistance development.

4.2 Water pollution

The general impression following from expert interviews and scientific literature is that the contribution of carbendazim, tebuconazole and propiconazole as active substances in biocides for PT7 and PT10 and in articles treated with such biocides, is marginal and historic. But there are some open questions, too. Roughly, there are three lines of argumentation.

1. *Currently measured concentrations of carbendazim in the environment in the Netherlands appear to be results of historic emissions of these persistent substances*

The RIVM report on risks from biocides (Wezenbeek and Komen, 2023) refers to measurements reported at the Water Quality Portal (www.waterkwaliteitsportaal.nl), where carbendazim is amongst the substances with the highest reported maximum concentrations in surface waters. However, it is noted that these high values appear to be incidental measurements (outliers) that are not representative for general surface water quality. This conclusion is also reached through analysis of the Dutch pesticide atlas.[34] This atlas provides insight into local soil use and exceedances in surface waters, based on measurement data from regional water managers.

The graphs below (figures 1-3) show for each of the substances the yearly observations and exceedances of the ecotoxicological limit value Environmental Quality Standard (EQS)[35] based on all measuring points in surface water in the Netherlands in the period 2010-2022.

[34] See: https://www.bestrijdingsmiddelenatlas.nl/atlas/1/1.
[35] Dutch limit value used is the JG-MKN, which is an ecotoxicological limit value. JG-MKN = JaarGemiddelde-MilieuKwaliteitsNorm, which may be translated to Annual average – Environmental Quality Standard (EQS). The MKN originates from the Water Framework Directive (2000/60/EC).

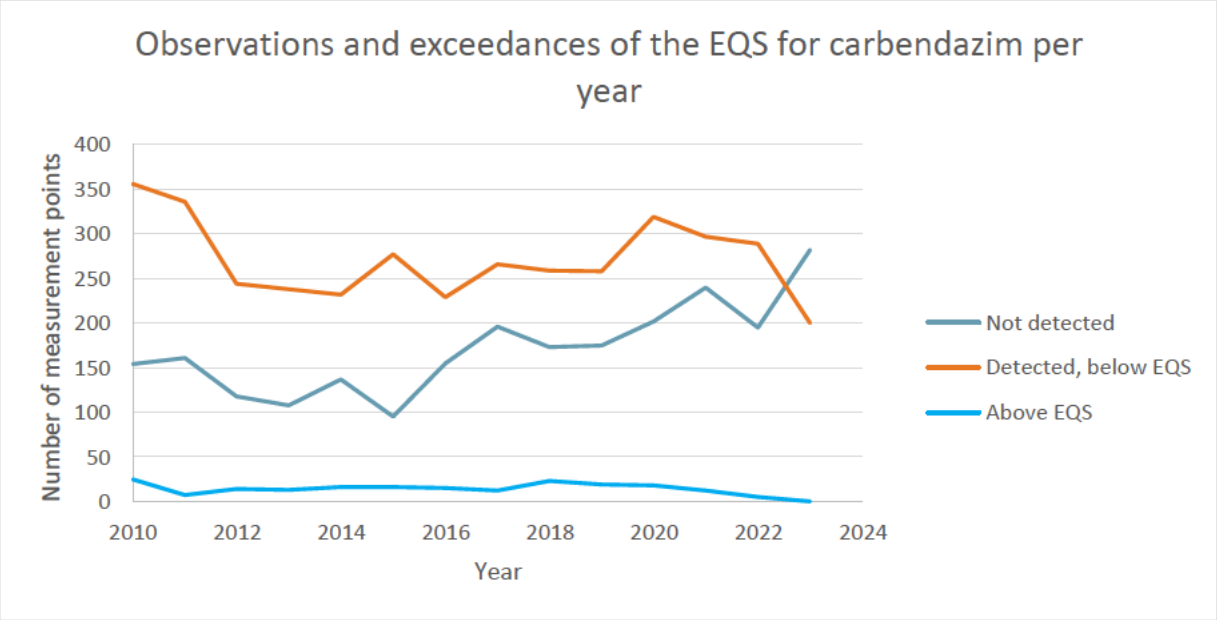

Figure 1: Observations and exceedances of the Environmental Quality Standard in surface water for carbendazim per year

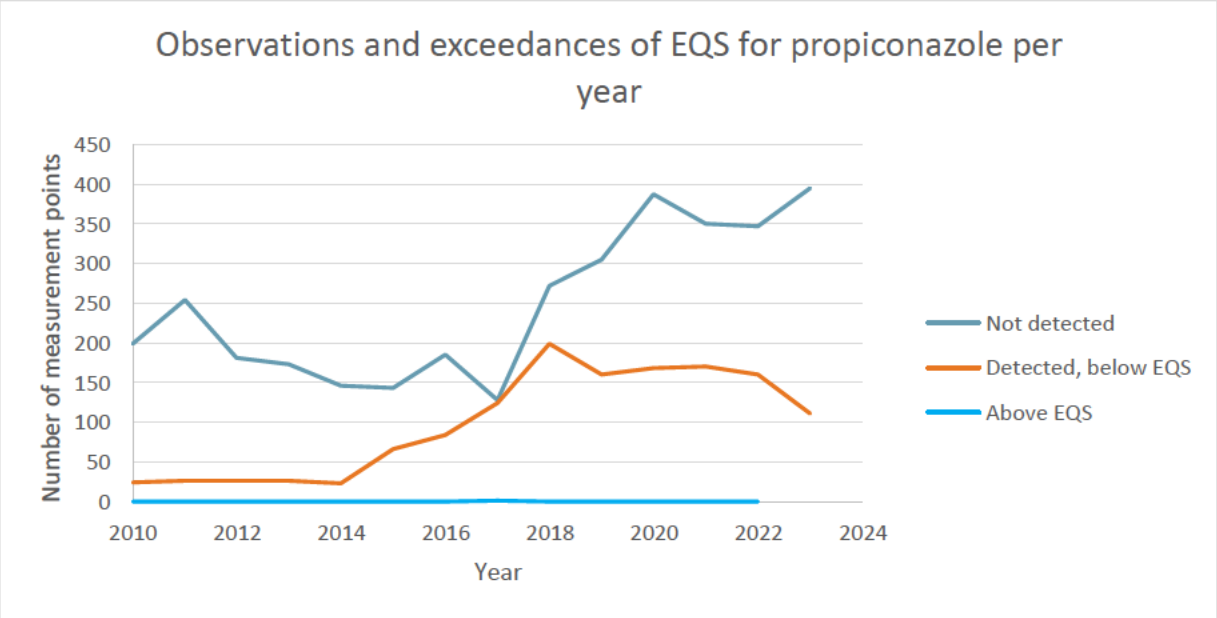

Figure 2: Observations and exceedances of the Environmental Quality Standard in surface water for propiconazole per year

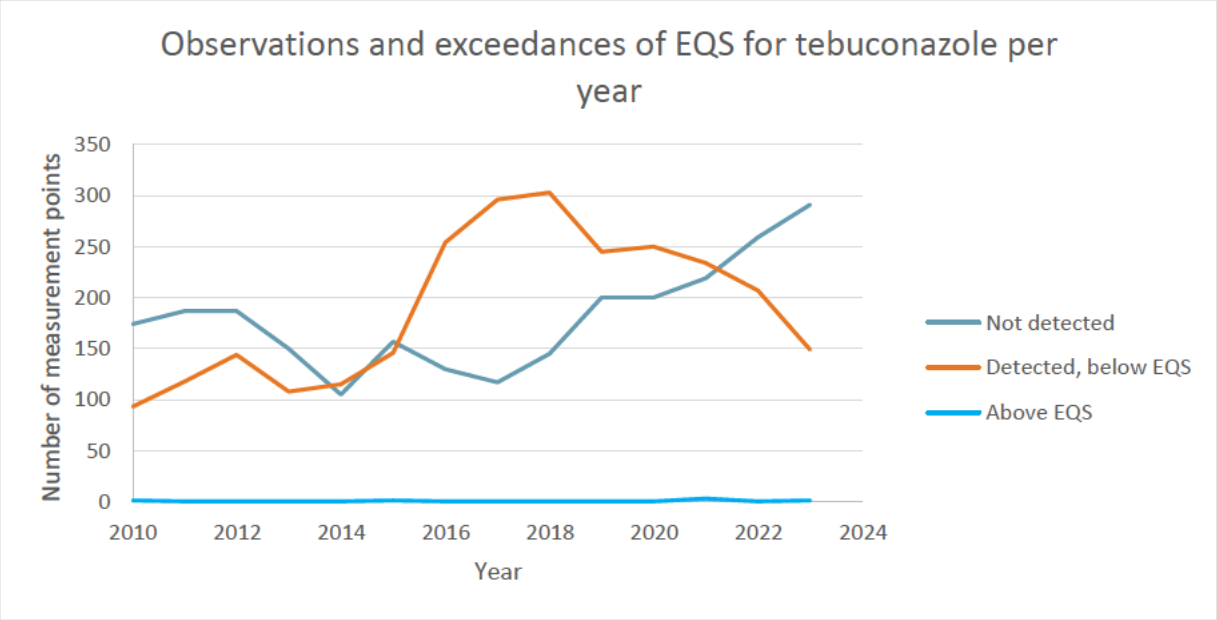

Figure 3: Observations and exceedances of the Environmental Quality Standard for tebuconazole in surface water per year

The data show that tebuconazole and propiconazole are detected in Dutch surface waters, though very rarely above the EQS. Carbendazim on the other hand, shows several exceedances each year since 2010, also in recent years. Notably, no standard exceedances were found in 2023 for carbendazim for the first time this decade. The carbendazim-exceedances are mainly found in and around agrarian areas and also in urban surface waters.

According to interviewed experts, these types of measurements can be typical for historically used persistent substances. These types of substances are still present in water and sediment and can come to the fore as peak measurements under specific weather conditions or after the ground has been stirred up (for instance by animals) (or after incidental illegal use of old stock of products with these substances near surface waters).

2. *Other emissions than those from biocidal applications, and particularly other emissions than those from the PT7 and PT10 applications discussed here, seem to (have) contribute(d) mostly to the high concentrations of carbendazim, tebuconazole and propiconazole*

Carbendazim has been used as an active substance in plant protection products until 2016, and thiophanate-methyl (that has carbendazim as metabolite) even until 2021. Tebuconazole is even still used for that purpose (the Dutch Ctgb-database contains 17 authorisations for plant protection products with tebuconazole).

The *Bestrijdingsmiddelenatlas* provides insight into correlations between agricultural land-use[36] and EQS-exceedances, see tables 8 and 9 below. Table 8 presents the correlations for the three substances studied and table 9 the correlations for thiophanate-methyl, the precursor of carbendazim. The EQS-exceedances for carbendazim may be related to their historical use around flower bulb, onion and leek cultivation, and/or the use of its precursor thiophanate-methyl for these crop-types. Given the amounts of carbendazim- and/or thiophanate-methyl based crop protection products used in direct vicinity of surface waters, in combination with their persistency in soils and aquatic sediments, it can

[36] It should be noted that correlations with other types of land use or of activities involving the use of biocides are not studied.

safely be assumed that their contribution to water pollution largely exceeds c.q. has largely exceeded the contribution by biocides.

Moreover, for both tebuconazole and propiconazole the application in products for wood conservation (PT8) is voluminous and widespread, also in the vicinity of surface waters, which also makes this a plausible source of water pollution (see further Le Blansch and Groot, 2024).

Table 8: Correlation between EQS-exceedances of the three active substances and local agricultural land use (data are available from 2018 to 2022 from Bestrijdingsmiddelenatlas.nl)

Active substance	Period	Land use/crop type	Correlation
Carbendazim	2020-2022	Flower bulb cultivation	Strong
		Onions	Present
	2018-2020	Leek	Strong
		Flower bulb cultivation	Present
		Onions	Present
Propiconazole	2020-2022	No exceedances	No exceedances
	2018-2020	No exceedances	No exceedances
Tebuconazole	2020-2022	No exceedances	No exceedances
	2018-2020	No exceedances	No exceedances

Table 9: Correlation between EQS-exceedances of thiophanate-methyl and local agricultural land use (data are available from 2018 to 2022 from Bestrijdingsmiddelenatlas.nl)

Active substance	Period	Land use/crop type	Correlation
Thiophanate-methyl	2020-2022	Flower bulb cultivation	Very strong
		Onions	Very strong
		Cereal/grain crops	Strong
		Potatoes	Present
	2018-2020	Onions	Strong
		Flower bulb cultivation	Strong
		Greenhouses	Present
		Tree farms	Present

A consulted expert states that the reason that no standard exceedances for carbendazim were found in 2023 can reasonably be explained as the result of banning thiophanate-methyl. After all, this compound was permitted until October 2021 (including the half year grace period). In 2022 there were already significantly fewer EQS-exceedances and in 2023 none at all. This seems to suggest that the use of old biocides was not the main route of emissions anyway. This does not mean that there are no emissions from other sources, but they are apparently low.

Besides the relation of historical use of carbendazim and its precursor thiophanate-methyl with crop types, the *Bestrijdingsmiddelenatlas* shows that sometimes the exceedances for carbendazim occur(ed) in urban areas. E.g. in both 2021 and 2020, 2 exceedances were found in urban areas. These could be due to the (historical) use of biocides or e.g. old stock leftovers, which would indeed be expected in urban areas. As stated in the previous paragraph, carbendazim which is very persistent, might also be retained in the soil for years before release to the surface water. Though there may be several other explanations for these urban findings, which are discussed below.

Specific research has been done as to the origin of carbendazim in surface waters. Older research was done by HAS kennistransfer (2007) and Van der Lans and Beltman (2008). Particularly the latter is interesting in that it proved some correlations between ongoing delivery of carbendazim from sediment and high surface water concentrations, but not in all investigated cases such correlations were found. In those latter cases the researchers expected that recent emissions caused these concentrations – which was of course a logical assumption in 2008.

An important, relatively recent (although carried out long before the date of the approval with large market impact) German study (Merel et al., 2018) found high concentrations of carbendazim in the Rhine from discharges of domestic wastewater. Further research (including leaching tests and analyses of discharges near paper industries) delivered substantial evidence that the carbendazim originated from paper and textile – which the researchers flag as 'overlooked sources of carbendazim'. Here may yet lie some open questions about the origin of carbendazim in Dutch surface waters as well. The found discharges of domestic wastewater would indeed correspond with the few EQS-exceedances of carbendazim in urban waters.

Note that the use of carbendazim for film conservation in paper was authorised until 2021. On our request, the Dutch branch association of paper and carton manufacturers (Royal VNP) states that in this sector carbendazim was used as a biocide in the past, but that this has been fully abandoned meanwhile.

Whether carbendazim is (in some cases) an ingredient in textile is hard to find out. The textile trade is highly international, and ingredient declarations are not always transparent. Here may, therefore, be a question worth further pursuing.

A consulted expert states that carbendazim is also yearly detected in wastewater treatment plants, though in low concentrations. He speculates on a few possible urban sources such as illegal use in cannabis cultivation and the use of medicinal antifungal agents, which would both indeed end up in the waste-water treatment plants. And similarly, waste processing companies are sometimes confronted with carbendazim in their waste streams, for example by processing construction materials that contain carbendazim.

3. *The contribution to these concentrations by emissions from PT7 and PT10 applications appear to only (have) be(en) limited.*

Finally, the findings reported in the precious chapter add to the impression that the contribution of PT7 and PT10 applications are and will be relatively low. Products and substances have been removed from the market, trade appears to have been zero for some years already for carbendazim in PT10, for tebuconazole in PT7 and PT10 and for propiconazole in PT7, and most of the treated paints and plaster appears to have been applied in the Eastern and Southern part of Europe.

4.3 Resistance development

As far as the contribution of tebuconazole and propiconazole for PT7 and PT10 to azole resistance is concerned, this can be expected to be marginal and historic for largely the same reasons as were mentioned above. These substances have been applied in far lesser volumes (if at all) for PT7 and PT10 than for non-biocidal use in plant production products and for biocidal use in wood preservation (PT8). Moreover, several articles point at still other widely dispersed and voluminous sources of azoles

in the environment that may give rise to azole resistance, like pharmaceuticals (human[37] and animal medicines) and cosmetics (Wezenbeek and Komen, 2023; Kahle et al., 2008).

As was described in chapter 2, carbendazim is also prone to cause resistance development, albeit by a different mechanism than the azoles (for which reason it does not contribute to azole resistance). Also here, the same arguments that were mentioned above lead to the expectation that the contribution of carbendazim for PT7 and PT10 to this resistance is marginal and historic.

[37] For this reason, it is remarkable that the European Commission calls for a report on the impact of the use of azole fungicides on the development of azole-resistant Aspergillus spp. (see also chapter 2) but asks to exclude human medicines from this report.

5. Conclusions

Based on the findings and evidence presented in the precious chapters, we can now draw our final conclusions on the research questions that were described in the first chapter.

- *Conclusions on question 1*

Question 1: Will there be any approval requests for these substances for PT7 and PT10, will there be authorisations of biocides based on them, and will there be such biocides and articles treated with these biocides on the EU market?

There will be no requests for reapproval of carbendazim and tebuconazole for PT7 and PT10, nor for propiconazole for PT7. The original producers/suppliers have indicated that they will not apply for reapproval and that they have already removed these active substances from the EU market (mainly because the approvals of these substances have come with restrictions that seriously impacted their markets). The deadlines for requests for approval have meanwhile expired.

According to the producers/suppliers of these active substances, there are no more biocides based on these substances on the EU market. Such products could still be legitimately marketed under transitional law in certain Member States (as there are for example authorised products in Belgium and notified products in Germany). However, for as far as data are available, they all indicate that none of these products are on the market (anymore).

As far as paints, adhesives and plaster with these ingredients are concerned, there may only be some historical stock that may lead to some incidental (and finite) use. The number of buildings and constructions that are treated with these paints, adhesives and plasters will rise no further. What remains is a historical leftover, that may nevertheless still leach for some time.

- *Conclusions on question 2*

Question 2: To what extent do historical, current and future use of these substances and products (biocides and treated articles) for PT7 and PT10 contribute to the problems surrounding surface water pollution and the occurrence of resistance?

The overall impression is that the extent to which carbendazim, tebuconazole and propiconazole in biocides for PT7 and PT10 and in articles treated with such biocides, contribute to surface water pollution, is marginal and historic. Current measurements of (high) concentrations of carbendazim in Dutch surface waters appear to be the result of historic emissions of this persistent substance. Also, it appears that emissions of carbendazim (and thiophanate-methyl, which has carbendazim as its metabolite) in the past, and of tebuconazole in the present as active substances in plant protection products, seem to (have) contribute(d) mostly to the high concentrations of these substances in the environment. To a lesser extent, the same holds true for tebuconazole and propiconazole as active substances in wood conservation products (PT8). Finally, the conclusions on research question 1 add to the impression that the contribution of PT7 and PT10 applications to water pollution are and will be marginal.

As far as the contribution of these active substances for PT7 and PT10 to azole resistance is concerned, this can be expected to be marginal and historic for largely the same reasons as were mentioned above. These substances have been applied in far lesser volumes (if at all) for PT7 and PT10 than for non-biocidal use in plant production products and for biocidal use in wood preservation

(PT8), and possibly by even more widely dispersed and voluminous use in (and disposal of) pharmaceuticals (human and animal medicines) and cosmetics.

- *Policy implications*

The overall conclusion following from these answers is that there is hardly or no relevance of specific policy and/or legal activity with respect to the reassessment of the approvals of carbendazim, tebuconazole and propiconazole for PT7 and PT10 (and the related authorisations).

In some cases, high carbendazim concentrations are measured in urban areas. There is some – older – evidence that this may originate from discharges of household wastewater containing carbendazim from textiles. It may be worthwhile to further explore whether use of carbendazim in (imported) textiles could indeed be (as this is called) an 'overlooked source' of carbendazim.

Appendix 1 List of sources

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Consulted organizations

Suppliers and/or authorisation holders
LANXESS Deutschland GmbH
Arxada AG

Applicants
Koninklijke VNP, brancheverenigingvan Nederlandse papier- en kartonfabrieken (Royal VNP, branch association of Dutch paper and carton manufacturers).

Experts
FOD Volksgezondheid Belgium
Ministry of Health, Republic of Croatia
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin - BAuA (Bundesstelle für Chemikalien) (Germany)
Independent expert

Consultations:

College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb)	Authorising body
Rijksinstituut voor Volksgezondheid en Milieu (RIVM) (2 persons)	Knowledge institute
Rijkswaterstaat (RWS) (2 persons)	Government

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