



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Initial inventory of alternatives to biocidal products containing formaldehyde or formaldehyde releasers

RIVM Report 2015-0186

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Colophon

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Synopsis

Initial inventory of alternatives to biocidal products containing formaldehyde or formaldehyde releasers

Although formaldehyde is the active substance in many disinfectants and preservatives, this chemical is recognized as a carcinogenic substance. Formaldehyde is therefore expected to be classified as such at EU level (Category 1B carcinogenic substance) with effect from 1 January 2016. This may imply that products containing formaldehyde that are currently available on the market will no longer be authorized. An initial inventory conducted by RIVM showed that sufficient chemical alternatives are available for most disinfectants and preservatives (biocides) containing formaldehyde. An important follow-up step would be a more specific check to demonstrate that these alternatives are actually suitable for each application and industrial sector in question.

Examples of applications for which alternatives are available include the disinfection of stables and animal housing, preservatives in detergents, paints and cooling systems, and slime control in the paper industry. For some biocidal applications using formaldehyde, only a very limited number of alternatives are available. These include products for the disinfection of mushroom-growing rooms, footwear and cattle hooves. The same holds for a range of preservatives, for example those used in lubricants and metalworking fluids.

No registered chemical alternative to formaldehyde is available for the disinfection of litter bins for sanitary towels. The same applies to biocides used for the (temporary) preservation of human and animal corpses and biological tissues. Although the use of formaldehyde is not authorized in these applications, it is still common practice.

Owing to formaldehyde's carcinogenic properties, it is recommended to limit or prevent exposure, pending a possibly restrictive policy. If alternatives are not yet available, their development should be encouraged (through innovation). In this respect, it is important to focus also on non-chemical alternatives, such as heating and ultraviolet radiation as preservation techniques. If good alternatives are already available, their use should be encouraged, for example through education and training.

Keywords: formaldehyde, biocides, alternatives, carcinogenic, disinfection, preservation

Publiekssamenvatting

Eerste inventarisatie alternatieven voor biociden met formaldehyde of formaldehyde releasers

Formaldehyde is de werkzame stof in veel desinfecteer- en conserveringsmiddelen, maar deze stof is kankerverwekkend. Daarom zal formaldehyde naar verwachting per 1 januari 2016 op Europees niveau als zodanig worden geclassificeerd (carcinogeen 1B). Dit kan betekenen dat formaldehyde-houdende middelen die momenteel op de markt zijn, niet meer worden toegelaten. Uit een eerste inventarisatie van het RIVM blijkt dat er voor de meerderheid van de toepassingen als desinfecteer- en conserveringsmiddel (biociden) voldoende chemische alternatieven beschikbaar zijn. Wel moet nog specifiek per sector en toepassing worden nagegaan of deze alternatieven daadwerkelijk geschikt zijn.

Voorbeelden van toepassingen waar alternatieven voor zijn, zijn stal- en dierruimte ontsmetting, conserveringsmiddelen in wasmiddelen, verven en koelsystemen en slijmbestrijding in de papierindustrie. Voor sommige toepassingen zijn nauwelijks alternatieven gevonden. Dit betreft bijvoorbeeld de ontsmetting van champignonteeltcellen, schoeisel en de hoeven van vee. Hetzelfde geldt voor een aantal conserveringsmiddelen, bijvoorbeeld voor smeermiddelen en metaalbewerkingsvloeistoffen.

Voor de desinfectie van afvalbakken voor maandverband (dameshygiëneboxen) blijkt geen enkel geregistreerd chemisch alternatief voor formaldehyde op de markt aanwezig. Dit geldt ook voor het (tijdelijk) conserveren van lichamen, dieren en weefsels. Hoewel dat niet is toegestaan, is het gebruik van formaldehyde voor deze conserveringen nog gangbaar.

Vanwege de kankerverwekkende eigenschappen van formaldehyde wordt aanbevolen de blootstelling eraan te beperken of te voorkomen, dit vooruitlopend op mogelijk restrictief beleid. Als er geen alternatieven zijn, moet worden gestimuleerd dat ze worden ontwikkeld (innovatie). Het is van belang hierbij oog te hebben voor niet-chemische alternatieven, zoals verhitting en uv-straling als conserveermethode. Wanneer goede alternatieven beschikbaar zijn, moet worden aangemoedigd om daarop over te stappen, bijvoorbeeld via voorlichting. Er is een Nederlandse versie van dit rapport, inclusief bijlagen, rapportnummer 2015-0069.

Kernwoorden: formaldehyde, biociden, alternatieven, carcinogeen, kankerverwekkend, ontsmetting, desinfectie, conservering

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Summary

With effect from 1 January 2016, the EU is expected to formally classify formaldehyde as a carcinogenic substance (Category 1B: "Presumed to have carcinogenic potential for humans, classification is largely based on animal evidence"). This may imply that products containing formaldehyde that are currently available on the market will no longer be authorized. Formaldehyde is the active substance in many biocides. So-called 'formaldehyde releasers' (substances that slowly release formaldehyde) are also used in biocides. The Dutch Ministry of Infrastructure and the Environment has commissioned the Dutch National Institute for Public Health and the Environment (RIVM) to take an initial inventory of market-authorized and possibly suitable chemical alternatives to biocides containing formaldehyde or formaldehyde releasers.

Biocides containing formaldehyde (releasers) as active substance are used in a wide range of applications, often as disinfectants or preservatives. Potentially suitable alternative biocides must have similar intended applications. It is also important that the active substance in the alternative product should not cause any adverse health effects comparable to those of formaldehyde.

In principle, sufficient chemical alternatives were found for a large number of applications, including disinfection of stables and animal housing, preservation of detergents, paints and cooling systems, and slime control in the paper industry. An important follow-up step to this initial inventory would be a more specific check to demonstrate that these alternatives are actually suitable for each application and industrial sector in question. An initially promising alternative may still turn out to be unsuitable, for example because it is not (sufficiently) effective against the target organism or because certain technical aspects of its application differ too much. The interpretation of 'sufficient alternatives' as used in this report is intended as an indication. In some cases, a single alternative may be regarded as 'sufficient', while in other cases four alternatives may not be sufficient for the intended application.

For some biocidal applications, only a limited number of alternatives were found, namely: disinfection of greenhouses, mushroom-growing rooms, footwear and animal hooves; preservation of soaps, lubricants, lubricating oils, diesel fuel and metalworking fluids; and slime control in the oil industry.

No registered chemical alternative to formaldehyde is available for the disinfection of litter bins for sanitary towels, or for the (temporary) preservation of human and animal corpses and biological tissues. In the latter case, the use of formaldehyde is not authorized, although it is still common practice.

This initial inventory has yielded several alternative active substances that may have harmful properties similar to those of formaldehyde. In

most cases, the relevant information is incomplete or unreliable. Further investigation is therefore required.

In view of the expected classification of formaldehyde as a Category 1B carcinogenic substance, measures should be taken to limit or prevent human exposure, pending possible restrictive measures. If human exposure can be convincingly demonstrated to be absent or negligible, the Biocidal Products Regulation (Regulation (EU) No. 528/2012) provides scope for the continued commercial availability of the products concerned. If good alternatives are already available, their use should be encouraged, for example through education and training. This is particularly relevant if human exposure to formaldehyde is expected to occur. If alternatives are not yet available, their development should be encouraged (through innovation). In this respect, it is important to focus also on non-chemical alternatives, such as heating and ultraviolet radiation as preservation techniques. Attention should also be devoted to preventive measures that may reduce or even eliminate the use of biocides.

The above recommendations are explicitly aimed at all parties involved, including policy departments, inspectorates, manufacturers, professional organizations, and the various industries that use biocides containing formaldehyde.

1 Introduction

1.1 Background

The Dutch Ministry of Infrastructure and the Environment has requested the Dutch National Institute for Public Health and the Environment (RIVM) to provide information about applications of biocides containing formaldehyde and so-called 'formaldehyde releasers' in the Netherlands. The question is whether sufficient authorized chemical alternatives are available for these applications on the Dutch market, if these substances were to be banned in the long term. Biocides containing formaldehyde releasers are biocides that release formaldehyde *in situ*. The phrase 'biocides containing formaldehyde (releasers)' is used in this report to refer to both biocides containing formaldehyde and biocides containing formaldehyde releasers.

The Ministry's request was prompted by the proposal of the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) for the harmonized classification of formaldehyde as a Category 1B carcinogenic substance ("May cause cancer") and a Category 2 mutagenic substance ("Suspected of causing genetic effects"). The classification of formaldehyde as a Category 1B carcinogenic substance is based on ample evidence from animal studies. This proposed classification in accordance with the CLP Regulation (Regulation (EC) No. 1272/2008) will be incorporated into law with effect from 1 January 2016.

Harmonized classification may lead to a ban or severe restrictions on the use of formaldehyde in biocides, depending on their application. Only products resulting in negligible or no human exposure will be authorized. Applications resulting in human exposure to formaldehyde will be banned in the long run. It is still unclear what consequences this reclassification of formaldehyde will have for the classification of formaldehyde releasers.

As indicated above, the scope of this report is limited to authorized biocides. This investigation comprises an initial inventory of potentially suitable chemical alternatives available on the market for the applications concerned. Where alternatives were found, as a follow-up step a more specific check to demonstrate that these alternatives are actually suitable for each application and industrial sector in question, should be performed.

1.2 Authorized Product Types containing formaldehyde (releasers)

There are currently dozens of biocides containing formaldehyde (releasers) available on the market in the Netherlands. Provisions for the authorization of biocides are made in the Biocidal Products Regulation (BPR, Regulation (EU) No. 528/2012) and its predecessor, the Biocidal Products Directive (BPD, Directive 98/8/EC). The biocide authorization procedure distinguishes between 22 different Product Types (PTs) (ECHA, 2015a). Under the Biocidal Products Directive, decisions have already been taken banning the use of specific active

substances in certain Product Types. As a follow-up, the ECHA Biocidal Products Committee (BPC) has set up a Work Programme under the Biocidal Products Regulation to assess whether or not the application of specific active substances within a Product Type is allowed.

Biocidal products containing formaldehyde

Under the Biocidal Products Directive, non-inclusion decisions have already been taken concerning the use of formaldehyde as an active substance in PTs 1, 4, 5, 6, 9, 11, 12, 13, 18, 20 and 21 (European Commission, 2013). A non-inclusion decision means that the substance in question may not be used in biocides belonging to the Product Type concerned. Any biocides belonging to the Product Type and containing the active substance must be taken off the market. It should be noted that these non-inclusion decisions are not related to the currently proposed reclassification of formaldehyde, but result from the unwillingness of applicants to submit a registration file for the Product Type concerned.

Formaldehyde as an active substance is currently not included in the scope of the Biocidal Products Regulation for any Product Type (European Commission, 2014), but it has been included in the BPC's Work Programme under the Biocidal Products Regulation for PT 2, PT 3 and PT 22. This means that a dossier will be submitted for the Product Type concerned, and that an assessment will be performed to determine if there is at least one safe application. If this is the case, and if a number of other criteria are fulfilled (e.g. sufficient efficacy), the active substance can be approved for the Product Type concerned and placed on a Union list of approved substances. The current Dutch market authorizations of biocides containing formaldehyde as an active substance concern biocides assigned to PT 2 and PT 3. There are currently no registered products on the market in the Netherlands for PT 22, although formaldehyde is used for the applications concerned. Products belonging to PT 22 are used for the preservation of human and animal corpses and biological tissues.

There are also some products available on the Dutch market that belong to PT 14, and in which formaldehyde is not an active substance but present as a so-called 'co-formulant'. Co-formulants are not assessed as part of the BPC Work Programme. Information about co-formulants is confidential. When biocides are assessed for authorization at the national level, a check is performed to determine if any co-formulants qualify as so-called 'Substances of Concern'. If this is the case, attention is devoted to this aspect in the risk assessment. The details of these provisions are outside the scope of this report. The current survey focuses both on biocides containing formaldehyde as an active substance and on biocides containing formaldehyde as a co-formulant.

Approval of formaldehyde as an active substance under the Biocidal Products Regulation is uncertain, given the classification now proposed by the RAC. According to the RAC opinion, formaldehyde is classified as a Category 1B carcinogen. This classification satisfies a criterion for exclusion under the Biocidal Products Regulation (Article 5, paragraph 1a). Although the Biocidal Products Regulation provides scope for exceptions (Article 5, paragraph 2), it is currently unclear if

formaldehyde can be authorized on this basis for applications in PT 2, PT 3 and PT 22.

On 9 February 2015, ECHA started a public consultation process further to the Biocidal Products Regulation. Formaldehyde was designated as a candidate for substitution, and the public has been requested to supply relevant information, including information about potentially suitable alternatives. This concerns applications belonging to PT 2 and PT 3. The consultation process was concluded on 10 April 2015. The responses may be consulted on the ECHA website (ECHA, 2015b).

Biocidal products containing formaldehyde releasers

In addition to biocides containing formaldehyde, there are also authorized biocides on the market in the Netherlands that contain a formaldehyde releaser as an active substance. This concerns seven active substances that have all been included in the BPC Work Programme for the Product Types for which products containing the relevant active substance are currently available on the Dutch market. For further information, please refer to Section 3.3.

Finally, biocides belonging to PT 8 and containing a formaldehyde releaser as a co-formulant are also authorized for the Dutch market. These products have also been included in the present report.

1.3 Structure of this document

Chapter 2 provides some background information about formaldehyde and formaldehyde releasers, and explains the set-up of the study. This chapter describes the restrictions applied and the nature of the 'initial inventory' performed. It also specifies the criteria used to determine the likely availability of 'sufficient alternatives', 'few alternatives' or 'no alternatives'.

Chapter 3 lists all biocides containing formaldehyde (releasers) authorized in the Netherlands, as indicated by the Board for the Authorization of Plant Protection Products and Biocides (CTGB). The unauthorized application of formaldehyde for the preservation of human and animal corpses and biological tissues (PT 22) is also included in the scope. The listed products have been investigated to determine the application(s) for which they are used, and to assess if there are other biocides that could be used as an alternative for the application(s) concerned. If information has been found indicating that the alternatives found may be unsuitable, this is reported. Based on the criteria established in Chapter 2, an assessment is performed to determine if there are sufficient, few or no alternative products available on the market.

Chapter 4 presents the conclusions of this survey as well as a number of recommendations.

The Dutch version of this report includes several appendices which provide detailed information about the following matters:

- the system for classification of substances under the CLP Regulation and the reclassification of formaldehyde;

- the non-inclusion decisions concerning the use of formaldehyde in various Product Types under the Biocidal Products Directive;
- the working methods and Dutch-language information sources used to search for alternatives;
- information about the classification of formaldehyde releasers in biocides available on the Dutch market and of the alternative substances found;
- a list of authorized products available in the Netherlands that contain formaldehyde and formaldehyde releasers, including an overview according to Product Type;
- authorized alternative biocides available in the Netherlands.

Because most of this information is specific to the situation in the Netherlands or readily available on the ECHA or European Commission websites, we have decided not to include the appendices in this English version of the report.

2 Set-up of the study

2.1 Guide to this chapter

This chapter starts by providing background information about formaldehyde and formaldehyde releasers (hereafter: 'formaldehyde (releasers)'), and about biocides that contain these substances. Section 2.3 then describes the method used to search for alternatives for the various applications of biocides containing formaldehyde (releasers). Section 2.4 lists a number of reasons why alternatives found may be unsuitable. The preconditions for the performance of this survey are then described, clarifying the nature of this 'initial inventory' (Section 2.5). Finally, Section 2.6 describes the criteria used to determine the likely availability of 'sufficient alternatives', 'few alternatives' or 'no alternatives'.

2.2 General information about formaldehyde (releasers)

Formaldehyde is an organic compound with the chemical formula CH_2O . It is a simple molecule that also occurs naturally. Formaldehyde is a broad-spectrum disinfectant. Because it has many modes of action, it is not known to cause resistance in the organisms it targets.

Formaldehyde is gaseous at room temperature. In biocides, formaldehyde is used as an active substance in three forms: as a gas, dissolved in water (formalin), and bound in formaldehyde releasers. Application of formaldehyde in gaseous form or as formalin has a rapid disinfectant effect.

Formaldehyde releasers are used in biocides to enable the gradual release of formaldehyde over a longer period of time. Formaldehyde releasers are used for the long-term preservation of various liquids, and to control slime formation in liquids. The release rate differs with the type of formaldehyde releaser used. This determines which formaldehyde releaser is suitable for which type of product.

In addition, the breakdown of some active substances in biocides releases formaldehyde as a degradation product. Such substances are not called 'formaldehyde releasers' because releasing formaldehyde is not their primary purpose.

There are also biocides that contain formaldehyde or formaldehyde releasers as a co-formulant.

The use of all these substances and types of products may result in human and/or animal exposure to formaldehyde. The authorization procedure for biocides at the national level takes account of the toxicity of any degradation products as well as any co-formulants present. In December 2014, the Formaldehyde Biocide Interest Group (FABI) of the European Chemical Industry Council (CEFIC) organized an information event in Vienna. During this meeting, general information was provided about formaldehyde (releasers), and representatives of various industries emphasized the benefits of its use. Formaldehyde manufacturers have called on government authorities to focus on the

actual risks, and not just the intrinsic properties of the substances used (as reflected in their classification).

2.3 Working methods and information sources used to search for alternatives

The following sources of information were consulted in the course of this survey:

- a biocides database created for the Human Environment and Transport Inspectorate (ILT) (Scheepmaker, 2012), last updated in 2013, which focuses mainly on authorized biocidal applications;
- the website www.middelenpakket.nl, a private initiative not created at the behest of the government; it does not guarantee a complete overview of registered substances and their applications;
- information available on the CTGB website at www.ctgb.nl;
- people working in the relevant industry, who were interviewed by telephone if no or few alternatives were found for a particular application.

In 2013, CTGB created a list of biocides containing formaldehyde (releasers) as active substance or co-formulant. Biocides assessed and authorized in 2014 were already included in this list. In June 2015, a check was performed to determine if the relevant products were still available on the market, and a few additional substances authorized in 2014 were added. We then looked up the specific applications for which each substance is used. This information was derived from the ILT biocides database (Scheepmaker, 2012) and the website www.middelenpakket.nl. The subsequent search for alternatives for the applications concerned was a complex process. The information on the CTGB website cannot be searched based on specific applications of biocides. For this purpose, we again used the aforementioned ILT biocides database and the website www.middelenpakket.nl. However, these information sources are not guaranteed to be complete, nor are they fully up-to-date. Furthermore, the applications are not described using standard terms and phrases. Once an alternative substance was found, we consulted the statutory directions and instructions for use available on the website www.ctgb.nl, to determine if the applications were truly comparable. In the case of a number of applications for which few alternatives were found, we conducted telephone interviews with people working in the relevant industry in order to obtain additional information. Since this concerns an initial inventory, we did not aim for a comprehensive or even representative sample of the industry concerned.

2.4 Potentially unsuitable alternatives

Alternatives found may turn out to be unsuitable for various reasons. The reasons relevant for this report are listed below, including a description of how they were taken into account.

Alternatives with similar harmful properties

When biocides containing substances with harmful properties are replaced by an alternative, the latter must present a significantly lower

overall risk for human and animal health and the environment (Biocidal Products Regulation, Article 23). Obviously, the substances concerned should not be replaced by biocides containing substances with the same or similar harmful properties. In order to assess the possible harmful properties of possible alternatives, we used the available information about the classification of the active substances that these alternatives contain.

The CLP Regulation (EC/1272/2008) includes provisions for the classification of substances. This Regulation distinguishes between 'harmonized classification' and 'self-classification'. The procedure for determining the actual properties of a substance is most extensive in the case of harmonized classification, and is carried out by ECHA's independent Risk Assessment Committee (RAC). This classification procedure is the most thoroughly substantiated, and therefore the most reliable, procedure. In the case of self-classification, a distinction can be made between substances registered under the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and substances not registered under REACH. We have assumed that self-classifications of substances in a REACH registration file are more reliable than other self-classifications, because more extensive consultations take place in the former case. However, this assumption cannot be substantiated. The reliability of self-classifications differs from case to case.

We looked up the CAS Registry Numbers of the approximately sixty alternative substances identified in this survey as well as those of the formaldehyde (releasers) mentioned in this report, and used these to check the classification of the alternatives in question. We first looked up the substances concerned in the so-called 'C&L Inventory' on the ECHA website. If the substance was present, its harmonized classification in the C&L Inventory has been included in this report. In the case of substances lacking harmonized classification, we checked if the substance was registered under REACH. If this was the case, we used the self-classification in the registration file (if completed). The C&L Inventory may contain different self-classifications, but we did not check these or include them in this report if the self-classification was entered in the REACH registration file. Any other self-classifications in the C&L Inventory have only been included in this report if no other information was available.

This report focuses primarily on the following CMR (Carcinogenic/Mutagenic/Reprotoxic) classifications: Category 1A and/or 1B carcinogenic, Category 1A and/or 1B mutagenic, and Category 1A and/or 1B reprotoxic. After all, the aim is to replace substances classified in these CMR categories with substances not classified as such (refer to Biocidal Products Regulation, Articles 5.1a, 5.1b and 5.1c). Other non-CMR properties such as acute toxicity were not taken into account in this report.

Priority substances of concern (ZZS substances)

Alternative substances that meet the criteria set out in Article 57 a to f of the REACH Regulation are assessed as unsuitable in the Netherlands. For identification of priority substances of concern (Zeer Zorgwekkende

stoffen; ZZS), using the REACH Article 57 a to f criteria, the following regulations and directives were taken into account:

- the CLP Regulation (Regulation EC 1272/2008);
- the REACH Annex XIV candidate list;
- the POP regulation (Regulation EC 850/2004);
- the Water Framework Directive (2000/60/EC);
- the OSPAR Convention (OSPAR list for priority action).

In this way, more substances than the Substances of Very High Concern (SVHCs) listed in the Candidate List under REACH are identified as priority substances of concern (ZZS). All of these ZZS substances meet the criteria as set out in REACH article 57 a to f. In this way, the national policy on priority of ZZS substances is in line with European legislation which is relevant for the Netherlands and facilitates the further implementation of this legislation (refer to RIVM, 2015).

Under the new Activities Decree (*Activiteitenbesluit*) and the new Activities Regulation (*Activiteitenregeling*), emissions to air of these substances must be minimized, and emission and immission standards apply. Similar regulations are being prepared under the Planning and Environment Act (*Omgevingswet*) for discharges to water. The use of alternative substances subject to these restrictions is therefore not advisable. We have therefore checked if the alternative substances found were included in the Dutch ZZS-list (refer to RIVM, 2015).

Alternatives that may induce resistance

As described above in Section 2.2, one advantage of the use of formaldehyde is that, as far as we know, it does not result in the development of resistance to antibiotics or resistance in the target organism. Alternatives that do result in the development of resistance are less suitable for certain applications, unless resistance effects can be reduced through the alternating use of different substances with different modes of action. The question is whether alternating use of different substances is possible for the application concerned. Simultaneous combined use of different active substances may also prevent resistance developing. Information about the development of resistance is not taken into account in the classification process. Furthermore, no standard method is currently available for assessing whether resistance development occurs, and if so, to what extent (Montforts *et al.*, 2015). A systematic assessment of the risk that use of alternatives will result in the development of resistance in target organisms is therefore not possible, and has not been performed. However, since any information about the development of resistance is helpful when assessing the suitability of alternatives, we have included such information if known to us.

It is not possible to just say that a specific minimum number of alternative active substances is required to prevent the development of resistance. A single broad-spectrum alternative substance may already be sufficient, provided this substance (like formaldehyde) does not result in the development of resistance. In addition, a number of products contain a combination of active substances, and this may help to prevent the development of resistance. Finally, the concentrations of the active substance(s) in the products may also differ, which may affect

their efficacy and the risk of resistance developing. A thorough analysis of this risk is therefore a complex task which falls outside the scope of this report.

Alternatives releasing formaldehyde as a degradation product

Some active substances in biocides release formaldehyde as a degradation product. Any information indicating that this is the case is included in the text, since it may render the substance concerned unsuitable for certain applications. When assessing biocides, CTGB takes degradation products into account. A biocide containing a substance that releases formaldehyde as a degradation product may still be authorized, depending on the intended application. We have therefore opted to consider products containing such substances as possible alternatives, on the understanding that formaldehyde may be released as a degradation product when the product is used for a specific application, making it unsuitable for the application concerned.

2.5 Restrictions applied to this initial inventory

This survey must be regarded as an 'initial inventory' for the following reasons:

- the information about applications of biocides that was used is not guaranteed to be either complete or fully up-to-date. Also, similar applications that are described in other terms may have been missed. The inventory of alternative products was carried out in 2014, and various changes have occurred since then. We have not rechecked all the information. The information compiled by CTGB cannot be searched by keyword for the different applications, which presents a problem for this type of research;
- the directions for use of biocides containing formaldehyde (releasers) have not been compared in detail with the directions for use of the alternatives found. The differences between the biocides containing formaldehyde (releasers) and the alternatives found may be too great with respect to the target organisms or the mode of application (different exposure time; spraying or wiping off with a cloth; etc.), or technical modifications may be required (e.g. due to unsuitability of the product for a specific type of material);
- the applicability of biocides depends on various properties (technical and otherwise) of the active substances and products (such as volatility, viscosity, corrosivity, and stability under specific circumstances). The present report cannot enter into this level of detail;
- the scope of our search did not include non-chemical alternatives such as heating and ultraviolet radiation;
- the number of interviews conducted was too small to produce a representative picture of the applications used in practice.
- We did not examine the financial consequences of a possible switch to a different product;
- the substance names were linked to CAS Registry Numbers in order to look up classification details. Although this step was checked, it is still possible that errors were made;

- we did not actively look up information about the possible development of resistance resulting from use of the alternatives found;
- we did not perform a check of all the alternative substances found to determine which degradation products may be formed.

This initial inventory is expressly intended to provide a general picture of the situation. There may be good alternatives available which we have not identified due to the dynamic nature of the biocides market, the unreliability of some information sources, and the fact that we have not always conducted an exhaustive search for alternatives. We have therefore decided to anonymize the information about the alternatives found. The actual product names have been replaced by 'Product A', 'Product B', etc.

As stated above, we have looked for classification data indicating possibly similar harmful properties of potential alternatives to biocides containing formaldehyde (releasers). Any information found (in the classification data or otherwise) that may indicate possible unsuitability as an alternative has been stated.

2.6 Criteria used to assess the availability of alternatives

In this report, the following criteria are used to assess the availability of alternatives:

- 'sufficient alternatives': at least six products with at least three different compositions in terms of active substances;
- 'few alternatives': one to four products with less than three different compositions in terms of active substances;
- 'no alternatives': no authorized biocides have been found that could be used as alternatives for the application concerned.

These criteria have been defined simply to be able to distinguish different groups. They are not substantive in nature.

Some products may have different names, although their composition in terms of active substances is exactly the same. These products may be derived from the same authorized 'parent product', and differ only with respect to their name, the directions for use, in product claim (i.e. target organisms), or in the mode of application. We have not examined these aspects for this initial inventory. This means that products with different names are always considered as separate products.

The interpretation of 'sufficient alternatives' as used in this report provides an indication. In some cases, a single alternative may prove to be sufficient eventually, while in other cases four alternatives are not sufficient for the intended application.

The active substances that the alternatives contain have been specified. Based on the details of these active substances and (future) information about the development of resistance when the relevant substance(s) is/are used for the application(s) concerned, a more detailed assessment may be performed at a later time to determine if the number of alternatives is truly sufficient.

In some cases, we have obtained information about alternatives that may be considered suitable in the future, but which have not yet been authorized. These alternatives are not taken into account in the above categorization, but they have been included. The pending reclassification of formaldehyde may be a reason to request authorization for these products.

We have also included information that may indicate possible unsuitability of alternatives due to the presence of substances with (possibly) similar harmful properties or of substances that release formaldehyde as a degradation product.

3 Results

3.1 Guide to this chapter

This chapter will first present the results of the survey of the data about the classification of substances. This concerns the classification data of the formaldehyde releasers and the active substances that occur in the alternative biocides we found. We also report whether the alternative substances found contain ZZS substances or substances that release formaldehyde as a degradation product. The authorized biocides containing formaldehyde (releasers) are then discussed in Section 3.3. We indicate which substances are used, and the applications for which biocides containing formaldehyde (releasers) are used. For each mode of application of biocides containing formaldehyde (releasers), the availability of possible suitable alternatives for the application in question is assessed in Section 3.4. If alternatives have been found that may be unsuitable, this is reported. Based on the criteria established in the previous chapter, we then determine whether there are sufficient, few or no alternatives. Section 3.5 provides a summary of the results.

3.2 Information about possible unsuitability – results

Classification of formaldehyde releasers

This report was prompted by the planned future classification of formaldehyde as a Category 1B carcinogenic substance further to the CLP Regulation (Regulation (EC) No. 1272/2008). However, this does not mean that all formaldehyde releasers will also be classified as such. For that reason, we have conducted a survey of the information that is currently available about the classification of formaldehyde releasers.

The survey of information about the classification of the formaldehyde releasers discussed in this report (see Table 1) reveals that one of the seven substances in question has been classified according to the harmonized classification scheme. This substance (2,2,2-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol) has not been classified as Category 1A and/or 1B carcinogenic, Category 1A and/or 1B mutagenic, and/or Category 1A and/or 1B reprotoxic. Information about one other substance (1,3-dimethylol-5,5-dimethylhydantoin) was found based on its registration under the REACH system. This substance has not been classified as Category 1A and/or 1B carcinogenic, Category 1A and/or 1B mutagenic, and/or Category 1A and/or 1B reprotoxic. The substance N,N-methylenebismorpholine (MBM) is not registered under the REACH system, but has been self-classified as a Category 1B carcinogenic substance. A proposal has been put forward to adopt this classification for the harmonized classification of MBM (ECHA, 2015d). On the list used in this report, MBM occurs in one product that is authorized for product types 6 and 13. Only self-classifications were available for the remaining four formaldehyde releasers, but these did not include self-classification as a Category 1A and/or 1B carcinogenic, Category 1A and/or 1B mutagenic and/or Category 1A and/or 1B reprotoxic substance.

It has also been proposed to classify another combination of substances containing a formaldehyde releaser as Category 1B carcinogens. This

concerns products of the reaction of paraformaldehyde with 2-hydroxypropylamine in the proportion of 1:1 or 3:2 (ECHA, 2015c). These substances are currently not used in biocides in the Netherlands, but this information shows there may be reasons to classify formaldehyde-releasing substances as Category 1B carcinogens. This ties in with the guideline in the CLP Regulation that a substance is classified as a Category 1B carcinogen if it contains more than 0.1% of another substance that has been classified as a Category 1B carcinogenic (Regulation (EC) No. 1272/2008: Article 3.6.3.1.1, Table 3.6.2).

Classification of alternative substances

The harmonized classification scheme was the principal starting point in the search for the hazardous properties of the alternative substances. Harmonized classification details turned out to be available for 35 of those substances. The self-classification data in the REACH registration files yielded useful information for an additional ten alternative substances.

The harmonized classification scheme reveals that disodium tetraborate (CAS Registry Number 1330-43-4) and potassium dichromate (CAS Registry Number 7778-50-9) have been classified as CMR substances. Disodium tetraborate is classified as a Category 1B reprotoxic substance, while potassium dichromate is classified as a Category 1B carcinogenic, Category 1B mutagenic and Category 1B reprotoxic substance. Disodium tetraborate is used in authorized wood preservatives (Product Type 8). Incidentally, this shows that products containing substances with harmful properties (in this case a Category 1B reprotoxic substance) may be authorized for certain applications. Potassium dichromate can be used to preserve biological tissues (Product Type 22). In the Netherlands, no products are authorized for Product Type 22.

Of the substances that were only self-classified, benzyl-C12-16-alkyldimethyl (CAS Registry Number 68424-85-1) turned out to be classified as a Category 1B carcinogen by one registrant. The name alkyl (C12-16) dimethylbenzyl ammonium chloride is also used for this substance. It has been self-classified on behalf of eleven companies. In addition, there are over twenty self-classifications on behalf of hundreds of companies that do not classify this substance as a Category 1B carcinogen. The ECHA website contains information showing that this classification as a Category 1B carcinogen may possibly be connected to impurities introduced during the production of this substance (ECHA, 2015e). Benzyl chloride may be present as an impurity, which would explain the possible classification as a carcinogenic. In the harmonized classification scheme, benzyl chloride has been classified as a Category 1B carcinogenic substance. If a product contains more than 0.1% of this substance as an impurity, this classification will also apply to the product in question (Regulation (EC) No. 1272/2008: Article 3.6.3.1.1, Table 3.6.2).

Further to the Biocidal Products Directive (Directive 98/8/EC, the precursor of the Biocidal Products Regulation), an Assessment Report for alkyl (C12-16) dimethylbenzyl ammonium chloride has been drawn up

for Product Type 8 (European Commission, 2012). This report states the following: *'The active substance Alkyl (C12-16) dimethylbenzyl ammonium chloride (C12-16-ADBAC) does not contain additives or impurities that would be of toxicological/environmental concern.'* It has therefore been demonstrated for Product Type 8 that benzyl chloride is not present in a concentration exceeding 0.1%. In the current inventory, benzyl-C12-16-alkyldimethyl (or alkyl (C12-16) dimethylbenzyl ammonium chloride) is mentioned as a component in possible alternative products for Product Type 2, Product Type 3 and Product Type 12. As of July 2015, 37 biocides have been authorized that contain this compound as an active substance (see www.ctgb.nl/toelatingen).

Two other substances for which only self-classifications are available have been classified as Category 1B reprotoxic substances. Sodium bromide (CAS Registry Number 7647-15-6) has been classified as such on behalf of a large group of 355 companies. Tetrakis(hydroxymethyl)phosphonium sulfate (CAS Registry Number 55566-30-8) has been classified as a Category 1B reprotoxic substance by five of the seventeen groups of companies, and six groups have classified it as a Category 2 reprotoxic substance. Further substantiation of the above self-classifications was not found. Sodium bromide is a component of alternative products for Product Type 11 and Product Type 12. Tetrakis(hydroxymethyl)phosphonium sulfate is present in alternative products for Product Type 12.

For the other alternatives discussed in this report, no harmonized classifications or self-classifications as Category 1A and/or 1B carcinogenic, Category 1A and/or 1B mutagenic and/or Category 1A and/or 1B reprotoxic substances were found.

Priority substances of concern (ZZS substances)

Of the alternative substances found, disodium tetraborate, potassium dichromate and mercury compounds turn out to be on the Dutch ZZS-list. In the case of disodium tetraborate and potassium dichromate, this is the result of their harmonized classification as CMR substances. Mercury compounds are designated ZZS further to the Water Framework Directive (Directive 2000/60/EC). As mentioned above, disodium tetraborate is used in authorized wood preservatives (Product Type 8). Although potassium dichromate and mercury chloride can both be used to preserve biological tissues (Product Type 22), this application is not authorized.

Substances releasing formaldehyde as a degradation product

As indicated in Section 2.5, we have not searched for information about degradation products. CTGB has indicated that although bronopol is not a formaldehyde releaser, formaldehyde may occur as a degradation product of this substance.

An authorization decision dating from 2014 (see www.ctgb.nl/toelatingen) contains the following text:

*'Bronopol as formaldehyde releaser
Formaldehyde may be released from bronopol under certain conditions. Available data indicate that the process is highly pH-dependent. Thus, in acidic medium (pH ≤ 4) the decomposition of bronopol to formaldehyde*

is virtually absent (half-life time of 880 days at 20 °C), while at neutral and alkaline pH the decomposition occurs much more quickly (half-life of 2 months at pH 8 according to Reregistration Eligibility Decision (RED) on bronopol published by the US EPA (October 1995). Based on the data provided by the applicant, the pH of the neat formulation is 3.5 at 22.4 °C. Based on this, no release of formaldehyde is expected for the neat formulation and thus no concern for formaldehyde exposure is expected during mixing and loading of the neat formulation. However, the pH of 1% aqueous solution of the formulation is 7.3 at 22.4 °C, indicating that hydrolysis to formaldehyde is likely to occur. As the formulation is intended for the use as an in-can preservative in water-based formulations (paints and coatings, polymer dispersions, detergents, plasters, putties, glues and lithographic solutions), secondary exposure to formaldehyde is considered possible. Therefore it will be considered in the risk assessment.'

The risk assessment for the product concerned contains information about the classification of formaldehyde as a Category 1B carcinogenic substance. It was then established that the predicted concentration of formaldehyde in air is below the applicable standard, which means the product can be authorized. As of July 2015, 28 biocides containing bronopol as an active substance have been authorized (see www.ctgb.nl/toelatingen). This means that, depending on their application, substances releasing formaldehyde as a degradation product may be authorized.

3.3 Authorized biocidal products containing formaldehyde (releasers)

CTGB mentions several different groups of biocides that contain formaldehyde (releasers).

Table 1 provides an overview of the active substances in authorized biocides containing formaldehyde (releasers). The table also lists the Product Types for which the substance in question has been included in the BPC Work Programme.

Table 1. Active substances in authorized biocidal products containing formaldehyde (releasers)

Substance name	CAS Registry Number	Abbreviation used ¹	PTs for authorized biocides	Product Types in BPC Work Programme
Formaldehyde	50-00-0	F	2, 3	2, 3, 22
(Ethylenedioxy) dimethanol	3586-55-8	E	2, 6, 11, 12, 13	2, 6, 11, 12, 13
3,3'-methylenebis [5-methyloxazolidine]	66204-44-2	3,3-M	2, 6, 11, 12, 13	2, 6, 11, 12, 13
Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5 (1H,3H)-dione (TMAD)	5395-50-6	TMAD	6, 12, 13	2, 6, 11, 12, 13
1,3-dimethylol-5,5-dimethylhydantoin (DMDMH)	6440-58-0	DMDMH	6, 13	6, 13

Substance name	CAS Registry Number	Abbreviation used¹	PTs for authorized biocides	Product Types in BPC Work Programme
2,2,2-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	4719-04-4	2,2,2-HT	6, 11, 12	6, 11, 12, 13
(Phenylmethoxy)methanol ²	14548-60-8	BHF	6, 13	6, 13
N,N-methylenebis(morpholine)	5625-90-1	MBM	6, 13	6, 13

1. Some of the abbreviations used are 'custom' abbreviations, which may also be in use for other substances.

2. This substance is also known as (benzyloxy)methanol or benzylhemiformal (BHF).

Table 2 lists the Product Types for which biocides containing formaldehyde (releasers) are authorized, as well as the applications concerned. It also lists the number of authorized biocides. This is only an indication, as the number of products on the market is subject to continuous change. The table shows that formaldehyde is mainly used as an active substance in a certain type of disinfectants (Product Type 2) and in veterinary hygiene products (Product Type 3). Formaldehyde as an active substance is only found in biocides for professional applications. In any case, consumer product applications are not allowed by CTGB because of formaldehyde's current classification as a Category 2 carcinogenic substance. Formaldehyde is a co-formulant in a number of rodenticides (Product Type 14). Formaldehyde releasers may be found as an active substance in various types of preservatives (Product Type 6, Product Type 11, and Product Type 13) as well as in slimicides (Product Type 12). In this respect, it should be noted that a variety of formaldehyde releasers is used within each Product Type. Finally, formaldehyde is widely used in thanatopraxy (light embalming / temporary preservation of deceased persons) and taxidermy (the preservation of human and animal corpses and biological tissues) (Product Type 22), although no biocides are authorized for this application.

Table 2. Indication of the number of biocidal products based on formaldehyde (releasers) or containing formaldehyde (releasers) as a co-formulant that are authorized for each Product Type

Product Type	Applications	Number of products and substance used ¹
Product Type 2 – Disinfectants and algaecides not intended for direct application to humans or animals	<ul style="list-style-type: none"> • Disinfection of litter bins for sanitary towels; disinfection of industrial areas, specifically disinfection of surfaces of production systems in the metal-processing industry • Cleaning and disinfection of surfaces, equipment and instruments in public areas in the healthcare sector • Disinfectants used in circulation systems in industrial production systems, with the exception of production systems in the veterinary, medical and (animal) food sectors • Disinfection of (indoor) public areas • Disinfection of cold stores / empty boxes / empty greenhouses / empty mushroom-growing rooms • Combined cleaning and disinfection of floors, walls and other surfaces • Cleaning and disinfection of empty rooms intended for the cultivation of mushrooms, food crops and ornamental plants 	13 (F) 2 (E) 1 (3,3-M)
Product Type 3 – Veterinary hygiene	<ul style="list-style-type: none"> • Disinfection of stables and animal housing; disinfection of animal hooves and claws; disinfection of footwear 	18 (F)
Product Type 6 – Preservatives for products during storage	<ul style="list-style-type: none"> • Preservation of paints, varnishes and inks • Preservation of other industrial liquids, such as glues, polymer dispersions (for construction materials) and liquids used in the production of paper, textile and leather; preservation of detergents; preservation of soaps • Preservation of lubricants; preservation of lubricating oils and diesel fuel; preservation of cosmetics, stimulants and biotechnological applications • Preservation of additives used in the paper and textile industry • Broad-spectrum in-can preservative for waterborne systems 	8 (E) 6 (3,3-M) 5 (TMAD) 3 (DMDMH) 3 (2,2,2-HT) 1 (BHF) 1 (MBM)

Product Type	Applications	Number of products and substance used ¹
P 8 – Wood preservatives	<ul style="list-style-type: none"> • Protection against insects and wood rot; removal of fungi; impregnation • Treatment of indoor wood to protect against wood-decay fungi 	2 (Co-E)
Product Type 11 – Preservatives for liquid-cooling and processing systems	<ul style="list-style-type: none"> • Used in (small) open recirculation cooling systems (wet cooling towers) • Used in (small) closed (recirculating) (wet) cooling-water systems • Used in process water systems • Used in pasteurizing plants 	4 (E) 2 (3,3-M) 1 (2,2,2-HT)
Product Type 12 – Slimeicides	<ul style="list-style-type: none"> • Used in the paper and pulp industry • Used in the oil industry • Biocidal additive in diesel engines to prevent slime formation 	3 (E) 4 (3,3-M) 2 (TMAD) 1 (2,2,2-HT)
Product Type 13 – Working or cutting fluid preservatives	Used for metalworking (cutting and shaping)	7 (E) 6 (3,3-M) 4 (TMAD) 3 (DMDMH) 1 (BHF) 1 (MBM)
Product Type 14 – Rodenticides	Indoor bait for rats and mice	2 (Co-F)
Product Type 22 – Embalming and taxidermist fluids	No authorized products	0 (F)

1. See Table 1 for the abbreviations used. The prefix 'co-' indicates that the substance is used as a co-formulant.

3.4 Authorized alternative biocidal products found

3.4.1 *General*

Table 2 shows that formaldehyde and formaldehyde releasers are often used for various (types of) applications that belong to one and the same Product Type. As described in Section 2.2, we looked for alternatives for biocides containing formaldehyde (releasers) for each type of application. We then looked up the classification data of the active substances in the authorized alternatives found, to find out if alternatives are potentially unsuitable for specific applications. As described in Chapter 2, interviews were conducted by telephone for a number of applications that have few alternatives. Occasionally, this approach produced information about non-authorized applications, non-authorized alternatives, or alternatives for which it is unclear whether they require authorization under the Biocidal Products Regulation. Any information that was obtained about alternatives that may be considered suitable in future has also been included. Finally, we added any information about the risk of resistance development that was available to us. All information collected in this way has been laid down in detail in an annex to the Dutch version of this report. The relevant information is summarized in the Sections below. Table 3 provides an overview, listing all alternative active substances found as well as any information about potential unsuitability. Any information available about the risk of resistance development is only mentioned in the main text if any problems in this area are expected because many of the relevant products are based on substances that are known for inducing resistance.

3.4.2 *Cleaning and disinfection of surfaces, equipment and instruments in the healthcare sector (Product Type 2)*

There are five products containing formaldehyde as an active substance that are used to disinfect surfaces, equipment and instruments in the healthcare sector. There are at least eight alternative products available for the disinfection of surfaces in the healthcare sector, and at least six alternative products for the disinfection of equipment and instruments. The search for alternatives was by no means exhaustive. In the end, a substance's compatibility determines in which situations the alternative can be used. A wide range of active substances is available for surface cleaning and disinfection (see Table 3), which suggests there are sufficient alternatives for this application. The active substances used in authorized products for the disinfection of equipment and instruments are less diverse, although the range of products is currently considered sufficient.

3.4.3 *Disinfection of litter bins for sanitary towels (Product Type 2)*

There are five formaldehyde-based products currently in use for the disinfection of litter bins for sanitary towels. These products ensure continuous disinfection for a period of five to six weeks. No chemical alternatives to formaldehyde are currently authorized for use in litter bins for sanitary towels. There are two other types of product on the market, but their effectiveness has not been demonstrated. It is unclear whether these alternatives should be considered biocidal products. One product is based on adding silver ions to the plastic of which the box is

made, while the other product is based on using granules to neutralize any smells.

3.4.4 *Disinfection of public areas (Product Type 2)*

A number of formaldehyde-based products have been authorized for the applications 'Disinfection of areas' or 'Disinfection of public areas'. Sufficient alternative substances are available for this application (at least seventeen). Most of the alternatives are based on didecyldimethylammonium chloride, a broad-spectrum disinfectant that targets a wide range of bacteria and fungi. Didecyldimethylammonium chloride belongs to the group of quaternary ammonium compounds. This group of substances is known to potentially result in the development of resistance (see Schets *et al.*, 2012, and Walsh *et al.*, 2003). In addition, there are a number of alternative products based on other active substances. According to the criteria used in this survey, the range of products and active substances is considered sufficient.

3.4.5 *Disinfection of production systems in the metal industries and other industries (Product Type 2)*

Three products belonging to Product Type 2 and based on a formaldehyde releaser are currently authorized (the other products belonging to Product Type 2 are directly formaldehyde-based). There is one product used for the application 'Disinfection of industrial areas, specifically disinfection of surfaces of production systems in the metal-processing industry'. The second product is used for the application 'Disinfectant in circulation systems in industrial production systems, with the exception of production systems in the veterinary, medical and (animal) food industry'. The application of a third product is described as 'Disinfection of production systems in the metal-processing industry'. No other alternative products with a similar application description were found. As these products contain a formaldehyde releaser, there appears to be a demand for disinfection products that have a long-lasting effect. If the exact mode of application and the purpose of these products are clear, a targeted search may be initiated for alternative products (which may currently already be authorized for other application) for the disinfection of production systems in the metal industry and other industries.

3.4.6 *Disinfection of cold stores, empty boxes and empty greenhouses (Product Type 2)*

Cold stores, empty greenhouses and similar facilities are disinfected in various industries. Two of these sectors have been investigated for this report: greenhouse horticulture and mushroom cultivation. As the use of formaldehyde is already the subject of investigation or debate in these industries, alternatives are discussed relatively extensively in this report. As indicated in Section 1.1, consultations with stakeholders will be required following this initial inventory in order to obtain a clear view of the technical suitability of any alternatives, for instance. In this survey a first follow-up step has already been taken for glasshouse horticulture and mushroom cultivation, enabling a number of technical observations (reservations) to be made. They are included in this report.

In the bulb growing industry there is also debate about the possibility of using formaldehyde as a biocide to disinfect flower bulbs through

immersion. However, according to CTGB this would be an application as a plant protection product. It therefore falls outside the scope of this report.

Disinfection of greenhouses

Two formaldehyde-based products are in use for the disinfection of greenhouses. If these were to be discontinued in the glasshouse horticulture industry, four alternative biocides based on five active substances are currently available on the market. Singular use of the product based on didecyldimethylammonium chloride is not advisable, as it may result in the development of resistance (see Section 3.4.4). A plant protection product based on benzoic acid is also available on the market. This product can be used for the application 'Agricultural and horticultural materials (covered)'. This may include application in empty greenhouses. One possible concern is that formaldehyde-based products are used in so-called fogging systems. The question is whether these systems are suitable for the alternative products, or whether the way they are used must be adapted.

Disinfection of mushroom-growing rooms

Two formaldehyde-based products are in use for the disinfection of mushroom-growing rooms. Currently, three possible alternative products based on hydrogen peroxide are available on the market. However, these products are corrosive. It is unclear to what extent this will reduce the depreciation period of metal components. The consequences of a ban on formaldehyde for mushroom growers are also unclear. The results of the EU research project 'MushTV' are expected by mid-2015. This project may result in additional alternative disinfection products or methods for the mushroom cultivation industry. As of August 2015, no results had been published on the MushTV website (www.mushtv.eu).

3.4.7 *Disinfection of stables and animal housing (Product Type 3)*

There are approximately twenty formaldehyde-based products on the market for the disinfection of stables and animal housing. For this application, more than thirty alternative products based on over ten different active substances were found. Singular use of products based on didecyldimethylammonium chloride is not advisable, as this substance may result in the development of resistance (see Section 3.4.4). Seven alternative products were found containing substances including alkyl (C12-16) dimethylbenzyl ammonium chloride (another name for benzyl-C12-16-alkyldimethyl). This substance was classified by one registrant as a Category 1B carcinogen.

In the Netherlands, no products containing formaldehyde are specifically authorized for chick incubators. Three alternative products have been authorized and are claimed by the manufacturers to be suitable for this purpose. The question is whether these products are suitable for disinfecting chick incubators. One of these products is authorized for the disinfection of hatching eggs, while the other two are authorized for the disinfection of animal shelters and associated areas. Using ozone may be an option for the future, but this method is not an authorized biocide application under the current transitional arrangements. For this

purpose, an application for the authorization of ozone for Product Type 3 must be submitted before 1 September 2016.

- 3.4.8 *Disinfection of footwear, animal hooves and claws (Product Type 3)*
Six formaldehyde-based products are in use for the disinfection of footwear, animal hooves and claws. Four alternative products were found for the disinfection of footwear, based on four active substances. Five alternative products for the disinfection of animal hooves were found. However, four of these products contain alkyl (C12-16) dimethylbenzyl ammonium chloride (also known as benzyl-C12-16-alkyldimethyl) as the active substance. This substance has been self-classified as a Category 1B carcinogenic substance. All in all, there are few alternative products available for the disinfection of footwear, animal hooves and claws. One potential problem is that these products must be effective when used in combination with large quantities of organic materials (e.g. manure).
- 3.4.9 *Preservation of detergents (Product Type 6)*
Thirteen products based on a formaldehyde releaser are in use for the preservation of detergents. Thirteen alternatives were found for this application, based on eight active substances. Two of the alternative products found may be unsuitable for specific applications because they contain bronopol, which may release formaldehyde as a degradation product. The number of alternatives for this application is considered sufficient.
- 3.4.10 *Preservation of soaps (Product Type 6)*
One product based on the formaldehyde releaser (ethylenedioxy)dimethanol is in use for the preservation of soaps. Seven alternative products were found for this application, one of which is based on glutaraldehyde and is specifically suitable for fabric softeners. Three additional alternatives were found that are based on the same two active substances. Finally, three products containing bronopol were found. These are possibly not suitable for all applications because they may release formaldehyde as a degradation product. The range of alternatives found specifically for the preservation of soaps is limited, and is barely sufficient according to the criteria used in this report. The question is whether the alternatives for detergents are also suitable, or can be rendered suitable, for soaps. In that case, authorization may be requested for this application.
- 3.4.11 *Preservation of paints, varnishes, inks and other industrial liquids (Product Type 6)*
Nineteen products based on a formaldehyde releaser are in use for the preservation of paints, varnishes, inks and other industrial liquids, such as glues, polymer dispersions (for construction materials) and liquids used in paper, textile and leather production. Four alternatives based on five active substances were found for this application, but this list is by no means exhaustive. A large number of products are also available for the individual applications. A sufficient number of alternative products based on a variety of active substances appear to be available for the preservation of paints, varnishes, inks and other industrial liquids, such as glues, polymer dispersions (for construction materials) and liquids used in paper, textile and leather production.

3.4.12 *Preservation of lubricants, lubricating oils and diesel fuel (Product Type 6)*

Eleven products based on a formaldehyde releaser are in use for the preservation of lubricants, lubricating oils and diesel fuel. One product contains N,N-methylene-bis-morpholine (MBM) as an active substance. In the future, this substance may be classified as a Category 1B carcinogen in the harmonized classification scheme. Four alternatives based on four active substances were found for this application. As this concerns only two different compounds of a combination of active substances, we may conclude that there are few alternatives.

3.4.13 *Wood preservatives (Product Type 8)*

Two wood preservatives belonging to Product Type 8 contain a formaldehyde releaser as a co-formulant: one product based on 3-iodo-2-propynyl butylcarbamate, and another product based on a combination of that substance with propiconazole. According to their directions for use, both products are used to combat blue stain fungi. Seventeen alternatives based on eleven active substances were found for this application. These include two products based on disodium tetraborate that may be unsuitable as an alternative for certain applications, as this substance has been classified as Category 1B reprotoxic in the harmonized classification scheme, and is also on the Dutch ZZS-list.

The information retrieved reveals that it is entirely possible to formulate products based on 3-iodo-2-propynyl butylcarbamate – possibly in combination with propiconazole – without using a formaldehyde releaser as a co-formulant. In addition, a sufficient number of alternative products have been found.

3.4.14 *Preservatives for open and closed cooling systems (Product Type 11)*

Seven products based on a formaldehyde releaser are in use as preservatives for open and closed cooling systems. Thirteen alternatives based on five active substances were found for this application. This information reveals that a sufficient number of alternatives are expected to be available for the application in question. One of those alternatives contains sodium bromide. This substance may be unsuitable for certain applications because it has been self-classified as a Category 1B reprotoxic substance.

3.4.15 *Slimicides used in the paper and pulp industry (Product Type 12)*

Three products based on a formaldehyde releaser are in use as slimicides in the paper and pulp industry. More than thirty alternative products based on over ten active substances were found for this application. This information reveals that a sufficient number of alternatives are expected to be available for the application in question. The alternatives found include four products that may be unsuitable for certain applications because they contain bronopol, which may release formaldehyde as a degradation product. Three products are based on sodium bromide, which has been self-classified as a Category 1B reprotoxic substance.

3.4.16 *Slimicides used in the oil industry (Product Type 12)*

Eight products based on a formaldehyde releaser are in use as slimicides in the oil industry. Six alternatives based on five active substances were found. These include two products based on alkyl (C12-16) dimethylbenzyl ammonium chloride. These products may be unsuitable for certain applications because this substance has been classified as a Category 1B carcinogen by one registrant. One of the products also contains tetrakis(hydroxymethyl)phosphonium sulfate, which has been self-classified as a Category 1B reprotoxic substance. Based on the criteria used in this report, the number of alternatives is considered barely sufficient.

3.4.17 *Fluid preservatives for metalworking (Product Type 13)*

Twenty-one products based on a formaldehyde releaser are in use as fluid preservatives for metalworking (cutting and shaping). These include one product containing N,N-methylene-bis-morpholine (MBM) as an active substance. In the future, this substance may be classified as a Category 1B carcinogenic in the harmonized classification scheme. Seven alternatives based on three active substances were found. According to the criteria used in this report, the range of alternative products for use as preservatives for metalworking is barely sufficient.

3.4.18 *Rodenticides to control mice, rats and other rodents (Product Type 14)*

Product Type 14 includes two authorized products containing difenacoum as an active substance and formaldehyde as a co-formulant. Both of these products are authorized for indoor use, and one product is also authorized for use in sewers. A sufficient number of alternative products containing difenacoum, brodifacoum, difethialone, flocoumafen and carbon dioxide as active substances are available for this application. Hence, there are sufficient alternatives that do not contain formaldehyde.

3.4.19 *Embalming and taxidermist fluids (Product Type 22)*

In the Netherlands, no authorized products are available on the market for Product Type 22. Consequently, no directions for use are available that describe how these products should be used safely. Nevertheless, formaldehyde is used for the temporary preservation of human corpses, the preservation of human bodies for scientific research, the preservation of animal corpses for display in museums and other purposes, and the preservation of biological tissues for diagnostic purposes in pathology research. The situation as regards alternatives (which, incidentally, are not authorized either) is as follows:

- no suitable alternatives are known to be available for the preservation of animal corpses and the preservation of human bodies donated to science;
- there are possible alternatives available for the temporary preservation of human corpses ('thanatopraxy', as allowed by law). These alternatives have the disadvantage that they are claimed to be suitable only for shorter periods (five to six days), whereas formaldehyde is suitable for the maximum permitted period of ten days. Incidentally, these alternatives are not authorized for Product Type 22 either;
- a number of good alternatives are known and in use for the preservation of biological tissues for pathology research, although

the relevant products are not authorized. Only after they have been assessed for admissibility will it be clear whether the alternatives used are indeed suitable. Depending on the type of tissue and the purpose of the fixation, the alternatives used contain different substances. An alternative based on potassium dichromate was also found, but it may be unsuitable in the light of the harmonized classification data (classification as, *inter alia*, a Category 1B carcinogen) and its inclusion on the Dutch ZZS-list. An alternative based on mercury chloride was also found. Since mercury is a ZZS, this product may also be unsuitable. No suitable alternatives are known to be available for a specific type of tissue analysis. Suitable alternative products and substances for the preservation of biological tissues are currently being investigated, in Germany for instance (see also Zanini, 2012). The substitution of formaldehyde for this application is being discussed in France.

Table 3. Information about authorized biocidal products as alternatives for biocidal products containing formaldehyde (releasers), per application

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
2	Cleaning and disinfection of surfaces, equipment and instruments in the healthcare sector	For surfaces: at least eight alternatives For equipment and instruments: at least six alternatives	For surfaces: sodium hypochlorite, quaternary ammonium compounds, ethanol, benzyl-C8-18-alkyldimethyl, chlorides, sodium p-toluenesulfonchloramide and hydrogen peroxide, alkyl (C12-16) dimethylbenzyl ammonium chloride, glucoprotamin and 2-propanol For equipment and instruments: sodium dichloroisocyanurate, sodium p-toluenesulfonchloramide and ethanol	-	For surfaces, there is one product based on alkyl (C12-16) dimethylbenzyl ammonium chloride. This substance has been self-classified as a Category 1B carcinogen.	Sufficient alternatives
2	Disinfection of litter bins for sanitary towels	No alternatives	-	There are two methods available, although their biocide status and effectiveness are unclear: one based on silver ions, and one based on granules.	Not found	No alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
2	Disinfection of public areas	At least 17 alternatives	Didecyldimethylammonium chloride, ethanol, sodium dichloroisocyanurate(dihydrate), alkyl (C12-16) dimethylbenzyl ammonium chloride (also known as benzyl-C12-16-alkyldimethyl), quaternary ammonium compounds, chloride and polyhexamethylene biguanide hydrochloride	-	There are three products containing alkyl (C12-16) dimethylbenzyl ammonium chloride (also known as benzyl-C12-16-alkyldimethyl). This substance has been self-classified as a Category 1B carcinogen. Singular use of didecyldimethylammonium chloride may result in the development of resistance.	Sufficient alternatives
2	Disinfection of production systems in the (metal) industry	No alternatives	-	Currently unclear, depends on exact purpose and mode of application	Not found	No alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
2	Disinfection of cold stores, empty boxes and empty greenhouses	For greenhouse horticulture: four biocides and one plant protection product For mushroom cultivation: three biocides	For greenhouse horticulture: hydrogen peroxide, peracetic acid, sodium hypochlorite, active chlorine, didecyldimethylammonium chloride and benzoic acid For mushroom cultivation: hydrogen peroxide and peracetic acid	An EU research project may produce new alternatives for mushroom cultivation	The alternatives found may be unsuitable for fogging systems Corrosiveness may be a problem for products containing hydrogen peroxide	Few alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
3	Disinfection of stables and animal housing	Over thirty alternatives	Peracetic acid, didecyldimethylammonium chloride, glutaraldehyde, quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, sodium percarbonate, tetraacetythylenediamine, sodium dichloroisocyanurate(dihydrate), sodium hypochlorite (as active chlorine), sodium p-toluenesulfonchloramide, hydrogen peroxide, chlorides, alkyl (C12-16) dimethylbenzyl ammonium chloride and N-(3-aminopropyl)-N-decylpropane-1,3-diamine	In the case of chick incubators, it is unclear whether products based on pentapotassium bis(peroxymonosulfate) bis(sulfate), sodium p-toluenesulfonchloramide and peracetic acid in combination with hydrogen peroxide are authorized for this specific application. Ozone – which is currently not authorized – may be considered suitable in future.	There are seven products containing alkyl (C12-16) dimethylbenzyl ammonium chloride (also known as benzyl-C12-16-alkyldimethyl). This substance has been self-classified as a Category 1B carcinogen. Singular use of didecyldimethylammonium chloride may result in the development of resistance.	Sufficient alternatives; situation for chick incubators unclear

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
3	Disinfection of footwear, animal hooves and claws	For footwear: 4 For animal hooves: 5	For footwear: pentapotassium bis(peroxymonosulfate) bis(sulfate), sodium p-toluenesulfonchloramide and hydrogen peroxides with peracetic acid For animal hooves: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, alkyl (C12-16) dimethylbenzyl ammonium chloride, didecyldimethylammonium chloride, glutaraldehyde, quaternary ammonium compounds and chlorides	-	There are four products used to disinfect animal hooves that contain alkyl (C12-16) dimethylbenzyl ammonium chloride (also known as benzyl-C12-16-alkyldimethyl). This substance has been self-classified as a Category 1B carcinogen. Singular use of didecyldimethylammonium chloride may result in the development of resistance. The substance may be less effective when used in combination with large quantities of organic materials.	Few alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
6	Preservation of detergents	13	1,2-benzisothiazol-3(2H)-one, 2,2-dibromo-2-cyanoacetamide, 2-phenylphenol, p-[(diiodomethyl)sulphonyl]toluene, glutaraldehyde, 5-chloro-2-methyl-2H-isothiazol-3-one, 2-methyl-2H-isothiazol-3-one and bronopol	-	There are two products based on bronopol, which may release formaldehyde as a degradation product	Sufficient alternatives
6	Preservation of soaps	7	Glutaraldehyde, 5-chloro-2-methyl-2H-isothiazol-3-one, 2-methyl-2H-isothiazol-3-one, 2-octyl-2H-isothiazol-3-one and bronopol	Products for the preservation of detergents may also be authorized for soaps.	There are three products based on bronopol, which may release formaldehyde as a degradation product	Barely sufficient alternatives
6	Preservation of paints, varnishes, inks and other industrial liquids, such as glues, polymer dispersions (for construction materials) and liquids used in paper, textile and leather production	Well over four alternatives	1,2-benzisothiazol-3(2H)-one, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, 5-chloro-2-methyl-2H-isothiazol-3-one, 2-methyl-2H-isothiazol-3-one, 2,2'-dithiobis[N-methylbenzamide] and other substances	-	Not found	Sufficient alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
6	Preservation of lubricants, lubricating oils and diesel fuel	4	5-chloro-2-methyl-2H-isothiazol-3-one, 2-methyl-2H-isothiazol-3-one, 1,2-benzisothiazol-3(2H)-one and zinc pyrithione	-	Not found	Few alternatives
8	Wood preservatives	17	3-iodo-2-propynyl butylcarbamate, propiconazole, tebuconazole, didecyldimethylammonium chloride, copper(II) oxide, flufenoxuron, sulfuranyl fluoride, disodium tetraborate, quaternary ammonium compounds, coconut alkyltrimethyl, chlorides	-	Two products based on disodium tetraborate have been found. This substance has been classified as Category 1B reprotoxic in the harmonized classification scheme, and is included in the Dutch ZZS-list.	Sufficient alternatives
11	Preservatives for open and closed cooling systems	13	2-methyl-2H-isothiazol-3-one, 5-chloro-2-methyl-2H-isothiazol-3-one, sodium hypochlorite (as active chlorine), bromochloro-5,5-dimethylimidazolidine-2,4-dione, sodium bromide	-	One product based on sodium bromide has been found. This substance has been self-classified as a Category 1B reprotoxic substance.	Sufficient alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
12	Slimicides used in the paper and pulp industry	Over thirty alternatives	N-(3-aminopropyl)-N-do decylpropane-1,3-diami ne, didecyldimethylammoniu m chloride, 1,2-benzisothiazol-3(2H)-one, 2-methyl-2H-isothiazol-3-one, 5-chloro-2-methyl-2H-is othiazol-3-one, bromochloro-5,5-dimeth ylimidazolidine-2,4-dion e, methylene-dithiocyanate , quaternary ammonium compounds, benzyl-C8-18-alkyldimet hyl, chlorides, 1,3-dichloro-5,5-dimeth ylhantoin, 1,3-dichloro-5-ethyl-5- methylimidazolidine-2,4- dione, 1-bromo-3-chloro-5,5-di methylimidazolidine-2,4- dione, sodium bromide, 2,2-dibromo-2-cyanoace tamide, ammonium bromide, glutaraldehyde and bronopol	-	There are four products based on bronopol that may release formaldehyde as a degradation product. Three products based on sodium bromide have been found. This substance has been self-classified as a Category 1B reprotoxic substance.	Sufficient alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
12	Slimicides used in the oil industry	6	1,2-benzisothiazol-3(2H)-one, glutaraldehyde, 2,2-dibromo-2-cyanoacetamide, tetrakis(hydroxymethyl)phosphonium sulfate and alkyl (C12-16) dimethylbenzyl ammonium chloride	-	There are two products containing alkyl (C12-16) dimethylbenzyl ammonium chloride. This substance has been self-classified as a Category 1B carcinogenic substance. One of those products also contains tetrakis(hydroxymethyl)phosphonium sulfate, which has been self-classified as a Category 1B reprotoxic substance.	Barely sufficient alternatives
13	Working or cutting fluid preservatives for metalworking (cutting and shaping)	7	2,2-dibromo-2-cyanoacetamide, 3-iodo-2-propynyl butylcarbamate and 1,2-benzisothiazol-3(2H)-one	-	Not found	Barely sufficient alternatives
14	Rodenticides to control mice, rats and other rodents	Many alternatives	Difenacoum, brodifacoum, difethialone, flocoumafen and carbon dioxide	-	Not found	Sufficient alternatives

PT	Application	Number of alternative products found	Active substances	Alternatives that may be suitable in future	Information about potential unsuitability	Final assessment of number of authorized alternative products found
22	Embalming and taxidermist fluids	No alternatives. No products belonging to Product Type 22 are authorized on the Dutch market, although formaldehyde is widely used. There are no suitable non-authorized alternatives for thanatopraxy and taxidermy applications either.	-	For thanatopraxy applications, non-authorized alternative products are available based on glutaraldehyde, phenoxyethanol, ethanol and polyethylene glycol. These are claimed to be only suitable for shorter preservation periods (5 to 6 days). A number of good alternatives are known and in use for the preservation of biological tissues, although the relevant products are not authorized. No suitable alternatives are known to be available for a specific type of tissue analysis.	Products for the preservation of biological tissues based on potassium dichromate (which is a ZZS and has been classified as a Category 1B carcinogenic, mutagenic and reprotoxic substance in the harmonized classification scheme) and mercury chloride (which is a ZZS) are potential unsuitable.	No alternatives

3.5 Summary of results

Table 4 provides an overview of the applications for which biocides containing formaldehyde (releasers) are in use, as well as our assessment of the number of chemical alternatives found. The main conclusions are described below.

Table 4. Overview of estimated number of chemical alternatives found for biocidal products containing formaldehyde (releasers), per application

PT	Application	Active substance in products used ¹	Number of alternative products found
2	Cleaning and disinfection of surfaces, equipment and instruments in the healthcare sector	F	Sufficient alternatives
2	Disinfection of litter bins for sanitary towels	F	No alternatives
2	Disinfection of public areas	F	Sufficient alternatives
2	Disinfection of production systems in the metal industry and other industries	FR	No alternatives
2	Disinfection of cold stores, empty boxes and empty greenhouses	F	Few alternatives
3	Disinfection of stables and animal housing	F	Sufficient alternatives
3	Disinfection of footwear, animal hooves and claws	F	Few alternatives
6	Preservation of detergents	FR	Sufficient alternatives
6	Preservation of soaps	FR	Barely sufficient alternatives
6	Preservation of paints, varnishes, inks and other industrial liquids, such as glues, polymer dispersions (for construction materials) and liquids used in paper, textile and leather production	FR	Sufficient alternatives
6	Preservation of lubricants, lubricating oils and diesel fuel	FR	Few alternatives
8	Wood preservatives	FR	Sufficient alternatives
11	Preservatives for open and closed cooling systems	FR	Sufficient alternatives
12	Slimicides used in the paper and pulp industry	FR	Sufficient alternatives
12	Slimicides used in the oil industry	FR	Barely sufficient alternatives
13	Working or cutting fluid preservatives for metalworking (cutting and shaping)	FR	Barely sufficient alternatives
14	Rodenticides to control mice, rats and other rodents	F	Sufficient alternatives
22	Embalming and taxidermist fluids	F ²	No alternatives

1. F = Formaldehyde; FR = Formaldehyde Releaser

2. In the Netherlands, there are no authorized products belonging to Product Type 22.

Authorized alternatives containing formaldehyde for disinfection applications

Product Type 2 and Product Type 3 include many products in use, that owe their disinfectant effect to the presence of formaldehyde as an active substance. The following may be concluded as regards the number of alternatives found for this application:

- sufficient alternatives: for disinfection of surfaces and instruments in the healthcare sector, disinfection of public areas, and disinfection of stables and animal housing;
- few alternatives: for disinfection of cold stores, empty boxes, empty greenhouses (including empty mushroom-growing rooms), footwear, and animal hooves;
- no alternatives: for disinfection of litter bins for sanitary towels.

The alternatives found for the application 'Disinfection of public areas' were mainly based on didecyldimethylammonium chloride. Singular use of this substance may result in the development of resistance.

With respect to the disinfection of empty greenhouses and/or mushroom-growing rooms, the question is whether the available alternatives can be applied in the fogging systems used for formaldehyde, and whether or not alternative products based on hydrogen peroxide cause excessive corrosion. An EU research project that is currently underway may offer new possibilities in this regard.

For the disinfection of footwear and animal hooves, it may be a problem that the few alternative products available are not sufficiently effective due to the presence of organic materials.

For the disinfection of litter bins for sanitary towels, two other types of product were found. It is unclear whether these products should be considered as biocides, and whether they are sufficiently effective.

Unauthorized alternatives for the (temporary) preservation of human and animal corpses and biological tissues using formaldehyde

In Product Type 22, formaldehyde is used for the temporary preservation of human corpses (thanatopraxy / light embalming), the preservation of human bodies for scientific research, the preservation of animal corpses for display in museums and other purposes, and the preservation of biological tissues for diagnostic purposes in pathology research. The first problem is that these are not authorized biocidal applications in the Netherlands, and that their safe use is hence not clearly laid down in the relevant directions for use. The second problem is that no good alternatives are available, with the probable exception of alternative products for most applications aimed at preserving biological tissues for pathology research (which, incidentally, are not authorized either).

Alternatives containing formaldehyde releasers for preservation of and slime control in liquid products

Product Types 6, 11, 12 and 13 include many products in use that owe their preservative or slime-controlling effect to the presence of a formaldehyde releaser as an active substance. The following may be

concluded as regards the number of alternatives found for this application:

- sufficient alternatives: for the preservation of detergents, soaps, paints, varnishes, inks and other industrial liquids, the preservation of liquids in cooling systems and for metalworking, and for slime control in the paper and pulp industry and in the oil industry;
- few alternatives: for the preservation of lubricants, lubricating oils and diesel fuel.

However, there are considerable differences between the applications for which sufficient alternatives were found. For the preservation of soaps and for slime control in the oil industry, the number of alternative products is barely sufficient according to the criteria used in this report. These alternatives also include a number of products containing active substances that may be unsuitable for certain applications. The question is whether the alternatives for detergents are also suitable, or can be rendered suitable, for the preservation of soaps. In that case, authorization may be requested for this application. For the preservation of metalworking fluids, the number of alternative products is also barely sufficient according to the criteria used in this report.

Alternatives for products containing formaldehyde or a formaldehyde releaser as a co-formulant

Product Type 8 (wood preservatives) and Product Type 14 (rodenticides) include a number of products that contain formaldehyde (releasers) as a co-formulant. For these applications, sufficient alternatives without formaldehyde (releasers) as a co-formulant appear to be available on the market.

Potentially unsuitable alternatives

The survey performed reveals that various alternative substances in authorized biocides are potentially unsuitable. They are:

- products containing benzyl-C12-16-alkyldimethyl also known as alkyl (C12-16) dimethylbenzyl ammonium chloride), which has been self-classified as a Category 1B carcinogen;
- products based on disodium tetraborate, which has been classified as a Category 1B reprotoxic substance in the harmonized classification scheme and is included in the Dutch ZZS-list;
- products based on sodium bromide, which has been self-classified as a Category 1B reprotoxic substance;
- products containing tetrakis(hydroxymethyl)phosphonium sulfate, which has been self-classified as a Category 1B reprotoxic substance;
- products containing bronopol, which may release formaldehyde as a degradation product;
- products based on didecyldimethylammonium chloride, which may result in the development of resistance in the case of singular use.

Products containing benzyl-C12-16-alkyldimethyl and didecyldimethylammonium chloride were predominantly found for applications belonging to Product Type 2 and Product Type 3. Products

containing the other substances listed above were found in preservation and/or slime control applications belonging to Product Type 6, Product Type 8, Product Type 11 and Product Type 12.

Unauthorized products based on potassium dichromate (which is a ZZS and has been classified as a Category 1B carcinogenic, mutagenic and reprotoxic substance in the harmonized classification scheme) and mercury chloride (which is a ZZS) were found for the preservation of biological tissues.

4 Conclusions and recommendations

4.1 Conclusions

Availability of alternatives

This initial inventory shows that, in principle, sufficient chemical alternatives are available for many applications of biocides containing formaldehyde (releasers). As indicated in Section 1.1, once alternatives have been found, an important follow-up step must always be carried out, in the form of a more specific check to demonstrate that these alternatives are actually suitable for each application and industrial sector in question. Alternative products may turn out to be unsuitable after all, for instance because the differences are too great with respect to the target organisms or the mode of application, because technical modifications may be required, or because the alternative lacks the required physical properties. The qualification 'sufficient alternatives' as used in this report provides merely an indication. In some cases, a single alternative may be regarded as 'sufficient', while in other cases four alternatives may not be sufficient for the intended application. Other aspects that have not been considered so far – such as the pricing of alternatives and the use of preventive measures or non-chemical alternatives – also have a bearing on the ultimate consequences of a possible ban on, or phase-out of, formaldehyde (releasers). Based on this initial inventory, we expect that a possible ban on or phase-out of biocides containing formaldehyde (releasers) will not have major consequences for most applications. The economic impact of such a ban or phase-out falls outside the scope of this report.

However, few chemical alternatives currently seem to be available for a number of applications of biocides containing formaldehyde (releasers), namely disinfection of greenhouses, mushroom-growing rooms, footwear and animal hooves, and preservation of lubricants, lubricating oils and diesel fuel. The number of alternatives found for the preservation of soaps and metalworking fluids and for slime control in the oil industry barely satisfies the criteria we used. In the case of applications with few alternatives, the risk is greater that a ban on or phase-out of formaldehyde (releasers) will result in problems.

In addition, it turns out that no registered chemical alternatives to formaldehyde are commercially available for the disinfection of litter bins for sanitary towels. Any ban on formaldehyde-based products used for the disinfection of these bins is expected to have major consequences for the cleaning industry.

There are also no registered alternatives available for the preservation (temporary or otherwise) of human or animal corpses and biological tissues. Because these are non-authorized applications of formaldehyde, the situation is in any case undesirable and requires attention.

Assessment of formaldehyde in the authorization procedure for biocidal products

In its authorization procedures, CTGB is expected to take the pending reclassification of formaldehyde as a Category 1B carcinogen into account. Proposals have already been put forward for the harmonized classification of some formaldehyde releasers as Category 1B carcinogens. When assessing biocides containing formaldehyde (releasers), CTGB is expected to determine whether human exposure to formaldehyde is non-existent or very limited. The same approach will also be applied if active substances are used that release formaldehyde as a degradation product.

Potentially unsuitable alternative active substances

Finally, this initial inventory has produced a number of alternative active substances that are possibly unsuitable because they (may) have harmful properties similar to those of formaldehyde, or because they release formaldehyde as a degradation product. The suitability of these substances as alternatives to formaldehyde (releasers) depends on the possible level of exposure to the relevant substance, and their actual harmful properties.

These potentially unsuitable alternative substances are benzyl-C12-16-alkyldimethyl (self-classification as a Category 1B carcinogenic substance), disodium tetraborate (harmonized classification as a Category 1B reprotoxic substance), sodium bromide (self-classification as a Category 1B reprotoxic substance), tetrakis(hydroxymethyl)phosphonium sulfate (self-classification as a Category 1B reprotoxic substance), and bronopol (which releases formaldehyde as a degradation product). The self-classification of benzyl-C12-16-alkyldimethyl as a Category 1B carcinogen may be the result of impurities in the production of this substance (impurity of more than 0.1% benzyl chloride). The question is therefore whether this impurity will occur in practice. All self-classifications provide relatively unreliable information since their substantiation is unclear. In the case of bronopol, it is unclear when the substance is degraded (and formaldehyde is formed), and where in the life-cycle this occurs.

In addition, singular use of didecyldimethylammonium chloride is not recommended, since this substance may result in the development of resistance.

4.2 Recommendations

Provide better access to CTGB biocide data

The CTGB biocides database cannot be searched based on specific applications (or keywords like 'resistance'). This caused problems during the performance of this survey. In the Netherlands, many biocides have been authorized based on an accelerated and simplified procedure. This has led to a large number of authorized biocides with directions for use that contain relevant information about the authorized application(s) and the required safety measures. We recommend providing better access to this information, so that users of substances can gain a better overview of suitable alternatives for specific applications. The information in the authorization decision should also be more readily

accessible, for instance the data about other substances considered (e.g. 'Substances of Concern').

Prioritize measures based on exposure level

In view of the expected reclassification of formaldehyde as a Category 1B carcinogen, it makes sense to institute measures that limit or prevent human exposure to formaldehyde in biocides. In view of the large number of applications in various sectors and industries, priorities will need to be defined on which the measures must focus.

Insight into human exposure levels is essential in order to define priorities and assess the need for measures. For this purpose, systematic distinctions must be made between open and closed applications, applications with fast or slow release mechanisms, etc. Factors such as usage frequency and volume must also be taken into account. It is important to identify applications where exposure is expected, cannot be excluded, or can be convincingly demonstrated to be impossible.

If exposure can be convincingly demonstrated to be impossible, risk reduction measures to limit usage are in principle not required. The Biocidal Products Regulation provides scope for such exceptions, even if the relevant substance is classified as a Category 1B carcinogen. Of course, the relevant active substance must be authorized for the relevant Product Type by the ECHA Biocidal Products Committee (BPC) as part of its Work Programme under the Biocidal Products Regulation. The Regulation does state that biocides classified as Category 1 carcinogenic, mutagenic and/or reprotoxic (CMR) qualify for substitution and comparative assessment. This means that an assessment must be performed to determine if any alternatives are available that pose less risk to human health and the environment. In this context, ECHA has already completed a public consultation procedure for formaldehyde, the results of which have been published (ECHA, 2015b). These findings can be taken into account when deciding which policy measures (if any) to take.

Encourage the transition to alternatives

If good alternatives to formaldehyde (releasers) are available, it is generally recommended to encourage a transition to these products. The availability and feasibility of non-chemical alternatives like heating and ultraviolet radiation must also be examined. Priority should be given to applications that are currently expected to result in human exposure to formaldehyde. For instance, a high level of priority is expected to be assigned to open applications for the disinfection of animal hooves (such products are applied by having cows walk through a container with disinfectant). Farm workers are often present during this procedure and may be exposed to formaldehyde as a result.

To facilitate the transition, up-to-date information must be available on biocides containing formaldehyde (releasers) and the alternatives currently available for specific applications. This information must be searchable based on the intended application, in line with the above recommendation concerning access to CTGB's biocides database.

Discussion concerning safe formaldehyde exposure levels

Where the implementation of measures is concerned, it is problematic that there is a lack of clarity about the possible implementation of a medical threshold value for formaldehyde levels in air (and the precise level of such a value). ECHA's Risk Assessment Committee (RAC) has stated that there is insufficient data to determine with certainty if the carcinogenicity of formaldehyde has a threshold value (ECHA, 2012). In 2014, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority (EFSA) was unable to determine a safe level of formaldehyde exposure for the skin, eyes or respiratory system (EFSA, 2014). In 2008, the Scientific Committee on Occupational Exposure Limits (SCOEL) adopted 'practical' threshold values for formaldehyde, while still classifying the substance as a genotoxic carcinogen (SCOEL, 2008). SCOEL is an advisory body to the European Commission. Under the Biocidal Products Regulation, existing medical threshold values are used to assess the risks posed by formaldehyde (releasers). A working group of the ECHA Biocidal Products Committee (BPC) discusses which values should be used within this framework. Where possible, we recommend promoting closer coordination at the EU level about the applicability of a medical threshold value and the level of such a value.

Assess the suitability of the alternatives found

As indicated in Section 1.1, once alternatives have been found, an important follow-up step must always be carried out. This must take the form of a more specific check to demonstrate that the alternatives found are actually suitable, feasible and affordable for each application and industrial sector in question, and to ascertain if any non-chemical alternatives are available. This is particularly important if few alternatives are found, but specific situations may also require specific substances. A number of issues is already flagged. With respect to healthcare, we recommend assessing if any ban on the use of formaldehyde should also apply to specific high-threat scenarios such as outbreaks of communicable bird flu or the Ebola virus. It may be advisable to define exceptions for these cases. The available alternatives for the disinfection of empty greenhouses and mushroom-growing rooms must be assessed for their suitability for use in the fogging systems used for formaldehyde. In addition, the possible corrosive properties of alternative products containing hydrogen peroxide must be examined. A current EU research project may result in new solutions for the mushroom cultivation industry, which would need to be evaluated. In addition, alternative products used for the disinfection of animal hooves must be assessed to determine their efficacy when used in combination with large quantities of organic materials.

Recommendations if no alternatives are found

If no good alternatives are available for formaldehyde (releasers), their development should be encouraged (through innovation). No registered chemical alternatives have been found for the disinfection of litter bins for sanitary towels. One key consideration is how this application of formaldehyde affects air quality. This aspect would need to be investigated to determine the impact of any transition to an alternative. In addition, the two other types of product currently on the market for

this application would need to be assessed to determine if they should be designated as biocidal products and if they are sufficiently effective.

Other applications for which no registered chemical alternatives were found include the temporary preservation of human corpses, the preservation of (human) corpses for scientific research, the preservation of animal corpses for display in museums and other purposes, and the preservation of biological tissues for diagnostic purposes in pathology research. These applications belong to Product Type 22 and require attention in any case because of the unavailability of authorized biocides (regardless of whether or not they contain formaldehyde). Consequently, no directions for use are available that describe how these products should be used safely. The industry is aware of this problem, but no solutions are forthcoming in the short term. Human exposure to formaldehyde cannot be excluded when formaldehyde is used for the temporary preservation of corpses at home (i.e. prior to burial or cremation). The use of formaldehyde for the fixation of biological tissues, the preservation of animal corpses, and the preservation of (human) corpses for scientific purposes should be assessed to determine if adequate measures are currently taken to prevent human exposure to formaldehyde.

Non-chemical alternatives and preventive measures

In general, we recommend raising awareness of non-chemical alternatives to applications of biocides containing formaldehyde (releasers), and promoting their development and use. Attention should also be devoted to possible measures to prevent or reduce the use of biocides. Directive 2009/128/EC on the sustainable use of pesticides is based on the principle that non-chemical alternatives and preventive measures are preferable. This Directive currently applies to pesticides used as plant protection products. It is still unclear if its scope will be expanded to include biocides. In 2015, the European Commission published a study on the sustainable use of biocides, which also devotes attention to preventive measures (European Commission, 2015). The scope of the present report is limited to chemical alternatives.

Risk of development of resistance

In the course of the survey, we noted that sometimes the main alternatives available contain one or more substances that may result in the development of resistance in target organisms in the case of singular use (e.g. didecyldimethylammonium chloride). If this is a known problem, CTGB will take it into account in its assessment. Since reducing the use of formaldehyde may lead to increased development of resistance, it is important to remain alert to this risk.

Potentially unsuitable alternative active substances

The present survey produced a number of alternative active substances that may not be suitable for specific applications. In many cases, the possible unsuitability of these substances is based on self-classifications that lack adequate substantiation. We recommend further investigation to determine the actual suitability of these alternatives. In the case of alternatives containing bronopol (which can release formaldehyde as a degradation product), the applications for which the product is suitable

and intended must be very clear in order to prevent incorrect use in applications that may result in the release of formaldehyde.

Alternatives to the use of formaldehyde (releasers) as co-formulants

Sufficient alternatives that do not contain formaldehyde (releasers) are commercially available for the examined biocides that belong to Product Type 8 (wood preservatives) and Product Type 14 (rodenticides) and that contain formaldehyde (releasers) as co-formulants. Such co-formulants are probably not truly necessary. We recommend assessing this matter and changing the product formulations if required. Such a measure would fall under the responsibility of the manufacturers concerned.

Parties involved

The above recommendations and questions to be answered are explicitly addressed at all parties involved, including policy departments, inspectorates, manufacturers, professional organizations and the various industries that use formaldehyde-containing biocides. Information about human exposure is highly relevant, and the industries and/or manufacturers concerned have an important role in this regard. Legislation on work-related risks requires employers to identify, and if necessary mitigate, any risks affecting employees. The manufacturers and industries involved may also provide input about the suitability of alternatives. Manufacturers may modify their product formulations in order to reduce the use of formaldehyde (releasers). Implementation of the above recommendations will require the joint involvement of the Ministry of Health, Welfare and Sport, the Ministry of Economic Affairs, and the Ministry of Social Affairs and Employment, as well as the Ministry of Infrastructure and the Environment. The Human Environment & Transport Inspectorate (ILT) and the Social Affairs and Employment Inspectorate also have a part to play in this regard. The Biocides Knowledge Network (KNB, www.kennisnetwerkbiodiciden.nl) can play a facilitating role in the discussions to be held.

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