Study of use and alternatives formaldehyde (PT2 and PT3)

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Authors
Dr. Kees Le Blansch
Renate Groot, MSc

Client
Ministerie van Infrastructuur en Waterstaat
Postbus 20906
2500 EX Den Haag

Controlled
Amanda Jacobs-Jansen, MSc

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Summary

- *Report and summary*

This report describes the results of a study into the current use, hazards, and risks of disinfectants (PT2 and PT3) based on the active substance formaldehyde, and into the replacement prospects of these disinfectants for various applications. This research was conducted on behalf of the Ministry of Infrastructure and Water Management (IandW), which wants to use its results to substantiate the Dutch position and input into EU decision-making on the reassessment of the approval of the exclusion substance formaldehyde.
This summary briefly outlines the results of the research.

- *Research method*

The research was carried out by means of desk research (study of the databases on the ECHA and Ctgb websites and document study) and interviews with those involved in and around the chain of production and use of the disinfectants in question. In total, exchanges took place with 10 producers and authorization holders, 16 (representatives of) users and 5 experts. In addition, 4 Dutch government parties were consulted about the sources and search directions involved.
Based on all this, the research has led to conclusions on the key questions, which are summarized below.

- *Authorisation*

The first main question is: which disinfectants for PT2 and PT3 based on the active ingredient formaldehyde are currently authorised and for which applications?

Conclusions:
- For PT2, disinfectants are authorised for:
  - Surfaces (including medical and laboratory instruments) and areas for people to stay in hospitals and other healthcare institutions (6 products)
  - Areas for growing consumer and decorative plants and mushrooms (3 products)
  - Hygiene containers in ladies' toilets (3 products)
- For PT3, disinfectants are authorised for:
  - Animal housing/stables and surfaces and materials therein (9 products)
  - Cattle and sheep hooves (4 products)
- All these products may only be applied by professionals. Nebulization can only be done by professionals with training in space disinfection.
- Compared to a previous inventory from 2015, it appears that no products are authorised anymore for disinfection of spaces and surfaces in the metal industry and in circulation systems, of public accesses, of cold rooms and empty boxes, and of footwear.

- *Use*

The second main question is: what is the current use of disinfectants (PT2 and PT3) based on the active substance formaldehyde, both qualitatively and quantitatively?

Conclusions in qualitative terms:
- In PT2 they are used (by means of nebulisation/evaporation) in the cultivation of consumer and decorative crops for room disinfection of empty greenhouses during crop rotation, in case there

was serious contamination during the previous cultivation, and at compost companies for mushroom cultivation between (and after) some of the production steps.
- In PT3, room disinfection by means of nebulisation mainly takes place in the poultry sector, and also in laboratory animal housing and in a laboratory where work is done with the foot and mouth virus. Formaldehyde is used for surface cleaning in the pig sector. In dairy farming, formalin is used in disinfectant hoof baths to prevent claw disorders in cows.
- Although there are authorised products on the market for these applications, the research shows that hospitals and other healthcare institutions, mushroom growers, and suppliers of hygiene containers for ladies' toilets can guarantee the required hygiene and prevent infections without using formaldehyde-based disinfectants.

Quantitative conclusions:
- Precise figures on the quantities of formaldehyde traded as an active substance for disinfectants in the Netherlands are not available. They are not publicly recorded and are considered confidential by companies.
- The world market for formaldehyde is large and growing (> 50 million tons per year, expected annual growth > 5%). Much of this is for non-biocidal applications for building materials, furniture, transport, and pharmaceuticals.
- Traded biocides are registered in Belgium and Croatia. In Belgium, for PT2 and 3 together 82 tons of formaldehyde were traded in 2018 and 135 tons in 2019. In Croatia, 2.6 tons of formaldehyde were on the market as an active substance in 2022, in addition to 60 tons of technical formaldehyde.

- *Risks*

The next main question is: what are the dangers and risks of using these products?

Conclusions:
- Formaldehyde can cause cancer, is suspected of causing genetic damage, can lead to local irritation or corrosion of the covering tissue and has a skin-sensitizing effect; In addition, it is toxic in the aquatic environment.
- Room disinfection by means of formalin nebulisation happens in closed spaces, is often done by hired specialist companies and is mostly (but not always) carried out by people that received some sort of training (there are no established competency requirements and hence no formal standard training). Given these circumstances, the risks to humans, animals and the environment can in principle be properly controlled, provided that the disinfection is conducted with sufficient expertise and that the disinfected area is not entered before it is deemed safe. These conditions are not met in all aspects and cases, particularly not in the broiler sector.
- The use of formalin for disinfecting hoof baths involves risks for humans, animal welfare and animal health. These are not always optimally managed, leading amongst other things to uncontrolled human exposure.

- *Alternatives*

From a preventative (integrated pest management) perspective, the main questions are: what is the risk awareness of the parties involved, what are the current options for prevention of infections and for replacing formaldehyde, and what drives and prevents substitution?

Conclusions about this are:
- In general terms, awareness of the risks of dealing with formaldehyde appears to be high in specialist disinfection companies, in cultivation of consumer and decorative crops, in composting companies for mushroom cultivation and in the FMD laboratory. It appears to be less high among

poultry farmers carrying out disinfection themselves and among dairy farmers that work with disinfectant hoof baths.

- About room disinfection:
  - Cultivation of consumption and decorative crops can mostly be done without the use of formaldehyde for room disinfection. However, sometimes persistent infections occur that can hardly be exterminated without using formaldehyde.
  - There are poultry farms with very modern stables, including pore-free surfaces, which achieve such a high level of hygiene that disinfection (with formalin) is no longer necessary. However, these companies are still the exception. Also, animal welfare considerations may lead to constructions that complicate hygiene (sticks, racks, and compartments; free range).
  - At composting companies for mushroom cultivation, preventive measures are hardly or not possible because of the presence of manure.
  - Alternative active substances are available for room disinfection. Some are actually used for room disinfection of smaller and easier to clean areas and/or if there was no high-risk contamination before. However, if there are high risks of contamination, larger spaces (with seams and cracks) and the presence of organic (residual) material (in combination with a certain time pressure), all those involved indicate that only room disinfection with formaldehyde provides sufficient security. This is due to properties of formaldehyde such as its broad-spectrum effect, stable nebulization, effectiveness at a greater distance and after a longer period of time, and longer lasting effectiveness and further impact, even in the presence of organic material.
- About disinfecting hoof baths:
  - Prevention of cow's claw disorders can be done by conducting a more animal and hoof-friendly way of dairy farming. Still, in case there are cows that are suffering from claw disorders, foot baths can be helpful to prevent further spread (and in some cases, to cure).
  - There are authorised alternatives for hoof disinfection with other active substances. However, dairy farmers more often choose formalin because of its effectiveness (which decreases less quickly under the influence of organic material than alternatives), its broad-spectrum effect and its low price, and out of habit. Alternatives score less on these points.

- *What if approval is granted or withheld?*

The final question is: what will be the impact of renewed approval or of a decision to withhold approval?

Conclusions:

- The impact of withholding approval will be that there is less certainty that infections can effectively be controlled.
  - For the cultivation of consumer and decorative crops and in mushroom cultivation, this means an increased risk of losing a significant part of the yield; in the case of plants, there is also a risk of the infection spreading to cultivation elsewhere, possibly also of invasive exotic infections.
  - For disinfecting animal housing: increased risks for animal health, animal welfare, public health (contaminated animal products) and the occurrence of resistance.[1]
  - For disinfectant hoof baths: some increased risk of occurrence and spread of hoof disorders, and of associated risks for animal health and animal welfare (which can possibly be addressed by dealing with underlying causes of claw disorders and/or using alternative products).
- In addition, other expected consequences of non-approval are mentioned:

[1] For the FMD laboratory, a conflict will arise with binding prescriptions of a European body.

  - Increasing use of biocides, because of attempts to achieve the same level of effectiveness of disinfection with less effective means.
  - Negative effects on business operations and results, because of longer cleaning times, more vacancy of stables and greenhouses and sometimes more expensive alternatives have to be purchased.
  - Increased risk of illegal use of (technical) formaldehyde, as it remains (cheaply) available on the market for other than biocidal applications.
- The expected impact of unconditional reapproval will be that the current handling of disinfectants with formaldehyde as the active substance will probably remain as it is now. The research shows that the following conditions are worth considering:
  - Withdrawal of approval for applications where it has been shown that hygiene can be guaranteed, and contamination can be prevented without formaldehyde. That is, for applications for which there are no longer authorisations or for which authorisations are no longer requested (see above), and furthermore for applications in hospitals and other healthcare institutions and for use in women's hygiene boxes.
  - (Further) conditions for authorisation of room disinfection by enforcing well-defined competency requirements for applicants, as well as a scheme for releasing rooms after disinfection (and possibly by requiring plans to prevent recurrence of contamination after disinfection). Another possible condition (following the German model) may be to introduce a duty to notify the Labour inspection when room disinfection with formaldehyde is taking place and to substantiate why formaldehyde is used instead of another substance.
  - (Further) conditions for authorisation of hoof disinfection by enforcing well-defined competency requirements for applicants (and possibly by requiring plans to tackle underlying problems); or withdrawal of the approval to use formalin for hoof baths altogether.

Onderzoek gebruik en alternatieven formaldehyde (PT2 en PT3)

Samenvatting

- *Rapport en samenvatting*

Dit rapport beschrijft de resultaten van een onderzoek naar het huidig gebruik, de gevaren en de risico's van desinfectiemiddelen (PT2 en PT3) op basis van de werkzame stof formaldehyde, en naar het vervangingsperspectief van deze desinfectiemiddelen voor de diverse toepassingen. Dit onderzoek is uitgevoerd in opdracht van het ministerie van Infrastructuur en Waterstaat (IenW), dat de resultaten ervan wil gebruiken voor onderbouwing van de Nederlandse standpuntbepaling en inbreng in de EU-besluitvorming over het al dan niet, dan wel onder voorwaarden goedkeuren van de exclusiestof formaldehyde.
Deze samenvatting geeft de uitkomsten van het onderzoek op hoofdlijnen weer.

- *Onderzoeksmethode*

Het onderzoek is uitgevoerd door middel van bureauonderzoek (bestudering van de databases op de ECHA- en Ctgb-websites en documentstudie) en interviews met betrokkenen in en om de keten van productie en gebruik van de betreffende desinfectiemiddelen. In totaal heeft uitwisseling plaatsgevonden met 10 producenten en toelatinghouders, 16 (vertegenwoordigers van) toepassers en 4 experts. Daarnaast zijn 4 Nederlandse overheidspartijen geconsulteerd over de betrokken bronnen en zoekrichtingen.
Op grond van dit alles heeft het onderzoek tot conclusies geleid over een aantal hoofdvragen, die hieronder worden samengevat.

- *Toelatingen*

De eerste hoofdvraag is: welke desinfectiemiddelen voor PT2 en PT3 op basis van de werkzame stof formaldehyde zijn momenteel toegelaten en voor welke toepassingen?

Conclusies:
- Voor PT2 zijn desinfectiemiddelen toegelaten voor:
  - Oppervlakken (inclusief medisch en laboratoriuminstrumentarium) en ruimten voor verblijf van mensen in ziekenhuizen en overige instellingen in de gezondheidszorg (6 middelen)
  - Ruimten voor kweek van consumptie- en siergewassen en paddenstoelen (3 middelen)
  - Hygiënecontainers in damestoiletten (3 middelen)
- Voor PT3 zijn desinfectiemiddelen toegelaten voor:
  - Dierverblijfplaatsen en oppervlakten en materialen daarbinnen (9 middelen)
  - Hoeven van rundvee en schapen (4 middelen)
- Toepassing hiervan mag alleen gebeuren door professionals. Verneveling mag alleen gebeuren door professionals met een opleiding voor ruimtedesinfectie.
- Vergeleken met een eerdere inventarisatie uit 2015 blijken er inmiddels géén middelen meer toegelaten te zijn voor desinfectie van ruimten en oppervlakken in de metaalindustrie en in circulatiesystemen, van publieke toegangen, van koelcellen en lege kisten en van schoeisel.

- *Gebruik*

De tweede hoofdvraag is: wat is het huidig gebruik van desinfectiemiddelen (PT2 en PT3) op basis van de werkzame stof formaldehyde, zowel kwalitatief als kwantitatief?

Conclusies in kwalitatief opzicht:
- In PT2 worden ze (door middel van verneveling/verdamping) gebruikt bij de kweek van consumptie- en siergewassen voor ruimtedesinfectie van bij teeltwissel leegstaande kassen, wanneer bij voorgaande teelt sprake was van een ernstige besmetting, en bij compostbedrijven in de paddenstoelenteelt tussen (en na) enkele van de productiestappen.
- In PT3 vindt ruimtedesinfectie door middel van verneveling vooral plaats in de pluimveesector, en daarnaast bij proefdierverblijven en in een laboratorium waar met het MKZ-virus wordt gewerkt. In de varkenssector vindt er oppervlaktereiniging mee plaats. In de melkveehouderij wordt formaline ingezet in desinfecterende hoefbaden om klauwaandoeningen bij koeien tegen te gaan.
- Hoewel hiervoor wel toegelaten middelen op de markt zijn, blijkt uit het onderzoek dat ziekenhuizen en overige zorginstellingen, paddenstoelentelers en leveranciers van dameshygiëneboxen de vereiste hygiëne kunnen waarborgen en besmettingen kunnen voorkomen zónder desinfectiemiddelen op basis van formaldehyde te gebruiken.

Conclusies kwantitatief:
- Precieze cijfers over hoeveelheden verhandelde formaldehyde als actieve stof voor desinfectiemiddelen in Nederland zijn niet te geven. Deze worden niet publiek geregistreerd, en worden door bedrijven als vertrouwelijk beschouwd.
- De wereldmarkt voor formaldehyde is omvangrijk en groeiende (> 50 miljoen ton per jaar, verwachte jaarlijkse groei > 5%). Een groot deel hiervan is voor niet-biocidale toepassingen voor bouwmaterialen, meubels, transport- en geneesmiddelen.
- In België en Kroatië worden verhandelde biociden wel geregistreerd. In België is voor PT2 en 3 samen in 2018 82 ton en in 2019 135 ton formaldehyde verhandeld. In Kroatië was in 2022 2,6 ton formaldehyde als actieve stof op de markt, naast 60 ton technische formaldehyde.

- *Risico's*

De volgende hoofdvraag is: wat zijn de gevaren en risico's van toepassing van deze middelen?

Conclusies:
- Formaldehyde kan kanker veroorzaken, wordt verdacht van het veroorzaken van genetische schade, kan leiden tot lokale irritatie of corrosie van het epitheel (dekweefsel) en heeft een huid-sensibiliserend effect; daarnaast is het toxisch in het aquatisch milieu.
- Ruimtedesinfectie door middel van verneveling van formaline gebeurt in afgesloten ruimten en wordt vaak (maar niet altijd) uitgevoerd door ingehuurde specialistische bedrijven, veelal (maar niet altijd) door mensen die hiervoor enige vorm van opleiding hebben gehad (er zijn geen vastgestelde competentievereisten en dus ook geen formele standaardtraining). Onder deze omstandigheden zijn de risico's voor mens, dier en milieu in principe goed te beheersen, mits de ontsmetting met voldoende deskundigheid gebeurt en de ontsmette ruimte niet wordt betreden vóór dat veilig is. Aan die voorwaarden wordt niet altijd en in alle opzichten voldaan, met name niet in de vleeskuikensector.
- Aan het gebruik van formaline voor desinfecterende hoefbaden zijn risico's verbonden voor mens, dierenwelzijn en diergezondheid. Deze worden niet overal optimaal beheerst, wat onder meer leidt tot ongecontroleerde menselijke blootstelling.

- *Alternatieven*

Vanuit preventief (*Integrated Pest Management;* IPM) perspectief zijn de hoofdvragen: wat is het risicobewustzijn van betrokken partijen, wat zijn de huidige mogelijkheden voor het voorkomen van infecties en voor vervanging van formaldehyde en wat drijft en verhindert overschakeling?

Conclusies hierover zijn:

- In algemene zin lijkt het bewustzijn van de risico's van de omgang met formaldehyde hoog te zijn bij gespecialiseerde desinfectiebedrijven, bij de teelt van consumptie- en siergewassen, bij composteringsbedrijven voor de champignonteelt en in het MKZ-laboratorium. Onder pluimveehouders die zelf desinfectie uitvoeren en onder melkveehouders die werken met desinfecterende hoefbaden lijkt dat risicobewustzijn minder hoog te zijn.
- Over ruimtedesinfectie:
  - De teelt van consumptie- en siergewassen kan grotendeels plaatsvinden zonder het gebruik van formaldehyde voor ruimtedesinfectie. Soms doen zich echter hardnekkige infecties voor die zonder gebruik van formaldehyde nauwelijks tot niet kunnen worden uitgeroeid.
  - Er zijn pluimveebedrijven met zeer moderne stallen, inclusief poriënvrije oppervlakken, die een dermate hoog niveau van hygiëne bereiken dat desinfectie (met formaline) niet meer nodig is. Deze bedrijven vormen echter nog de uitzondering. Ook kunnen dierenwelzijnsoverwegingen leiden tot constructies die de hygiëne juist bemoeilijken (stokken, rekken en compartimenten; vrije uitloop).
  - Bij composteerbedrijven voor de champignonteelt zijn preventieve maatregelen niet of nauwelijks mogelijk vanwege de aanwezigheid van mest.
  - Voor ruimtedesinfectie zijn alternatieve werkzame stoffen beschikbaar. Sommige worden ook daadwerkelijk ingezet voor ruimteontsmetting van kleinere en beter schoon te maken ruimten en/of als er daarvóór geen sprake was van hoog risico-besmettingen. Als echter sprake is van hoge risico's van besmettingen, grotere ruimten (met naden en kieren) en aanwezigheid van organisch (rest-) materiaal (met ook nog een zekere tijdsdruk), geven alle betrokkenen aan dat alleen ruimtedesinfectie met formaldehyde voldoende zekerheid biedt. Dit vanwege eigenschappen als breed spectrum-werking, stabiele vernevelbaarheid, effectiviteit op grotere afstand en na langere tijd, en langer durende effectiviteit en verdere inwerking, ook bij aanwezigheid van organisch materiaal.
- Over desinfecterende hoefbaden:
  - Klauwaandoeningen kunnen voor een groot deel worden voorkomen door een dier- en klauwvriendelijkere manier van melkveehouderij te bedrijven. Als zich echter toch klauwaandoeningen voordoen, kunnen voetbaden nuttig zijn om verdere verspreiding ervan te voorkomen (en deze in sommige gevallen te genezen).
  - Voor hoefdesinfectie zijn er toegelaten alternatieven met andere actieve stoffen. Melkveehouders kiezen echter vaker voor formaline vanwege de effectiviteit (die minder snel afneemt onder invloed van organisch materiaal dan bij alternatieven), breed spectrum-werking en lage prijs, en uit gewoonte. Alternatieven scoren op deze punten minder.

- *Wat als wel of geen goedkeuring*

De finale vraag is: wat zal de impact zijn van hernieuwde goedkeuring dan wel van een besluit tot het onthouden van goedkeuring?

Conclusies:

- De impact van het onthouden van goedkeuring zal zijn dat er minder zekerheid is dat besmettingen effectief kunnen worden bestreden.
  - Bij de teelt van consumptie- en siergewassen en bij paddenstoelenteelt betekent dat een vergrote kans op het verloren gaan van een aanzienlijk deel van de opbrengst; bij planten bovendien kans op verspreiding van de besmetting naar teelt elders, mogelijk ook van invasieve exotische infecties.

  - Bij desinfectie van dierenverblijven: verhoogde risico's voor diergezondheid, dierenwelzijn, volksgezondheid (besmette dierlijke producten) en voor het optreden van resistentie.[2]
  - Bij desinfecterende hoefbaden: enig verhoogd risico op optreden en verspreiding van klauwaandoeningen, en daarmee samenhangend risico voor diergezondheid en dierenwelzijn (mogelijk op te vangen met alternatieve middelen en aanpak onderliggende oorzaken van klauwaandoeningen).
- Daarnaast worden nog als te verwachten consequenties van niet-goedkeuring genoemd:
  - Toenemend biocidegebruik, doordat toch geprobeerd wordt met minder effectieve middelen eenzelfde mate van effectiviteit van desinfectie te realiseren.
  - Negatieve invloed op de bedrijfsvoering en -resultaten, doordat langer gereinigd moet worden, er meer leegstand is en soms duurdere alternatieven aangeschaft moeten worden.
  - Verhoogd risico van illegaal gebruik van (technische) formaldehyde, aangezien dit voor andere dan biocidale toepassingen (goedkoop) in de markt verkrijgbaar blijft.
- De te verwachten impact van een hernieuwde goedkeuring zonder daar verdere voorwaarden aan te verbinden, zal zijn dat de huidige omgang met desinfectiemiddelen met formaldehyde als werkzame stof waarschijnlijk blijft zoals deze nu is. Uit het onderzoek komt naar voren dat de volgende voorwaarden het overwegen waard zijn:
  - Intrekken van goedkeuring voor toepassingen waar is gebleken dat de hygiëne gewaarborgd en besmettingen voorkomen kunnen worden zónder formaldehyde. Dat wil zeggen: voor de toepassingen waarvoor al geen toelatingen meer gelden resp. niet meer worden aangevraagd (zie hierboven), en voorts voor toepassingen in ziekenhuizen en overige instellingen in de gezondheidszorg en voor toepassing in dameshygiëneboxen.
  - Het stellen van (verdere) voorwaarden bij de goedkeuring voor ruimteontsmetting door er welomschreven competentievereisten voor toepassers, een regeling voor vrijgave van ruimten na ontsmetting (en eventueel eisen voor planvorming voor het voorkomen van herhaling van besmetting ná desinfectie) aan te verbinden. Ook kan worden overwogen om (naar Duits model) een verplichting in te voeren om de Nederlandse Arbeidsinspectie te infomeren wanneer ruimtedesinfectie met formaldehyde gaat plaatsvinden, en om een onderbouwing aan te leveren waarom met formaldehyde wordt gewerkt in plaats van met een andere actieve stof.
  - Het stellen van (verdere) voorwaarden bij de goedkeuring voor hoefdesinfectie door er welomschreven competentievereisten voor toepassers (en eventueel eisen voor planvorming voor aanpak van onderliggende problemen) aan te verbinden; dan wel het volledig intrekken van deze goedkeuring.

[2] Voor het MKZ-laboratorium zal er een conflict ontstaan met desinfectievoorschriften van een Europese instantie waar het zich aan heeft te houden.

1. Introduction

1.1 Background to the study

The Biocidal Products Regulation (BPR; EU/528/2012) prohibits the use in biocidal products of active substances with carcinogenic, mutagenic or reprotoxic (CMR), endocrine disrupting, PBT or vPvB[3] properties (Article 5(1)). Exceptions to that ban are only possible if the risk of use is demonstrably negligible, if the active substance is essential to prevent or control a serious danger to human or animal health or to the environment, or if non-approval of the active substance would have disproportionate negative impact on society when compared with the risk to human and animal health or the environment arising from the use of the substance (Article 5(2)).

The approval of active substances is reassessed at regular intervals, in addition to the fact that the European Commission can reconsider an approval at any time based on new information. This also applies to active substances that have been approved based on Article 5(2) of the BPR.

Formaldehyde was approved as an active substance for disinfection for PT2 and PT3[4] in 2017 and 2019 respectively, in a procedure that started before the BPR came into effect, and therefore differently than based on Article 5.2.[5] However, it has been determined that formaldehyde meets the criteria 5(1)(a) and 10(1)(a) of the BPR. This makes it a so-called 'exclusion substance' (and a candidate for substitution).

The approval of formaldehyde for PT2 and PT3 is scheduled for reassessment soon (expected in 2025). The decision-making regarding reapproval or phasing out takes place in the Standing Committee on Biocidal Products (SCBP), which includes the Ministry of Infrastructure and Water Management (IandW) for the Netherlands. For its input into this reassessment in the SCBP, IandW needs up-to-date insight into the use and replacement perspective of formaldehyde for PT2 and PT3. The present report has been prepared to function as such a knowledge document, describing the impact of reapproval or phasing out of this substance.

[3] PBT: persistent, bioaccumulative, toxic; vPvB: very persistent, very bioaccumulative

[4] PT2 and PT3: Product types (or product types) 2 and 3. The BPR distinguishes 22 product types into 4 main groups. Product type 2 concerns disinfectants and algaecides that are not used directly on humans or animals. This includes products for disinfection of surfaces, materials, equipment, and furniture that are not used for direct contact with food or animal feed. These products are used in, among others, the following areas: swimming pools, aquariums, bath water and other water; air renewal systems; walls and floors in private, public, and industrial spaces and other spaces where professional activities are carried out. This may also include products for disinfection of air, water that is not used for human or animal consumption, chemical toilets, wastewater, hospital waste or soil.
Product type 3 concerns disinfectants for veterinary hygiene purposes, such as disinfectants, disinfectant soaps, products for oral and body hygiene or with an antimicrobial effect. This may also concern products for disinfecting materials and surfaces in connection with the housing or transport of animals.

[5] The approval states: “According to the “Note on the principles for taking decisions on the approval of active substances under the BPR” for draft assessment report and the conclusions of its evaluation submitted by the evaluating Competent Authorities before 1 September 2013, the exclusion and substitution criteria as defined in the BPR have to be assessed, but the principles of the Biocidal Products Directive will apply for the decision-making. This means that though formaldehyde fulfils Article 5(1)(a) of Regulation (EU) No 528/2012, Article 5(2) of Regulation (EU) No 528/2012 is not of relevance for the approval decision.”

1.2 Purpose of the study

The objective of the research project described here is as follows.

The aim of the project is:
- to map:
  - ✓ (what is known of) the current use and the hazards and risks of disinfectants (PT2 and PT3) based on the active substance formaldehyde,
  - ✓ and what the replacement perspective is for these products, respectively for these applications,
- and to make this knowledge transparent in a report to substantiate the Dutch position and input into the SCBP.

This research builds on - and will also refer to - previous inventories that have been made regarding the use and replacement of formaldehyde.[6] In particular, this concerns the RIVM study into alternatives to biocides with formaldehyde or formaldehyde releasers from 2015,[7] and the subsequent research carried out by Bureau KLB in 2016 into the use and replacement of formaldehyde in the sectors involved[8] (Both studies looked broader than only at PT2 and 3).

In addition, in the context of the approval of formaldehyde for PT2 and 3 (see BPC opinions 2017 and 2019),[9] ECHA has held public consultation rounds on possible replacement or alternative substances or techniques.[10] This research also builds on that.

1.3 Research questions

As the purpose of the study already indicates, the main question is: what is known about the current use, the hazards and risks and the replacement perspective of disinfectants (PT2 and PT3) based on the active substance formaldehyde? This main question has been elaborated in this project in the following sub-questions.

The question about the use and dangers and risks of these substances can be divided into several sub-questions:
- Which disinfectants for PT2 and PT3 based on the active substance formaldehyde are currently authorised and for which applications?
- What is known about the current use of disinfectants (PT2 and PT3) based on the active substance formaldehyde (and, if possible, also its historical development),
  - ✓ both qualitative (nature of application, field of application, function)
  - ✓ and quantitative (volumes)?
- What is known about the dangers and risks of using these products?

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[6] In essence, the ANSES report 'Encouraging formaldehyde substitution in several occupational sectors' (2022) should also be mentioned here. However, this report also includes the replacement of technical formaldehyde (i.e. not used as a biocide). None of the biocidal formaldehyde applications that were treated concern PT2 or 3.
[7] Wezenbeek et al. (2015): *Eerste inventarisatie alternatieven voor biociden met formaldehyde of formaldehyde releasers* (RIVM-rapport 2015-0069)
[8] Le Blansch en Heesen (2016): *Verkenning van de toepassing van biociden met formaldehyde (-releasers). Alternatieven beschikbaar in betrokken sectoren?* Den Haag, Bureau KLB.
[9] BPC opinion in the application for approval of the active substance: Formaldehyde; Product Type 2 (ECHA/BPC/181/2017) en Product Type 3 (ECHA/BPC/233/2019).
[10] However, the BPC notes about these consultations: “The BPC could not further assess potential alternative substances, due to lack of information received during public consultation.”

The questions about the replacement perspective are informed by the Integrated Pest Management (IPM) principle. According to this principle, prevention, and monitoring form the basis and the first step to prevent or control harmful organisms. If preventive measures prove insufficient, non-chemical measures are used as a second step. If these are also not sufficient, low-risk biocides are used. If this is not sufficient, biocides with an acceptable risk are used, and as a final step, a biocide that poses a risk and/or contains an undesirable substance. The IPM principle is a cornerstone of the Dutch government's 'Strategic framework for the use of biocides in prevention and control of unwanted organisms.'[11]

Answers to the following questions are important for the replacement perspective:

- To what extent are prevention and monitoring (or can they be) applied and effective to prevent or control infections?
- To what extent are low- and/or acceptable risk (or can they be) applied and effective to prevent or control infections?
- Can the use of disinfectants based on formaldehyde be reduced?
- What drives and what prevents substitution?
  - ✓ What is the risk awareness of the various actors dealing with disinfectants based on formaldehyde?
  - ✓ What are drivers and motives for adapting alternatives and for preventing avoidable use? What are bottlenecks and barriers to adapting alternatives?
- What will be the impact of renewed approval or of a decision to withhold approval?

1.4 The approach of this study

• *The approach in general terms*

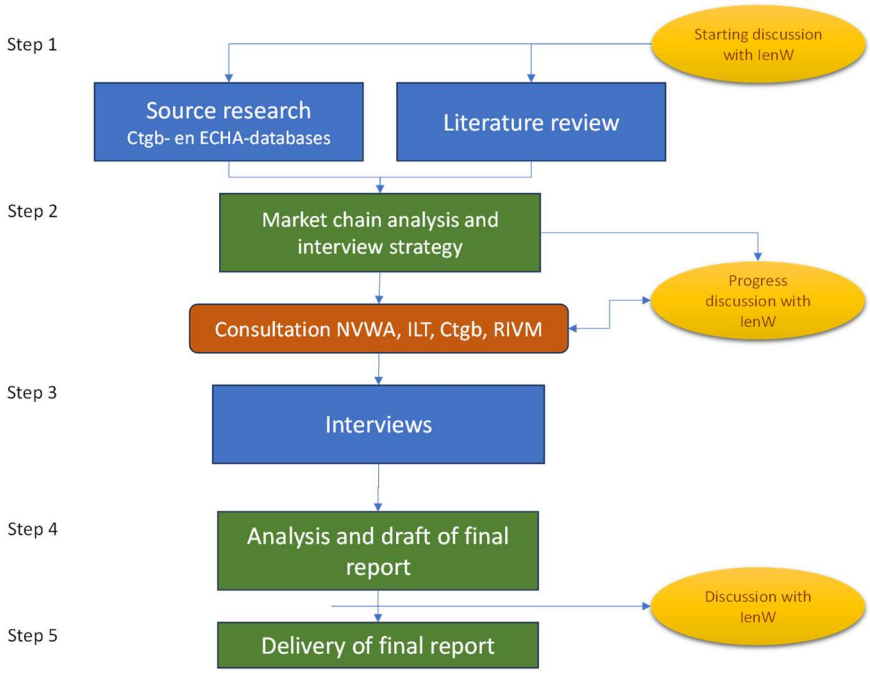
To answer the questions described above, a study was carried out in 5 steps. Two steps were aimed at data collection, namely the desk research in step 1 and the interviews in step 3. In intermediate step 2, a market chain analysis was carried out based on the insights obtained (which parties play a role where?) and an interview strategy was set up (with which of those parties do we want to talk about what?). Several relevant government parties were also consulted during this step to determine whether all relevant themes, data and parties were adequately covered. After the interviews in step 3, the data obtained were analysed and reported in draft form (step 4). The final report was delivered in step 5.

Consultations took place with the commissioning body (IandW) at essential moments in the process: at the start of the project (start of step 1), at the end of step 2 and for a discussion of the draft final report (between steps 4 and 5).

Figure 1 below shows the broad outline of the approach used. The individual steps are explained in more detail in the following subsections.

[11] Ministerie van Infrastructuur en Waterstaat (2023): *Strategisch kader voor de inzet van biociden bij het voorkomen en beheersen van ongewenste organismen*

Figure 1: Broad outline of the research



- *Step 1: Desk research*

The desk research was carried out along two lines:

– The databases on the Ctgb and ECHA websites were searched for the approval of formaldehyde for PT2 and PT3 and for the authorizations of PT2 and PT3 biocides based on formaldehyde. In particular, it has been mapped out:
  - ✓ who the producers/applicants are;
  - ✓ what the specific applications, intended use are (including any special forms of disinfection, treated objects) and specific instructions for use; and
  - ✓ any additional comments and opinions.

– A literature search was carried out for relevant publications on, among other things, formaldehyde, disinfectants based on formaldehyde, alternatives for disinfectants PT2 and PT3 based on formaldehyde, innovations in disinfection.

- *Step 2: Market chain analysis and interview strategy*

A chain analysis was carried out based on this information. It was mapped out who the upstream and downstream producers are, to which markets (and companies) they supply for which use, and which other (sector) organizations play a relevant role in this area and/or have relevant expertise.
It was also examined to what extent answers to the various research questions could already be distilled from the data obtained (for example about volumes and about hazard and risk properties). Any gaps in these answers were taken into account when determining the interview strategy.

Based on the chain analysis, it was determined who are the relevant parties to be interviewed. A distinction was made between players with a unique information position and more generic players from whom exploratory information (and possible referrals) can be obtained. Based on all this and the further research questions as stated above, an interview strategy was drawn up, including the question items to be addressed by the various players.

The overview described above of available or unavailable information and of parties to be interviewed has been submitted to several government parties (NVWA, ILT, Ctgb, RIVM and commissioning body IandW); This was to check completeness and with a view to possible additional search directions.

- *Step 3: Interviews*

The interview strategy was then implemented. Parties in all links of the production and application chain have been approached (in some cases, umbrella organizations were approached to represent the users). The first approach took place by email, followed by either a written exchange of information or by a telephone, online or (in several cases) face-to-face interview.

Within the confines of the scope of and available means for this research, the authors have done their utmost to consult all relevant parties in and around the various value chains and relevant parties with specific expertise. In most, but unfortunately not all, cases, contact was established, and a fruitful exchange of information took place.

In total, information was exchanged with the following types and numbers of parties involved. Appendix 1 to this report provides a further description of this.

Table 1: Numbers and types of consulted parties

	Number of interviewed persons	Number consulted in writing
Producers / authorization holders (Including producers of alternatives)	7	3
Applicants / umbrella organizations of applying sectors	11	5
	(including 1 professional organization that consulted 22 professionals in the grassroots)	
Experts	5	

Global (not verbatim) reports were made of the interviews. If so required, respondents were sent the report for approval.

- *Step 4 en 5: Final reporting*

Based on all this, an overall analysis was carried out and a draft version of the present report was drawn up. This was submitted to the ministry of IandW. After questions and comments were processed, the present final report was sent to the client for approval.

1.5 Reading Guide

The remainder of this report is structured as follows:

- The next chapter (2) describes the most important results of the desk research. It is described what is known about the functional and hazardous properties of formaldehyde, for which applications in PT2 and 3 disinfectants with active substance formaldehyde are authorised and what is otherwise known about the nature and size of the current market.
- Chapter 3 mainly describes the results of the interviews. It is described whether and how disinfection takes place in the various areas of application of formaldehyde-based disinfectants for PT2 and 3 (including the possible use of alternatives).
  Note: in the interviews, sometimes also mention was made of use of formaldehyde-based disinfectants for non-authorised (illegal) applications. As this is only relevant to a limited extent in the context of reassessment of the approval of formaldehyde (and is most of all an enforcement issue), this has not been included in this report.
- Chapter 4 discusses some other matters that fall outside the scope of the previous chapters (i.e. outside PT2 and 3 and outside use conditions in the Netherlands).
- Chapter 5 draws conclusions from all this, and in particular about the question of what the impact will be of re-approval or of a decision to withhold approval for formaldehyde-based disinfectants for PT2 and 3.

The appendices contain an overview of sources consulted (appendix 1) and an overview of the authorizations for disinfectants based on formaldehyde for PT2 and 3 (appendix 2).

2. Formaldehyde in PT2 and 3; properties, application, and market data

2.1 Introduction

This chapter describes, mainly based on desk research:

- What is known about the functional and hazard properties of formaldehyde (section 2.2). This mainly concerns data of a natural scientific nature that have largely been known and established for a longer time. The description in this chapter is therefore largely based on the assessments of the evaluating competent authority[12] (in this case Germany) and opinions of the Biocidal Product Committee (BPC);[13]
- For which applications in PT2 and 3 disinfectants with active substance formaldehyde are authorised (section 2.3). Current data on this are taken from the websites of ECHA and Ctgb (reference date November 1, 2023) (and are compared with older data); and
- What else is known about the nature and size of the current market (section 2.4).

2.2 Properties

- *Functional properties*

In the context of PT2 and 3, formaldehyde (as well as formalin, which is a (usually 37%) solution of formaldehyde in water, stabilized with methanol) is used for disinfection purposes. The disinfectant effect is due to the fact that formaldehyde interacts with proteins, DNA and RNA. The interaction with proteins results from a reaction with the primary amide and the amino groups. It reacts with carboxyl, sulfhydryl, and hydroxyl groups. Furthermore, formaldehyde reacts with nucleic acid (e.g. DNA of bacteria or viruses). It inhibits viral DNA synthesis by forming DNA cross-links and can modify viral proteins. It penetrates bacterial spores and fungal conidia, acts sporostatic and inhibits germination.

Because of these mechanisms of action – with a broad antimicrobial spectrum – formaldehyde is a bactericide, a fungicide and a virucide (and is also active against yeasts and spores).

- *Hazardous properties for human health*

As indicated in the introduction, formaldehyde qualifies as an exclusion substance under the BPR. This is mainly the result of the conclusion (based on animal data) that formaldehyde can cause cancer (carcinogen category 1b) and that it is suspected of causing genetic damage (mutagenic category 2).

Furthermore, formaldehyde is highly chemically reactive, which means that it can lead to local irritation or corrosion of the covering tissue (i.e. the tissue that forms the lining of the body surface, blood vessels and the various body cavities in humans and animals). A skin-sensitizing effect of formaldehyde has also been established, which means that it is a skin allergen (category 1a).

[12] *Assessment Report Formaldehyde Product-type 02 (Disinfectants and algaecides not intended for direct application to humans or animals)*; November 2019 eCA: Germany; *Assessment Report Formaldehyde Product-type 03 (Veterinary hygiene);* November 2019 Germany.
[13] Biocidal Products Committee: *Opinion on the application for approval of the active substance: Formaldehyde Product type: 2;* ECHA/BPC/181/2017; Biocidal Products Committee: *Opinion on the application for approval of the active substance: Formaldehyde Product type: 3;* ECHA/BPC/233/2019

- *Hazardous properties for the environment*

Formaldehyde (dissolved in surface water) is toxic in the aquatic environment, which means that it can be harmful to aquatic organisms.
Because formaldehyde is (rapidly) biodegradable, there is no persistence and little chance of accumulation in the environment – and further dangers to the environment are therefore limited.
Because formaldehyde is not specific for one cellular target, the development of resistant microorganisms is not expected and has so far not been observed.

2.3 Authorized applications

- *PT2*

According to the Ctgb and ECHA databases, disinfectants with formaldehyde as the active substance for PT2 (i.e. disinfectants that are not used directly on humans or animals) are authorized for use in the Netherlands for the applications shown in table 2 below.

Table 2: Authorized applications of disinfectants with formaldehyde as active substance for PT2
(Source: Ctgb and ECHA databases; reference date November 1, 2023)

Authorized application	For application in:
Cleaning and disinfection of surfaces in hospitals and other healthcare institutions, including medical and laboratory instruments	Hospitals and other healthcare institutions
Cleaning and disinfection of areas intended for the stay of people in hospitals and other healthcare institutions	
Disinfection by nebulisation in empty spaces intended for the cultivation of consumer and decorative crops and mushrooms	Cultivation of consumer and decorative crops and mushrooms
Cleaning and disinfection of hygiene containers in ladies' toilets	Hygiene containers in ladies' toilets

For all these authorisations for PT2, application may only be done by professional applicators, as stated in the instructions for use. Application by means of nebulisation may only be done by professionals who have completed training in room disinfection.

If we compare the current authorized applications with those found in the RIVM research in 2015 (see footnote 5), it can be noted that at the time there were still authorized products for a number of applications that are no longer there. These applications were (Wezenbeek et al. 2015, p. 26):

- Room disinfection of industrial spaces specifically for disinfection of surfaces of production systems in the metal processing industry
- Disinfection in circulation systems in industrial production systems, with the exception of production systems in the veterinary, medical and (animal) food sector
- Room disinfection public access
- Disinfection of cold rooms, empty boxes, empty greenhouses, empty mushroom cells

The 2016 Bureau KLB study (see footnote 6) already found that formaldehyde-based disinfectants were no longer used for most of these applications. Only for disinfection of empty mushroom cells formaldehyde-based disinfectants were still in use.

- *PT3*

The Ctgb and ECHA databases show that disinfectants with formaldehyde as the active substance for PT3 (i.e. for veterinary applications) are authorised in the Netherlands for the applications shown in table 3.

Table 3: Authorized applications of disinfectants with formaldehyde as active substance for PT3
(Source: Ctgb and ECHA databases; reference date November 1, 2023)

Authorized application	For application in:
Cleaning and disinfection of surfaces, materials in animal housing and associated areas	Animal husbandry
Disinfection by nebulisation in animal housing with associated stables and materials (machines and tools)	
Disinfection of hooves of cattle and sheep by means of hoof baths	

The authorizations for PT3 also stipulate that application may only be done by professional users, and that application by means of nebulisation may only be done by professionals who have completed training in room disinfection.

If we compare these authorised applications with those found in the RIVM study in 2015, it can be noted that at the time there were still products authorised (based on formaldehyde) for the disinfection of footwear. This authorisation no longer exists in the Netherlands.

2.4 Market data

- *Products, authorisations, and suppliers*

On the reference date (November 1, 2023), a total of 25 disinfectants with formaldehyde as an active substance were authorised for the Dutch market for PT2 and 3 (12 for PT2 and 13 for PT3). The authorizations for these products are in the names of a total of 9 authorization holders. A total of 11 suppliers of formaldehyde as an active substance for PT 2 and 3 are registered with ECHA for the Dutch market (4 for PT2 and 8 for PT3).

Table 4 shows these figures further broken down.

Table 4: Numbers of products, authorization holders, and suppliers of active substance

	PT 2	PT 3
Number of authorised products	12	13
… of which for hospitals/health care	6	
… of which for cultivation of consumption and decorative crops and mushrooms	3	
… of which for hygiene containers in ladies' toilets	3	
… of which for animal husbandry		13
… of which for room disinfection		3
… of which for surface disinfection		6
… of which for disinfecting hoof baths		4
Number of authorisation holders	9	9
Number of suppliers of active substance formaldehyde	4	8

	PT 2	PT 3
… of which also authorization holder	1	2

If we compare these numbers of authorized products with the numbers found in the RIVM study in 2015, it can be noted that there are now fewer authorized products than then. In 2015, there were 16 authorized products for PT2 and 18 for PT3. This decrease is partly the result of the disappearance of products that were authorized for the expired applications mentioned above.

- *Market volumes*

An attempt was made to gain insight into the amount of formaldehyde as an active substance and the quantities of the relevant disinfectants for PT2 and 3 on the Dutch market. This proved to be hardly or not possible when looking for public sources in the Netherlands, as there is no registration of this.[14] Interviewed companies – except for a few – indicated that this is confidential company information that they do not wish to share in the context of this research.

However, a rough general indication of the amount of formaldehyde in circulation can be obtained from several public sources.[15] There is a sizeable and rapidly growing market for formaldehyde worldwide. At the turn of the century, world production was around 10 to 12 million metric tons annually, around 2010 it was in the order of 30 million metric tons and around 2016 it was above 50 million metric tons. Annual growth of more than 5% is also predicted for the coming years. A large part of the formaldehyde is intended for markets and products other than biocides. It is used, among other things, to produce engineering plastics and resins, especially urea, phenol, and melamine resins, in addition to a wide range of other (intermediate) chemicals. A wide range of industrial applications are dependent on formaldehyde, such as in building and construction, furniture, automotive, aviation, pharmaceuticals, and cosmetics. Asia Pacific (China, India) is the largest market for formaldehyde (more than half), Europe is in second place.

As mentioned, the formaldehyde market for use as an active substance in disinfectants represents a small part of the total formaldehyde market.[16] Some interviewees also emphasized this.

General indications of the amount of formaldehyde for disinfection applications on the European market can be obtained from Member States where the volumes of traded active substances and biocides are registered.

- One of those countries is Belgium. The market data that suppliers are obliged to provide – numbers and tonnages of active substances and products per year – are published on a website,[17] albeit only at the level of Product Groups and PTs. Further inquiries revealed that data for 2018 and 2019 are currently[18] available on formaldehyde for PT2 and 3 (and only in combination). These are shown below, with some context figures.

[14] In an interview, one of the discussion partners noted that it is possible for the government to make a calculation of this, based on indications of market size that applicants provide in their authorization applications.
[15] The data in this paragraph are taken from: Winkelman, 2003; Global Market Data, 2021; Mahdi et al., 2023; Grand View Research, 2022.
[16] There is also mention of an increase in global use of formaldehyde for biocidal applications, although this is said to be slowed down by safety regulations (Global Market Data, 2021; Grand View Research, 2022).
[17] See: apps.health.belgium.be/files-dwh-ext/files/gau/index.html
[18] In Belgium, registration started in 2018; After 3 years, figures at substance level become passively public.

Table 5: Market quantities of formaldehyde in Belgium, with some context figures

	2018	2019
Tonnage of formaldehyde on the BE market for PT2 and 3	82	135
Number of active substances PT2 on the BE market	55	58
Tonnage of active substances PT2 on the BE market	5.233	8.981
Number of active substances PT3 on the BE market	31	31
Tonnage of active substances PT3 on the BE market	572	872

It is visible that formaldehyde has a relatively small share in the entire amount of active substances in PT 2 and 3.
Some Dutch interviewees indicate that the Belgian market for the applications in question is reasonably comparable to the Dutch market.

– Another Member State where volumes of traded active substances and biocides are registered is Croatia. Inquiries there revealed that they only have figures for formaldehyde placed on the market in 2022, as a chemical substance (technical formaldehyde, in the form of formalin) and as an active substance in biocides (not specified by PT). Table 6 shows these.

Table 6: Market quantities of formaldehyde in Croatia

	2022
Formaldehyde as substance (37% solution)	60
Formaldehyde as active substance in biocidal product (ton)	2,6

Those involved note that Croatia is a small market, which is not expected to be comparable to the Dutch market. The figures show that in Croatia too the market for formaldehyde for use as an active substance is a small part of the total market for formaldehyde.

3. Current use in application areas

3.1 Introduction

The following paragraphs describe for each of the application areas for which formaldehyde-based disinfectants are authorised, how the actual disinfection takes place, what the use of the relevant authorized agents is, under what circumstances this takes place and why.

The description in this chapter is mainly based on interviews with and written answers from those involved. Where these parties gave different or even opposite answers, this is stated in the text. However, the analysis showed that this is very rarely the case; A fairly consistent picture emerges from the communications from the parties.

The interviews also sometimes mention the use of formaldehyde-based disinfectants for unauthorized (illegal) applications. Because this is only relevant to a limited extent in the context of the reassessment of the authorization of formaldehyde (and is mainly an enforcement issue), this has not been included in this chapter.

As already indicated in the introductory chapter, the disinfection practices found will also be described against the background of the findings from the previous study that took place in 2016 (Le Blansch and Heesen, 2016).

3.2 Disinfection of surfaces and areas intended for people's stay in hospitals and other healthcare institutions (PT2)

Overall picture:
- **There are strong indications that hospitals and other healthcare institutions can guarantee hygiene and prevent infections without using formaldehyde-based disinfectants.**
- **This applies to both surface disinfection and room disinfection.**
- **In general, a different legal framework applies to disinfection of medical devices such as equipment, instruments, beds, and mattresses, which means that this falls outside the scope of the BPR and this research.**

Disinfection in healthcare usually consists of a combination of disinfection of surfaces (floors, walls, ceilings, and lamps) and disinfection of so-called medical devices (and sometimes room disinfection by means of nebulisation).
Medical devices are all medical equipment and instruments, but also beds and mattresses, for example. A different legal framework than the BPR applies to medical devices.[19] For medical devices, the manufacturer prescribes how they must be disinfected (which can result in hospitals stocking dozens of different disinfectants). Formaldehyde can also be prescribed as a disinfectant for medical devices (particularly in the context of the LTSF ('Low Temperature Steam and Formaldehyde') sterilization technique; a technique that is not common in the Netherlands) (see Le Blansch and Heesen, 2016, p. 44-45). Since this falls outside the scope of the BPR, it also falls outside the scope of this research.

[19] Namely the European Regulations (EU) 2017/745 and (EU) 2017/746 and the Dutch Medical Devices Act. Article 2(2b) of the BPR states that it shall not apply to biocidal products or treated articles that are within the scope of Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC. The latter directives were later converted into the aforementioned (EU) 2017/745 and (EU) 2017/746).

The 2016 study already found that formalin is no longer (or only sporadically) used for disinfection in healthcare (Le Blansch and Heesen, 2016, p. 16). This was concluded with great certainty for the cleaning of surfaces. In addition, it was stated – with slightly less certainty – that formalin is no longer used for room disinfection in healthcare.

The guidelines that apply to infection prevention also determine the method of disinfection in healthcare. These are the old WIP guidelines, which are gradually being replaced by SRI guidelines. The – outdated – WIP Guideline for cleaning and disinfection in hospitals (from 2000, slightly revised in 2009) prescribes chlorine for disinfection of large surfaces, and possibly ethanol for smaller surfaces. Concentrations of chlorine are not stated.

This WIP guideline will soon be replaced by the SRI guideline, which has been drafted and is now in the authorization phase. It appears that this directive no longer prescribes specific substances but refers to the Ctgb and ECHA websites for the selection of substances authorized for these applications. In this way, users have access to (currently three) disinfectants with formaldehyde as the active substance (in addition to 151 other products).

In the context of the current research, the professional association VHIG[20] was asked about the use of disinfectants containing formaldehyde. In response to this question, the association conducted a survey among its members. Infection prevention experts from a total of 22 hospitals (including university medical centres) and nursing homes responded. All these responses confirm that the institutions concerned do not work with formaldehyde-based disinfectants (queried based on brand names of approved agents).

In an explanation, the VHIG reports that hydrogen peroxide is usually used for room disinfection (fogging or manually). Institutions in the East of the country sometimes use products based on quaternary ammonium compounds, following current practice in Germany. There are also hospitals and nursing homes that use chlorine for this purpose.

According to the interviewed, the awareness of the importance of the infection prevention through strict hygiene measures and the awareness of the risks of formaldehyde (and its alternatives) among infection prevention experts in healthcare is high.

A major manufacturer/supplier of biocides (including biocides based on formaldehyde) reports that disinfection with formalin still takes place in healthcare to a limited extent (room or otherwise), however without further specification.

3.3 Cultivation of consumer and decorative crops (PT2)

Overall picture:

- **In cultivation of consumer and decorative crops, greenhouses that are empty during a crop rotation are only disinfected with nebulised formalin if the previous cultivation involved a persistent virus, fungal or bacterial infection that is difficult to combat otherwise. If possible, the use of formalin is avoided.**
- **Disinfection with formaldehyde is carried out by a hired company with trained personnel. No one else enters the greenhouse during disinfection. According to those involved, risks are thus adequately controlled.**

[20] The VHIG is the professional association for infection prevention experts working in various areas of healthcare, including hospitals, nursing and care homes, private clinics, and public healthcare.

– **Stakeholders hold it for important that also in the future formaldehyde can be used in serious cases of infection. In these cases, alternatives are less effective (especially in large greenhouses with organic residual material), oxidize greenhouse frames and gutters, among other things, and entail high costs and major damage risks.**

- *Application*

The 2016 study found that in greenhouse horticulture, in cases where pests are imminent or present for which no crop protection products are available, formaldehyde is used during crop rotation for disinfection of the greenhouses by means of 'fogging' (Le Blansch and Heesen, 2016, p. 19).

In 2023, fogging of formalin still (sometimes) takes place, although greenhouse horticulture is reportedly becoming increasingly 'greener'. The sector indicates that room disinfection with formaldehyde-based agents only takes place in serious cases, when a crop rotation involves a persistent, difficult-to-control (enveloped, plant-pathogenic) virus, fungal or bacterial contamination. This happens for example in cases in which the tomato brown rugose fruit virus (ToBRFV) that threatens tomato and pepper cultivation and which has quarantine status in the EU, proves to be difficult to control.[21]

The frequency of crop changes varies from crop to crop. Roses are only changed once every 10 years. Tomatoes, peppers, and eggplants are generally replaced once a year, while cucumber crops are replaced up to four times a year.

According to the sector itself, awareness in the sector of the importance of cautious use of pesticides is very high. Preferably no substances are used, or if necessary, less dangerous substances than formaldehyde are preferred.

Illustrative of this is the 'planet proof' label that various supermarket chains use for plant-based products. Suppliers who carry that label undertake not to use formaldehyde. Exceptions to this are only possible in exceptional cases, in the case of special infections. In that case, a consultation committee will decide whether the use of formaldehyde is justified.

The disinfection step is one of the last steps in a crop rotation, after the greenhouses have first been emptied and thoroughly cleaned. The disinfection – nebulisation of formaldehyde – is generally carried out by a hired disinfection company with trained personnel. During the entire disinfection step, which takes several days, the entire staff of the greenhouse company has time off. In the eyes of those involved, risks are thus adequately controlled.

- *Alternatives*

In general, the sector is well able to prevent and control infections without using formaldehyde, by taking proper hygiene measures and disinfecting with low- or acceptable risk biocides. However, in certain cases of persistent and harmful infections, there are several reasons why alternative measures and biocides are not sufficient and treatment with formaldehyde is required, according to the sector. The most important of these is the fast and effective action of formaldehyde over a broad spectrum, which exceeds that of the other active substances. A related advantage is that formaldehyde is (and

[21] The elimination scenario that is prescribed by the Netherlands Food and Consumer Product Safety Authority (NVWA) to exterminate ToBRFV does not include the use of formaldehyde. Three other disinfectants are mentioned. Spokespersons from the sector say these disinfectants are indeed mostly used and that they are often – but not always – effective. It is for circumstances in which these other disinfectants have proven not to be effective that the sector argues it requires formaldehyde as a fall-back option.

remains) considerably more effective in larger spaces than other disinfectants, even if there are still traces of organic material there. This is important in greenhouse horticulture, where greenhouses sometimes cover enormous areas and are not easy to compartmentalize.

Greenhouses have aluminium frames and steel gutters. Many other disinfectants are too strong oxidizers for this material and their use would lead to damage. Once rusting, materials cannot be disinfected at all.

An economic reason is also mentioned: in general, there is time pressure on the crop change, it is a tightly planned process. During the disinfection, as mentioned, all work comes to a standstill. It is therefore important that disinfection is done relatively quickly and effectively. This can be done with formaldehyde in 2 days, after which the period of planting begins.

In other circumstances – smaller greenhouses, milder infections –alternatives such as hydrogen peroxide and peracetic acid can be effective in exterminating potentially persistent and harmful infections.

It is important for greenhouse horticulture growers to be able to rely on the effectiveness of disinfection. Against certain infections there are no resistant plant varieties and control is hardly possible. When an infection occurs, a significant part of the yield is quickly lost, with seriously negative economic consequences.

Organic greenhouse growers who are confronted with an infection only work with hydrogen peroxide and peracetic acid. If they are confronted with a very persistent virus, they have no choice but to grow a completely different crop after the rotation.

3.4 Mushroom cultivation (PT2)

Overall picture:
- **In mushroom cultivation, currently only compost companies carry out disinfection with formaldehyde. Mushroom growers manage to adequately ensure hygiene in the cultivation cells with other measures.**
- **For mushroom cultivation, it is pivotal that there are no unwanted fungal forms in the supplied substrate. This can be guaranteed with formaldehyde. There doesn't seem to be any effective alternatives for compost companies.**
- **At compost companies, disinfection with formaldehyde takes place between (and after) some of the production steps. This is done by trained people, at times when there are no other people in the halls and tunnels.**
- **The sector is currently developing an adapted spraying license training course tailored to its own needs, which includes handling formaldehyde.**

- *Application*

The 2016 report describes that in mushroom cultivation, formaldehyde is used for room disinfection at two places in the chain: at composting companies and at growers. Now, in 2023, it appears that this only happens at one place in the chain: composting.[22] Reportedly, the growers no longer disinfect (with formaldehyde).

[22] For mushroom cultivation, disinfectants with formaldehyde are authorised for use (by nebulisation) in empty spaces intended for the cultivation of mushrooms. Note that disinfection at composting companies is not covered by this authorization.

The general description in the 2016 report of mushroom cultivation and of the importance of hygiene is still correct, although there are now fewer growers. In 2016 there were approximately 125, now there are between 70 and 90 mushroom companies. There are 6 composting companies. About the cultivation: “The composting company supplies the substrate with the desired fungal spores to the grower. With this substrate a grower can achieve two or three 'flights' (harvests) in about 5 to 6 weeks before the substrate needs to be replaced. The yield and the number of harvests depend on the pressure of other fungi. And therefore, of hygiene and clean working. The challenge for the composting company is to supply substrate with as few unwanted mold spores as possible. The challenge for the grower is to work cleanly in the cultivation cell, i.e. to reduce the introduction of unwanted fungal spores” (Le Blansch and Heesen, 2016, 17-18).

Nowadays, mushroom growers manage to adequately guarantee hygiene with other measures, including effective removal of dirty compost ('champost'), proper cleaning, and steaming the empty cell at an elevated temperature (75 ^{0}C). (In that context, the recent high electricity prices were problematic). For some of the growers, the hygienic standard is now so high that they also no longer need crop protection products.

The compost is made from straw with horse manure and chicken manure, which is processed in three production phases – in different 'tunnels' – into a usable substrate with good fungal spores. Disinfection with formaldehyde takes place in some of those steps. In the first, and in some companies also in the second, step, hygienization takes place in a different way (for example, the compost itself becomes warm), making prior disinfection unnecessary. In the last step, and in some companies also after the last step, before loading, disinfection takes place by evaporating paraformaldehyde or nebulising formalin.

Whether companies also disinfect in this way in the second step and after the third step depends on the risk assessment they make. The main risk is that the substrate contains unwanted fungal spores, such as the spider web fungus. Contamination with this fungus can be disastrous, according to a spokesperson. Instead of two to three flights, only one flight is possible, and it then delivers only 20 to 30% of the yield.

- *Alternatives*

Preventive measures are hardly or not possible because of the presence of manure. The composting sector has looked for alternatives to formaldehyde. This is problematic in a general sense because of the presence of organic residual material in the tunnels. Tests have taken place in composting companies with sodium hypochlorite. However, this caused problems with films on the walls and cracks in the concrete floors that were not sufficiently disinfected.

- *Method*

Disinfection with formaldehyde and subsequent ventilation take place at times when no people are present in the halls and the empty tunnel. After a while, people may enter the hall again. There are no fixed rules as to when this is or whether a measurement should take place beforehand. The moment of re-entry is based on experience and odour perception.

The disinfection is carried out under controlled conditions and by certain persons who have a spraying license and who follow additional internal training in room disinfection. The 'mushrooms' department of LTO Netherlands, together with the Recognition Board (‘Bureau Erkenningen’) and the Ministry of Agriculture, Nature, and Food Quality, is currently developing an adapted spraying license training course that is specifically tailored to mushroom cultivation, including compost production (and to the

people who work in these sectors). Room disinfection with formaldehyde is part of the training to be developed.

3.5 Hygiene containers in ladies' toilets (PT2)

Overall picture:
- **The research has not yielded any indications that there are hygiene containers with formaldehyde-based disinfectants on the market.**
- **Some suppliers of hygiene containers disinfect with agents based on other active substances; others only do odour masking.**

Hygiene containers are placed in (ladies') toilets for the hygienic disposal of sanitary towels (as well as incontinence and diaper material), and to prevent them from being flushed down the toilet. In general, these containers are used in a return system, where they are periodically collected, emptied, and cleaned. After the cleaning step, disinfectants can be added to the container, as well as odour masking agents.

The 2016 investigation found market parties that used disinfectants with formaldehyde as the active substance. However, even then it was noted that the market was moving away from disinfection (with formalin). Increasingly, companies focused on odour masking. Disinfectants were only (still) used in places with an increased risk of contamination, such as hospitals and nursing homes.

In the context of the present study, several suppliers of hygiene containers were approached and asked whether they use formaldehyde-based disinfectants in their containers. None of the companies answered this question affirmatively. However, several companies appear to use other disinfectants, with active substances such as ethanol and DDAC (in addition to other companies that indeed only do odour masking).

The 2016 report cited an authorization holder who indicated that it is not profitable to develop alternatives for disinfection of hygiene containers due to the shrinking market. Moreover, with an alternative it was said to be technically difficult to achieve the same degree of effectiveness as with formaldehyde, because with the latter the effectiveness of the product is based on the formation of disinfectant vapor. It is remarkable that the responding users have indeed found alternatives in the field of products that are generally authorised as means for disinfecting surfaces, and which they say are sufficiently effective.

No responses were received from authorization holders of formaldehyde-based disinfectants specifically authorized for use in hygiene containers.

3.6 Disinfection of animal housing (PT3)

Overall picture:

- **Room disinfection by means of formalin nebulisation mainly occurs in the poultry sector. It also takes place in laboratory animal housing, in a laboratory where work is done with the foot-and-mouth disease virus (FMD) (where disinfection is carried out following prescriptions of a European body), and in the pig sector.**
- **In (the few) poultry farms that have very modern stables, including pore free surfaces (and that do not provide their poultry free range), a high level of hygiene can be achieved by prevention and cleaning. In these stables, disinfection (with formaldehyde) is no longer required.**
- **Many if not most of the current poultry farms have less modern stables that contain larger spaces with seams, cracks, and built-in areas and in which organic material is present. Moreover, animal welfare considerations may lead to constructions in and around stables that further complicate hygiene (sticks, racks, and compartments; free range). Under these conditions, in cases of high risks of contamination (i.e. of passing on high-risk infections from the previous flock to the next) the use of formalin is required to achieve effective disinfection.**
- **In large parts of the poultry sector, the pig sector and in laboratory animal housing, disinfection is carried out by specialized companies with trained staff. In some parts of the broiler sector and in the FMD laboratory, this is done by own personnel.**
- **The authorisation requires that nebulisation of formalin may only be done by trained persons. However, there are no established competency requirements for the nebulisation of formalin, and there are therefore no recognized or non-recognized training courses. Practice shows a varied picture in this respect. There are companies that have extensive internal training and independent examinations in place. But there are also poultry farmers who do it the way their fathers did it before them.**
- **The risks to humans, animals, and the environment of room disinfection with formalin can in principle be controlled effectively, provided this is done with sufficient expertise and the disinfected room is not entered too early. It does not look like these conditions are met in all aspects and all cases, particularly not in the broiler sector.**

3.6.1 Poultry sector

- *Application*

Room disinfection with nebulised formalin sometimes takes place in the poultry sector during the vacancy between two production cycles, so that the new flock of young chicks is not infected with infectious diseases from the previous flock. In principle, formaldehyde is only used when a transmissible disease has occurred in the previous flock, such as Salmonella (a zoonosis) or the Reovirus, and when insufficient effectiveness can be expected from alternative means, especially due to the size of the stable and the presence of organic material.

When an infectious disease occurs in poultry, it is not unusual for the poultry farmer to consult a poultry veterinarian about how to deal with it. These poultry veterinarians have their own department within the KNMvD[23] and are therefore involved in quality assurance in the poultry sector (see also later in this section). When it comes to the use of formaldehyde for room disinfection, the proceeding from this department is that advice should be rather restricted, it is 'no, unless'. However,

[23] Koninklijke Nederlandse Maatschappij van Dierenartsen; *'Royal Dutch Society of Veterinarians'*

in the event of major risks, it may be necessary to use it, provided it is well substantiated and with an action plan to prevent future contamination.

- *Method*

Disinfection takes place by closing the doors and ventilation grilles after cleaning, and then by nebulising the formalin. In many cases the nebulizer can be switched on and off remotely, sometimes this is done by people in 'moon suits'. After the formalin has been able to do its work - which can be determined with bio-indicators in the room - the vapor is often discharged to the outside air through natural ventilation (sometimes also via forced ventilation), and sometimes (in secondary rooms) neutralized with ammonia. There are no fixed procedures for re-entering the stables; it is often up to the poultry farmer involved to determine when it is safe to enter the stable again. (Incidentally, several examples have been reported of local residents who experienced nuisance from ventilation of formalin fumes to the outside air, and of yard visitors who, when entering stables that were warming up again, noticed that they were exposed to formalin, sometimes also from 'puddles' in the stable).

Disinfection with formalin is often carried out by specialized companies with trained personnel. The training is a requirement of the authorisation of the product (see the previous chapter). In practice, the nature and intensity of this training vary, as there are no established competency requirements for the nebulisation of formalin - and therefore no recognized or non-recognized training courses. Some companies have developed their own training courses, which cover, among other things, hygiene, safety, and the correct use of personal protective equipment. In a few cases, independent examination has also been arranged.

In some cases, disinfection is carried out by the poultry farmer himself. This is particularly the case at larger companies in the broiler sector, where flocks are changed every 7 to 9 weeks and where all stables are often emptied at the same time (all in – all out system). Experts estimate that disinfection is carried out by the company itself at roughly half of the broiler farms. It is not known whether and, if so, which training the people involved have followed for this. Expectations are that most of them do it – so to speak – the way their fathers did it before them and have had no specific training.

Other poultry farmers, such as laying poultry farmers and poultry breeders, have less frequent vacancies between production cycles. These farmers usually have the disinfection carried out by hired disinfection companies.

The voluntary 'IKB Kip' chain quality system (IKB chicken)[24] (managed by the AVINED foundation) applies in and around the poultry sector. This quality system is based on certification schemes that contain several requirements for cleaning and disinfecting stables. According to the scheme, cleaning and disinfecting can either be carried out by the farmer himself (with or without personnel), or by poultry service companies.

The scheme hardly contains any further quality and qualification prescriptions for poultry farmers that carry out the disinfection themselves. However, in case the disinfection is carried out by poultry service companies, the certification scheme for poultry service companies applies ('Pluimvee service bedrijven; PSB) (the so-called IKB PSB certification scheme), which also includes fumigation companies. This scheme sets requirements for training,[25] hygiene, safety, use of resources and

[24] 'IKB' stands for Integrated Chain Management. 'IKB Kip' is a voluntary chain quality system for all links in the poultry sector: the entire chain. The content of the IKB Kip certification scheme is determined together with representatives from the sector, societal organizations, and customers.
[25] It is determined that the training and professional experience for each employee must always and demonstrably be recorded.

working methods at fumigation companies. This is checked by the Certifying Authority. Some poultry service companies have united in the NVPSB.[26] By the end of 2023, 15 disinfection companies are IKB PSB recognized.
IKB Kip and IKB Ei (IKB Egg) also work with a system and a register of certified poultry veterinarians.

According to interviewees, IKB Kip clearly contributes to the quality, professional level and safety of disinfection carried out by poultry service companies. The same does not hold true, however, for disinfection carried out by poultry farmers.

- *Alternatives*

There are reportedly poultry farms with very modern stables, including pore-free surfaces, that achieve such a high level of hygiene that disinfection (with formalin) is no longer necessary. However, these companies are still the exception (and on the other hand there is a trend towards more free range for poultry, which increases the risks of contamination).

All parties involved report that most current stables are less modern and contain larger spaces with seams, cracks, and built-in areas. Many of them have sticks, racks and compartments installed for the welfare of the chickens. In these stables it is hardly or not possible to remove all organic residues, even with thorough cleaning. Particularly in the larger chicken houses with organic residues, non-chemical agents (hot water or UV light) and disinfectants based on active substances other than formaldehyde do not provide sufficient guarantee that pathogens are killed (in addition to the fact that they are often less practical to handle). Unlike formaldehyde, alternative active substances (quaternary ammonium compounds, glutaraldehyde, hydrogen peroxide, chlorine) lose their effectiveness upon contact with organic material, have a reduced effect on organic material, and lose their effectiveness at greater distances. Also, not all alternatives have the same broad-spectrum effect as formaldehyde. Ineffective disinfection then carries the risk of resistance. That risk does not apply to formaldehyde, according to those involved. And finally, there is residue formation, especially with quaternary ammonium compounds, which can have consequences for wastewater, for example. Formalin has no residue.

However, some stakeholders emphasize that with the application of more hygienic housing systems and management, certain alternatives that entail fewer risks can indeed be effective.

If the previous flock of poultry has been free of pathogens, a lighter disinfectant will suffice, which is then used to reduce the number of micro-organisms. In that case, the alternatives mentioned above can be used.

Those involved indicate that if formaldehyde were no longer available as an active substance, this would entail increased risks for animal health, animal welfare, public health (contaminated animal products) and the occurrence of resistance. It is expected that biocide use would increase as a result, because attempts would be made to achieve the same level of disinfection effectiveness with less effective means. It would also have a negative impact on business operations and results because more and longer cleaning is required, there is more vacancy and sometimes more expensive alternatives must be purchased. Several parties also point out the risk of illegal use of (technical) formaldehyde since it remains available (cheaply) on the market for other than biocidal applications.

[26] NVPSB: Nederlandse Vereniging van Pluimvee Service Bedrijven (Dutch Association of Poultry Service Companies).

- *Risks*

All those involved are of the opinion that the risks of room disinfection with formaldehyde for humans, animals and the environment can in principle be properly controlled, provided this is done with sufficient expertise, and the disinfected room is not entered too early. However, there is room for serious doubts as to whether these conditions are met in all cases.

3.6.2 Laboratory animal rooms

- *Application*

Laboratory animal rooms (often in or near academic hospitals, pharmaceutical companies, and large research institutes for e.g. cancer research) are often specially built and equipped to meet high hygienic standards (easy to clean, good ventilation system, under- or overpressure where necessary). If there is a serious contamination (e.g. animals infected with pinworms), the rooms are emptied, cleaned, and curatively disinfected with formaldehyde. This is one of the few disinfectants that is effective at killing pinworms.

- *Method*

The disinfection is carried out by hired, specialized companies with employees who have been internally trained for this. Disinfection of laboratory animal accommodations is characterized by the fact that clients place high demands on effectiveness, but also on safety for people and the environment, including the safety of the operator, and that time and money play relatively less of a role. Specialized companies are expected to draw up work protocols and a timetable so that everyone knows who must do what and when. All this is to ensure safety. Consequently, disinfection is carried out to a high standard:

- The buildings are brought in under-pressure and/or are completely closed, so that the removal of fumes can be regulated.
- Although formaldehyde is the most effective for control of the pinworm, for safety reasons (e.g. the room cannot stand negative pressure, or the building cannot be empty) hydrogen peroxide can be chosen. However, this is less effective. It is not possible to work with quaternary ammonium compounds due to the sticky residue formation.
- Disinfection with formaldehyde is carried out by teams of 2 to 3 people (including a safety guard) who communicate with each other via walkie-talkie contact.
- Those who work in the areas to be disinfected wear chemical-resistant clothing and work with respiratory protection.
- Bio-indicators (BIs) are placed in the rooms. After disinfection, these are taken to the laboratory and placed in the incubator. If there is no growth after two days, the BIs are negative, and the disinfection is effective.
- During disinfection and venting of the building/room, appropriate measures are taken to prevent risks for the environment and humans. Fans will be installed and, where necessary, a larger area will be cordoned off around the building. Mandatory signs will also be placed.
- Neutralization with ammonia is often not an option, as copper pipes will then corrode.
- The rooms are only released when it appears that the measurements are below the limit value and there are no risks of entering the building/room.

- *Risks*

Those involved believe that under these conditions the risks to people and the environment of working with formaldehyde are adequately controlled.

3.6.3 Scientific research FMD

- *Application*

In a Dutch laboratory where people work with the foot-and-mouth disease virus (FMD), formalin is nebulised to disinfect the high containment unit, the access locks, and the equipment (including laptops). The research into FMD is related to the implementation of (legal) tasks to support the Dutch government in the monitoring of notifiable diseases and crisis management. The risks associated with the FMD virus, and its handling are such that guidelines are being issued at European level.[27] The guideline for laboratories working with the FMD virus[28] prescribes procedures using formalin for the disinfection of both rooms (Chapter V) and equipment (Chapter VI).

- *Method*

Disinfection with formalin is carried out – approximately weekly – by certain laboratory employees who are internally trained in, among other things, effective disinfection, and the use of personal protective equipment. After room disinfection, neutralization takes place with ammonia (neutralization cannot be done in this way when disinfecting laptops). In addition to the regular disinfection, the unit is sometimes also sprayed clean (by the same employees, with appropriate protective measures) to remove paraformaldehyde. The effectiveness of the disinfection is determined with bio-indicators. There is a fixed procedure for releasing the room.

- *Alternatives*

The laboratory is bound by the aforementioned regulations and is therefore not in a position to explore or apply alternatives. A switch to an alternative can only take place when this alternative has been validated at European level as an effective means against the risks of possible spread of the FMD virus and this is subsequently prescribed to the laboratories involved.

- *Risks*

A person involved notes that the risks for people and the environment can in principle be easily controlled during this disinfection with formalin, but that the human factor always plays a role. More clarity about what users need to know and are able to do would therefore be desirable.

3.6.4 Housing of other animals

In pig farming, stables are sometimes disinfected with formalin. The scale on which this happens is more limited than in poultry farming. A similarity with poultry farming is that stables are rather difficult to clean of organic material. Furthermore, the use of antibiotics in pig farming is under pressure, which leads to greater pressure on hygiene and more use of disinfectants.

In pig stables this often involves surface disinfection with foam or spraying of sub-areas. In pig farming it rarely happens that the entire stable is empty, as this is not typical for business operations. Only when there is a 'major reset', there are no animals in the stable. In such a case, formalin nebulization can be used.

[27] This is done by the Special Committee on Biorisk Management (SCBRM) of the European Commission for the Control of Foot-and-Mouth Disease (EvFMD).
[28] Minimum Biorisk Management Standards for laboratories working with foot-and-mouth disease virus (MBRMS) Update / May 2023

3.7 Disinfectant hoof baths (PT3)

Overall picture:
- **Formalin is used in dairy farming to treat claw disorders in cows.**
- **Formalin is used because of its effectiveness, broad spectrum effect and low price and out of habit; alternatives (except for the unauthorized copper sulphate) score less on these points.**
- **The use of formalin involves risks for humans, animal welfare and animal health, which are not optimally controlled everywhere. For this reason, it is advocated to establish training requirements for the users, and to (also) tackle the underlying causes of claw problems, or to withdraw the approval altogether.**

- *Application*

In dairy farming, formalin (in a 4% solution) is used in foot baths to clean, disinfect, and harden the claws of cows. This is done to prevent claw disorders: infectious or non-infectious disorders of the lower part of the cattle's leg. The foot baths, open containers of at least three meters, are filled with liquid to a level of more than 12 centimetres. The cows are led through this after milking.

Foot baths were used by approximately 60% of dairy farmers in 2017. Of these, 90% use formalin, about 50% (the prohibited) copper sulphate and 10% other substances.[29] These percentages are reported to have decreased slightly five years later (50% of dairy farmers, 60 to 70% formalin).[30] Formalin is used because of its effectiveness,[31] broad spectrum effect and low price, and out of habit. The alternative based on copper sulphate is not authorised because of its harmfulness to the environment and animals (the cow can suffer copper poisoning).

- *Method*

The foot baths are filled by the dairy farmers involved (or by contractors or a cattle pedicurist). This is done either manually or using a dosing or automatic filling machine. Dairy farmers have not had any specific education or training for this (which is also not a requirement from the authorisation). Regular replacement is necessary because the animals drag organic material into the foot bath, which at a certain point is at the expense of effectiveness (although this happens less quickly with formalin than with some other products). Used foot baths are emptied into the manure pit or into the sewer, in accordance with the instructions for use.

- *Risks*

The use of formalin in foot baths poses risks to humans. The formalin evaporates, exposing those in the stable. When manually filling and refilling the foot baths, this exposure is (even) higher. To reduce the risks, some suppliers of formalin supply pump systems for automatic dosing, whether or not combined with a mat that the animals walk over.

A report from the RIVM (2023, 59) states that the Dutch Labor Inspectorate found several violations regarding (un)safe storage of formaldehyde during an inspection project on cattle farms. Additionally, the Netherlands Labour Authority mentions that it has found that farmers had unnecessary large amounts of formaldehyde in stock (which sometimes appeared to be technical formalin, not

[29] Figures taken from E. van Belt (2018): 'Foot bathing in Dutch dairy farming'; graduation thesis at Aeres University of Applied Sciences.
[30] Expert estimates, cited in Wakker Dier, 2022, p.8
[31] Wakker Dier, 2022, p.7 refers to two scientific review articles that provide a varying picture of the effectiveness of formalin, also in comparison with other substances.

authorised as a biocide), and that they handled formalin carelessly without use of personal protection equipment.

With a view to responsible handling of formaldehyde and control of its risks, several parties advocate that training requirements be imposed on dairy farmers with regard to the handling of chemicals, including biocides in particular. This would have to be an accredited course. Inclusion in the curriculum of agricultural training courses has also been advocated several times (in the same way as this has now happened with antibiotics) (previously also by the Livestock Farming working group of the Kennisnetwerk Biociden, 2011).
For some other parties (e.g. inspections), the ongoing poor management of the risks of formalin calls for the complete withdrawal of approval for use in hoof baths.

In terms of animal welfare and health, the use of formalin in foot baths is controversial. The NGO Wakker Dier points out that animals with open wounds on their claws suffer from formalin biting into the wounds, whereas it does not promote healing. Wakker Dier considers foot baths in general as a questionable solution for an animal-unfriendly way of dairy farming: 'hard and unhygienic stable floors covered with a layer of manure, high milk production standards that deteriorate the general condition of the cow, too much concentrate feed and lack of opportunities to graze in the meadow' (Wakker Dier, 2022).
Experts interviewed also state that it is especially important to address underlying causes of claw problems. In some respects, the foot bath can be regarded as a stopgap measure for suboptimal animal husbandry. However, on the other hand, a foot bath can prevent the spread of certain conditions and it can help (not every foot condition is the same).

- *Alternatives*

Thus, from an IPM perspective the main alternative to foot baths appears to be a more animal and hoof-friendly way of dairy farming. Nevertheless, in case there are cows that are suffering from claw disorders, foot baths can be helpful to prevent further spread (and in some cases, to cure).

There are authorised alternatives for claw disinfection with other active substances. These products are often more expensive. Sometimes these products bring risks of their own and may be less effective. In addition, the effectiveness of some products decreases rapidly under the influence of the organic material that is dragged into the foot bath (faster than with formalin).

For this very reason, a manufacturer of an alternative in-situ product based on 'active chlorine generated from sodium chloride by electrolysis' has developed a 2-step protocol: first a cleansing and then a disinfecting foot bath. This system is in use at a number of dairy farms (often in combination with drinking water disinfection with the same system), and with positive results in several places. However, when applying for approval to ECHA, this manufacturer is faced with the fact that the ECHA guidance assumes effectiveness in a 1-step protocol.[32]

[32] However, all instructions for use of formaldehyde-based hoof disinfectants also include the following text: 'First clean the hooves to be disinfected thoroughly with clean water'.

4. Other matters

4.1 Introduction

In addition to what has been said about the use of, and alternatives for disinfectants with formaldehyde in PT2 and 3 in the Netherlands, a number of interview partners also referred to considerations and possible consequences of approving or not approving formaldehyde as an active substance in other product types than PT2 and 3 respectively outside of the Netherlands. The following paragraphs deal with this.

4.2 Relationship with other PTs

Reference was made by an interview partner to the possible consequences of no longer approving formaldehyde for PT2 and 3 for other PTs (product types).

In several other PTs, formaldehyde-adduct active substances are used, the so-called formaldehyde releasers. These PTs concern preservatives (main group 2), and in particular PT 6 (preservation during storage), PT11 (preservation of liquid cooling and processing systems), PT12 (slime control) and PT13 (liquid preservatives for processing and cutting). It is stated that these are all relatively minor applications, with small markets. The studies that are submitted for these applications with the requests for (renewed) approval of the formaldehyde releasers, all refer to the formaldehyde dossier for the risk analysis.
It is stated that if the authorisation for formaldehyde in PT2 and 3 were not renewed, this would eventually lead to the disappearance of the formaldehyde adduct active substances in these other PTs.

4.3 Practices in neighbouring countries

Several sources point to the way in which matters concerning the handling of disinfection with formaldehyde is arranged in neighbouring countries, as suggestions for how matters can also be arranged in the Netherlands or in the EU.

These references are described below, including the sources that support them.

- *Use of biocidal products containing formaldehyde in general*
  In Germany, the regulations for the handling of hazardous substances are laid down in the Hazardous Substances Ordinance[33] (In German: 'Gefahrstoffverordnung', short "GefStoffV"). This ordinance also lays down special regulations for biocides in general and fumigation in particular. The rules of this Ordinance and the applicable state of the art are further specified in technical rules (German "Technische Regeln für Gefahrstoffe", short "TRGS") (See next paragraph).

  If biocidal products classified with acute toxicity cat. 1-3 or specific target organ toxicity (SE or RE) cat. 1, or with cat. 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity are used, the competent German labour inspectorate must be notified, and employees must have comprehensive training with an officially recognized certificate. This will usually apply to biocidal products containing formaldehyde as active substance.

[33] https://www.baua.de/DE/Themen/Chemikalien-Biostoffe/Gefahrstoffe/Taetigkeiten-mit-Gefahrstoffen/pdf/Hazardous-Substances-Ordinance.pdf?__blob=publicationFile&v=1

- *Disinfection of animal housing (PT3)*
  In Germany, fogging with formaldehyde is expressly classified as fumigation. If fumigations are performed, a permission from the competent German labour inspectorate is required and fumigators must have comprehensive training with an officially recognized certificate.

  For disinfection of a room with formaldehyde, TRGS 522 ('Raumdesinfektion mit Formaldehyd') applies.[34] This stipulates, among other things, that it must be substantiated why formaldehyde is used instead of another substance. The 'Regel' also contains detailed requirements for risk assessments, staff training, work procedures, safety measures and medical first-aid provisions. The 'Regel' also prescribes that the professionals carrying out the room disinfection no sooner release the disinfected room than after having established through measurements that the formaldehyde concentration in the room is below threshold value (0.3 ppm formaldehyde; 20 ppm ammonium) (there are no provisions for this in the Netherlands).

– It is reported by an interview partner that in Germany – partly because of the reporting obligation mentioned above – 10 to 15% of room disinfections with formaldehyde are checked by the labour inspectorate. The interview partner points out from his own experience that room disinfections have never been checked by the labour inspectorate in the Netherlands.

- *Disinfectant hoof baths (PT3)*
  Some sources suggest – apparently incorrectly – that the use of formalin in hoof baths is more strictly regulated in Belgium than in the Netherlands. For example, the Dutch NGO Wakker Dier claims that formalin is not allowed in hoof baths in Belgium.[35] Apart from the one single source that it refers to, no further evidence can be found to substantiate this claim. Moreover, the Belgian authorisation database does contain authorised products with formaldehyde as the active substance for hoof disinfection of sheep and cattle (reference date November 1, 2023).
  Another suggestion made by an interview partner, that in Belgium it is mandatory for those who prepare disinfectant hoof baths to have received training for this, also lacks evidence.

[34] BAuA - Regelwerk - TRGS 522 Raumdesinfektion mit Formaldehyd - Bundesanstalt für Arbeitsschutz und Arbeitsmedizin. It should be noted that this 'Technical rule' is currently being revised and is expected to be republished under a different name in 2025.
[35] See Wakker Dier, 2022, 7; here reference is made to an article on the internet from 2015: "Discutabele producten regeren het voetenbad - Faculteit Industriële Ingenieurswetenschappen (kuleuven.be)."

5. Conclusions

5.1 Introduction

The previous chapters presented the findings of the desk research and consultation with stakeholders on the use of and alternatives to formaldehyde for disinfection in PT2 and 3. Based on this, in the following paragraphs we draw conclusions about the authorizations for, the use of, the risks of and the alternatives for disinfectants based on formaldehyde for PT2 and 3. Finally, we deduce from all this what the consequences would be of renewed approval or of a decision to withhold approval for formaldehyde as an active substance for these applications.

5.2 Authorisations

The first main question was: which disinfectants for PT2 and PT3 based on the active substance formaldehyde are currently authorised and for which applications?

The conclusions about this are:
- For PT2, disinfectants are authorised for:
  - Surfaces (including medical and laboratory instruments) and rooms for people to stay in hospitals and other healthcare institutions (6 products)
  - Areas for growing consumer and decorative plants and mushrooms (3 products)
  - Hygiene containers in ladies' toilets (3 products)
- For PT3, disinfectants are authorised for:
  - Animal housing/stables, and surfaces and materials within them (9 products)
  - Cattle and sheep hooves (4 products)
- Application of these products may only be done by professional applicators. Nebulization may only be carried out by professionals who have completed training in room disinfection.
- Compared to a previous inventory from 2015, it appears that no products are authorised anymore for disinfection of rooms and surfaces in the metal industry and in circulation systems, of public accesses, of cold rooms and empty boxes and of footwear.

5.3 Use

The second main question was: what is known about the current use of disinfectants (PT2 and PT3) based on the active substance formaldehyde (if possible, also its historical development), both qualitatively (nature of application, field of application, function) as quantitatively (volumes)?

The conclusions in qualitative terms are:
- PT2 disinfectants with formaldehyde are used (by means of nebulisation/evaporation):
  - in the cultivation of consumer and decorative crops, for room disinfection of empty greenhouses during crop rotation, in cases where there was serious infection during previous cultivation,
  - and at compost companies in mushroom cultivation between (and after) some of the production steps.
- In PT3, room disinfection by means of formalin nebulisation mainly takes place in the poultry sector (after infection in the previous cycle), and also in laboratory animal housing, in a laboratory where work is done with the FMD virus (according to prescriptions of a European body), and in the pig sector (the latter also includes surface cleaning).
  In addition, formalin is used in disinfectant hoof baths in dairy farming to prevent claw disorders in cows.

- Although there are authorised products on the market for this purpose, the research shows:
  - that hospitals and other healthcare institutions are able to guarantee hygiene and prevent infections without using formaldehyde-based disinfectants (neither for surfaces nor for room disinfection);
  - that mushroom growers manage to adequately ensure hygiene in the cultivation cells with other measures, allowing them to do without formaldehyde-based disinfectants; and
  - that suppliers now disinfect their hygiene containers for ladies' toilets boxes with authorised products based on other active substances, or only use odour masking.

The conclusions in quantitative terms are:

- Since there is no registration of quantities of traded biocides in the Netherlands and since (most) companies consider this information to be confidential, it is not easy to give an accurate picture of the amount of formaldehyde traded as active substance for disinfectants.
- It is known that the world market for formaldehyde is extensive and growing (more than 50 million metric tonnes per year with an expected annual growth of over 5%). A large part of this is for non-biocidal applications in building materials, furniture, automotive and pharmaceutical sectors.
- Some information has been obtained about the amount of formaldehyde as an active substance on the Belgian and Croatian market. In Belgium, this amounted to 82 tons in 2018 and 135 tons in 2019 (in total in those years in Belgium, there were 5,800 and 9,900 tons of active substances traded in PT2 and 3). In Croatia there were 2.6 tons of formaldehyde in 2022 as an active substance on the market, next to 60 tons of technical formaldehyde.
- The Belgian market for PT2 and 3 is reportedly fairly comparable to the Dutch; the Croatian market is not.

5.4 Risks

The next main question is: What is known about the dangers and risks of these products?

The conclusions about this are:

- The danger properties of formaldehyde are: can cause cancer, is suspected of causing genetic damage, can lead to local irritation or corrosion of cover tissue and has a skin-sensitising effect; In addition, it is toxic in the aquatic environment.
- Room disinfection by means of nebulizing formalin (in the cultivation of consumption and decorative crops, in composting for mushroom cultivation and in the disinfection of animal housing) is mostly carried out by people that received some sort of training (there is no formal standard training), often coming from hired specialist companies, and in closed spaces in which – except for sometimes the hired specialists with personal protection – no people are present. In the poultry sector, a (voluntary) quality certification scheme (IKB Kip) further regulates the professional quality and safety of fumigation by poultry service companies (but hardly so for the disinfection done by poultry farmers themselves).
  Given these circumstances, the risks for humans, animals and the environment can in principle be properly controlled, provided that the disinfection is conducted with sufficient expertise and the disinfected room is not entered before it is deemed safe. These conditions are not met in all aspects and all cases, particularly not in the broiler sector. For that reason, several parties argue for the prescription of (mandatory) competence requirements for applicants, and for regulation of the release of disinfected rooms. Reference is made to how matters are arranged in Germany, including the duty to notify the Labour inspection when room disinfection with formaldehyde is taking place and to substantiate why formaldehyde is used instead of another substance.
- The use of formalin for disinfecting hoof baths brings along risks for humans, animal welfare and animal health. They are not always optimally managed, leading amongst other things to

uncontrolled human exposure. For that reason, it is argued that mandatory training requirements should be prescribed for users, and that the underlying causes of claw problems should (also) be tackled (or that the approval to use formalin for hoof baths should be withdrawn altogether).

5.5 Alternatives

From a preventative (integrated pest management) perspective, the main questions are: what is the risk awareness of the parties involved, what are the current possibilities for prevention of infections and for substituting formaldehyde, can its use be reduced, and what drives and hinders substitution?

The conclusions about this are:

- About the awareness of risks:
  - Generally speaking, awareness of the risks of handling formaldehyde appears to be high among people working in specialised room disinfection companies, in cultivation of consumer and decorative crops, in composting companies for mushroom cultivation and in the FMD laboratory. (The same holds true for infection prevention specialists in healthcare and for companies supplying hygiene containers in ladies' toilets, who do not work with formaldehyde anymore).
  - In similar general terms, risk awareness appears to be less high among poultry farmers carrying out room disinfection themselves and among dairy farmers that work with disinfectant hoof baths.
- Cultivation of consumption and decorative crops can mostly be done without the use of formaldehyde for disinfection. The voluntary 'planet proof'-label, that various supermarket chains use for plant-based products, only allows for the use of formalin under exceptional circumstances. However, these circumstances do arise from time to time.
- Reportedly, there are poultry farms with very modern stables, including pore-free surfaces, which achieve such a high level of hygiene that disinfection (with formalin) is no longer necessary. However, these companies are still the exception. Also, animal welfare considerations may lead to constructions that complicate hygiene (sticks, racks, and compartments; free range).
- At composting companies for mushroom cultivation, preventive measures are hardly or not possible because of the presence of manure.
- As far as room disinfection in the cultivation of consumption and decorative crops, in composting for mushroom cultivation and in animal housing are concerned:
  - Alternative active substances for formaldehyde are available, such as hydrogen peroxide and peracetic acid, hypochlorite, quaternary ammonium compounds, glutaraldehyde, chlorine. Some of these substances are actually used for room disinfection, in cases of smaller and easier-to-clean spaces and/or circumstances in which there are no or less high-risk settings from earlier crops or groups of animals. In choosing the alternative, specific attention is still needed for corroding effects of some of these active substances, and for the fact that some of them (in particular quaternary ammonium connections) are residue-forming.
  - When there are high risks of infections, larger spaces (with seams and cracks) and presence of organic (residual) material (often also in combination with a certain time pressure), all parties involved indicate that only room disinfection with formaldehyde offers sufficient certainty. This is the result of specific properties of formaldehyde, such as its broad-spectrum effect, its stable nebulableness, its effectiveness at greater distance and after a longer period, its non-corrosive character, and its longer effectiveness and further effect, also in the presence of organic material.
    (Because of the high risks involved, the FMD laboratory is obliged to disinfect with formalin according to prescriptions of a European body).
- Prevention of cow's claw disorders can be done by conducting a more animal and hoof-friendly way of dairy farming. Nevertheless, in case there are cows that are suffering from claw disorders,

foot baths can be helpful to prevent further spread (and in some cases, to cure).
For hoof disinfection there are authorised alternatives with other active substances. However, dairy farmers opt for formalin more often because of its effectiveness (which also decreases less quickly under the influence of organic material than with alternatives), its broad-spectrum effect and its low price, and out of habit. Alternatives score less on these points.

5.6 What if approval is granted or withheld?

The final question is: what will be the impact of renewed approval or of a decision to withhold approval?

The conclusions about this are:

- In a general sense, the impact of withholding approval will be that – even though companies may start cleaning more intensive and use other products – there is less certainty that infections can be effectively controlled. For the various application areas, this means:
  - For the cultivation of consumption and decorative crops: an enlarged chance of losing a significant part of the yield; Moreover, the chance of further infection of cultivation elsewhere – possibly also with invasive exotic infections (in the case of infections with EU quarantine status).
  - For composting for mushroom cultivation: an enlarged chance of losing a significant part of the yield (for example with spider web fungus).
  - For disinfection of animal housing: increased risks for animal health, animal welfare, public health (infected animal products) and for the occurrence of resistance.[36]
  - For disinfecting hoof baths: possibly some increased risks of occurrence and spread of claw disorders, and of associated risks for animal health and animal welfare (which may be addressed by using alternative products and dealing with underlying causes of claw disorders).
- In addition to these application-specific consequences, other expected consequences of non-approval are mentioned:
  - Increased use of biocides because of attempts to achieve the same degree of effectiveness of disinfection with less effective means.
  - Negative effects on business operations and results, because of longer cleaning times, more vacancy of stables and greenhouses, and sometimes more expensive alternatives that have to be purchased.
  - Increased risk of illegal use of (technical) formaldehyde, since formaldehyde will remain (cheaply) available in the market for other than biocidal applications.
- On the other hand, the expected impact of unconditional renewed approval is that the current handling of disinfectants with formaldehyde as active substance will probably remain as it is now. The research shows that the following conditions may be worth considering:
  - Withdrawal of approval for applications where it has been found that hygiene can be guaranteed, and infections can be prevented without the use of formaldehyde. That is, for the applications for which there are no longer authorisations or for which authorisations are no longer being requested (see above), and furthermore for applications in hospitals and other healthcare institutions and for application in women's hygiene boxes.
  - (Further) conditions for authorisation of room disinfection by enforcing well-defined competency requirements for applicants, as well as a scheme for releasing rooms after disinfection (and possibly by requiring plans to prevent recurrence of contamination after disinfection). Another possible condition (following the German model) may be to introduce

[36] For the FMD laboratory, a conflict will arise with the regulations of the SCBRM - see section 3.6.3.

a duty to notify the Labour inspection when room disinfection with formaldehyde is taking place and to substantiate why formaldehyde is used instead of another substance.

- (Further) conditions for authorisation of hoof disinfection by enforcing well-defined competency requirements for applicants (and possibly by requiring plans to tackle underlying problems) (or withdrawal of the approval to use formalin for hoof baths altogether).

0 Appendix 1: List of sources

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Consulted organisations

Suppliers and/or authorisation holders	
Arxada AG	Supplier
Ecolab B.V.	Authorisation holder
Interhygiene GmbH	Supplier
Schippers Europe B.V.	Authorisation holder
Synerlogic B.V.	Supplier and authorisation holder
THESEO Deutschland GmbH (part of Arxada AG)	Supplier
Watter B.V.	Supplier
YOU Solutions Germany GmbH (part of Arxada AG)	Authorisation holder
(Representatives of) applicants	
CWS Hygiene Nederland B.V.	Company
Glastuinbouw Nederland	Branch association
Land- en Tuinbouworganisatie Nederland (LTO), sector paddestoelenteelt	Branch association
Lavans	Company
Raggers B.V.	Company
Saniq	Company
Soludax B.V.	Company
Stichting AVINED	Chain organisation
Topp B.V.	Company
Van Eck Bedrijfshygiëne B.V.	Company
Vereniging Hygiëne en Infectiepreventie in de Gezondheidszorg (VHIG)	Professional organisation
Wageningen Bioveterinary Research	Knowledge institute
Experts	
Federale Overheidsdienst Volksgezondheid - België	Government body
Mr. H. Hortensius	Expert
Koninklijke Nederlandse Maatschappij voor Diergeneeskunde - Platform van pluimveedierenartsen	Professional organisation
Ministry of Health, Republic of Croatia	Government body
Netherlands Labour Authority	Inspectorate
Royal GD (Gezondheidsdienst voor Dieren)	Knowledge institute
Consultations:	
College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb)	Authorising body
Inspectie Leefomgeving en Transport (ILT)	Inspectorate
Nederlandse Voedsel- en Warenautoriteit (NVWA)	Inspectorate
Rijksinstituut voor Volksgezondheid en Milieu (RIVM)	Knowledge institute

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Appendix 2: Overview of authorised disinfectants for PT2 and PT3 with Formaldehyde as an active substance

Appendix 2: Overview of authorised disinfectants for PT2 and PT3 with Formaldehyde as an active substance

Product name	PT	Active substance(s)	Authorisation holder	Sector
CID 20	PT2	Didecyldimethylammoniumchloride (DDAC), formaldehyde, glutaaraldehyde	Cid Lines N.V.	Hospitals and other healthcare institutions
	PT3			Animal husbandry
DES-F	PT2	Formaldehyde	Brenntag Nederland B.V.	Cultivation of consumption and decorative crops, mushrooms
	PT3			Animal husbandry
	PT3			Animal husbandry
FoodClean DES 60	PT2	Didecyldimethylammoniumchloride (DDAC), formaldehyde, glutaaraldehyde	Fink Tec GmbH	Hospitals and other healthcare institutions
	PT3			Animal husbandry
	PT2			Hygiene containers
Formaldehyde 37% Brenntag	PT3	Formaldehyde	Brenntag Nederland B.V.	Animal husbandry
Formulation MC-A-9 (NL)	PT2	Didecyldimethylammoniumchloride (DDAC), formaldehyde, glutaaraldehyde	YOU Solutions Germany GmbH	Hospitals and other healthcare institutions
	PT3			Animal husbandry
	PT2			Hygiene containers
Intra Multi-Des	PT2	Didecyldimethylammoniumchloride (DDAC), formaldehyde, glutaaraldehyde	Intracare B.V.	Hospitals and other healthcare institutions
	PT3			Animal husbandry
	PT2			Hygiene containers
MS Formades	PT2	Formaldehyde	Schippers Europe B.V.	Cultivation of consumption and decorative crops, mushrooms
	PT3			Animal husbandry
	PT3			Animal husbandry
Nerta BAC-CID 200	PT2	Didecyldimethylammoniumchloride (DDAC), formaldehyde, glutaaraldehyde	Entaco N.V.	Hospitals and other healthcare institutions
	PT3			Animal husbandry
	PT3			Animal husbandry
Roloxid 50	PT2	Didecyldimethylammoniumchloride (DDAC), formaldehyde, glutaaraldehyde	Orthochem B.V.	Hospitals and other healthcare institutions
	PT3			Animal husbandry
SYN-Formaline 37%	PT2	Formaldehyde	Synerlogic B.V.	Cultivation of consumption and decorative crops, mushrooms
	PT3			Animal husbandry
	PT3			Animal husbandry

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Contact information

Beneluxweg 125
4904 SJ Oosterhout
Postbus 40
4900 AA Oosterhout
E. SecrSave@Anteagroup.nl

www.anteagroup.nl