Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Formaldehyde

Product type: 3

ECHA/BPC/233/2019

Adopted

10 December 2019

Opinion of the Biocidal Products Committee

on the approval of the active substance formaldehyde for product type 3

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 3 of the following active substance:

Common name:	**Formaldehyde**
Chemical name(s):	**methanal**
EC No.:	**200-001-8**
CAS No.:	**50-00-0**
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

In April 2008, Germany received the so called “Formaldehyde Core-Dossier” provided as appendix to the formaldehyde releaser dossiers. The core dossier contains solely the hazard part which was discussed and harmonised by all member states responsible for the evaluation of a formaldehyde releaser dossier. The core dossier was discussed at the first Technical Meeting of 2012.

Following the submission of an application by Ewabo Chemikalien GmbH & Co. KG, Lysoform Dr. Hans Rosemann GmbH and Synthite Ltd. as well as Interhygiene GmbH on 26 June 2009, the evaluating Competent Authority Germany submitted an assessment report and the conclusions of its evaluation to the Commission on 29 July 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC (BPC-13, BPC-33) and the Commission via the Biocides Technical Meetings. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available at http://www.echa.europa.eu/web/guest/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations/-/substance-rev/5401/term on 9th February 2015, in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 10 April 2015.

Adoption of the BPC opinion

Rapporteur: Germany

The BPC opinion on the application of approval of the active substance formaldehyde in product type 3 was adopted on 10 December 2015. Due to the entry into force of Regulation (EU) 2017/2100[1] the Commission returned the BPC opinion to the Agency on 26 April 2018 with the request to revise the opinion already adopted by the Biocidal Products Committee (BPC), related to the application of the criteria for endocrine disrupting properties as laid down in this regulation. The BPC opinion was then finally adopted on 10 December 2019.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of BPR.

The first version of the BPC opinion was adopted by consensus. The final version of the BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

[1] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the formaldehyde in product type 3 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of formaldehyde in product type 3.

Formaldehyde interacts with proteins, DNA and RNA in vitro. 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 bacteriophages or viruses). It inhibits viral DNA synthesis by forming DNA cross-links (e.g. in SV40) and can modify viral proteins (e.g. HBsAg and HBcAg of HBV). It penetrates bacterial spores and fungal conidia, acts sporostatic and inhibits germination.

The active substance is a formaldehyde solution in water (25-55.5% formaldehyde, <7% methanol as stabilizer).

Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are available for the matrices soil, water, air and for food of animal origin.

EFSA has prepared three opinions on the use of formaldehyde as a feed additive[2]. A decision by the Commission under Regulation (EC) No 1831/2003 is published[3]. A harmonized classification according to Regulation (EC) No 1272/2008 is available.

Current classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* Skin Corr. 1B Skin Sens. 1 Muta. 2 Carc. 1B
Labelling	
Pictograms	GHS06, GHS05, GHS08

[2] Application from Regal, opinion of 28/01/2014 : https://www.efsa.europa.eu/fr/efsajournal/pub/3561; Application from Adiveter, opinion of 28/01/2014 : https://www.efsa.europa.eu/en/efsajournal/pub/3562; Scientific Opinion on the safety and efficacy of formaldehyde as a feed hygiene substance in feed for pigs and poultry, opinion of 01/07/2014 : https://www.efsa.europa.eu/en/efsajournal/pub/3790

[3] Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwjCpYq-m8blAhWSaVAKHao5BAAQFjAAegQIARAC&url=https%3A%2F%2Feur-lex.europa.eu%2Flegal-content%2FEN%2FTXT%2FPDF%2F%3Furi%3DCELEX%3A32018R0183%26from%3DEN&usg=AOvVaw375OaFnAsFmI6FQ4BsWgG5

Signal Word	Danger
Hazard Statement Codes	H301 H311 H331 H314 H317 H341 H350
Specific Concentration limits, M-Factors	Skin Corr. 1B; H314: C ≥25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Sens. 1; H317: C ≥ 0.2 %

The proposed classification and labelling according to Regulation (EC) No 1272/2008 is presented below. The eCA (DE) plans to submit a classification proposal to ECHA in September 2020.

Proposed classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox. 4 Acute Tox. 3 Acute Tox. 2 Skin Corr. 1B Skin Sens. 1A Muta. 2 Carc. 1B
Labelling	
Pictograms	GHS06, GHS05, GHS08
Signal Word	Danger
Hazard Statement Codes	H302 H311 H330 H314 H317 H341 H350
Specific Concentration limits, M-Factors	Skin Corr. 1B; H314: C ≥25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % STOT SE 3; H335: C ≥ 5 % Skin Sens. 1A; H317: C ≥ 0.2 %
Justification for the proposal	
A harmonised classification for the a.s. exists. The changes to the existing classification are based on: • Acute oral toxicity: Category 4 instead of category 3*, based on an oral LD_{50} value of 640 mg/kg bw in rats, lower values reported in the literature are either not reliable or the test substance was not formaldehyde; • Acute dermal toxicity: Category 3 instead of category 3*, based on a dermal LD_{50} of 270 mg/kg bw in rabbits; • Acute inhalation toxicity (gases): Category 2 instead of category 3*, based on LC_{50} values of 1 mg/L x 0.5 h and 0.6 mg/L x 4 h in rats. • Acc. to Regulation 1272/2008/EC, labelling as EUH071 “Corrosive to the respiratory tract” in addition to classification for inhalation toxicity is foreseen if the mechanism of toxicity is corrosivity. • Based on EC3 values of 0.33- 0.96 % in various LLNAs, an induction rate of 100 % following intradermal injection at 0.25 % a.s. in the GPMT and a high frequency of occurrence in humans at relatively low exposure, formaldehyde should be subclassified into Skin Sens. Cat. 1A (strong sensitiser) instead of category 1.	

b) Intended use, target species and effectiveness

Formaldehyde is applied as a disinfectant for veterinary hygiene in areas in which animals are housed, kept or transported to prevent animal diseases (PT3). This includes the disinfection of animal housings, the disinfection of vehicles in epidemic cases, the disinfection of eggs used for breeding (not for human consumption) as well as the disinfection of animals´ feet. Formaldehyde is used by professionals as aqueous solution by spraying, wiping and fogging/fumigation.

The efficacy studies performed are sufficient at the approval stage. Tests performed with the active substance show that formaldehyde has a bactericide and fungicide activity at a concentration of ≥ 0.5% within short term contact time (60 min) and at concentration of 0.05% within long term contact time (24 hrs). Further tests using formaldehyde show a sufficient disinfecting efficacy against viruses at concentrations between ≥ 0.064 and ≥ 0.92 after 120 min exposure. The proposed application rates of 0.05% - 12% of formaldehyde seem reasonable if formulated to a product.

Formaldehyde is a highly reactive chemical that interacts unspecific with multiple cell structures like protein, DNA, RNA and lipids. Since aldehydes are intermediates from a variety of biochemical pathways detoxification systems for these highly toxic substances in low concentrations are a vital necessity for all prokaryotic and eukayotic organisms. In prokaryotes and fungi, dependent oxidation systems or glutathione-independent formaldehyde dehydrogenases, formaldehyde dismutases, methylformate synthase.

As formaldehyde is not specific for one cellular target, the development of resistance is unlikely if sufficiently high formaldehyde concentrations are guaranteed that exceed the capacity of the innate detoxification systems.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Formaldehyde is of high chemical reactivity, causing local irritation or corrosion at exposed epithelia. There is also convincing evidence for skin sensitisation by the a.s. Formation of DNA-protein links is thought to lead to clastogenic effects. At concentrations causing cytotoxicity in the respiratory tract with induction of regenerative cell proliferation, formation of nasopharyngeal cancer has been established in rats.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion[4]**
Disinfection of animal housing – wet disinfection (by spaying)	Primary inhalation and dermal exposure occur during: - dilution of b.p. (40% and 24% a.s.) - spraying of surfaces in stable (1.2% and 0.7% a.s.) - cleaning of spray equipment	Professional user[5]	**Not acceptable** with protective gloves, protective coverall, RPE[6]
Disinfection of animal housing – fogging disinfection	Primary inhalation and dermal exposure occur during dilution of b.p. (40% a.s.). During the fogging and during the following ventilation time the operator is not present therefore primary inhalation and dermal exposure to 16% a.s. is not expected.	Professional user[2]	**Acceptable** with protective gloves, RPE[3], use of automated fogging system
Disinfection of eggs (hatchery) by fogging/fumigation)	Primary inhalation and dermal exposure to 40% a.s. during preparation of the disinfectant (dilution to 20% a.s.) and loading of equipment inside the disinfection chamber (sluice) and hatcher.	Professional user[2]	**Acceptable** with protective gloves, RPE[3]
Disinfection of vehicles in epidemic cases) by spraying	Primary inhalation and dermal exposure occur during: - dilution of b.p. (40% a.s.) - spraying of vehicles (4% a.s.) - cleaning of spray equipment	Professional user[2]	**Not acceptable** with protective gloves, protective coverall, RPE[3]
Disinfection of animals' feet – footbath	Primary inhalation and dermal exposure to 40% a.s. during dilution of b.p. to 2% a.s and during pouring of residues for disposal (2% a.s.). Inhalation exposure during observation of animals passing the footbath.	Professional user	**Acceptable** with protective gloves, RPE[3]
Secondary exposure	Secondary inhalation and dermal exposure of professional bystander is not expected since the access to treated areas is restricted	Professional user	**Acceptable** with RMM
Disinfection of animal housing – wet disinfection of small surfaces	Primary inhalation and dermal exposure to 24% a.s. occur during dilution of b.p. and spreading of diluted disinfectant (0.7%) by pouring and brushing with a broom	Professional user[2]	**Acceptable** with protective gloves, protective coverall, RPE[3]

[4] This column refers to the overall conclusion of both systemic and local risk assessment

[5] Professionals adequately trained (expected to have a profound knowledge and experience of the efficacy and hazards of formaldehyd including adequate first aid measures, functionality of personal protective equipment, legal basis and instructions for use, e.g. room sealing, installation of a danger area of adequate size, protection measures including engineering and procedural measures as well as correct selection and proper use of effective PPE, exact dosage, safeguarding of sufficient concentration and clearance measurement, in order to avoid an critical exposure of themselves and/or bystanders and/or subsequent workers)

[6] In addition safety goggles have to be worn due to local effects if no full face mask as respiratory protective equipment (RPE) is worn. Personal protective equipment (PPE) shall be substituted by engineering, technical and/or administrative equipment according to Dir.98/24/EC and Dir.2004/37/EC if possible.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**	**Conclusion[4]**
Secondary exposure	Secondary inhalation and dermal exposure of professional bystander is not expected since the access to treated areas is restricted	Professional user	-
Secondary exposure of bystanders	**Secondary exposure:** Bystanders exposure during or after treatment	General public	**Acceptable** if exposure is prevented by adherence to RMM (e.g. no entry during treatment; re-entry only after appropriate waiting period; closed premises during both treatment and waiting period; prevent access to footbaths)
Residues in food	**Secondary exposure**: Consumer exposure via residues in food of animal origin	General public	For applications in the presence of animals dietary risk assessment required at product authorisation level. For applications in the absence of animals: **acceptable**

The occupational risk assessment for formaldehyde takes into account systemic effects as well as local effects of the active substance. In addition to the systemic risk characterisation which is carried out with the Acceptable Exposure Level (AEL) approach a risk characterisation for local effects after inhalation exposure is performed with an Acceptable Exposure Concentration (AEC) as reference value. To assess the local dermal effects of formaldehyde a qualitative risk assessment according to the Guidance for Human Health Risk Assessment, Volume III – Part B was carried out.

For the following exposure scenarios the risk assessment does indicate an acceptable risk taking into account the prescribed protection measures: disinfection of animal housing – fogging disinfection, disinfection of eggs – hatchery and disinfection of animals´ feet – footbath. Regarding these three scenarios, the risk characterisation is considered to be sufficiently comprehensive and reliable.

For the following exposure scenario the risk assessment does indicate an acceptable risk taking into account the described protection measures (protective gloves and coverall, RPE, goggles): Disinfection of animal housing – wet disinfection, small surfaces. Regarding this scenario, the risk characterisation is considered to be sufficiently comprehensive and reliable. It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

The risks for the other scenarios (disinfection of animal housing – wet disinfection and disinfection of vehicles in epidemic cases) are unacceptable for the professional use despite the described risk mitigation measures.

The risks for the scenario “disinfection in animal housing – wet disinfection (spraying)” are unacceptable despite the described risk mitigation measures.

Risk of secondary exposure of the general public is acceptable if exposure is prevented by adherence to appropriate RMM.

With regard to potential residues in food of animal origin only representative uses in the absence of animals were evaluated, concluding that no relevant residues in food of animal origin are expected. However, it was noted that for applications in the presence of animals the assessment of potential residues in food of animal origin should be finalised at product authorisation level.

With regard to animal welfare, the footbath scenario might result in sensitization.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Disinfection of animal housings (wet disinfection and disinfection by fumigation/fogging in stables of fattening pigs, broiler, turkeys)	Emissions to air as result of application by fogging/fumigation or wet disinfection (spraying was assessed as default type of application) followed by ventilation due to volatilisation from treated surfaces Emissions to soil and groundwater via aerial deposition. Considering the physico-chemical properties of formaldehyde as a worst case it is expected that formaldehyde is exclusively released into the air. Thus, releases into slurry/manure and/or waste water are not expected.	**Acceptable**
Disinfection of eggs (hatchery) by fogging/fumigation	Emissions to air due to volatilisation from treated surfaces as result of application by fogging/fumigation. Emission to sewage system due to air filter cleaning leads to indirect emission to surface water/sediment. The application of sewage sludge and aerial deposition may lead to exposure of soil and groundwater.	**Acceptable**
Disinfection of vehicles by spraying (epidemic)	Emissions to air and to sewage system as result of application by spraying (washing system) and due to volatilisation from treated surfaces. Emission to sewage system leads to indirect emission to surface water/sediment. The application of sewage sludge and aerial deposition may lead to exposure of soil and groundwater.	**Not acceptable**
Disinfection of animals' feet	Emissions sewage system and/or slurry system as result of application by bathing or dipping animal´s feet (tubes or mats) and due to discharge of left-over disinfectant. Emission to sewage system leads to indirect emission to surface water/sediment. The application of sewage sludge and/or slurry on agricultural land may lead to exposure of soil and groundwater. Emissions to air as result of volatilisation.	**Not acceptable**

The use of formaldehyde for the disinfection of animal housings and hatcheries does not pose an unacceptable risk to the environment. In contrast, unacceptable risks have been identified for all relevant environmental compartments when formaldehyde is used for the disinfection of vehicles (in cases of an epidemic) and in order to disinfect animals' feet. Therefore, further refinement options of the environmental effects or exposure assessment

should be taken into account and/or risk mitigation measures (RMM) need to be applied in order to allow a safe use in these scenarios.

As a result of the refined risk characterisation it was shown that the identified unacceptable risks can be mitigated sufficiently, if remaining product quantities are not released to waste water or slurry/manure systems but collected and disposed of as hazardous waste.

The disposal of used formaldehyde solution following the disinfection of vehicles (in case of an epidemic) and animals' feet as a measure to minimise the release of the a.s. to the environment has been evaluated quantitatively with the environmental risk characterisation. It was shown that no risks are to be expected if remaining quantities of the formaldehyde solution are collected during its use and disposed of afterwards as hazardous waste. Thus, if it can be demonstrated that these measures are feasible in the respective scenarios and compatible with national requirements, they should become mandatory at the stage of product authorisation. These provisions then have to be written on the labels and provided in the safety data sheets of the corresponding products.

With respect to the scenario "animals' feet disinfection" the disposal of used formaldehyde solution is probably not a feasible measure. However, the use of disinfection mats can be an alternative application method where lower amount of the biocidal product might be needed. However, no detailed information has been provided by the applicant and no environmental risk assessment has been carried out for this scenario. It is suggested to assess the use of disinfection mats as an alternative to footbath at the stage of product authorisation.

Finally, it is concluded that on base of the currently available data no safe use of formaldehyde in the animals' feet scenario can be demonstrated.

Overall conclusion

A safe use for human health and environment is identified for the following scenarios: Disinfection of animal housings **by fogging,** disinfection of egg hatchery **by fogging/fumigation** and wet disinfection of small surfaces **by wiping**.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	Cat 1B	Formaldehyde fulfils criterion (a) of Article 5(1)
	Mutagenicity (M)	Cat 2	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Not P and not vP	Formaldehyde does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of
	Bioaccumulative (B) or very Bioaccumulative (vB)	Not B and not vB	

	Toxic (T)	not T	Article 10(1)
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data.	No conclusion can be drawn whether formaldehyde fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn based on the available data.	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	No classification required. Formaldehyde does not fulfil criteria (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	For formaldehyde no concerns regarding critical effects according to Article 10(1)(e) are identified.		
Proportion of non-active isomers or impurities	Formaldehyde is not considered to have a significant proportion of non-active impurities. Formaldehyde does not fulfil criterion (f) of Article 10(1).		

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[7], with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"[8] and with "Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment"[9] agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

[7] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)
[8] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)
[9] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details).

Consequently, the following is concluded:

Formaldehyde does meet the exclusion criteria laid down in Article 5(1)(a) of Regulation (EU) No 528/2012 by being classified as Carc 1B.

Formaldehyde does meet the conditions laid down in Article 10(1)(a) of Regulation (EU) No 528/2012, and is therefore considered as a candidate for substitution. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of formaldehyde for PT 3 was submitted before 1 September 2013.

According to the "Note on the principles for taking decisions on the approval of active substances under the BPR"[7] 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 formaldeyhde fullfills 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.

2.2.2. POP criteria

As formaldehyde is not P, B or vB, it does not meet the criteria for being a persistent organic pollutant.

2.2.3. Identification of potential alternatives substances or technologies, including the results of the public consultation for potential candidates for substitution

During public consultation 2 confidential and 11 non-confidential submissions were received from third parties. The received information was not evaluated by the evaluating Competent Authority or the BPC.

In all of the received information it is stated, that formaldehyde is effective against a wide variety of microbiological organisms like bacteria, fungi, enveloped and non-enveloped viruses, yeasts and spores.

The different applications of formaldehyde are described in the received information. The disinfection of animal housings and stables as well as the disinfection in poultry flocks are described. Formaldehyde is used as disinfectant in hatcheries and for the hatchery equipment material. It is also used as disinfectant of dairy cattle in footbaths.

It is stated in the received information that formaldehyde is effective against a broad antimicrobial spectrum. Formaldehyde is non-corrosive and exhibits good material compatibility towards wooden surfaces, bricks, electronic and mechanical equipment. It is biodegradable and not persistent, stable during storage. Formaldehyde has superior penetration properties and the resistance to inactivation by blood and organic matter is low. The fumigated substance can reach all inaccessible areas and crevices in the animal facility. It enables a high control of infectious diseases.

The third party information received for PT 3 also mentions some alternatives: peracetic acid (only virucidal), chlorine (not effective in contact with organic matter) and glutaraldehyde (not effective against non-enveloped viruses). It is stated that all alternative products are ineffective by comparison to formaldehyde or damaging to the chick/egg.

Alternatives are available and proven effective but at least 10 times more expensive than formaldehyde. Further alternatives are mainly based on organic acids and quaternary ammonia compounds which are completely metabolized after storage in the manure pit.

For PT 3, currently 19 active substances are approved.

The BPC could not further assess potential alternative substances, due to lack of information received during public consultation.

2.3. BPC opinion on the application for approval of the active substance formaldehyde in product type 3

In view of the conclusions of the evaluation, it is proposed that formaldehyde shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: 25 – 55.5% formaldehyde in aqueous solution (minimum purity 87.5% w/w with regard to formaldehyde).
2. Methanol is identified as relevant impurity (stabilizer) with a maximum content of 7%.
3. Formaldehyde is considered a candidate of substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012.
4. The authorisations of biocidal products are subject to the following condition(s):
    a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.
    b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
    c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to
        i. professional users for products used in disinfection by spraying of animal housing and of vehicles in epidemic cases;
        ii. secondary exposure of the general public;
        iii. surface water, sediment, soil and groundwater following use of products for disinfection of vehicles and disinfection of animal's feet by bathing or dipping.
    d. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified, and any appropriate risk mitigation measures shall be taken into account to ensure that the applicable MRLs are not exceeded.
5. The placing on the market of treated articles is subject to the following condition(s):
    a. The person responsible for the placing on the market of a treated article treated with or incorporating the active substance formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of the Regulation (EU) No 528/2012.

Formaldehyde gives rise to concern for human health, i.e. it is acute toxic by oral, dermal and inhalation route, it is carcinogenic of category 1B as well as mutagenic category 2. It is skin corrosive category 1B as well as skin sensitising category 1. In addition, formaldehyde is considered a candidate of substitution in accordance with Article 10(1)(a) of Regulation (EU) No 528/2012. Therefore, inclusion in Annex I of Regulation (EU) 528/2012 is not acceptable.

2.4. Elements to be taken into account when authorising products

1. The active substance formaldehyde is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation.
2. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
    a. If an unacceptable risk for professional users is identified for the product, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products should be used with appropriate personal protective equipment.
    b. An unacceptable risk for professionals is identified for products which are not applied in a closed system (e.g. fumigation in a chamber) or a sealed room (e.g. fogging disinfection of animal housing). If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these products shall not be authorised.
    c. If an unacceptable risk for the general public is identified as consequence of secondary exposure to vapours and to freshly treated (wet) surfaces from wiping and mopping, appropriate RMM need to be applied. This includes a waiting time where no one is allowed to enter treated rooms. Product-specific waiting times can be defined on the basis of product-specific data. Otherwise, the re-entry period of 1 hour applies. If formaldehyde is applied by fumigation, the air concentration shall be monitored, and re-entry only allowed when the air concentration is below 0.1 mL/m3 (= AEC).
    d. An unacceptable risk for professionals is identified for disinfection of vehicles (epidemic cases) and products applied by spraying for the disinfection of animal housing. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these products shall not be authorised.
    e. An unacceptable risk is identified for the environment for products used for the disinfection of animals' feet. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these products shall not be authorised. An option to refine the environment risk assessment is to submit an anaerobic biodegradation simulation test in manure/slurry if releases of formaldehyde solutions into manure storage facilities cannot be ruled out.
    f. An unacceptable risk is identified for the environment for products used for the disinfection of vehicles in case of an epidemic use. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures (i.e. residues to be collected and disposed of as hazardous waste) or by other means, these products shall not be authorised.

3. When authorising a product for use as preservative footbath, animal welfare has to be considered thoroughly. The concern has to be resolved that a daily exposure to 2% formaldehyde solution may cause dermal sensitisation. This might be addressed by an observational study.
4. For product applications in the presence of animals a dietary risk assessment has to be provided.

2.5. Requirement for further information

Sufficient data has been provided to verify the conclusions on the active substance, permitting the proposal for the approval of formaldehyde in product type 3.

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