Formaldehyde
How long does it have left? (An update)

In 2016, Bioquell produced a white paper highlighting the reclassification of Formaldehyde as a human carcinogen and discussing the potential implications for the future of Formaldehyde as an antimicrobial fumigant under the Biocidal Products Regulation (BPR). Five years on, this paper will provide an update on the position of Formaldehyde, which has become clearer with the publication of the European Commission approval, outlining the use scenarios and risks associated with the use of Formaldehyde as a biocide.

On the 28th July 2015, the UK Health & Safety Executive (HSE) issued the following statement in its Biological Agents ebulletin:

> *HSE therefore recommends that users start to look into the development of alternative gaseous disinfectants (to Formaldehyde) for rooms and equipment, whilst there is time to do so.*

The concern over the use of Formaldehyde as a fumigant for the disinfection of enclosures and warnings about its possible banning have been circulating for many years in an attempt to educate Formaldehyde users and, as per the HSE statement, give them adequate time to investigate and implement alternative technologies.

The classification of Formaldehyde as a carcinogenic and mutagenic chemical means that under Article 5 of the Biocidal Products Regulation (BPR) it should not be authorised, unless there is evidence that the substance is essential or that not approving it would have a disproportionate adverse impact on society. Where such evidence or impact supports the substance approval, any authorisation can only be granted for a maximum of 5 years, before the substance must go through the entire authorisation process again.

In 2017, the European Chemicals Agency (ECHA) Biocidal Products Committee (BPC) issued its opinion on the authorisation and use of Formaldehyde in Product Type (PT) 2. PT2 covers use in private area and public health areas (i.e. hospitals, laboratories, research facilities, manufacturing facilities, etc). The BPC concluded that:

> *An acceptable risk for human health and the environment has only been identified for the scenario "disinfection of room by automated fogging in an epidemic case". Regarding this use, an acceptable risk for the surface water compartment was only found when appropriate RMM (risk management measures) are applied.*

The BPC identifies use in case of an epidemic as once per year. As such, the BPC concluded that it was acceptable to use Formaldehyde for enclosure fumigation once per year. The committee state that Formaldehyde fumigation poses an unacceptable risk to surface water contamination because Formaldehyde must be neutralised with ammonia forming methenamine, which will then hydrolyse to form Formaldehyde and Ammonia in surface water – presenting an unacceptable risk to aquatic organisms. To allow the use of Formaldehyde fumigation once per year, the methenamine produced by the Formaldehyde neutralisation must be removed from surfaces using damp cloths or mops and those cloths and mops disposed of as hazardous waste. The BPC state that this risk mitigation is ONLY applicable to the epidemic case (i.e. once per year use) and is not deemed suitable for standard disinfection processes (i.e. daily or weekly use).

> *It has to be highlighted that this RMM is only applicable for the epidemic case (low quantities of waste, rare event) whereas this is not deemed applicable for standard disinfection processes.*

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On the 25th November 2020 the BPC opinion was ratified and the European Commission published its official approval on the use of Formaldehyde as a biocidal product. Formaldehyde has been approved for use in PTs 2 and 3, but only for a period of 3 years. The approval period begins on the 1st Feb 2022 and thus will expire on the 31st Jan 2025. The approval reflects the BPC opinion with specific emphasis of the approval placed on assessment of products for room disinfection by fumigation in relation to their impact on the aquatic environment and their use in cases of epidemic (i.e. once per year).

SO WHAT DOES THIS MEAN FOR FORMALDEHYDE FUMIGATION?

Manufacturers selling Formaldehyde as a biocide for use as a fumigant in sealed enclosures have until the 1st Feb 2022 (i.e. the date the approval comes into force) to submit dossiers in support of their products. If a dossier is not submitted to support the product, the manufacturer has 6 months to stop selling and withdraw the product from the market. The position applies in both Great Britain under GB BPR and Europe under EU BPR. If a manufacturer decides to submit a product dossier, the dossier must support the use of the product as a fumigant and must provide data to support enclosure fumigation at a frequency greater than once per year if the product is intended to be used for frequent decontamination. Formaldehyde fumigation is conducted using an automated system and thus efficacy data must be generated for the product in accordance with efficacy test standard EN 17272:2020.

With the approval for Formaldehyde limited to 3 years, Formaldehyde product manufacturers will be questioning the commercial viability of creating and submitting a dossier containing efficacy data on the use of Formaldehyde as a fumigant. Product dossiers take years to review and approve and thus as the Formaldehyde authorisation is only valid for 3 years, timescales may make it unviable for manufacturers to submit supporting dossiers.

FORMALDEHYDE BIOCIDAL PRODUCTS

The Biocidal Product Regulation applies to both the placing on the market and the use of biocides. Many users of Formaldehyde purchase Formaldehyde as a laboratory chemical from chemical merchants. This Formaldehyde is not placed on the market as a biocide and is not intended to be used as a biocide.

Users who take this industrial or laboratory Formaldehyde and use it as a fumigant to decontaminate enclosures are acting illegally – they are conducting an illegal process.

CONCLUSION

In summary, although Formaldehyde has been approved for use as a fumigant for enclosures, the approval is extremely limited (i.e. for use in case of epidemic, defined as once per year) and when used requires that the neutralisation by-product is carefully removed and treated as hazardous waste. The time limitation on the approval of Formaldehyde to only 3 years may make it commercially unviable for Formaldehyde product manufacturers to spend hundreds of thousands of pounds producing the necessary data to support the use of the product.

As the UK HSE stated back in 2015, users of Formaldehyde should look at alternative gassing methods for room and equipment decontamination whilst there is time to do so – that time is rapidly running out as the 1st Feb 2022 approval deadline looms.

Hydrogen peroxide vapour (HPV) technology from Bioquell has been shown to be a suitable replacement for Formaldehyde. Bioquell has worked with vaccine manufacturers and government institutions to investigate the efficacy of HPV and compare it to Formaldehyde. These studies have been published in the peer-reviewed scientific literature.

References

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BIOQUELL
52 Royce Cl
Andover
SP10 3TS, UK
www.bioquell.com

EUROPE HEADQUARTERS
Richtistr. 7
8304 Wallisellen
Switzerland
www.ecolablifesciences.com

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