Webinar: Analysis of alternatives and tools to support substitution of biocides

Questions and answers

This document is based on the questions received during the webinar organised on 26 April 2023 and the input from the different speakers. Editorial changes have been made to improve clarity and similar questions have been combined.

For the most up-to-date advice, contact us or refer to our website.

#	Question	Answer
1	I would like to know which biocides can be used in food contact lubricants	For this specific question, please send a request to Helpdesk support - ECHA (europa.eu)
2	What are the options and requirements to include multifunctional neutralizing agents on the database for alternatives?	In SUBSPORTplus, it is possible to assign several functions or uses to one substance. In addition, the substance can be described in the substitution case. The ChemSec Marketplace welcomes all alternatives that fulfil their criteria.
3	Do downstream users have a role to play in analysis of alternatives and substitution?	Absolutely. Downstream users have a key role to play in this field as they know best how the substances and products are used. This knowledge is necessary for searching, identifying and assessing the alternatives. Downstream users such as formulators and users of biocidal products can inform their suppliers about their uses and the suitability of the alternatives they have already tested. This will help suppliers in developing or searching for alternatives.

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		Downstream users should also search themselves for alternatives. They can do their own analyses of alternatives to have a better understanding of what is available on the market and how these perform against the assessment criteria. Prevention methods and non-chemical alternatives should be carefully considered as, in certain cases, they have the potential to either fully replace or significantly reduce the need for using hazardous biocidal substances. Providing adequate information and training offers not only on biocidal products but also on preventive and alternative measures is very important to enable them to make informed decisions. When third-party consultations on alternatives are conducted (e.g. the consultations hosted by ECHA on alternatives to biocidal active substances which are candidate for substitution according to Article 10(3) of the BPR), it is essential for the authorities to receive the input from downstream users to collect additional insight on the suitability of alternatives (e.g. in addition to the information submitted by an applicant for the substances candidate for substitution). One of the lessons learnt in the field test that was performed in the Netherlands was that if you want to adopt a safe by design approach, then an intensive interaction between all the different parties in the supply chain is particularly important, especially because you want to identify as many options as possible. This approach also requires considering demands from the end users or downstream parties in the supply chain. And in this way, you also identify and might be able to tackle some challenges that are associated with the innovation system and which the new alternative should function. Then you can think about prevailing norms or regulations, perhaps of values or even things like perceptions. Overall, downstream users have a key role to play for the market to move to safer alternatives or prevention methods.
4	There can be many uses of an active substance. How can a supplier of active substance take this diversity into account in its analysis of alternatives, taking into account that the supplier might not be aware of all uses?	Knowledge of the uses is key for searching, assessing and developing alternatives which are suitable for the uses in question. For this reason, suppliers of biocidal active substances looking for safer alternatives should investigate within their supply chains to gain a better understanding of the uses. Once this is done, they should search for potential alternatives to the different uses and assess them to the extent feasible, aiming at an analysis of good quality, meeting the standards, such as the ECHA guidance on alternatives to biocidal substances. The guidance is flexible and the assessment should be tailored to the case the author of the analysis should strive for an assessment of good quality for all intended uses.
5	The hazard profile of some potential	Indeed, several active substances are still under evaluation or re-evaluation, so the hazard

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	alternatives is under re-evaluation by the authorities. How to take this into account when performing our analysis of alternatives?	profile is not confirmed yet. ECHA's recommendation is to take the latest authoritative information into account, noting that this can change at a later stage. The assessment made is a description of the situation at the time of writing.
6	As a downstream user, why should I comment in the third parties' consultations on alternatives to active substances and how can I be informed about it?	Third parties' participation in the consultations is essential. This is to allow the collection of additional insight on potential alternatives. Such information collected as part of the consultations on alternatives to substances candidates for substitution made according to Article 10(3) of the BPR (published here) are used by authorities in the approval process of these substances. Information is especially sought on the suitability of the potential alternatives. The comments should be as specific and substantiated a possible to support the authorities' evaluation. See also response to question 3. The ongoing consultations hosted by ECHA are listed on ECHA's homepage under the heading "consultations". You can also subscribe to ECHA's weekly news via this page to receive the most important updates from the agency, including about the launch of consultations.
7	Can ECHA help industry in establishing a dialogue between companies to search and implement safer alternatives?	ECHA currently does not organise dialogues between companies to discuss alternatives but strongly encourages stakeholders such as industry associations, national authorities/agencies, NGOs or business support organisations to facilitate these information exchanges. These dialogues are valuable platforms for sharing information and experience on alternatives and substitution issues among stakeholders, fostering overall the adoption of safer alternatives. These dialogues also help authorities to understand obstacles and challenges. ECHA supported or co-organised in the past substitution supply-chain workshops. Example of workshop structure and lessons learned are available via this page.
8	Field testing of alternatives to biocidal antifouling paints: what is an important lesson of this field test with regards to Safe by Design?	One of the lessons learned in the field test that was performed in the Netherlands was that if you want to adopt a safe by design approach, then an intensive interaction between all the different parties in the supply chain is important, especially because you want to identify as many options as possible. This approach also requires considering demands from the end users or downstream parties in the supply chain. And in this way, you also identify and might be able to tackle some challenges that are associated with the innovation system and which the new alternative should function. And then you can think about prevailing norms or regulations, perhaps of values or even things like perceptions.
9	What do you think could ECHA do to support non-chemicals alternatives	The ECHA guidance on analysis of alternatives to biocidal active substances highlights the importance of non-chemical alternatives and includes a dedicated section for these.

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	even more?	Applicants of substances which are candidate for substitution are requested to submit an analysis of alternative according to this guidance and should therefore properly search for non-chemical alternatives and assess them in a similar way as chemical alternatives. Beside the guidance which contains references to websites and organisations providing further guidance or support on non-chemical alternatives, ECHA raises awareness on the existence of such supporting initiatives from stakeholders. This webinar is one example of this.
10	How could we be supported in taking substitution decisions?	An analysis of alternatives is not meant for only listing and comparing potential alternatives with each other and with the substance to be substituted. The goal of an analysis of alternatives is to guide a decision process on a specific substitution issue, so that it is an *informed* decision, aiming at avoiding regrettable substitutions. The decision which has ultimately to be made depends on the criteria listed upfront in the scoping phase of the analysis of alternatives and is case-specific. In practice, trade-offs have often to be made since there is not always an alternative which scores the highest on all criteria. There are several methods to compare and possibly weigh the different criteria to help selecting the most appropriate alternative. We advise you to watch session "S1: Scoping the assessment" and "S5: Making and implementing decisions" of ECHA's substitution training to learn more about decision-making in substitution project. To ensure that all the important criteria are taken into account for assessing the alternatives and deciding on the one which is the most appropriate for your case, it is key to consult upfront your main stakeholders (internally: your departments responsible for marketing, manufacturing process, R&D, HSE, etc. and externally: your clients, R&D centres, etc.).
11	Can you clarify how the alternatives on ChemSec Marketplace are assessed? Do you make a detailed chemical hazard assessment for each chemical or substituent?	What we do is that we gather the information that we can get from the supplier regarding the hazardous properties, and then we check that against our requirements that we have or the criteria we have for a product to be a fit for marketplace. And in some cases, of course, we cannot get all that information. We cannot get maybe all the constituents of a specific product or maybe not all the information. And if we cannot get that, and we don't have the resources to do a full chemical hazard assessment of all the different chemicals or different substitute substances. So, what we do then is that we put the responsibility on the companies, they have to show and they have to verify to us that their product fulfil our criteria, and then we can put it on the marketplace. So, in those cases, it's the companies that must take the responsibility for telling us that they fulfil the criteria. We don't do the full chemical hazard assessment, except when we cannot get the information. To do that, we request it from the company or put the responsibility on them.

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12	Are there any other resources like ChemSec Marketplace on safer alternatives available?	No similar ones, Subsport has the same aim, but not the same setup of alternatives. There are specific reports on specific uses, but ChemSec Marketplace is the only one with a broad approach.
13	Subsportal: If I cannot find information on alternatives for my specific case, is there any help that can support me directly regarding substitution?	SUBSPORTplus has a contact form where you can direct your questions to us. And we try to offer support, where we can, in the sense that, we can try to redirect you to another source if searches in SUBSPORTplus databases or provided information was not successful. We also take up new information and integrate it into the platform if needed. So, if there is a need for specific information, we can add it. So, it is important for us to stay in contact with the users to improve the platform. What we cannot do is to support your alternative assessment directly as we would have a conflict of interest as an authority.
14	Michaela can you say what in-can preservatives have been looked at in the mentioned study? Could you shortly mention what was the outcome of the study/workshop on in-can preservatives?	The focus was on isothiazolinones and formaldehyde donors. The study focussed on identifying technical suitable in-can preservatives as alternatives with lower risks. Information was coming from interviews with different stakeholders on the technical requirements and performance. Alternatives discussed are e.g., dry paint, avoidance of biocides by using high pH, better process hygiene etc. If you are interested, please have a look at the study.
15	When will permethrin become a candidate for substitution? It appears that neither the final BPC Opinion, nor the CAR addendum has been published, yet.	For this specific question, please send a request to Helpdesk support - ECHA (europa.eu)
16	Is the pH-Technology a non-chemical alternative in contrast to biocides?	More details on the actual technology would be needed to respond to this question, however, if it mainly relies on chemical substance(s) it would qualify as a chemical alternative. Non-chemical alternatives would be the avoidance of chemicals.
17	The new Biocides AoA Guidance states that: Stakeholder involvement should take place outside the applicant's supply chain (as well as within). Can it be further explained from a practical perspective what degree of consultation is expected outside the supply chain on potential alternatives?	The analysis of alternatives (including the consultation outside the supply chain) needs to be tailored and proportionate to the case. The external consultation is meant to gather additional insight on potential alternatives which might not been (fully) known if you were only investigating your own supply chain. This broadens the perspective of substitution and is an essential step of the process. Applicants of biocidal active substances meeting the exclusion criteria should demonstrate an overall high level of efforts in searching and analysing potential alternatives. The consultation of stakeholders outside the supply chain could be done in various ways such as the launch of online surveys, interviews, events, etc. Naturally, in these interactions, competition law, protection of confidential business information and all other applicable laws should be respected. This process can also be facilitated by the use of specialised consultants and trustees.

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18	Subsportplus and Chemsec Marketplace: how do you assess non-chemical alternatives?	SUBSPORTplus has a methodology on how to assess alternative substances but so far, there is no guidance on how to assess non-chemical alternatives. For the time being, we would rely on the feedback of the users regarding safety, performance and implementation. Surely, this would need to be developed.
19	Due to the extreme interpretation given to the scope of the BPR, alternatives and preventive measures fall under the scope of the BPR (and its heavy approval path) what kills development of such alternatives. Any perspective to revise the scope of the BPR to give room for such alternatives?	As indicated in recital 3 of the BPR, "The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment. […]". Biocidal products and active substances are intended to kill, prevent, control or render harmless harmful organisms. Therefore, due to their intrinsic properties, biocidal products and the active substances within them can pose risks to human and animal health and the environment. It is therefore necessary to conduct adequate assessment to ensure that they are used safely These assessments can be demanding, but the BPR also provides simplified authorisation procedures for products with a more favourable environmental or human or animal health profile (inclusion of substances in Annex I of the BPR and subsequent simplified authorisation procedure detailed in Chapter V of the BPR and in the Implementing Regulation (EU) No 88/2014 for Annex I inclusion/amendment). In this sense the BPR aims at ensuring the safety of the use of biocidal products while encouraging innovation for safer products.
20	To Ms Wieck: do your institute intends to produce other guidance documents for assessing non-chemical alternatives for other types of use? (other than rodenticides)	Within the SCOTTY initiative at the German Environment Agency, testing of non-biocidal alternatives is considered as an important part of the transition to a sustainable use of biocides. The next step we are going to take is a research project to develop testing guidance for thermal alternatives to algaecides to remove algae from walkways for example. This project will start this autumn 2023. Further proposals from downstream users or cooperation with other parties on this topic are very welcome.
21	How can users know what kind of anti-fouling they need?	It differs per individual case what kind of antifouling you need. In the campaign in the Netherlands, it is not said which option you have to use, but a range of options is presented as was shown during the presentation. For boats in German marinas, there is a map on the homepage of the German Environment Agency depicting the fouling pressure in German waters (in German here). This is supposed to help users taking informed decisions in line with proper use of biocidal products according to Article 17(5) of the Biocidal Products Regulation.
22	What is the allowed biocide content in "biocide-free" paint? Isn't it < 2 mg/kg?	In case the paint has been treated with, or intentionally incorporates one or more biocidal products, it is considered a treated article. However, a treated article that has a primary biocidal function shall be considered a biocidal product.

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		In cases where a biocidal active substance in sufficient concentration to be active is present in an article (e.g., paint) or in a part thereof, it needs to be decided on a case-by-case basis, taking into account the nature and features of the article (including claims) and knowledge on the biocidal treatment made during production, whether the finished good qualifies as a treated article or not with regards to those active substances. For more information please also see CA-Sept13-Doc.5.1.e_rev1. We would recommend contacting the national authority relevant to your case to clarify the matter. Matters concerning the scope of the BPR are not under the remit of ECHA.
23	To Mr Vermeent: would RIVM initiate similar practical testing of alternatives on other uses, or would it be left now to industry actors themselves?	The RIVM had no representation at the webinar, so this question is left unanswered. Parties from industry have also a certain responsibility themselves to find alternatives.
24	BPR processes are not innovation friendly, companies with alternative technologies have extreme difficulty in even finding a CA to evaluate new chemistries. When will we see an innovation-friendly system?	See reply to question 19.
25	Is an alternative assessment required at active substance approval or also at product authorisation?	Active substances meeting one of Art. 5(1) criteria shall not be approved unless it is shown that at least one of the conditions set out in Art. 5(2) of the BPR is met. For this purpose, according to Art. 6(1)(c), the applicant needs to submit evidence that Art.5(2) is applicable. Art.5(2) specifies that the availability of suitable and sufficient alternative substances or technologies shall be a key consideration when deciding on the approval of substances meeting the exclusion criteria. In this sense, the submission of an analysis of alternatives by the applicant for a substance meeting the exclusion criteria is required. Applicants of substances which are candidate for substitution but not meeting the exclusion criteria (i.e. substances meeting at least one of the conditions listed under Article 10(1)(b) to (f)) are advised to also submit an analysis of alternatives as part of their application. Biocidal products containing an active substance which is candidate for substitution according to Art.10(1) of the BPR are subject to a comparative assessment as part of the product authorisation/renewal procedure (Art. 23 of the BPR). This comparative assessment is in essence an analysis of alternatives at product level, made by the competent authority according to the "Technical Guidance Note on comparative assessment of biocidal products". The applicant for an authorisation/renewal for a biocidal product is not required to submit an analysis of alternatives as part of this process.

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26	Any significant case studies on public health disinfectants? e.g., water disinfectants, true alternatives - effective, available in sufficient quantities and cost effective. Are we thinking big enough? large scale management of water for huge infrastructure. Boat fouling is very small in scope.	One example for disinfectants in the medical sector is a Viennese database on disinfectants (WIDES) to support substitution of hazardous products. There is information on efficacies, OSH and environmental protection properties of commercially available disinfectants and their ingredients. There has been a project by the German foundation "Deutsche Bundesstiftung Umwelt" (DBU) on chemical leasing of disinfectants in a hospital that focussed on an optimised use of disinfectants. The final report (in German) is available here: https://www.dbu.de/OPAC/ab/DBU-Abschlussbericht-AZ-26035.pdf.
27	Biocides need to be registered. The problem is if we find a non-hazardous replacement then this compound is not registered and consequently has not been used. How to go forward then?	The Review Programme aims to assess all existing (it is considered existing if it was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development) and new biocidal active substances in a harmonized way. All biocidal products containing only approved existing and/or new biocidal active substance(s) require an authorisation in accordance with the BPR. However, as the Review Programme takes time, there are transitional measures in place. For example, biocidal products containing existing active substances that are still under assessment in the Review Programme can be made available on the market and used (subject to national laws) pending the final decision on the approval of the active substance (and in case a product authorisation application in line with the BPR is submitted for such a product before the approval date of the active substance, the product can also remain on the market up to 3 years after the application submission). Products containing new active substances that are still under assessment may also be allowed on the market, where a provisional authorisation is granted. It is recommended to adopt a broad view in identifying potential alternatives. The purpose is to find safer alternatives which are available and feasible from a technical and economic perspective. See sections 2.3, 3.3.2.1 and 3.4.5 of the ECHA guidance on alternatives to biocidal substances for additional information on the types of alternatives to consider in the analysis and the availability criterion.
28	How do manufacturers determine what substances are in their products? Is there any requirement for suppliers to list every single chemical that may be present?	*Applicants* need to declare the complete composition of products in accordance with Annex III, Title 1, paragraph 2.3 of the BPR in the application for the authorisation of a biocidal product. Once the authorisation is granted, the *authorisation holders* (who could be a different entity than the applicant) take full responsibility for the products they make available on the market. As indicated in CA-May14-Doc.5.1-Final, "knowledge of the active substance and non-active substances essential for proper use of the biocidal product is one of the elements that shall

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		allow authorisation holders to comply with their obligations under the BPR". With that being said, whether or not the complete composition of these products is known to authorisation holders, they take full responsibility for the products they place on the market.
29	If you find an alternative that is not listed as PT6 or PT7 biocide in Belgium, we cannot use the product even though the product is less harmful. How can this be solved?	To be lawfully used in a given Member State the biocidal products has to comply with the legal requirements. In case product contains a new active substance, it cannot be placed on the market until the active substance is approved or included in Annex I of the BPR, and the product is authorised (exception is provisional authorisation). If the product contains an existing active substance that is approved or included in Annex I of the BPR, it can only be placed on the market for this use in that Member State, if it is either authorised in line with the BPR, or it complied with the national legislation of that Member State for transitional biocidal products and at the same time a product authorisation application was submitted for it before the approval date of the active substance for this use in that Member State.
30	When assessing the economic feasibility of an alternative, can a holistic approach also be used? That is, even if the 1-vs-1 price is the same, maybe there are different treatment costs, application costs, frequency of treatment.	Yes, a holistic approach like described here is reasonable and is recommended under the TRGS 600 (technical rules for hazardous substances in DE), when it comes to implementation of an alternative. The same is recommended in the ECHA guidance on analysis of alternatives to biocidal active substances: it is the overall cost difference for the user over a certain period of time which needs to be considered. This generally includes several other considerations that just the unit price of a biocidal product.
31	Which efficacy tests can be performed for non-chemical alternatives? How will the authority assess their efficacy?	Under the BPR, there is currently only one guidance which has been recognised by the BPC[1] for evaluating the efficacy of non-chemical alternatives. It concerns the non-chemical alternatives (mechanical traps) to rodenticides and was developed by the German Environment Agency (Umweltbundesamt – UBA): Guidance for the Evaluation of Rodent Traps: Part A Break back/Snap traps (umweltbundesamt.de)). In the appendices of this guidance test protocols and factors to be considered when conducting efficacy tests are mentioned. Additional recognised guidance would be needed for evaluating the efficacy of other types of non-chemical alternatives. See also reply to question 20.

[1] https://echa.europa.eu/documents/10162/3443005/art.75_rodent_traps_final_bpc_opinion_en.pdf/

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