KEEP YOUR BIOCIDAL PRODUCTS ON THE MARKET

TNO triskelion bv

PRODUCT AUTHORISATION AFTER APPROVAL OF ANNEX I LISTING

We can help you to identify whether the active substance(s) within your product are currently under review with regard to a specific product type and advise you on the best way forward.

Today only a few active substances have been listed on Annex I of Directive 98/8/EC (mainly for P T8, 12, 14, 18 and 19). Annex I listing indicates that the active substance on this annex can be used in a given biocidal product type. Decisions on Annex I listing take place at EU level. For the manufacturer of actives it means that they can sell the active substance for biocidal product purposes in the EU. For the biocidal product producer this means that a National authorisation is needed to sell products containing the active substance.

The review of the majority of active substances is still ongoing. However, many reviews are approaching finalisation and the drafts of the decisions on the Annex I listing are expected to be finalised within the next year or two.

If your product contains these biocidal actives, or a combination of these active substances, then you need to get your biocides ready for product authorisation.

For active substances listed on Annex I of directive 98/8/EC, national provisions no longer apply so if you want to keep your product on the market you need to ensure that your product is authorised in every member state where you sell your product. The dossier to apply for authorisation should be submitted to a reference member state (MS) by the date of Annex I inclusion if you want to keep your product on the market. The MS should decide within 12 months whether to authorise your product or not. If the MS decides not to grant you an authorisation, your product must be removed from that market within 6 months.

Now is the time to look at what action you need to take for the active substances used in your products so that you can continue to sell your product in line with the conditions of the regulation.

If the active substance within your product is approved for listing on Annex I and/or your product contains a combination of active substances, then we can help you in the process of product authorisation, submit the dossier in one MS and apply for mutual recognition in another. In consultation with you, we select the approach that is in your best interests.

OUR SERVICES

Our regulatory specialists have expertise in every step of the dossier preparation and submission process. We have built up an extensive network of contacts with the competent authorities. We also know the biocide manufacturing industry and can offer mediation services to facilitate cooperation on dossiers and the exchange of biological data between companies.

THE FOLLOWING SHORTLIST IS A TASTE OF WHAT WE CAN OFFER AS CONSULTANTS:

- Mediate in obtaining a letter of access (if you are not the data holder).
- Data requirement analysis.
- Completeness check of any existing biocide dossiers.
- Quality assessment of existing data.
- Prepare a cost-effective test strategy with a minimum of required studies, and clear and scientific based waivers.
- The complete risk assessment of your product.
- Dossier compilation and submission.
- Dealing with the CA (Competent Authority) and subsequent comments after submission or during the completeness check.

Having selected the best way forward, which includes identifying the specific data that you need to obtain product support, in conjunction with TNO, our parent company, we can help you carry out the necessary studies:

Physical and chemical data
Analysis: identity and purity, storage stability, method developments in various media (depending on the active substance this could include; water, soil, sediment, sediment, activated sludge, serum, urine).
Efficacy testing for the following applications:

- Disinfectants and general biocidal products (Main group 1: PT 1 ,2 ,3 ,4 ,5)
- Preservatives (Main group 2; PT6 -13)
- Preservatives for food and feed stock (PT20)
- Antifouling (PT21)

Toxicity testing: all needed toxicity testing, including the determination of skin absorption.
Environmental testing: all needed environmental fate and ecotoxicity testing.
Human exposure assessment
Environmental exposure assessment: determine fate and behaviour.

The rationale for any testing required within the product authorisation phase is to:

- Ensure that the active substance in your product is the same as that listed on Annex I (analysis studies).
- Indicate any intrinsic dangerous physical chemical properties.
- Indicate any properties of the product that may be harmful to human and environment.
- Substantiate your biocidal claim by efficacy testing.

You can rely on the combination of services mentioned above to get your product on the market. Our aim is a successful dossier submission and product authorisation of your product.

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TNO TRISKELION BV
TNO Triskelion is a contract research organization active in toxicology research, analytical chemistry and chemical risk analyses. The mission of TNO Triskelion is to guarantee the quality and safety of food ingredients, chemical substances and medicines. TNO Triskelion is a subsidiary of TNO, the Netherlands Organisation for Applied Scientific Research.

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