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Compliance for biocides in Switzerland

Biocide product

Substance, mixture or article intended to act against harmful organisms such as bacteria, fungi or insects by any means other than mere physical or mechanical action. Products for crop protection are not biocides, but plant protection products.
Ex. for biocide product: kitchen disinfectant

Treated article

Substance, mixture or article treated with a biocide product, the primary function of the article is not the function as a biocide
E.g.: Adhesive with a conserving agent

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In the area of biocides a large change is ongoing in Europe. Active substances are systematically re-evaluated having consequences for biocide products and treated articles. In the coming years, the main group of disinfectants are being evaluated next. How can you maintain compliance for Switzerland?

THE MAIN ASPECTS

- In Switzerland, the Ordinance on Biocidal Products (OBP) regulates the placing on the market and use of biocidal products as well as treated articles. The regulation was adapted in 2014 to the European regulation (BPR) and is currently being revised further.
- The term treated articles was introduced in 2014. Certain requirements are to be considered. In particular, treated articles may only contain notified or approved active substances.
- User of biocidal products: Biocidal products may only be used for specific uses in accordance with the requirements contained in the authorisation. Users do not need an own authorisation, but there must be an authorisation within the supply chain. Due to the very high fees for an authorisation acc. to the EU harmonized procedure, it can be expected that certain biocidal products will no longer be marketed and therefore alternatives must be sought.
- Authorisation for biocidal products: Swiss manufacturers and importers are the ones responsible to hold an authorisation. A company selling commercial products under its own name is considered to be a manufacturer.
- For many products, transitional authorisations can still be applied for. Once all active substances for a particular use (product type) have been approved, applications for authorisation must be submitted in accordance with the European harmonized procedure. If an authorisation according to the harmonized procedure exists in an EU country, recognition of this authorisation can be applied for in Switzerland.

Further information from the notification authority for chemicals: treated articles, (information requirements and guidance); active substances; authorisation procedure etc.: https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html (some pdfs in German only)

TRANSITIONAL AUTHORISATION	AUTHORISATION ACCORDING TO THE EUROPEAN HARMONIZED SYSTEM
Application barely contains product type specifc information requirements	product type specific information requirements for the dossier
electronic submission via Swiss product register (RPC) and mailing	Dossier compilation in IUCLID-format and submission via R4BP3 (portal by ECHA)
effort for dossier preparation: few hours to 1 day plus processing time of authorities: 2 months	For first time authorisation AL: Time frame required for dossier preparation: ca. 1.5 years (incl. performance of studies) plus processing time of authorities: 1 year
proof of efficacy only for certain uses, no proof of stability required	proof of efficacy and stability required
no risk assessment required	New: comprehensive risk assessment for human and environment
Fees of authorities, e.g.: Authorisation AN: 1'000 CHF	Fees of authorities, e.g.: Recognition in Switzerland: 5'000 - 10'000 CHF first time authorisation Switzerland AL: 30'000 - 60'000 CHF

REQUIRED ACTIONS AS A USER

- Identify biocidal products, treated articles and biocidal active substances in own use and for distribution to third parties
- Observe active substance evaluation by authorities
- Get into contact with biocide product suppliers (supplier's intention to apply for authorisation, cover of your own use in the application for authorisation, product availability in the future / alternatives / options for support)
- Define your strategy (e.g. change supplier, adapt recipe, assortment tightening, seek long-term secure of a biocidal product authorisation in your own supply chain)

HOW WE CAN SUPPORT YOU

Generally

- Analysis of your situation and assurance of compliance (active substances biocide products, treated articles)
- Monitoring the state of active substances in the evaluation process
- Advice on specific questions on biocide topics
- Communication with ECHA or national authorities as well as with suppliers
- Company specific training on biocides

For manufacturers / importers

- Strategy for authorisations, advice and implementation (union authorisation vers. national authorisation, authorisation for single products or product families, recognitions)
- Consortia management for joint biocid product authorisations by several manufacturers in collaboration with our Arcadis team in Belgium
- Art. 95 listing
- Preparation of dossiers for authorisation acc. to the Biocidal Products Regulation BPR, Regulation (EU) 528/201 (testing strategy, IUCLID dossier, risk assessment)
- Commissioning and monitoring of laboratory tests (internal laboratory for ecotoxicology / environmental behavior or via partner laboratories)