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Sustainability Support Services (Europe) AB

One Stop for 'ACCREDITED' Chemical Regulatory Compliance Services & Solutions

Important Update from Sustainability Support Services (Europe) AB related to Export Declaration.

In July of this year, Sustainability Support Services (Europe) AB i.e. SSS launched an online system for its client companies to enable them to submit the export declaration online. All the companies were sent individual login details by SSS office; using which they could submit their export details online. The hard copy details that the companies had sent for the earlier years have also been noted and shall be integrated into the system.

Considering that this was the first time that this exercise was being tried out, some companies did face initial problems to which there was prompt assistance provided by REACH Support office in India as well as from the Swedish office of SSS and all the companies were provided prompt solutions to their problems**. SSS would like to thank all the companies that submitted export details online for their co-operation and patience!**

However, there are a few companies that have not submitted the export details as yet. It is important for such companies to note that they shall have to first complete this essential compliance requirement and other non-compliances, if any. Continued non-compliance could result in delays in processing of the buyer request (certificates, tonnage coverage, etc.). Though the deadline for submission of export declarations is over, companies that have not submitted the online export declaration can yet proactively approach SSS and SSS would provide such companies with an option to become compliant.

The focus of this newsletter is on an upcoming European regulation that can have an impact on Indian biocides exports to Europe. Presented below is short and concise information related to the BPR regulation for the information of all companies concerned.

Impact of the Biocidal Product Regulation (EU) No 528/2012 for non-European Manufacturers and Exporters of Biocides to Europe

Understanding BPR

The Biocidal Products Regulation (BPR) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. This regulation aims to

improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. **This Regulation shall apply to biocidal products and treated articles.**

The regulation has entered into force in all the European Member States from 1 September 2013, with a transitional period for certain provisions. **BPR has repealed the Biocidal Products Directive (Directive 98/8/EC) from 1 September 2013.**

Important Definitions

1. **Biocidal Product** - Biocidal product means any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.
2. **Active Substance** - Active substance means a substance or a micro-organism that has an action on or against harmful organisms.
3. **Existing Active Substance** - Existing active substance means a substance which 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.
4. **New Active Substance** - New active substance means a substance which was not 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.
5. **Treated Article** - Treated article means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.
6. **Letter of Access** - Letter of access means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of this Regulation.
7. **Union Authorization** - Union authorization means an administrative act by which the Commission authorizes the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof.
8. **National Authorization** - National authorization' means an administrative act by which the competent authority of a Member State authorizes the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof.

Biocides – Various Product Types (PTs)

Main Group	**Product Type**	**Sector of Use**
MAIN GROUP 1: Disinfectants	Product-type 1	Human hygiene
	Product-type 2	Disinfectants and algaecides not intended for direct application to humans or animals
	Product-type 3	Veterinary hygiene
	Product-type 4	Food and feed area
	Product-type 5	Drinking water
MAIN GROUP 2: Preservatives	Product-type 6	Preservatives for products during storage
	Product-type 7	Film preservatives

	Product-type 8	Wood preservatives
	Product-type 9	Fibre, leather, rubber and polymerised materials preservatives
	Product-type 10	Construction material preservatives
	Product-type 11	Preservatives for liquid-cooling and processing systems
	Product-type 12	Slimicides
	Product-type 13	Working or cutting fluid preservatives
MAIN GROUP 3: Pest control	Product-type 14	Rodenticides
	Product-type 15	Avicides
	Product-type 16	Molluscicides, vermicides and products to control other invertebrates
	Product-type 17	Piscicides
	Product-type 18	Insecticides, acaricides and products to control other arthropods
	Product-type 19	Repellents and attractants
	Product-type 20	Control of other vertebrates
MAIN GROUP 4: Other biocidal products	Product-type 21	Antifouling products
	Product-type 22	Embalming and taxidermist fluids

Implications on Non-European Manufacturers and Exporters of Biocides to Europe

The BPR regulation places compliance obligations for non-European companies if they happen to be exporting biocidal products containing active substances; both “existing” active substances and “new” active substances as well as treated article in the European markets.

Compliance Process

Within the BPR, there is a list of active substance suppliers that is published by ECHA. This list is known as the “Article 95 List”. Non-European companies that manufacture similar active substances as in the Article 95 list shall have to apply for “inclusion” in this list. **Inclusion on the list is key for biocidal products to remain on the market after 1 September 2015.**

The process for inclusion in the active substances/product supplier list (Article 95 List) includes the following:

- ECHA publishes a list of the relevant substances for which a complete substance dossier has been submitted and accepted or validated by an EU Member State in a procedure provided under the BPD or BPR.
- Non-European substance suppliers or product suppliers will need to make a submission to be included on the list.

- Such applicants have to submit certain information to ECHA as specified in Article 95(1), paragraph 2: a dossier, a letter of access (LoA) or a reference to a dossier for which all data protection periods have expired.
- Letter of access (LoA) cost shall have to be paid to the data owner indicated by ECHA in the Article 95 list by submitting an online Inquiry through the R4B platform (Register for Biocidal Products)
- The submission will also be subject to a fee similar to the ECHA REACH registration fee.
- ECHA carries out a compliance check on the information submitted by the alternative suppliers and decides whether or not the application is compliant with the requirements of Article 95
- If the non-EU supplier's application passes the compliance check and the application is approved, ECHA will include the supplier on the list.

The figure below gives a schematic representation of the compliance process is depicted below

It has been indicated by the European Chemicals Agency (ECHA) which is the nodal agency for the BPR as well as REACH, that non-European manufacturers shall have the option to comply with BPR through a European legal entity (similar to the "only representative" within REACH).

As per the latest update by ECHA released towards the middle of August 2014, the name of the European representative (of non-European manufacturer) shall also be displayed in the Article 95 list.

SSS (Europe) AB shall be happy to help your company comply with the BPR regulation and we look forward to your compliance assistance request.