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Subject: Solenis' position on Biocidal Products and the REACH Regulation

The **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) Regulation (EC) Number 1907/2006) is a regulation of the European Union Economic Area (EEA). It entered into force on 1st June 2007 and is adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the European Union chemicals industry.

2.2.4 Substances regarded as registered

Substances manufactured or imported for certain uses are regarded as being registered, and therefore no registration will be required for these substances for these uses. This applies to:

- substances in biocidal products as described below; and
- substances in plant protection products as described below.

2.2.4.1 Substances for use in biocidal products

According to Article 3(1)(c) of Regulation (EU) No 528/2012 (BPR) **'active substance'** means a substance or micro-organism that has an action on or against harmful organisms.

A biocidal product may be composed of only one active substance, with or without coformulants, or it may be a mixture containing several active substances.

Active substances manufactured or imported for use in biocidal products are regarded as registered for the uses in biocidal products in the following situations:

- (1) The active substance has been approved in accordance with Regulation (EU) No 528/2012 (BPR), or
- (2) The active substance is under assessment in the review programme of existing active substances established under Article 16(2) of Directive 98/8/EC and continued under Article 89 of BPR.

Biocidal Products are out of Scope for the REACH Registration because they are regarded as registered under the Biocidal Products Regulation ((EU) No 528/2012 (BPR)) regulation. See section 2.2.4 of Guidance on registration

If you have any more questions, please contact us via your Solenis representative or send an e-mail to <u>REACH-Solenis@solenis.com</u>.

Yours sincerely, Product Regulatory REACH Team

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