POSITION PAPER

ON REGULATION (EU) NO 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE PLACING ON THE MARKET AND USE OF BIOCIDAL PRODUCTS AND SALT (NACL) FOR *IN SITU* GENERATION

Brussels, 6th May 2014

The Regulation (EU) N°528/2012 repeals and replaces Directive 98/8/EC on the use and placing on the market of biocidal products from 1 September 2013 onwards. EuSalt supports the concept of the creation of a centralised Europe-wide authorisation system for biocides. Authorisations recognised across the EU of biocide products and the creation of an EU list of active substances that may be used in biocidal products will create a simplified legal framework for placing those products on the EU market. However, the extension of the scope to precursors of active substances, as enacted in the Regulation, casts high uncertainty as to the possibility to continue to market these precursors.

1. Uncertainty about the status of "precursors"

The new Regulation controls the sale and use of biocide products and the active substances used in biocide products that may be harmful to human health and the environment. The scope of the definition of biocidal products was extended to include pre-cursors, among other types of substances. As a result, salt (sodium chloride, NaCl) used in *in-situ* electrochlorination of brine is subject to regulation, for it is a precursor of active chlorine. Therefore, a clear and common European understanding of the status of precursors and the associated authorisation procedure are necessary. Should it be otherwise, national legislations will deal with precursors differently, thus contributing to the fragmentation of the Single Market.

2. Uncertainty evaluation process of pre-cursors

The evaluation process applicable to precursors is yet to be determined. Should this assessment follow a procedure similar to that applied to active substances, it will induce a significant, yet disproportionate, financial burden for either salt producers or machine manufacturers. This will also bar some products broadly used for decades from entering the market. Such products would include salt used in electro-chlorination processes applied to disinfect water in many private and public applications such as drinking water, as well as water treatment for swimming pools.

1. Legal uncertainty about the status of "pre-cursors"

Regulation (EU) n°528/2012 (BPR) regulates the sale and use of biocidal products and of active substances used in the latter and that may be harmful to human health and the environment. The scope was extended compared to that of Directive 98/8/EC to now include precursors of active substances, among others.

As per article 3(a) of the BPR, biocidal products are defined as:

- "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,
- Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used 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."

Consequently, the scope of the above-mentioned definition includes salt (sodium chloride, NaCl), used in *in-situ* electro-chlorination of brine as a precursor of active chlorine.

Guidance documents[1] were published to clarify the legislative status of precursors used to generate active substances. However, no clear indication regarding the approval process of those substances has been determined, as yet.

The salt industry is concerned that should there be no clear European understanding of the way precursors should be treated and assessed under the BPR, national legislations will adopt diverging views on the matter. This will result in non-harmonised approach across the EU that will fragment the Single Market, as well as defeat the purpose of the Regulation to set up a European-wide authorisation system for biocides.

2. Uncertain evaluation process of precursors

Previous exchanges and guidance from the European Commission have contributed to clarify a few issues related to the identification and management of active substances generated *in situ* and their precursors in the context of the review programme (see Annex I to the BPR):

[1] "Way forward on the management of *in-situ* generated active substances in the context of BPR', European Commission, DG ENV. A.3, CA-July13-Doc.5.1.1.

a) “Products supplied with the intention to be used as biocidal products fall within the scope of the Biocidal Products Directive ('BPD') unless otherwise excluded, for example by Article 1(2) of the BPD, and such products need to be authorised.

b) Biocidal active substances that are not directly supplied to the user but are formed in-situ at the place of intended use are, in many cases, also within the current scope of the BPD and therefore need to be evaluated.

c) When the use falls within the scope of the BPD, the in-situ generated active substance and any precursor(s) supplied with a biocidal intention should be listed in the Annex I entry of the BPD.

d) The dossier and the assessment report need to contain the appropriate information on both precursor and in-situ generated active substances in order to properly assess the safe production and use of the biocidal product.”

Guidance documents further pointed out that the Annex I listing should indicate the active substance generated in-situ, as well as any precursors placed on the market with a biocidal intention. The means of generation could also, where relevant, be included in Annex I.

As a general rule, the Annex I entries should indicate the in-situ generated active substance and list the different precursors supplied with a biocidal claim, and which have been assessed and authorised. However, The evaluation process applicable to precursors is yet to be determined. Should this assessment follow a procedure similar to that applied to active substances, it will induce a significant, yet disproportionate, financial burden for either salt producers or machine manufacturers. This will also bar some products broadly used for decades from entering the market. Such products would include salt used in electro-chlorination processes applied to disinfect water in many private and public applications such as drinking water, as well as water treatment for swimming pools.

In addition, as a natural mineral with no safety risk associated to it, salt is excluded from the scope of the REACH Regulation. Having a heavy authorisation procedure under the BPR, then, seems rather disproportionate. Beside the significant financial burden of the evaluation process, this costs would weight on salt producers, stigmatising one particular link of a well-integrated supply chain, namely salt producers. Indeed, the electro-chlorination process is composed of water, salt and a device called electro-chlorination. It is the combination of these elements that produces active chlorine that is then used as a disinfectant.

EuSalt is the non-profit organisation representing the common interests of salt producers located across Europe. As the voice of the salt industry, our aim is to create an interactive platform and facilitate information exchange between the industry and European and international stakeholders.