Making available on the market and use of biocidal products

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In accordance with Regulation (EU) No 528/2012, the Commission presented a report on the authorisation of biocidal products by the Union.

Background to the report: as a reminder, Regulation (EU) No 528/2012, applicable since 1 September 2013, lays down rules on the placing on the market and use of biocidal products. It provides that active substances must be listed in Annex I to that Regulation (so-called 'low risk active substances') or approved at EU level and included in a Union list of approved active substances before they can be used in biocidal products. Secondly, biocidal products containing an active substance require authorisation before they can be placed on the market and used.

The procedure for Union authorisation is the following: the European Chemicals Agency (ECHA) receives the application and, following its assessment by an evaluating competent authority of a Member State, ECHA organises a peer review process resulting in an opinion delivered by its Biocidal Products Committee (BPC). This opinion will be the basis for the Commission to decide on whether or not to grant the Union authorisation, and under which conditions.

By 31 December 2017, **no Union authorisation has been granted yet**, as the regulatory process for the first applications requesting a Union authorisation has not been completed. Therefore, the Commission is **not in a position to make a comprehensive analysis** of the functioning of current provisions in the Regulation on Union authorisation.

Consequently, this report provides a **factual overview** of the applications for Union authorisation submitted until 1 October 2017 and some preliminary conclusions based on the limited experience gained so far with the existing applications for Union authorisation.

Number and types of applications: until the end of 2017, **a total of 115 applications** for Union authorisations have been submitted, 70 (60.9%) thereof under Regulation (EU) No 528/2012 while 45 (39.1%) have been submitted under Commission Implementing Regulation (EU) No 414/2013.

Regarding the type of authorisation sought, 20 applications (17.4%) involved single biocidal products while 95 (82.6%) involved biocidal product families. **This latter figure is significantly higher than the estimates** in a survey carried out by two industry associations in 2015. Furthermore, the trend in the submission of applications for EU authorisation in recent years shows that this procedure is increasingly being used.

This seems to indicate that **Union authorisation is attractive** under the current fee amounts laid down by the Commission Implementing Regulation (EU) No 564/2013, in particular for biocidal product families. However, it will only be possible to fully assess the success of this procedure a few years after the actual issue of Union authorisations.

Products covered: the main product-types covered by the current applications are **disinfectants** (48.7%), followed by applications including a combination of disinfectant and preservative uses (45.2%) and finally by insecticides (5.2%) which corresponds to product-type.

Therefore, Union authorisation seems to **respond to the needs** of applicants to reach the whole Union market for widely used biocidal products with similar conditions of use across EU.

Applications for Union authorisation concern 16 active substances representing 38 active substance /product-type combinations. All of these are existing active substances as defined in Article 3(1)(d) of Regulation (EU) No 528/2012.

Only 2 out of the **16 active substances** fulfil one of the substitution criteria referred to in Article 10(1)(b) to (f) of Regulation (EU) No 528/2012. This finding is consistent with the objective of **discouraging prospective applicants** to submit applications for Union authorisation of products containing active substances fulfilling the substitution criteria.

The Union authorisation procedure is mainly used by applicants to request the authorisation of **biocidal product families** (82.6% of the applications) that cover a high number of existing products in the markets of Member States. Taking into account that most applications for Union authorisation are also intended for more than one product-type (85%), this may add a certain degree of difficulty for the evaluating competent authorities to timely validate and assess the applications.

The report also notes the following:

- 58% of applications are today assessed by **one Member State only**: the driving factors behind the applicants' choice of Member States should be further explored in order to find a more balanced distribution of the workload between Member States;
- a significant proportion of applications was incomplete and required further submission of information. In this respect, **proper planning** of early pre-submission meetings between the applicant and the evaluating competent authority should be further promoted;
- **about 21% of the applicants having submitted Union authorisation applications are SMEs**: the possibility to implement a system of payment of fees by instalments should be further considered in order to better understand their effect on the number of applications submitted by SMEs.

The Commission will include a **more comprehensive assessment** of the Union authorisation procedure in its composite report to the European Parliament and the Council on the implementation of Regulation (EU) No 528/2012. The composite report will be based on the reports submitted by Members States to the Commission on the implementation of the Regulation in their respective territories, which are due by 30 June 2020.