European Regulation (EU) No 528/2012 (or BPR), which came into force on 1 September 2013, follows on from European Directive 98/8/EC aimed at harmonising the regulations of the Member States of the European Union and ensuring the unity of the single market. However, the main purpose of this regulation is to ensure a high level of protection for humans, animals and the environment by only <u>placing on the market</u> those active substances and biocidal products that are effective and entail an acceptable risk for humans and the environment.

The Regulation is implemented in two phases:

1. An assessment of the biocidal active substances leading, if the active substance fulfils the conditions for approval of the BPR (Article 4), to an approval regulation. The European Commission has drawn up a positive list of active substances approved at EU level;

2. An assessment of the products (containing the approved biocidal active substances), which may lead to a national MA (valid only in the country that has issued the authorisation decision) or EU MA (valid in all the countries of the European Union).

In France, since the 1st July 2016 national authorisations previously issued by the Ministry of the Environment, Energy and the Sea (MEEM) are issued by the French Agency for Food, Occupational and Environmental Health & Safety (ANSES).

WARNING: French regulation is not translated. Please contact us to helpdesk-biocides@anses.fr in order to have more explanation.