The procedures for submitting MA applications depend on the status of the active substances making up the biocidal product. A <u>simplified diagram</u> **[**] acts as a guide.

The approval date for a biocidal active substance is specified in the approval regulation for this substance and also corresponds to the deadline for submitting a marketing authorisation application dossier for a product containing this substance. In accordance with Article 89 of Regulation (EU) No 528/2012, products containing existing active substances (Art.3.1 d) may continue to be placed on the market and used according to the national procedures, as long as these active substances are undergoing assessment and until their approval ("transitional" regime). Products containing new

active substances (Art.3.1 e) may not be placed on the market and used before being authorised according to Regulation (EU) No 528/2012.

The status of the biocidal active substances and their approval date can be consulted on the \underline{w} ebsite of the European Chemicals Agency (ECHA)

Once an approval decision has been made for all of a product's active substances for the product type(s) (PT) concerned, the product leaves the "transitional" regime and must obtain a marketing authorisation in accordance with the BPR.

A period of around 18 months is prescribed between the publication of the approval regulation for an active substance and the approval date laid down in this Regulation. During this period, the economic operators must compile their authorisation application dossiers for the biocidal products, in order to submit them by the deadline. If no dossier is submitted within the timeframes for products on the market during the transitional period, these products will be withdrawn from the market (see Article 89 of the BPR). Economic operators, in particular industrial companies already placing biocidal products on the market and wishing to keep them on the market during the transitional period, are therefore responsible for carefully following the review programme for the active substances, in order to prepare for the deadlines for submitting authorisation applications. All authorisation applications must be submitted before the submission deadline.

The application for marketing authorisation can be made in France as an application for a first MA, or an application by parallel or sequential mutual recognition.

- In the case of an application for a first MA, France is the "Rapporteur Member State". ANSES carries out the assessment of the dossier and submits its report to the other countries before the decision is taken, if the applicant has applied for parallel (or simultaneous) mutual recognition.

- In the case of an application by mutual recognition, another Member State of the European Union carries out the assessment of the dossier, and ANSES will analyse the draft decision and the assessment report of the Rapporteur Member State in order to propose an MA.

A table summarising

the characteristics of the different current types of application is available. This document is for information purposes; only the regulatory texts are authentic.