

# *Guidance on Notification, Authorization and Mutual Recognition of Biocidal Products*

## **Notification**

If the active substance is still pending approval and listing in Annex I or IA, a notification is necessary in Malta. This is done by downloading the required form from MSA's website (FCC 402 Authorization Registration Form for Biocides <http://www.msa.org.mt/rad/pesticides/downloads/FCC402%20Authorization%20-%20Registration%20of%20Biocide.doc> ) and submitting the labels (as required), safety data sheet and the signed form. A notification will be issued depending on the active substances and product type. Validity is for 2 years or less if the Annex I listing (or the decision for a non-inclusion) is less than 2 years.

For a product to be notified, the active substance has to be listed in both Annex I and Annex II of Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:325:0003:0065:EN:P DF>) and not banned through a Commission Decision ([http://ec.europa.eu/environment/biocides/non\\_inclusions.htm](http://ec.europa.eu/environment/biocides/non_inclusions.htm) ).

A product has to be classified as a Product Type (please see Document on Product Types). Annex II of Regulation (EC) No 1451/2007 specifies which active substances can be used for what product types.

## **Authorization**

When the active substance has been approved for use, this substance will be listed in Annex I or IA of Directive 98/8/EC concerning the placing of biocidal products on the market. When the active substance is listed in this Annex and reaches its Date of Inclusion, the notification is now no more valid, and the manufacturing company (or owner of the active substance) will have to apply for an authorization of a biocidal product through the R4BP (register for biocidal products) (<https://webgate.ec.europa.eu/env/r4bp/user.language.cfm?CFID=872&CFTOKEN=f6f315c615a41fe6-ECCA03A4-9038-EB4E-D6D921FD8A41DA8A&jsessionid=57083b1b6190756a7269TR> ) at commission level.

The owner has to choose a Member State where to authorize the product. A certificate with an authorization number will be issued by the responsible competent authority of that chosen Member State.

If a decision is taken that the active substance will not be listed in Annex I, the active substance will be banned and a grace period is given so that any stocks remaining will be exhausted. The notification first issued will not be valid anymore and no more consignments will enter the Member State.

## **Mutual Recognition**

When the product is authorized in a Member State, the authorization holder may then apply for a mutual recognition in other Member States. The owner must present the certificate issued by the competent authority of that chosen Member State authorizing the product for the first time on the market to the other Member States where the authorization holder is intending to apply for a simple mutual recognition to place the product on the market. This must also take place through R4BP.

## **Note**

One must note that a notification is only valid before the active substance is put in Annex I/IA. A notification cannot take place instead of a mutual recognition.

All biocidal products must be first notified and then authorized/mutually recognized to be put on the market. A notification/mutual recognition is required in every Member State the product is to be sold. Therefore it is not a free market.

One must not forget that a biocidal product has to be authorized according to its product type. There are 23 different product types. E.g. if a biocidal product has been authorized for use for product type 2, a new authorization must be issued if it is intended to be used as product type 3.

For applicable fees please look at Document MSA Provision of Services – Fees ([http://www.msa.org.mt/rad/MSA\\_Provision\\_Of\\_Services\\_Fees.pdf](http://www.msa.org.mt/rad/MSA_Provision_Of_Services_Fees.pdf))

Additional information can be found at the Commission's website: <http://ec.europa.eu/environment/biocides/index.htm>

