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APPLICATION FORM FOR THE RENEWAL OF AUTHORISATION OF A PLANT PROTECTION PRODUCT AUTHORISED IN ACCORDANCE TO ARTICLE 40 OF REGULATION (EC) No 1107/2009

GUIDANCE FOR DULY FILLING IN THE APPLICATION FORM FOR 'RENEWAL OF AUTHORISATION OF A PLANT PTOTECTION PRODUCT (PPP)'

1. **General guidelines for each application form submitted**

   When an application form for the renewal of authorisation of a plant protection product authorised through Mutual Recognition is submitted; The relevant sections should be duly filled in, where the details of the product, applicant, Maltese representative and application type should be indicated. The relevant compulsory documentation indicated should be submitted in tandem with this application. Furthermore, the payment of applicable fee and filling-in of the Payment Details section should also be provided upon the submission of the application.

2. **Change in Trade Name of the Plant Protection Product.**

   When an authorisation holder decides to change the trade name with which the product has been authorised for the placing on the market in Malta, the Change in Trade Name Section should be filled in and both the trade name with which the product is authorised and the newly proposed trade name should be included.

3. **Change in Authorisation holder / Local Representative of the Plant Protection Product.**

   When there is a change in the currently authorised entity to place the plant protection product on the local market or a change in the local representative of the product, the Change in Authorisation Holder Section needs to be adequately filled in. Information on the 'new' authorisation holder and local representative will have to be provided.

4. **Change in Chemical Composition of the Plant Protection Product**

   In case of a change in chemical composition of the plant protection product, the Change in Chemical Composition Section needs to be completely filled in. Both information on the 'currently' authorised chemical composition of the product and the 'new' chemical composition should be provided. In this case, all SDSs for the substances, which were not provided in the original submission of the application, should be provided. If the change in the chemical composition will result in a change of the classification and/or labelling of the product, the Change in the Classification and Labelling Section should also be filled in by indicating the new classification and labelling of the product in accordance to Regulation (EC) No 1272/2008.

5. **Change in Final Classification and Labelling of the Plant Protection Product**

   When a change in the final classification and/or labelling of the product occurs, the Change in the Classification and Labelling Section should be completely filled in by indicating the new classification and labelling of the product in accordance to Regulation (EC) No 1272/2008. Furthermore, justifications for the change in classification should be provided accordingly.

6. **Change in Authorisation Conditions of Label**

   When a change in the Authorisation Conditions, such as label extension and/or changes in the dose of the product occurs, the Change in Authorisation Conditions of Label Section should be completely filled in where information on the new/proposed authorisation conditions should be provided.

7. **Change in Packaging**

   In case of changes in packaging, the Change in Packaging Section should be completely filled in where information on the packaging sizes and their respective packaging type should be indicated.

8. **Change in the Manufacturing Sites**

   In case of changes in the manufacturing sites, the Change in Manufacturing Sites Section should be completely filled in where the name and details of the manufacturing sites shall be provided.

9. **Other Administrative Changes**

   In case of other administrative changes, the Other Administrative Changes Section should be completely filled in where information related to administrative changes shall be indicated.