

GUIDANCE FOR DULY FILLING IN FORM FOR 'CHANGE IN LABELLING OF A PLANT PROTECTION PRODUCT' (PPP)

1. 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 **General Information** section should be filled in and both the trade name with which the product is authorised and the newly proposed trade names should be included. Revised labels in the original language, Maltese and English languages should also be provided. Payment of applicable fee and filling in of the **Payment** section should also be provided upon submission of application.

2. 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 **Details of Current Authorisation Holder** section needs to be adequately filled in. Information on both the 'current' authorisation holder/local representative and the 'new' authorisation holder/local representative will have to be provided. Revised labels in the original language, Maltese and English languages should also be provided. Payment of applicable fee and filling in of the **Payment** section should also be provided upon submission of application.

3. Change in Chemical Composition of the Plant Protection Product

In case of a change in chemical composition of the plant protection product, the **Chemical Composition of Current Product** and the **New Chemical Composition of the Product** sections need 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 Safety Data Sheets (SDSs) for the ingredients 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 **Final Classification and Labelling – Existing Classification, Final Classification and Labelling – Proposed Classification and Classification and Labelling Requirements for Hazardous Substances and Mixtures** sections would also need to be filled in. If applicable, revised labels in the original language, Maltese and English languages should also be provided. Payment of applicable fee and filling in of the **Payment** section should also be provided upon submission of application.

4. 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 **Final Classification and Labelling – Existing Classification, Final Classification and Labelling – Proposed Classification and Classification and Labelling Requirements for Hazardous Substances and Mixtures** sections should be completely filled in. All information should be filled in as appropriate and non-relevant sections can be left out. Any sections for which information will not be provided, will be considered as non-relevant. Endpoints included in the **Classification and Labelling Requirements for Hazardous Substances and Mixtures** section which are not applicable can be marked as "N/A". Product labels which will not be revised by the stipulated deadline will have their authorisation withdrawn. Revised labels in the original language, Maltese and English languages should also be provided. Payment of applicable fee and filling in of the **Payment** section should also be provided upon submission of application.

5. Change in Safety Data Sheets (SDSs) of the active ingredient/s and/or co-formulants and/or final formulation of the Plant Protection Product

When information in the SDSs provided with the original application to place the plant protection product on the market changes, a new revised SDS should be provided.