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European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes PP 1/243 (2)

Efficacy evaluation of plant protection products
Evaluation biologique des produits phytosanitaires

PP 1/243 (2) Effects of plant protection products on transformation processes

Specific scope

This Standard provides general guidance on the need for data on possible effects of plant protection products on processes for the transformation of harvested crops and on the use of preliminary data to avoid the need for subsequent testing. It does not provide specific tests.

Specific approval and amendment

First approved in 2005–09.
Revision to update references approved in 2014–09.

Definition of transformation

Many crops are processed after harvest and the final product may be totally different in nature from the raw crop. The most obvious examples are industrial processes such as milling of cereals or extraction of specific components such as sugar from beet or oil from rape. These processes are physical or chemical and do not depend on biological activity. The same applies to freezing, canning or juicing of fruits or vegetables. Plant protection products applied to the crops may remain as residues in the harvested crop or the processed product, and affect their quality (by taint, in particular; see EPPO Standard PP 1/242 *Taint tests*), but do not affect the process as such.

Other processes depend on biological activity, e.g. the action of yeast in brewing, wine-making or baking, and are potentially sensitive to residues of plant protection products. These processes are referred to as 'transformation' of the harvested crop, and it is essential to consider the risk of adverse effects of plant protection products on such transformation processes. In cases where yeast (e.g. *Saccharomyces cerevisiae*), or lactic and propionic acid bacteria, are involved, it would naturally be expected that fungicides would pose the greatest risk.

On this basis, regulation (e.g. Commission Regulation 284/2013, EU, 2013) may require investigation of possible adverse effects if there are indications that the use of a plant protection product could have an influence on transformation processes (e.g. use of plant growth regulators or fungicides close to harvest or after harvest), or where use of similar products has been found to have an adverse influence.

When should transformation be addressed?

In preparing the biological dossier, the applicant should consider whether there is a need for data on possible effects of the test product on transformation processes, or whether a reasoned case can be presented to justify not supplying such data. The main crops which may be subjected to transformation processes include grapevine (winemaking), cereals (baking and brewing) and hop (brewing),[1] However, other crops such as apples (cider making), or vegetables (conservation by fermentation, e.g. sauerkraut) or crops for silage could also be considered.

If the applicant can demonstrate that residues are undetectable, or that any residues will not affect yeasts, a reasoned case may be sufficient to address these requirements. Data from preliminary screening tests for biological activity may provide valuable evidence of the absence of effects on yeasts or lactic bacteria.

If residues are detected and it has not been possible to rule out fungicidal activity, the effect of the active substance (and/or major metabolites if relevant) on appropriate species of yeast or lactic bacteria should be investigated, as

[1]Malting of barley is not considered to be a transformation process (and is addressed by seed germination studies as described under Phytotoxicity PP1/135). This transformation assessment relates to the extent to which the brewing process may be subsequently affected.

a first step, in laboratory tests. These tests should be carried out at doses relevant to the residue levels which typically occur in the harvested crop, and at least at the double dose. If effects are seen in these tests, further laboratory testing should be carried out to determine the margin of safety. Testing of effects on actual transformation processes should only be necessary as a last resort. Guidance on methodology can be obtained from relevant organizations (e.g. brewing, winemaking,[2] baking industry).

Registration authorities in different EPPO Member Countries are encouraged to accept data from studies made in other Member Countries provided they are conducted by appropriate and reputable organizations.

References

EU (2013) Commission Regulation 284/2013of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. *Official Journal of the European Union* L 93, 85–152.

OEPP/EPPO (2005) EPPO Standard PP 1/242 Taint tests. *Bulletin OEPP/EPPO Bulletin* **35**, 573–579. (The collection of PP1 Standards is also available at http://pp1.eppo.int/list.php.)

OEPP/EPPO (2010) EPPO Standard PP 1/268 Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine. *Bulletin OEPP/EPPO Bulletin* **40**, 260–265. (The collection of PP1 Standards is also available at http://pp1.eppo.int/list.php.)

[2]OEPP/EPPO (2010) EPPO Standard PP 1/268 Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine.