ANNEX

PART A

CHEMICAL ACTIVE SUBSTANCES

SECTION 6

Residues in or on treated products, food and feed

6.3. Magnitude of residue trials in plants

The objectives of magnitude of residue trials in plants shall be the following:

— to quantify the highest likely residue levels of all components of the different residue definitions in treated crops, at harvest or outloading from store, in accordance with the proposed GAP, and

— to determine, where appropriate, the decline rate of plant protection product residues in plants.

Circumstances in which required

These studies shall always be performed where the plant protection product is to be applied to plants or plant products that are used as food or feed or where residues from soil or other substrates can be taken up by such plants except where extrapolation from adequate data on another crop is possible.

When planning residue trials, it shall be borne in mind that information on the residues in ripe or unripe crops may be of interest with respect to the risk assessment in other areas like ecotoxicology or worker safety.

Test conditions

Supervised residue trials shall correspond to the proposed critical GAP. The test conditions (such as maximum number of proposed applications, shortest interval between applications, maximum application rate and concentration, most critical safety intervals[(1)] with regard to exposure) shall be defined to identify the highest residues which may reasonably arise and shall be representative of the realistic conditions at the critical GAP in which the active substance is to be used.

When establishing a supervised residue trial programme, factors such as main growing areas and the range of conditions, likely to be encountered in the main growing areas concerned shall be considered.

Differences in agricultural production methods (for example outdoor versus indoor uses), seasons of production and types of formulations shall be taken into account.

For the evaluation of residue behaviour and the setting of maximum residue levels (MRLs) according to Regulation (EC) No 396/2005, the Union shall be divided into two zones, a Northern European and a Southern European zone. For the purpose of use in greenhouses, as post-harvest treatment and for treatment of empty storage rooms, one residue zone shall apply.

The number of trials necessary is difficult to determine before the evaluation of their results. Assuming all other variables having an impact on the residue levels are comparable, the minimum number of trials shall vary for each residue zone between a minimum of 4 trials for a minor crop and a minimum of 8 trials for a major crop.

However, if the GAP is the same in both residue zones, 6 trials equally distributed in the representative growing zones are normally sufficient for a minor crop.

The number of studies to be performed may be reduced if residue trials show that the residue levels in plants or plant products are lower than the LOQ. The number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops.

In cases were a ‘zero’ residue situation is predicted from representative plant metabolism studies, three trials shall be performed for commodities significant in diet. No trials shall be required for commodities insignificant in diet. A ‘zero’ residue situation shall be predicted where no detectable residues occur in studies with exaggerated application rates compared to the envisaged ones.

Provided that conditions are comparable and that trials are widely spread over different zones, it shall be sufficient to carry out trials over one growing season.

Part of the trials may be replaced by trials performed outside the Union, provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable.

Trials showing the residue behaviour in post-harvest treatments shall be carried out at different locations with different cultivars. A set of trials shall be carried out for each application method and storage condition, unless the worst case residue situation can be clearly identified.

Where a plant protection product has both a field use and an indoor use with the same GAP, a full data package shall be submitted for both situations, unless it is already accepted that one use is the critical GAP.

It shall be checked on a case-by-case basis, taking into account plant morphology and application conditions, whether extrapolation from the crop used for the metabolism study to other crops belonging to the same crop group is possible.

Where a significant part of the consumable commodity is present at the time of application, half of the supervised residue trials reported shall include data to show the effect of time on the level of residue present (residue decline studies), unless the consumable part is not exposed during application of the plant protection product under the proposed conditions of use. For crops harvested after blossom (such as fruits or fruiting vegetables) a significant part of the consumable crop is present from full blossom (BBCH 65) onwards. In case of most crops from which leafy parts are harvested (for example lettuce), this condition is satisfied if 6 true leaves, leaf pairs or whorls are unfolded (BBCH 16).

In case of an active substance for which an ARfD has been derived, the distribution of residues among single units may be investigated through variability studies. If a sufficient number of results is available, the default variability factor may be replaced by a specific factor derived from these studies.

(**1**) Safety intervals refer in this Section to pre-harvest intervals (PHIs), withholding periods or storage periods in the case of post-harvest treatments.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/556 reg. 21(4)
- Annex Pt. A s. 8 word omitted by S.I. 2019/556 reg. 21(5)(b)(xiv)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by S.I. 2020/1567 Sch. 2 para. 61
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by S.I. 2020/1567 Sch. 2 para. 61
- Annex Pt. B s. 9 words omitted by S.I. 2019/556 reg. 21(5)(c)(vi)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by S.I. 2019/556 reg. 21(2)(a)
- Art. 1(2) inserted by S.I. 2019/556 reg. 21(2)(b)