

APPENDIX C**TESTING OF PLANT PROTECTION PRODUCTS IN ROTATIONAL CROPS**

The current guideline on residues in rotational crops has not been further elaborated and discussed with Member States' experts since it is expected that the European Plant Protection Organisation will finalise soon a test guideline on rotational crops which might supersede the current guideline.

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1 Summary

1.1 The problem

In order to prevent rotational crops from becoming contaminated to an unacceptable level, when testing a plant protection product the residue situation in these crops must also be considered. A distinction is made between three different cases:

1. Loss of the treated crop before harvest (ploughing)
 - following crop
2. Main crop is treated
 - following crop is not treated with the same active substance
3. Main crop is treated
 - following crop in the same year is also treated with the active substance

Before an authorization can be given for a plant protection product, with regard to the residue situation in rotational crops it must be made clear,

- whether such tests should be carried out,
- how the test should be carried out, and
- how the results are to be assessed.

The following test is suggested:

1.2 Testing

PRELIMINARY TEST

Step 1: Residues in soil

From existing results on the residue behaviour of the active substance in soil, a test is carried out to determine whether after 100 days less than 10 % of active substance and bioavailable metabolites can be detected. If yes, - apart from a few exceptions -, further tests on rotational crops are unnecessary. An exception would be, for example, an unacceptable accumulation.

Step 2: Theoretical estimate

Using a model calculation, from the actual amount of active substance used, the time between treatment and harvest, and also from the breakdown kinetics in the soil, the theoretical residue in the plant at the time of harvesting the rotational crop is calculated.

Step 3: Soil - plant transition factor

The calculation in step 2 is checked by estimating the probable soil - plant transition factor, taking into consideration existing data on uptake, distribution, mode of action and the chemical and physical properties of the active substance.

MAIN TEST

Step 4: Model tests

In model tests (culture vessels, greenhouse, lysimeter, small plots), the worst case residue situation is simulated. The test is carried out on representatives of certain groups of rotational crop plant. If it is relevant, the plant availability of bound residues is also tested. These studies should also characterize the chemical nature of the residues which may occur in following crops and should therefore be carried out with radioactive labelled active substance.

Step 5: Field tests

If no satisfactory clarification has been possible after the first four steps, the actual residue situation should be tested in field tests under conditions closest to those found in agricultural practice. Adequate attention should be paid to influencing factors such as the plant, soil and climate.

1.3 Comments and summary

A test in a maximum of five steps is suggested. If it becomes evident at any stage that no unacceptable residues can be expected in rotational crops, there is no need to carry out the test at the next step. Up to and including the third step, this is a preliminary test, which is based on existing knowledge and requires no further tests.

In the main test (from step 4), model tests are appropriate if they can be used to obtain reproducible and concrete results and time and costs can be saved compared with field tests. This applies in particular to the testing of the plant availability of bound residues. Field tests (step 5) should be carried out at 2-4 locations in 1-2 growing seasons in parallel with representative plants. The tests should provide information as to whether the rotational crop must be limited (e.g. safety interval for sowing or planting of rotational crops). They also serve to compile data for determining maximum residue levels for residues in rotational crops.

2 **Introduction**

In testing the residue behaviour of a plant protection product in/on plants and plant products, in certain cases the residue situation for rotational crops should be considered as well as the crop which has been treated. Such considerations are necessary in order to avoid unacceptable contamination (i.e. maximum residue limits being exceeded) in rotational crops.

The following guidelines are only recommendations. In some cases it may be more appropriate to select different test conditions. The obligation of the applicant on his own responsibility to prepare the data required for the assessment and submit it remains unchanged.

3 **Purpose and objective of the test**

The residue situation in rotational crops must always be considered if, after the treated crop has been harvested (or in the event of early ploughing), it is possible to sow or plant a crop which can be used as a foodstuff and/or feed.

Rotational crops must be considered particularly in commercial vegetable-growing with its close crop rotations. For applications in ornamental plants it must be borne in mind that ornamental plants and vegetables can be cultivated in rotation.

Where rotational crops are concerned, a distinction is made between three cases:

1. Loss of the treated crop before harvest (ploughing^{*})
 - following crop
2. Main crop is treated
 - following crop is not treated with the same active substance
3. Main crop is treated
 - following crop in the same year is treated with the active substance too

The data enable the possible residues in rotational crops to be estimated and in some cases enable maximum residue levels to be determined. It can also provide information as to whether, in the interest of protecting the health of man and animals, the application and/or replanting must be limited (e.g. by determining a safety interval for the replanting of certain crops).

4 Report on the residue situation

When an application is made for an authorization for a plant protection product, a report on the residue situation in rotational crops is always required. If no data is submitted, a reason for this must be given.

If it is to be used around railway lines, on non-cultivated land without any trees, paths and places with trees, for the purpose of protecting stocks and in seed treatment agents, the rotational crop is of no importance. It is sufficient to make a suitable comment to this situation.

Apart from some exceptions, this also applies for uses on ornamental lawns, sports fields and in forest areas.

With regard to applications in fruit-growing (except for strawberries), vineyards, hops and asparagus cultivation, see Section 5.6 (Continuing investigations).

5 Testing

For testing and preparing the necessary documents, in order to keep costs within acceptable limits, it is advisable to proceed in stages. If it transpires at one stage that no relevant residues are likely, there is no need to carry out the test in the next step.

Relevant residues are present if they exceed the established maximum residue limit. If no maximum residue limits have yet been established for a new active substance, the residues in the rotational crop are regarded as relevant if, at the time of harvesting, in the parts of the plant to be used as foodstuffs, they exceed the limit of determination. Residues of less than 0.01 mg/kg are not taken into consideration.

If maximum residue limits for the active substance concerned are not yet listed in the directives referring to this, it is recommended that an enquiry be made to ascertain whether provisional values have been established.

A plan in stages is proposed for the testing. In steps 1-3 (preliminary test), use is made of existing knowledge. For the main test (steps 4-5), it is suggested that before carrying out field tests (step 5), it should be checked whether time and money can be saved by carrying out model tests (step 4).

* Ploughing is to be considered particularly in applications in the following crops:
 Agriculture: grain, rape, sugarbeet
 Vegetable-growing: carrots, onions

5.1 Step 1: Consideration of the breakdown behaviour in soil

Contamination of the rotational crop with residues is effected through the soil. For a first approximation therefore, the persistence of the active substance in the soil must be tested.

If 30 days after application, less than 10% of the originally applied quantity of active substance including any bioavailable metabolites are present, a further test is not necessary. If after 100 days in the soil less than 10% is present, further testing can be dispensed with, if it is known that the residues are not accumulating in the plant.

In the case of the latter, however, the test must be continued if a maximum residue limit has already been established for the possible rotational crops, which is less than 1/10 of the maximum residue limit applicable to the crop which has been treated.

If a substantial portion of the originally applied quantity of active substance is in the soil as a bound/non-extractable residue at the likely time of replanting or during the vegetation time of the rotational crop, and/or accumulation in the soil is possible as a result of repeated use, it must be stated whether and how much of the bound residues can be taken up by plants.

Model tests (see step 4) should be carried out, using radioactive labelled active substances, in order to determine the chemical nature of the residues which may result in following crops, if on the basis of other knowledge e.g. regarding the chemical structure of the active substance and its possible transformation products, no decision is possible.

5.2 Step 2: Theoretical estimate of the residue in rotational crop

If 100 days after application there is still more than 10 % of the applied quantity of active substance including its relevant metabolites available for uptake by the rotational crop, it is recommended that a theoretical estimate of the expected residue in the rotational crop be made before carrying out further tests. The calculation is based on the known breakdown behaviour of the active substance including its metabolites in the soil.

In order to calculate the concentration in the soil, as an approximation it can be assumed that, after the soil has been turned, the active substance is evenly distributed in the top 20 cm of the soil, so that e.g. with a soil density of 1.5 g/cm³ and an amount of active substance of 1.0 kg/ha there is an initial concentration of approx. 0.35 mg/kg.

With the early use of herbicides and with soil disinfecting agents, for example, average periods from the time of treatment to the beginning of vegetation of the rotational crop can be estimated:

- at ploughing 30 days,
- in vegetable growing 70 days,
- in agriculture (rotational crop in the year of treatment) 150 days, and
- in agriculture (rotational crop in the following year) 365 days.

As far as insecticides, acaricides, fungicides etc. are concerned, as a rule these should be considered on a case-by-case basis. 70 days is suggested as the average vegetation period of the rotational crop for vegetable growing, and 150 days for agricultural crops. With these standard times and the known breakdown behaviour of the active substance in soil the residue situation in the soil at the time of harvesting the rotational crop can be estimated.

It is recommended that three transition factors be considered in estimating the residue situation in the rotational crop.

Transition factors*)

| | |
|------|---------------------------------------|
| 1/10 | Only very little uptake from the soil |
| 1 | Good uptake from the soil |
| 10 | Accumulation in the plant |

$$\text{*) Transition factor} = \frac{\text{relative residue in the plant (mg/kg)}}{\text{relative residue in the soil (mg/kg)}}$$

If according to this estimate, at the time of harvesting of the rotational crop the residue, in the parts of the rotational crop which can be used as foodstuffs, even in the least favourable case (accumulation), is below 0.01 mg/kg (i.e. below 0.001 mg/kg in soil) or below the established maximum residue limit for the rotational crop, no further tests are required.

With other words:

If at the time of harvesting the rotational crop less than 0.001 mg ai/kg soil are calculated to be present in the top 20 cm of the soil (i.e. < 3 g ai/ha), than there is no need for further investigations and residues in rotational crops can be assumed to be not relevant.

If a maximum residue limit for the active substance for the rotational crop has not yet been established, the residue predicted should be below the limit of determination.

If higher residues are calculated, further testing is carried out in accordance with step 3.

5.3 Step 3: Estimation of the soil - plant transition factor

Details on the uptake, distribution, mode of action and the metabolism in plants must be compiled during the development of any plant protection product if an authorization is being sought. In some cases, this information as well as further details on chemical and physical properties such as water solubility, n-octanol/water distribution coefficient and adsorption/desorption constants enable a sufficiently safe answer to be given to the question of whether and to what extent residues are taken up through the roots. If according to this estimate, and with the aid of the calculation in accordance with step 2, the residue in the rotational crop is below the limit values referred to in step 2, further tests are not required. Otherwise, further tests in accordance with step 4 and/or step 5 must be carried out.

5.4 Step 4: Model tests

Before carrying out field trials (step 5) under the conditions normal in professional gardening and agricultural practice, in order to save time and money for example, it may be useful to carry out model tests under controlled, reproducible conditions e.g. in culture vessels, in the greenhouse, in lysimeters or on small plots. These tests should simulate the worst case situation with regard to the quantity of residues still possible in practice, i.e.

- highest foreseeable rate of application * ,
- latest possible application,
- earliest possible harvest of a rotational crop, and
- unfavourable breakdown situation in the soil by the appropriate choice of
 - type of soil,
 - pH value, and
 - dampness of the soil.

It is recommended to select a soil type which experience has shown to break down the active substance most slowly, unless there is a particular concern over the degradation products in soil and their uptake into plants.

As far as possible and sensible, a radioactive labelled active substance should be used for the model tests. The technical active substance can also be used however. If a formulation is used, this should at least correspond to the type of formulation intended. If there are indications that the formulation influences the residue behaviour, these must be taken into consideration. The substance should be added to soil not covered by any plant material. It can also be useful to apply a homogeneous mixture of soil with the test substance. It should only be worked into the soil (e.g. tilling) if this is normally carried out in agricultural practice. The active substance should age in the soil for 30 days before planting/sowing the rotational crop. If the ageing period is changed or no ageing takes place, a reason must be given.

The choice of rotational crop is up to the applicant.

Crops must be chosen which are grown as rotational crops in agricultural practice and which in terms of residue formation are representative of certain groups of crop.

The following are suggested as being representative of certain groups:

| crop | representative of |
|---------------------------|--------------------|
| lamb's lettuce or spinach | leafy vegetable |
| carrots or turnips | root vegetable |
| cauliflower | brassica vegetable |
| wheat | cereals |

In making the choice, the characteristics of the active substance, insofar as they are of importance for the uptake of the active substance by the plants, should be taken into consideration.

In order to determine the residues in the soil (top 20 cm) and in the plant, in each trial samples should be taken at the times marked (X).

* possible multiple applications during a growing season should be considered carefully

| Sampling time | Samples Soil | Plant |
|--|-----------------|-------|
| 1. Day of treatment | X | - |
| 2. Planting of the rotational crop | X | - |
| 3. As soon as sufficient plant material is available | X | X |
| 4. Earliest possible utilization (harvest) | - | X |
| 5. Normal harvesting of the rotational crop | X | X |

If according to the results from step 4 it is probable that the residues in the rotational crop are greater than the maximum residue limit or the other limit values specified, field tests must be carried out in order to clarify the situation.

5.5 Step 5: Field tests

Field tests should provide information on the actual residue situation in rotational crops. The tests should be carried out so as to include the situation which may possibly arise in agricultural practice and which is least favourable in terms of residue contamination of the rotational crops. With regard to the test conditions below,

- application rate,
 - application technique
 - time of planting/sowing the rotational crop
 - tillage
 - sampling
 - aging, and
 - representative rotational crop
- see the details for step 4.

The field tests must be carried out under normal conditions in agricultural practice. The proposed formulation should be used for the tests. It should at least be of the same type of formulation. Indications of any influence of the formulation on the residue behaviour must be taken into consideration. Soils should be chosen which experience has shown to break down the active substance most slowly, unless there is a particular concern over the degradation products in soil and their uptake into plants.

It has however proved to be the case that sometimes, with a limited number of field tests, it is difficult to be sure that the least favourable situation has been included. These difficulties can be reduced if, unlike in the usual method (treatment to the preplanting), the soil is not treated with the appropriate quantity of active substance until 30 days before the rotational crop is planted or sown.

The number of tests and the choice of representative plants depends on the test situation in question. To clarify the residue situation it has proved worthwhile to repeat the tests in a second growing season and to carry them out each test year at at least two (preferably four) locations. At each location, several (generally three) crops which are representative for rotational crops and residue formation should be tested in parallel. Trials should be carried out in major areas of cultivation or production and should be sited to cover the range of representative conditions likely to be met in the use of the pesticide.

5.6 Continuing investigations

Tests after repeated application in one rotation over several years or in permanent crops [e.g. fruit (excluding strawberries), vineyards, hops and asparagus] should only be carried out if the active substance tends towards an unacceptable accumulation in the soil and can be taken up by the rotational crop in relevant quantities. In general such tests are only required once a plant protection product has been authorized.

6 **Report**

Details of the test, including calculations (steps 1 - 3), must be submitted. The results of the model and field tests should be reported and provided with a summary and assessment which also contains conclusions with regard to the estimation of maximum residue levels and rotational crop growing restrictions (e.g. safety interval) or continuing tests. Any unusual features, e.g. on the tillage and in the taking of samples, must be reported and reasons given.

7 **References**

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