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Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs

Revisions history

When	What
Rev. 10.3 of 13.06.2017	Introduction of one new extrapolation, agreed in June 2017 PAFF meeting (from apple and/or pears to kaki/Japanese persimmons).
Rev. 10.2 of 23.09.2016	Revision of: - Table 3 (Recommended extrapolations), - Table 4 (Addendum to the recommended extrapolations table).
Rev. 10.1 of 01.12.2015	Revision of: - Chapter 1: Introduction - Chapter 6: Comparable residue behaviour in different crops - Deletion of Table 2 (very minor crops) - Previous tables from 3 to 6 replaced by: Table 2 (Extrapolation main rules on number of trials needed), Table 3 (Recommended extrapolations), Table 4 (Addendum to the recommended extrapolations table).
Rev. 9 of 24.03.2011	Inclusion of paragraph 1.1 Modification of paragraphs 4.1, 6.1.2, 6.2 New distribution of crops in France (Annex 1) List of major crops (table 1) Extrapolation tables 3 and 4
Rev. 8 of 01.02.2008	Extrapolation tables (tables 3 to 6)

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1 Introduction

This document provides guidelines on comparability, extrapolation, group tolerances and data requirements for pesticides residues in food and raw agricultural commodities. It is aimed not only at those intending either to register a plant protection product or to establish a maximum residue limit (MRL) for a plant protection product in a specific commodity in the European Union but also at those responsible for regulating such substances and commodities.

On the basis of existing knowledge and findings it can be assumed that, taking the least favourable trial conditions, the residue behaviour in/on plants or plant products is, under certain circumstances, comparable. In such cases, existing knowledge about the residue behaviour in one situation can be transferred to another, and the scale of the trials for the comparable situation can be reduced, or trials may even be completely unnecessary.

In the following guidelines, residue situations which are assumed to be comparable on the basis of currently available information are described, and recommendations are made as to the type and scale of the residue trial results which have to be submitted. However, new findings may result in a change of assessment of comparability.

A number of rules are based on conventions and considerations of plausibility.

Naturally, it is not possible to describe all conceivable situations, and even in established cases special factors frequently intervene which are difficult to evaluate. Deviations from these guidelines may be acceptable if fully documented and scientifically justified.

The responsibility of the applicant to submit all the data necessary for the evaluation remains unaffected.

The guidance document will be again reviewed when the work of the OECD group on the “Crop trials guidance” will be completed. At that time, the general concepts exposed in chapters 2-5 will be updated, and also brought fully in line with the requirements introduced by Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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.

1.1 Application date

The revision **10.2** of this guidance document has been presented to and noted by the representatives of the Member States during the PAFF Committee meeting of **23 September 2016**.

This revision of the guidance document is immediately applicable, as from 23 September 2016. It applies to new applications but also to those applications where assessment was already carried out by a Member State under the previous version. In such cases EFSA should use the new version to make its assessment. Where applications are already advanced in the EFSA assessment procedure and use of the new guidance would delay the overall procedure, no retroactive amendments should be carried out. The same principles apply to the Art. 12 review process.

2 **General principles**

2.1 Least favourable trial conditions

When testing residue behaviour, the principle is to choose the trial conditions that, under realistic circumstances, would be the least favourable. The 'least favourable trial conditions' are those which under the given circumstances produce what would probably be the highest residue situation according to intended use (e.g., maximum (proposed) number of applications, highest prescribed dosage, shortest PHI). The trial conditions should also be representative of the main growing regions, influence of varieties, standard application methods and times, spreading of the trials over more than one - usually two - growing seasons.

It is mainly the results of controlled residue trials that form the basis for the estimation of maximum residue levels of plant protection products in or on products of plant and animal origin. Maximum residue levels are set as high as necessary on the basis of application as provided for authorisation and as low as possible for reasons of preventive health care, and never under any circumstances higher than can be justified on toxicological grounds. In individual cases, the result of this may be that if the least favourable application conditions provided for in the authorization cease to apply, then the maximum residue limit may be set on the basis of the next most unfavourable conditions. In this case, results of residue trials must always be submitted if it can be supposed with good reason that on consideration of these next most unfavourable residue conditions the maximum residue limit might possibly be reduced by at least one category.

2.2 Definition of comparability

Comparability of residue levels for relevant different harvested crops can be assessed using 1) appropriate statistical methods and 2) taking into account the results of the calculated MRLs using the OECD calculator.

As regards point 2) results are considered comparable if the resulting maximum residue levels according to the recommended calculation procedure with the OECD calculator fall into the same or a neighbouring maximum residue limit category after rounding up or down to the nearest maximum residue limit category.

2.3 Comparative trials

Comparative trials at a single trial site must be organised in such a way that to the greatest possible extent genuinely comparable conditions can be expected. Owing to largely unpredictable weather conditions, trials at several different sites, with a sufficient regional spread, are necessary as a general principle. The number of trial sites depends on the question under investigation, but as a rule it should not be less than four for a major crop. The trials are to be carried out under conditions as close as possible to represent normal practical conditions of agriculture. Under special circumstances, however, it may also be appropriate to carry out trials under controlled conditions, e.g., in climate-controlled chambers, in which the factors that influence residue behaviour can be controlled.

2.4 Consideration of existing information and experience

The systematic evaluation of existing information and experience often make it possible to reduce the number of trials needed, or to answer the question under investigation without carrying out further trials. When evaluating trial results, existing information should always be considered and evaluated.

2.5 Properties of active substances (stability, volatility, mode of action, uptake and distribution)

It has been shown in certain cases that residue behaviour of different active ingredients is comparable. This presupposes that sufficient information (i.e. metabolism, physical-chemical properties, residue results) already exists for these active ingredients. If comparability is assumed, then this must be carefully substantiated with the existing information.

2.6 Non-relevant residues

Residues are considered to be non-relevant in the sense of the following rules if their content in the harvested product is below the limit of determination (i.e., generally between 0.01 and 0.1 mg/kg). This is often the case with the early application (e.g. applications in autumn or spring) of herbicides, applications of non-systemic insecticides and fungicides on fruits prior to flowering, and seed dressings.

The fact that no detectable residues occur or residues are non-relevant is often due to the properties of the active substance, the type and timing of application, the rate of application, and the results of metabolic studies and studies of the plant's uptake and distribution of the compound.

If no quantifiable residues occur under the least favourable trial conditions, no further trial results are required if intended use conditions are changed to less unfavourable ones.

If, however, in situations where non-relevant residues can be expected with a high degree of probability, then as an exception to the basic rules it may be possible for all trials to be carried out within one growing season. However caution must be used in generating only one season data for outdoor crops particularly if relevant residues occur in related crops since differences in residue profiles can occur between seasons. In any case, if contrary to expectations relevant detectable residues should be found, results must be obtained in a second growing season.

When the residues of an active substance are foreseen to be below the limit of quantification (limit of determination) and at least two residue trials confirm this then no further trials are normally necessary. In the case of relatively unstable residues, this interval should be checked.

3 **Changes in the trial parameters**

The following guidelines presuppose that in each case the original situation is sufficiently well documented.

If, when changes are made to the trial parameters, the obtaining of further residue results is considered not to be necessary, then thorough justification for this must be submitted. A justification could be, for instance, that existing trial results show that relevant residues are unlikely to occur.

3.1 Changes in formulation

Ideally, and as a general principle, residue trials should be carried out using the formulation to which the authorisation applies, or for which the application has been made. If there is a significant change in formulation, therefore, new residue trials are, in principle, necessary. It has proved sufficient to carry out four comparative trials on each crop selected. Data are not needed for all crops, but should be generated for 3 major crop groups which may be treated - data for a single representative crop for each group should be generated, e.g. a fruit, a leafy crop, a root crop, a cereal/grass crop, pulses and oilseeds, etc.). The trials should preferably be carried out on crops that would be expected to show high levels of residues. The timing of treatment is also important in this situation. Where treatments are made to the soil or to the seed the formulation is not important and where treatment is to a very young crop the effect of co-formulants is likely to be minimal. In cases of minor changes in formulation, which would not be expected to have any influence on efficacy and residue behaviour, additional trials may be waived.

Notwithstanding the above, experience shows that EC, WP, WG, and SC formulations usually produce comparable residues (especially if the last application is more than seven days prior to harvest) and well-justified and documented departures from the above could be considered.

Changes in formulations on the basis of a change in the content of formulants need to be evaluated on a case by case basis. Special consideration should be given to changes in the content of adjuvants like wetting agents which lead to a better penetration of the active substance into the plant particularly where the PHI is less than 7 days.

3.2 Changes in application rate

In order to encompass the least favourable trial conditions, the trials must as a matter of principle be carried out using the highest rate (e.g. kg/ha) of application. In the case of active substances which act via the soil (e.g., pre-emergence herbicides), the application rate appropriate for the particular type of soil should be used. The conditions for comparability of trials with different application rates and for using the 25% rule are laid down in the "Principles and guidance for application of the proportionality concept" which was agreed in the 45th session of CCPR¹ with the support of the EU. If residue trials with a higher application rate than the intended uses indicate that no detectable residues are to be expected, the number of trials can be reduced.

3.3 Changes in number of applications

¹ Appendix VIII of Rep 13/PR and Annex C of the Risk Analysis Principles (Procedural Manual of the Codex Alimentarius Commission)

In order to encompass the least favourable trial conditions, the trials must be carried out as a matter of principle using the maximum number of application provided for in the registered GAP. It is generally the last application prior to harvest that is crucial to residue behaviour in the harvested crop. The number of applications prior to flowering, on the other hand, is generally of lesser importance. In the case of relatively persistent residues in plants, the results can be assumed to be comparable if the number of applications are increased or reduced by not more than 25 % (e.g., 4 ± 1 or 8 ± 2 applications). In the case of relatively non-persistent residues in plants, the results can also be assumed to be comparable if the number of applications are increased or reduced by more than 25 %. Persistence should be defined on a case-by-case basis on the basis of residue-decline studies.

3.4 Changes in application method

Different application methods, such as spraying, drenching, dusting, misting and granule spreading, will as a rule not produce comparable residue results, and must therefore be documented separately. The results from normal spraying and low-volume spraying may be comparable for a comparable rate of application for the active substance per ha. However where both, low-volume and normal spray applications, are the usual methods, both methods of application ought to be documented according to standard application practice in the basic data set submitted.

In tall crops one should take note of the fact that the application rate may depend on the surface area of the leaves. For this reason in former times the amount applied was given in kg ai per hl. In such cases residue trials should be carefully planned. In certain circumstances it may be necessary to explain that a residue trial result fall within a given GAP.

3.5 Changes in timing of application; changes in pre-harvest interval

The stage of development of the crop at the time of application and the time intervals between applications, especially between the last two applications, are important factors influencing the level of residues. Because the least favourable residue situation is the determining factor when establishing maximum residue limits (MRLs), then applications at later stages of development will encompass applications made at earlier stages of development, just as applications at shorter intervals before harvesting will encompass applications at longer intervals before harvesting (but note Section 2.1).

In the case of changes in pre-harvest interval of not more than 25 %, experience has shown that the residue results can be assumed to be comparable.

3.6 Area of application (outdoors, under glass, in store, protective covering)

The results of outdoor trials are not normally comparable with the results of trials carried out under other conditions of application. The climatic conditions, above all, under glass, under plastic, or in climate-controlled chambers or in stores, but also the other parameters that differ from those in outdoor trials, generally create markedly different residue situation than that found in outdoor testing. Therefore, separate studies are necessary for each area of application unless a 'worst case' can be clearly identified.

3.7 Simultaneous changes in several trial parameters

The 25 % rule (mentioned in Sections 3.2, 3.3 and 3.5 for purposes of comparability) only applies where just one of the parameters is changed. Where more than one parameter is changed at the same time, the effects may be cumulative, or may cancel each other out.

Thus, for example, increasing the application rate by 20 %, while at the same time reducing the number of applications from 4 to 3, will probably result in comparable residue behaviour. If however, the number of applications were instead increased from 4 to 5, it would be likely that the residue behaviour would no longer be comparable. The stability of the active substance and the timing of applications and intervals between applications naturally also play a crucial part in this.

If more than two trial parameters are changed at the same time, experience suggests that it is then no longer possible to assume comparable residue behaviour with any sufficient degree of certainty.

4 **Comparable climatic zones/weather influences**

One important parameter influencing the residue behaviour is the climatic difference between production areas. Due to the inherently higher level of homogeneity in residues arising from post-harvest treatments or protected crops, one should differentiate between outdoor applications, glasshouse applications and post-harvest treatments. Some of the following observations were recommended during the Scientific Workshop held at the Pesticides Safety Directorate, York, UK on 6-8 September 1999.

4.1 Outdoor applications

Although the climatic conditions and weather influences in the two geographical zones described below are comparable, trials data should be representative for the different zones where an EU authorisation is granted or envisaged.

Northern and Central Europe (NEU):

Sweden, Norway, Iceland Finland, Denmark, United Kingdom, Ireland, Belgium, The Netherlands, Luxembourg, Germany, Poland, Czech Republic, Slovakia, Austria, Hungary, Switzerland, Estonia, Latvia, Lithuania, Romania, Slovenia.

Southern Europe and the Mediterranean (SEU):

Spain, Portugal, Italy, Greece, Malta, Croatia, Serbia, Bosnia and Herzegovina, FYROM (Former Yugoslav Republic of Macedonia), Turkey, Bulgaria, Cyprus.

France:

France metropolitan territory is divided between the two geographical zones. Annex 1 illustrates the distribution of France regions and departments in the zones and the corresponding crops distribution.

Data from different countries within the same region may reflect different cultural practices and they might therefore be rejected. The agricultural practice defining the worst-case situation should be used to generate data to define the MRL. Results from regions that are not climatically comparable cannot in general serve as a total substitute for trials carried out in comparable regions. They do, however, add to knowledge about the residue behaviour of the active substance.

The evaluation of intended uses within the EU should be based on residue data mainly generated within the EU. 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 are comparable.

4.2 Glasshouse applications

In the past it was demonstrated by comparative trials that for protected crops (glasshouse, plastic tunnel where the environmental conditions can be controlled) only one zone in Europe may exist. In these trials especially the temperature was measured and it was shown that for growing crops under glass an optimum range in temperature is necessary which is independent from the geographical region in Europe as defined above. Since cultivation under glass is predominantly a European practice, little data are available to show that this is true for the rest of the world. Cultural conditions were essentially optimised to suit the protected crop and it should be possible with further work (comparison of crop/growing conditions) to decide whether glasshouses could be considered as a "single zone" on a world-wide basis.

The evaluation of intended glasshouse uses within the EU should therefore be based on residue data generated within the EU assuming that this is one "single zone". Generally trials should be spread over different Member States (from both regions as designed above) and seasons.

In case of photo degradable active substances this proposal should be carefully considered. In such a case it may be necessary to still conduct trials in both regions as described in point 4.1.

4.3 Post-harvest treatments

Residues arising from post-harvest treatments are expected to have an inherently higher level of homogeneity and not to be affected by climatic conditions. Differences in residue level may be associated with different store types and an inhomogeneous distribution of the applied plant protection product within the stored products. With regard to the required number of trials post-harvest treatments were therefore considered as a "single zone" world-wide.

Post-harvest treatments on cereals should generally produce a homogeneous and predictable residue. Where the residue is persistent or where the required storage interval is small, the MRL may be set at the application rate without residue trials data. However, it should be noted that processing studies with incurred residues were likely to be necessary as a result of post-harvest treatments.

Post-harvest treatments on potatoes should also produce a predictable residue, but less homogeneous than for cereals and trials will be required. Post-harvest spraying or dipping of fruits and vegetables produces a less predictable residue, but possibly more homogeneous than for potatoes and trials will be required.

5 Residue decline studies/values at harvest

Residue decline studies are residue trials with samples taken usually on five occasions, of which two are often fixed times: the day of the final application and the time of harvesting. In all cases the proposed pre-harvest intervals, or growth stage at treatment, must be taken into account when taking samples. Residue decline studies are not normally required when there is no significant part of consumable crop present at the time of application.

Despite higher trial and analysis costs, residue decline studies have several advantages over values at harvest (the taking of samples at the time of harvesting) in that they provide an opportunity of assessing the residue behaviour over a period of time, and from the dissipation curve obtained in this way it is possible to make a relatively reliable estimate of residues at the time of harvesting (e.g., by identifying outliers and/or the important influencing factors, such as relative decrease in residues as a result of plant growth and the effects of the weather (temperature, precipitation)). In addition, residue decline studies also make possible to monitor initial deposits.

From the above it will be clear that residue decline studies are particularly appropriate and necessary in cases where a pre-harvest interval has to be determined, or where the possibility cannot be ruled out that various different pre-harvest intervals may be considered. Especially in these cases the last sampling time need not to coincide with the PHI. Where PHIs of up to 3 days are foreseen, residue at harvest studies with sampling at 0 and 3 days are sufficient. At a PHI of 4 to 7 days, decline studies can be shortened to 3 sampling points. Only in a few specific circumstances (especially systemic substances which are taken up by roots) it may be necessary to take samples beyond the proposed PHI.

If a plant protection product is used several times during the growing season of a crop, it is recommended, that the first sample should be taken immediately prior to the final application; this makes it possible to ascertain the influence of the previous applications on the level of residues.

Under certain circumstances (e.g., in the case of applications of a plant protection product in cereals prior to flowering), owing to the fact that the sample material is not comparable (green matter, ears, grain/straw) it is sufficient to carry out trials consisting of less than five sampling times (e.g. three sampling times).

Experience has also shown that in some circumstances the knowledge gained from about 2 - 3 value-at-harvest results from different trials may be comparable with that gained from a single residue decline study.

As already stated, in a normal residue decline study samples are taken, following treatment, from a single treated plot at appropriate intervals right up to harvesting. Alternatively, it is possible to carry out so-called 'reverse residue decline studies', and this is especially recommended where the pre-harvest interval may range over a relatively long period of time. In a reverse residue decline study, the product is applied to neighbouring plots at intervals corresponding to the possible treatment period prior to harvesting, and samples are taken from all the plots at the same time, at harvesting. For an explanation of 'reverse residue decline studies', see Figure 2.

6 Comparable residue behaviour in different crops

6.1. Prerequisites

Before discussing residue behaviour some prerequisites have to be fulfilled.

Firstly, it is essential to know the metabolism, uptake, distribution, and expression of residues in plants of the active substance in question. It is also desirable to know the mode of action to help explain the possible behaviour of the active substance in the plants. If this is not known, then nothing can be stated about the possibility of extrapolation in advance.

Extrapolation of residue data for different crops presumes that the following are comparable:

- conditions of use with regard to the amount of active substance applied, the time of application, the number of applications, and the interval between applications;
- application methods (e.g. by-hand, type of machines, seeding rate);
- formulation used and presence of synergists/adjuvants;
- climatic conditions.
- soil characteristics (acid, basic) and its texture

The applicant must substantiate with documentary evidence that all variables including Good Agricultural Practice (GAP) are comparable. In all cases, all the available facts must be considered by an experienced expert in order to make the evaluation.

6.2 Extrapolation main rules

The very first factor which must be considered in order to set the number of trials needed is whether the crop is considered as 'major' or 'minor'.

The second factor to be considered is whether the extrapolation regards a single crop or a group of crops.

Third factor is the moment of the application of the plant protection product, as for seed and post-harvest treatments fewer trials are required.

The main rules on the number of trials necessary to allow extrapolations are summarized in the Table 2. It must be born in mind that the table reflects only the most common situations. Some flexibility can be considered in specific cases, unforeseen in the table, and which need to be well detailed.

6.2.1. 'Major crops'

The following are the criteria used for classifying a crop or a product as 'major' in the European Union:

- Daily intake contribution > 0.125 g/kg bw/day (mean daily consumption over the population) in GEMS Food Cluster Diet applicable to the concerned zone and relevant cultivation area (> 20 000 ha) and/or production (> 400 000 tonnes per year) in the zone

or

- Cultivation area > 20 000 ha and Production > 400 000 tonnes per year

For the selection of major crops for the World zone (for import tolerances) only the following criterion is used:

- Daily intake contribution > 0.125 g/kg bw/day (mean daily consumption over the population) in at least one of the 4 GEMS Food Cluster Diets or the crop is major in one of the EU residue zones.

The list of the 'major crops' is reported in Table 1.

6.2.2. Other considerations

Commission Regulation (EU) No 283/2013 has clarified that the numbers of studies to be performed may be reduced if residue trials show that the residue levels in plant 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. Further reduction of the number of trials to 2 trials is possible in case of a zero residue situation.

An important information which needs to be taken into account is the properties of the active substance and in particular if it is considered as:

- non-systemic active substances, i.e. the active substance and/or relevant metabolites are not transported in the plant;

or

- systemic active substances, i.e. the active substance and/or relevant metabolites are transported in the plant.

(Though, it has been recognised that some active substances display an intermediate behaviour between the two main categories).

Consideration must be also given to the timing of application and the direction of use of the active substance.

6.3 Recommended extrapolations

The list of recommended extrapolation is reported in Table 3.

Considering the moment in which the plant protection product is applied to the crop, four different situations usually occur in the cultivation practices:

1. Last application of the pesticide takes place after forming of the edible part of the crop;
2. Last application of the pesticide takes place before forming of the edible part of the crop;
3. Seeds pesticides treatments;
4. Post-harvest applications of pesticides.

The four above situations correspond to the last four columns of Table 3.

6.3.1 Last application of the pesticide takes place after forming of the edible part of the crop

In this case extrapolation can normally be proposed based on the assumption that morphology determines the residue behaviour of the different crops. There is unlikely to be much difference between systemic and non-systemic substances in such a case.

If the active substance is not applied directly to edible parts of plants and if a transport to edible part of plants is unlikely to occur one can differentiate two cases where contamination might occur: soil-directed application of the active substance or plant-directed application of the active substance.

Case 1: Application is directed to the soil, edible parts of plants grow above the ground

Application to the soil means direct application to the soil, application to the soil with incorporation, and application with shield. When the edible parts of the plants are growing above the soil surface, and it is unlikely that the active substance is transported to the edible parts of plants, residues in these plant parts can only occur by spray drift. In this case results are necessary to demonstrate the correctness of the assumptions made, to show that residues are below the limit of quantification.

Case 2: Application is directed to the plant, edible parts of plants grow underground

When the edible parts of the plants are growing under or close by the soil surface and it is unlikely that the active substance is transported to edible parts of plants, then residues in these plant parts only can occur by dropping down of the spray solution e.g. when there are cracks in the soil or where a portion of the edible part is exposed at the surface. In this case results are necessary to demonstrate the correctness of the assumptions made, to show that residues are at the limit of quantification.

6.3.2 Last application of the pesticide takes place before forming of the edible part of the crop

For non-systemic active substances, when the plant product to be harvested is not yet formed at the time of the last application, then this use is not usually relevant (for the evaluation of residue behaviour) and therefore represents a non-residue situation. Normally no residue trials would be necessary if the situation was adequately documented and scientifically justified.

Exceptions may occur:

1. The possibility of contamination of the harvested crop needs to be considered, and if necessary residue field trial data may need to be generated.

2. If products for animal feed may be harvested before the regular harvest of the crop for human consumption. These exemptions could be defined as follows: on the basis of the feed intake it is proposed to conduct 4 trials each on rape forage and on (sugar or fodder)-beet leaves and tops and 8 trials on cereal forage and straw.

For systemic active substances, it is much more difficult to make recommendations due to the complex nature of the problem. Nevertheless data on metabolism and distribution of the active substance and the method of application of the plant protection product may help in solving the problem.

It might well be that this represents a non-residue situation but residue trials on representative crops are necessary to demonstrate the correctness of the assumptions made, to show that residues are below the limit of quantification, and to show the residue situation in products used for animal feed before forming edible parts for human consumption.

These extrapolations should apply to both systemic and non-systemic active substances with the provision that consideration needs to be given to metabolism data for each substance for which extrapolations are being proposed.

6.3.3 Seeds pesticides treatments

When a systemic active substance is applied to seeds the levels of residues in the harvested product would probably be below the LOQs, but this needs to be demonstrated.

Data may not necessarily be needed for all crops. If studies for 3 major crops representative of the crop groups treated, e.g. cereals, oilseeds and vegetables, show no quantifiable residues, then no further studies are necessary for the other crops or groups of crops. The trials should preferably be carried out on crops with a short vegetation period.

However, when contrary to expectations, quantifiable residues should be found, results must be obtained on all potential crops.

When a non-systemic active substance is applied to seeds, no residues should normally be found in plants or plant products and therefore normally no residue trials are necessary.

However, a special consideration should be given to the root vegetables for which a contamination from the treated seed could occur. In this case, a no-residue situation cannot be granted only on the fact that the active substance is a non-systemic one.

6.3.4 Post-harvest pesticides applications

In the case of post-harvest treatments there exists a broad range of different uses which could not easily be summarized. In the case of post-harvest uses, not only plant products, but also processed (including dried) products, are treated.

If the active substances are shown to be stable and if it can be demonstrated that the plant protection product could be distributed uniformly, no residue trials may be necessary, since in such a case the application rate determines the residue.

6.4 Addendum to the recommended extrapolation (Table 4)

The species nomenclature and the commodities codes used in the Table 3 are the same of the last version of the Annex I to Regulation 396/2005 (Regulation 752/2014), which became applicable from the 1st January 2015.

However, few particular terms which refer to specific crops or group of crops characteristic have been used in Table 3. The Addendum to the recommended extrapolations (Table 4) gives the explanations of these particular terms, which are not present in the Annex I to Regulation 396/2005.

7 References

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Figure 1:

Comparison of 'normal' and 'reverse' residue decline studies

Normal test series

one trial plot	samples taken on five occasions
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i.e. - 1 trial plot; treatment and sampling carried out on the single plot at intervals of time, eg., 0, 7, 14, 21 and 28 days after last treatment.

Reverse residue decline studies

1st trial plot	treatment 28 days before harvest
2nd trial plot	treatment 21 days before harvest
3rd trial plot	treatment 14 days before harvest
4th trial plot	treatment 7 days before harvest
5th trial plot	treatment immediately before harvest

i.e. - 5 neighbouring trial plots
- treatment at intervals of time (28, 21, 14, 7, 0 days before harvest on the appropriate plot)
- Sampling on all plots on the same day at the time of harvesting.

Table 1:

List of major crops.

(All crops not mentioned in this table are assumed to be minor crops).

Group of crops	Major crops	Region		
		N	S	W
1. Fruits				
(i) Citrus fruit	Grapefruits Oranges Lemons Mandarins		X X X X	X X X X
(ii) Tree nuts				
(iii) Pome fruits	Apples Pears	X X	X X	X X
(iv) Stone fruits	Apricots Cherries Peaches Plums	X X	X X X X	X X X X
(v) Berries and small fruits				
(a) Table and wine grapes	Table grapes Wine grapes		X X	X X
(b) Strawberries	Strawberries	X	X	X
(c) Cane fruit (other than wild)				
(d) Other small fruits and berries				
(vi) Miscellaneous fruit				
(a) Miscellaneous fruit - edible peel				
(b) Miscellaneous fruit - inedible peel, small	Kiwi		X	X
(c) Miscellaneous fruit - inedible peel, large	Bananas Pineapples			X X
2. Vegetables				
(i) Root and tuber vegetables				
(a) Potatoes	Potatoes	X	X	X
(b) Tropical root and tuber vegetables				
(c) Other root and tuber vegetables except sugar beet	Beetroot Carrots	X X	X X	X X
(ii) Bulb vegetables	Onions	X	X	X
(iii) Fruiting vegetables				
(a) Solanacea	Tomatoes Peppers	X X	X X	X X
(b) Cucurbits - edible peel	Cucumbers Courgettes	X	X	X X
(c) Cucurbits - inedible peel	Melons Watermelons	X	X X	X X
(d) Sweet corn				
(iv) Brassica vegetables				
(a) Flowering brassica	Cauliflower	X	X	X
(b) Head brassica	Head cabbage	X		X
(c) Leafy brassica				
(d) Kohlrabi				
(v) Leaf vegetables and fresh herbs				
(a) Lettuce and other salad plants including Brassicacea	Lettuce	X	X	X
(b) Spinach and similar (leaves)				
(c) Vine leaves				

Group of crops	Major crops	Region		
		N	S	W
(d) Water cress				
(e) Witloof				
(f) Herbs				
(vi) Legume vegetables (fresh)	Beans (with pods) Peas (without pods)	X X	X X	X X
(vii) Stem vegetables (fresh)	Leek	X		X
(viii) Fungi				
(ix) Seaweeds				
3. Pulses, dry	Beans Peas	X X	X X	X X
4. Oil seeds and oilfruits				
(i) Oilseeds	Peanut Sunflower seed Rapeseed Soya bean Cotton seed	X X X X	X X X X	X X X X
(ii) Oilfruits	Olives for oil production Palm nuts		X	X X
5. Cereals	Barley Maize Oats Rice Rye Sorghum Wheat	X X X X X X	X X X X X X	X X X X X X
6. Tea, coffee, herbal infusions and cocoa				
(i) Tea (<i>Camellia sinensis</i>)	Tea (<i>Camellia sinensis</i>)			X
(ii) Coffee beans	Coffee beans			X
(iii) Herbal infusions				
(iv) Cocoa (fermented beans)	Cocoa			X
(v) Carob (st john's bread)				
7. Hops				
8. Spices				
9 Sugar plants	Sugar beet	X	X	X
12. Crops exclusively used for animal feed	Fodder beet	X		X

Notes:

N = Northern Europe

S = Southern Europe

W = World productions

X = Major Crop

Table 2:

Extrapolation main rules on the number of trials needed.

from		to		N° trials needed, in each geographical zone (NEU or SEU), to allow extrapolations	
				after and before forming of the edible part	seed and post-harvest treatments
Major crop	→	Single major crop	=	8	4
Minor crop				not possible	not possible
Major crop	→	Single minor crop	=	4	4
Minor crop	→				
Major crop	→	Group with only minor crops	=	6	4
Minor crop	→				
Major crop	→	Group with minor and major crops	=	8	4
Minor crop				not possible	not possible
Major crop	→	Group with minor and major crops (with residues lower than LOQs)	=	4	4
Minor crop	→			3	3

Table 3:
Recommended extrapolations

This table is an integral part of the document SANCO 7525/VI/95, Rev. 10.3.

The extrapolations are listed taking into consideration the crop to which the extrapolations are allowed.

The double arrows symbol is used when both the crops involved in the extrapolation belong to the same group/subgroup (ex.: stone fruits).

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0100000	Category 01: FRUITS, FRESH or FROZEN; TREE NUTS							
0110000	Citrus fruits	lemons (0110030)	↔	mandarins (0110050) limes (0110040)	YES	YES		
		8 trials on oranges (0110020) and/or grapefruits (0110010) + 8 trials on lemons (0110030) and/or mandarins (0110050)	→	Whole group Citrus fruits (0110000)	YES	YES		
		4 trials on oranges (0110020) + 4 trials on mandarins (0110050)	→					YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0110000	Citrus fruits	apples (0130010) (minimum 4 trials on apples) + citrus fruits (0110000)	→	Whole group Citrus fruits (0110000)		YES		
		apples (0130010) (minimum 4 trials on apples) + stone fruits (0140000)	→			YES		
0120000	Tree nuts	6 trials in total on two representatives of the group Tree nuts (120000), except coconuts (0120050)	→	Whole group Tree nuts (0120000)	YES (1)	YES		
		4 trials on brazil nuts (0120020) or cashew nuts (0120030) or hazelnuts/cobnuts (0120060) or pistachios (0120100)	→					YES (1)(4)

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0120000	Tree nuts	apples (0130010) (minimum 4 trials on apples) + citrus fruits (0110000)	→	Whole group Tree nuts (120000)		YES		
		apples (0130010) (minimum 4 trials on apples) + stone fruits (0140000)	→			YES		
0130000	Pome fruits	apples (0130010)	→	Whole group Pome fruits (130000)	YES	YES		YES
		apples (0130010) (minimum 4 apples trials) + pears (0130020)	→		YES	YES		
		apples (0130010) (minimum 4 trials on apples) + citrus fruits (0110000)	→			YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0130000	Pome fruits	apples (0130010) (minimum 4 trials on apples) + stone fruits (0140000)	→	Whole group Pome fruits (130000)				
0140000	Stone fruits	apricots (0140010)	→	peaches (0140030)	YES	YES		
		plums (0140040)	↔	apricots (0140010)				YES
		peaches (0140030) + apricots (0140010) (with minimum 50% of the trials on apricots)	→	apricots (0140010)	YES	YES		
			→	peaches (0140030)				
		apples (0130010) (minimum 4 trials on apples) + citrus fruits (0110000)	→	Whole group Stone fruits (140000)				
apples (0130010) (minimum 4 trials on apples) + stone fruits (0140000)	→							

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0140000	Stone fruits	sour cherries/morello cherries (0140020-006)	↔	cherries (sweet) (0140020)	YES	YES		
0150000	Berries and small fruits	4 trials on strawberries (0152000) + 4 trials on any representative of the subgroups: - (a) grapes, - (c) cane berries, - (d) other small fruits and berries	→	Whole group Berries and small fruits (0150000)		YES		
0151000	Subgroup (a) grapes	table grapes (0151010) or wine grapes (0151020)	↔	wine grapes (0151020)	YES	YES		
			↔	table grapes (0151010)	YES	YES		
		table grapes (0151010) + wine grapes (0151020)	↔	wine grapes (0151020)	YES	YES		
			↔	table grapes (0151010)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0153000	Subgroup (c) cane fruits	raspberries (red and yellow) (0153030)	↔	blackberries (0153010)	YES	YES		
		raspberries (red and yellow) (0153030)	→	Whole subgroup (c) cane fruits (0153000)	YES	YES		
		any two representative of the subgroup (c) cane fruits (0153000)			YES	YES		
0154000	Subgroup (d) other small fruits and berries	currants (black, red and white) (0154030)	→	Whole subgroup (d) other small fruits and berries (0154000)	YES	YES		
		4 trials on currants (black, red and white) (0154030) + 2 trials on any representative of the subgroups: - (a) grapes (0151000); - (d) other small fruits and berries (0154000)	→		YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0160000	Miscellaneous fruits	one representative of each of the three subgroups of the group Miscellaneous fruits (4 trials each)	→	Whole group Miscellaneous fruits (01560000)		YES		
0161000	Subgroup (a)edible peel	apples (0130010) and/or pears (0130020)	→	Kaki/Japanese persimmons (0161060)	YES	YES		
		table olives (0161030)	↔	olives for oil production (0402010)	YES	YES		
0162000	Subgroup (b) inedible peel, small	kiwi fruits (green, red, yellow) (0162010) and/or passionfruits/maracujas (0162030)	→	Whole subgroup (b) inedible peel, small (0162000)	YES	YES		YES
0163000	Subgroup (c) inedible peel, large	avocados (0163010) and/or mangoes (0163030)	→	Whole subgroup (b) inedible peel, large (0163000), except bananas (0163020)				YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0200000	Category 02: VEGETABLES, FRESH or FROZEN							
0210000	Root and tuber vegetables	8 trials on carrots (0213020) + 8 trials on potatoes (0211000)	→	Whole group Root and tuber vegetables (0210000)	YES	YES		
0212000	Subgroup (b) tropical root and tuber vegetables	potatoes (0211000)	→	Whole subgroup (b) tropical root and tuber vegetables (0212000)	YES	YES		YES
		sweet potatoes (0212020)	→		YES	YES		YES
		yams (0212030)	→		YES	YES		YES
		6 trials in total from potatoes (0211000) + sweet potatoes (0212020) + yams (0212030)	→		YES	YES		YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0213000	Subgroup (c) other root and tuber vegetables except sugar beets	carrots (0213020)	→	Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000)	YES	YES		YES
		swedes/rutabagas (0213100)	↔	turnips (0213110)	YES	YES		
		swedes/rutabagas (0213100) or turnips (0213110)	→	celeriacs/turnip rooted celeries (0213030)	YES	YES		
			→	horseradishes (0213040)	YES	YES		
		sugar beets (0900010)	→	beetroots (0213010)	YES	YES		
		sugar beets (0900010)	→	celeriacs/turnip rooted celeries (0213030)	YES	YES		
			→	horseradishes (0213040)	YES	YES		
			→	swedes/rutabagas (0213100)	YES	YES		
			→	turnips (0213110)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0213000	Subgroup (c) other root and tuber vegetables except sugar beets	4 trials on carrots (0213020) + 4 trials on any major crop of the: - subgroup (c) other root and tuber vegetables except sugar beets (0212000); - group Bulb vegetables (0220000); - group Stem vegetables (0270000.	→	Whole subgroup (c) other root and tuber vegetables except sugar beets (0213000)			YES	
0220000	Bulb vegetables	onions (0220020)	→	garlic (0220010)	YES	YES		
				shallots (0220030)	YES	YES		
		leeks (0270060)	→	spring onions/green onions and Welsh onions (0220040)	YES	YES	YES	
		onions (0220020)	→	Whole group Bulb vegetables (0220000)			YES	YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0220000	Bulb vegetables	4 trials in total on onions (0220020) + leeks (0270060)	→	Whole group Bulb vegetables (0220000)			YES	
		4 trials on carrots (0213020) + 4 trials on any major crop of the: - subgroup (c) other root and tuber vegetables except sugar beets (0212000); - group Bulb vegetables (0220000); - group Stem vegetables (0270000.	→				YES	YES
0230000	Fruiting vegetables	8 trials on tomatoes (0231010) + 8 trials on cucumbers (0232010)	→	Whole group Fruiting vegetables (0230000), except sweet corn		YES		
		4 trials on tomatoes (0231010) + 4 trials on cucumbers (0232010)	→				YES	

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0230000	Subgroup (a) solanaceae	tomatoes (0231010)	→	aubergines/eggplants (0211030)	YES	YES		
		peppers (0231020)	→	okra/lady's fingers (0231040)	YES	YES		
0232000	Subgroup (b) cucurbits with edible peel	cucumbers (0232010)	→	Whole subgroup (b) cucurbits with edible peel	YES	YES		
		courgettes (0232030)	→		YES	YES		
		cucumbers (0232010) + courgettes (0232030) (8 trials in total)	→		YES	YES		
0233000	Subgroup (c) cucurbits with inedible peel	melons (0233010)	→	Whole subgroup (c) cucurbits with inedible peel	YES	YES		YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0234000	Subgroup (d) sweet corn	immature maize*	→	sweet corn (0234000)	YES	YES	YES	
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)	8 trials on head cabbages (0242020) + 8 trials on cauliflower (0241020)	→	Whole subgroups (a) flowering brassica (0241000) and (b) head brassica (0242000)		YES		
		4 trials on any major crop of the group Brassica vegetables (excluding brassica roots and brassica baby leaf crops) (0240000) + 4 trials on any major crop of the subgroup (a) lettuces and salad plants	→	Whole group Brassica vegetables (excluding brassica roots and brassica baby leaf crops) (0240000)			YES	
0241000	Subgroup (a) flowering brassica	4 trials on cauliflower (0241020) + 4 trials broccoli (0241010)	→	Whole subgroup (a) flowering brassica (0241000)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0243000	Subgroup (c) leafy brassica	kales (0243020)	→	Whole subgroup (c) leafy brassica (0243000)	YES	YES		
		lettuces (0251020), pre-emergence*	→	Whole subgroup (c) leafy brassica (0243000), pre-emergence*		YES		
0250000	Leaf vegetables, herbs and edible flowers	4 trials on any major crop of the group Brassica vegetables (excluding brassica roots and brassica baby leaf crops) (0240000) + 4 trials on any major crop of the subgroup (a) lettuces and salad plants	→	Whole group Leaf vegetables, herbs and edible flowers (0250000), except subgroups: - (c) grape leaves and similar species (0253000); - (d) watercresses; - (e) witloofs/Belgian endives			YES	
0251000	Subgroup (a) lettuces and salad plants	lettuces (0251020) (trials from open leaf varieties*)	→	Whole subgroup (a) lettuces and salad plants (0251000)	YES	YES		
		lettuces (0251020), pre-emergence*	→	Whole subgroup (a) lettuces and salad plants (0251010), pre-emergence*		YES		
		lettuces (0251020) (trials from open leaf varieties*)	→	escaroles/broad leaved endives (0251030)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0251000	Subgroup (a) lettuces and salad plants	spinaches (0252010) and/or lamb's lettuces (0251010) and/or lettuces (0251020) (trials from open leaf varieties*)	→	roman rocket/rucola (0251060)	YES	YES		
		and/or escaroles/broad leaves endives (0251030)	→	red mustards (0251070)	YES	YES		
		and/or Roman rocket/rucola (0251060) and/or chards/beet leaves (0252030)	→	baby leaf crops (including brassica species) (0251080)	YES	YES		
0252000	Subgroup (b) spinaches and similar leaves	spinaches (0252010)	→	Whole subgroup (b) spinaches and similar leaves (0252000)	YES	YES		
		lettuces (0251020) (trials from open leaf varieties*)	→					
		lettuces (0251020), pre-emergence*	→	Whole subgroup (b) spinaches and similar leaves (0252000), pre-emergence*		YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
254000	Subgroup (d) watercresses	lettuces (0251020) (trials from open leaf varieties*)	→	Whole subgroup (d) watercresses (0254000)	YES	YES		
0256000	Subgroup (f) herbs and edible flowers	any representative of the subgroup (f) herbs and edible flowers (0256000), except sage (0256050), rosemary (0256060), thyme (0256070), laurel/bay leave (0256090)	→	Whole subgroup (f) herbs and edible flowers (0256000)	YES	YES		
		spinaches (0252010)	→					
		lettuces (0251020) (trials from open leaf varieties*)	→					
		spring onions/green onions and Welsh onions (0220040) and/or leeks (0270060)	→	chives (0256020)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:					
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*		
0260000	Legume vegetables	beans (with pods) (0260010)	↔	peas (with pods) (0260030) (2)	YES	YES				
		beans (without pods) (026020)	↔	peas (without pods) (0260040) (2)	YES	YES				
		beans (with pods) (0260010)	→	Whole group Legume vegetables (0260000)			YES			
		peas (with pods) (0260030)	→							
		beans (pulses) (0300010)	→					YES		
		peas (pulses) 0300030)	→							
0270000	Stem vegetables	spring onions/green onions and Welsh onions (0220040)	→	leeks (0270060)	YES	YES				
		celeriers (0270030)	→	cardoons (0270020)	YES	YES				
			→	Florence fennels (0270040)	YES	YES				
			→	rhubarbs (0270070)	YES	YES				

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0270000	Stem vegetables	leeks (0270060)	→	Whole group Stem vegetables (0270000)			YES	
		4 trials on onions (0220020) + 4 trials on leeks (0270060)	→				YES	
		4 trials on carrots (0213020) + 4 trials on any major crop of the: - subgroup (c) other root and tuber vegetables except sugar beets (0212000); - group Bulb vegetables (0220000); - group Stem vegetables (0270000).	→				YES	
0280000	Fungi, mosses and lichens	any representative of the group Fungi, mosses and lichens (0280000)	→	Whole group Fungi, mosses and lichens (0280000)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0300000	Category 03: PULSES							
		beans (0300010)	→	Whole category PULSES (0300000) (2)	YES	YES	YES	YES
		peas (0300030)	→		YES	YES	YES	YES
		beans (0300010) + peas (0300030)	→		YES	YES	YES	YES
		beans (with pods) (0260010)	→			YES	YES	YES
		peas (with pods) (0260030)	→			YES	YES	YES
		beans (with pods) (0260010) + peas (with pods) (0260030)	→			YES	YES	YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0400000	Category 04: OILSEEDS AND OIL FRUITS							
0401000	Oilseeds	rapeseeds/canola seeds (0401060)	→	linseeds (0401010)	YES	YES	YES	YES
			→	poppy seeds (0401030)				
			→	mustard seeds (0401080)				
			→	gold of pleasure seeds (0401130)				
		4 + 4 trials of two representatives of the major oilseeds*, except peanuts/groundnuts (0401020)	→	all minor oilseeds*	YES	YES	YES	YES
		any representatives of the group Oilseeds*, except peanuts/groundnuts (0401020)	→	Whole group Oilseeds (0401000), except peanuts/groundnuts (0401020)		YES	YES	
8 trials on any representatives of the group Oilseeds* + 4 trials on peanuts/groundnuts (0401020)	→	Whole group Oilseeds (0401000)			YES			

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0401000	Oilseeds	4 trials on soya beans (0401070) + 4 trials on peanuts/groundnuts (0401020)	→	Whole group Oilseeds (0401000)				YES
		sunflower seeds (0401050) or rapeseeds/canola seeds (0401060) or cotton seeds (0401090)	→	sunflower seeds (0401050)				YES
			→	rapeseeds/canola seeds (0401060)				YES
			→	cotton seeds (0401090)				YES
0402000	Oil fruits	olives for oil production (0402010)	↔	table olives (0161030)	YES	YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0500000	Category 05: CEREALS							
		barley (0500010)	→	oat (0500050)	YES			
		maize/corn (0500030)	→	sorghum (0500080)	YES	YES	YES	
		maize/corn (0500030)	→	common millet/proso millet (0500040)	YES	YES	YES	
		wheat (0500090)	→	rye (0500070)	YES			
		barley (0500010)	→	oat (0500050); rye (0500070); wheat (0500090).		YES		
		oat (0500050)	→	barley (0500010); rye (0500070); wheat (0500090).		YES		
		rye (0500070)	→	barley (0500010); oat (0500050); wheat (0500090).		YES		

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
		wheat (0500090)	→	barley (0500010); oat (0500050); rye (0500070).		YES		
		4 trials on any of barley (0500010), oat (0500050), rye (0500070), wheat (0500090)	→	barley (0500010); oat (0500050); rye (0500070); wheat (0500090).			YES	YES
		4 trials on maize/corn (0500030) or sorghum (0500080) + 4 trials on anyone of barley (0500010), oat (0500050), rye (0500070) or wheat (0500090)	→	Whole category CEREALS (0500000)			YES	YES
		wheat (0500090)	→	barley (0500010); oat (0500050); rye (0500070); wheat (0500090).				YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0600000	Category 06: TEA, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS							
0620000	Coffee beans	cocoa beans (0640000)	↔	coffee beans (0620000)				YES
0631000	Subgroup (a) herbal infusions from flowers	any representative of the subgroups: - (a) herbal infusions from flowers (0631000); - (b) herbal infusions from leaves and herbs (0632000).	→	Whole subgroup (a) herbal infusions from flowers (0631000)	YES	YES	YES	YES
		any representative of the groups: - Bud spices (0850000); - Flower pistil spices (0860000); - Aril spices (0870000).	→					YES
0632000	Subgroup (b) herbal infusions from leaves and herbs	any representative of the subgroups: - (a) herbal infusions from flowers (0631000); - (b) herbal infusions from leaves and herbs (0632000).	→	Whole subgroup (b) herbal infusions from leaves and herbs (0632000)	YES	YES	YES	YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0632000	Subgroup (b) herbal infusions from leaves and herbs	any representative of the subgroup (f) herbs and edible flowers (0256000) (5)	→	Whole subgroup (b) herbal infusions from leaves and herbs (0632000)	YES	YES	YES	YES
		lettuces (0251020) (trials from open leaf varieties)* (5)	→		YES	YES	YES	YES
		any representative of the groups: - Bud spices (0850000); - Flower pistil spices (0860000); - Aril spices (0870000).	→					YES
0633000	Subgroup (c) herbal infusions from roots	any representative of the subgroup (c) herbal infusions from roots (0633000).	→	Whole subgroup (b) herbal infusions from roots (0633000)	YES	YES	YES	YES
		any representative of the group Root and tuber vegetables (0210000) (5)	→		YES	YES	YES	YES
		any representative of the group Root and rhizome spices (0840000)	→					YES
640000	Cocoa beans	coffee beans (0620000)	↔	cocoa beans (0640000)				YES

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0800000	Category 08: SPICES							
0810000	Seed spices	any representative of the group Seed spices (0810000)	→	Whole groups Seed spices (0810000) and Fruit spices (0820000)	YES	YES	YES	YES
0820000	Fruit spices	any representative of the group Fruit spices (0820000)	→	Whole groups Seed spices (0810000) and Fruit spices (0820000)	YES	YES	YES	YES
0840000	Root and rhizome spices	any representative of the group Root and rhizome spices (0840000)	→	Whole group Root and rhizome spices (0840000)	YES	YES	YES	YES
		any representative of the subgroup (c) herbal infusions from roots (0633000)	→					
		any representative of the group Root and tuber vegetables (0210000)	→					

Code number	Group or Subgroup	Extrapolation			Allowed for treatments:			
		Trials available	Direction	Possible extrapolation	After forming of the edible part*	Before forming of the edible part*	Seed treatments	Post harvest*
0850000 0860000 0870000	Bud spices Flower pistil spices Aril spices	any cultivated representative of the subgroups: - (a) herbal infusions from flowers (0631000); - (b) herbal infusions from leaves and herbs (0632000).	→	Whole groups Bud spices (0850000); Flower pistil spices (0860000); Aril spices (0870000).	YES	YES		
0900000	Category 09: SUGAR PLANTS							
		carrots (0213020)	→	sugar beets (090010)			YES	YES
		4 trials on carrots (0213020) + 4 trials on any major crop of the: - subgroup (c) other root and tuber vegetables except sugar beets (0212000); - group Bulb vegetables (0220000); - group Stem vegetables (0270000).	→	sugar beets (090010)			YES	YES
		sugar beets (0900010)	→	chicory roots (0900030)	YES	YES		
		carrots (0213020)	→					
		maize (whole plant fresh)	→	sugar canes (0900020)		YES (3)		

Footnotes to Table 3

*	For the explanation of the terms: - after forming of the edible part; - before forming of the edible part; - post harvest; - immature maize; - pre-emergence; - lettuces from open leaf varieties; - major oilseeds; - minor oilseeds; see the Addendum to the recommended extrapolations table (Table 4).
(1)	The extrapolation is not allowed from trials of pistachios (0120100), if the last application took place at a growth stage, when the pistachios were already open.
(2)	Consideration should be given to possible contamination from mechanical harvesting.
(3)	Extrapolation allowed only for herbicides.
(4)	Post-harvest use refers to nuts after the removal of the shell.
(5)	An appropriate concentration factor must be applied.

Table 4:

Addendum to the recommended extrapolations table.

Explanations of terminology used in the Table 3 of this guidance and not present in the Annex I to Regulation (EC) No 396/2005.

	Term	Explanation
1	After forming of the edible part	The expressions "after forming of the edible part" and "before forming of the edible part" correspond to the definition given in the Annex to Commission Regulation (EU) No 283/2013 of 1 March 2013, Section 6.3. Magnitude of residue trials in plants):
2	Before forming of the edible part	<p><i>"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.</i></p> <p><i>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)".</i></p> <p>In case of cereals "before forming of the edible part" must be intended as before stage BBCH 51.</p>
3	Post harvest	<p>Post harvest treatments can be authorized for:</p> <ul style="list-style-type: none"> - plants, as defined in Art. 3 of Reg. 1107/2009 (live plants and live parts of plants, including fresh fruit, vegetables and seeds) or - plant products, as defined in Art. 3 of Reg. 1107/2009 (products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, but excluding plant).
4	Immature maize	Maize harvested at BBCH stage 75, and in any case before BBCH stage 85.
5	Lettuces, open leaf varieties	<p>The following varieties listed in part B of Annex I to Regulation (EC) No. 396/2005:</p> <ul style="list-style-type: none"> - 0251020-002 - Cutting lettuces (<i>Lactuca sativa</i> Cutting group) - 0251020-004 - Romaines/cos lettuces/lollo bionda/lollo rosso (<i>Lactuca sativa</i> Cos group)
6	Lettuces, closed leaf varieties	<p>The following varieties listed in part B of Annex I to Regulation (EC) No. 396/2005:</p> <ul style="list-style-type: none"> - 0251020-001 - Crisp lettuces/iceberg lettuces (<i>Lactuca sativa</i> Crisphead group) - 0251020-003 - Head lettuces/cabbage lettuces (<i>Lactuca sativa</i> Butterhead group)

7	Pre-emergence	Prior to the emergence of the seedlings from the ground
8	Major oilseeds	<p>The oilseeds which are major crop in NEU zone, in SEU zone, in both zones or in the world:</p> <ul style="list-style-type: none"> - peanuts/groundnuts (0401020); - sunflower seeds (0401050); - rapeseeds/canola seeds (0401060); - soyabeans (0401070); - cotton seeds (0401090).
9	Minor oilseeds	<p>The oilseeds which are not major crops in NEU zone, in SEU zone, in both zones or in the world:</p> <ul style="list-style-type: none"> - linseeds (0401010); - poppy seeds (0401030); - sesame seeds (0401040); - mustard seeds (0401080); - pumpkin seeds (0401100); - safflower seeds (0401110); - borage seeds (0401120); - gold of pleasure seeds (0401130); - hemp seeds (0401140); - castor beans (0401150); - others (0401990).

Annex 1:

Division of France into two geographical zones

Division of France into two regions
(as described in Section 4)



Annex 1 (continued):

Regions and Departments of France

NORTHERN FRANCE			SOUTHERN FRANCE		
Regions		Departments	Regions		Departments
Ile-de-France	75	(Ville-de-)Paris	Pitou-Charentes	16	Charente
	77	Seine-et-Marne		17	Charente-Maritime
	78	Yvelines		79	Deux-Sèvres
	91	Essonne		86	Vienne
	92	Haute-de-Seines	Aquitaine	24	Dordogne
	93	Seine-Saint-Denise		33	Gironde
	94	Val-de-Marne		40	Landes
	95	Val-d'Oise		47	Lot-et-Garonne
Champagne-Ardenne	08	Ardennes	64	Pyrénées-Atlantiques	
	10	Aube	Midi-Pyrénées	09	Ariège
	51	Marne		12	Aveyron
	52	Haute-Marne		31	Haute-Garonne
Picardie	02	Aisne		32	Gers
	60	Oise		46	Lot
	80	Somme		65	Hautes-Pyrénées
Haute-Normandie	27	Eure		81	Tarn
	76	Seine-Maritime		82	Tarn-et-Garonne
Centre	18	Cher	Rhône-Alpes	01	Ain
	28	Eure-et-Loire		07	Ardèche
	36	Indre		26	Drôme
	37	Indre-et-Loire		38	Isère
	41	Loir-et-Cher		42	Loire
	45	Loiret		69	Rhône
Basse-Normandie	14	Calvados		73	Savoie
	50	Manche		74	Haute-Savoie
	61	Orne	Languedoc-Roussillon	11	Aude
Bourgogne	21	Côte-d'Or		30	Gard
	58	Nièvre		34	Hérault
	71	Saône-et-Loire		48	Lozère
	89	Yonne	66	Pyrénées-Orientales	
Nord-Pas-de-Calais	59	Nord	Provence-Alpes-Côte-d'Azur	04	Alpes-de-Haute-Provence
	62	Pas-de-Calais		05	Hautes-Alpes
Lorraine	54	Meurthe-et-Moselle		06	Alpes-Maritimes
	55	Meuse		13	Bouches-de-Rhône
	57	Moselle		83	Var
	88	Vosges	84	Vaucluse	
Alsace	67	Bas-Rhin	Corse	2A	Corse-du-Sud
	68	Haut-Rhin		2B	Haute-Corse
Franche Comte	25	Doubs			
	39	Jura			
	70	Haute-Saône			
	90	Territoire de Belfort			
Pays de la Loire	44	Loire-Atlantique			
	49	Maine-et-Loire			
	53	Mayenne			
	72	Sarthe			
	85	Vendée			
Bretagne	22	Côte d' Armor			
	29	Finistère			
	35	Ille-et-Vilaine			
	56	Morbihan			
Limousin	19	Corrèze			

NORTHERN FRANCE			SOUTHERN FRANCE		
Regions		Departments	Regions		Departments
	23	Creuse			
	87	Haute-Vienne			
Auvergne	03	Allier			
	15	Cantal			
	43	Haute-Loire			
	63	Puy-de-Dôme			

Annex 1 (continued):

Distribution of crops in France¹

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	S
120000	(ii) Tree nuts (shelled or unshelled)	
120010	Almonds	S
120020	Brazil nuts	W
120030	Cashew nuts	W
120040	Chestnuts	S
120050	Coconuts	W
120060	Hazelnuts (Filbert)	S
120070	Macadamia	W
120080	Pecans	W
120090	Pine nuts	S
120100	Pistachios	W
120110	Walnuts	S
120990	Others	
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	N+S
130020	Pears (Oriental pear)	N+S
130030	Quinces	N or S
130040	Medlar	N or S
130050	Loquat	N or S
130990	Others	
140000	(iv) Stone fruit	S
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	S
151020	Wine grapes	N+S
152000	(b) Strawberries	S
153000	(c) Cane fruit	N or S
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	N or S
154020	Cranberries	N or S

¹ This table has been made on the basis of data of area and production (Agreste data base). Crops present at 80% or more (area and production) in one zone are reattached to this zone. For important crops near this threshold and/or crops with potentially different GAPs between North and South residue trials from the two zones (N+S) may be required according to minor and major crops requirements (e.g. wine grapes - area : 83% South, production : 81% South).

Minor crops without data on area and production and/or not clearly reattached to one zone are identified as N or S. in this case, residue data from North and/or South are admissible.

Crops not present on metropolitan territory (e.g in Outermost Regions of France) are identified as W (world).

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
154030	Currants (red, black and white)	N
154040	Gooseberries (Including hybrids with other ribes species)	N or S
154050	Rose hips	N or S
154060	Mulberries (arbutus berry)	N or S
154070	Azarole (mediteranean medlar)	N or S
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	N or S
154990	Others	
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	W
161020	Figs	S
161030	Table olives	S
161040	Kumquats (Marumi kumquats, nagami kumquats)	W
161050	Carambola (Bilimbi)	W
161060	Persimmon	W
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	W
161990	Others	
162000	(b) Inedible peel, small	
162010	Kiwi	S
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	W
162030	Passion fruit	W
162040	Prickly pear (cactus fruit)	W
162050	Star apple	W
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	W
162990	Others	
163000	(c) Inedible peel, large	W
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	N+S
212000	(b) Tropical root and tuber vegetables	W
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	N
213020	Carrots	N+S
213030	Celeriac	N
213040	Horseradish	N
213050	Jerusalem artichokes	N or S
213060	Parsnips	N or S
213070	Parsley root	N or S
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	N+S
213090	Salsify (Scorzонера, Spanish salsify (Spanish oysterplant))	N

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
213100	Swedes	N
213110	Turnips	N
213990	Others	
220000	(ii) Bulb vegetables	
220010	Garlic	N or S
220020	Onions (Silverskin onions)	N
220030	Shallots	N
220040	Spring onions (Welsh onion and similar varieties)	N or S
220990	Others	
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	S
231020	Peppers (Chilli peppers)	S
231030	Aubergines (egg plants) (Pepino)	S
231040	Okra, lady's fingers	W
231990	Others	
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	N or S
232020	Gherkins	N or S
232030	Courgettes (Summer squash, marrow (patisson))	S
232990	Others	
233000	(c) Cucurbits-inedible peel	S
234000	(d) Sweet corn	S
239000	(e) Other fruiting vegetables	
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	N
242000	(b) Head brassica	N
243000	(c) Leafy brassica	N or S
244000	(d) Kohlrabi	N
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb's lettuce (Italian cornsalad)	N
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	N+S
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	N+S
251040	Cress	N or S
251050	Land cress	N or S
251060	Rocket, Rucola (Wild rocket)	N or S
251070	Red mustard	N or S
251080	Leaves and sprouts of Brassica spp (Mizuna)	N or S
251990	Others	
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	N

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
252020	Purslane (Winter purslane, garden purslane, common purslane, sorrel, glassworth)	N or S
252030	Beet leaves (chard) (Leaves of beetroot)	N or S
252990	Others	
253000	(c) Vine leaves (grape leaves)	S or W
254000	(d) Water cress	N or S
255000	(e) Witloof	N
256000	(f) Herbs	N or S
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	N+S
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	N
260030	Peas (with pods) (Mangetout (sugar peas))	N+S
260040	Peas (without pods) (Garden pea, green pea, chickpea)	N
260050	Lentils	N
260990	Others	
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	N+S
270020	Cardoons	N or S
270030	Celery	N or S
270040	Fennel	N or S
270050	Globe artichokes	N
270060	Leek	N+S
270070	Rhubarb	N or S
270080	Bamboo shoots	W
270090	Palm hearts	W
270990	Others	
280000	(viii) Fungi	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	N or S
280020	Wild (Chanterelle, Truffle, Morel ,)	
280990	Others	
290000	(ix). Sea weeds	
300000	3. PULSES, DRY	N
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	N
401020	Peanuts	S or W
401030	Poppy seed	N
401040	Sesame seed	S or W
401050	Sunflower seed	N+S
401060	Rape seed (Bird rapeseed, turnip rape)	N+S
401070	Soya bean	S

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
401080	Mustard seed	N
401090	Cotton seed	W
401100	Pumpkin seeds	S
401110	Safflower	S
401120	Borage	N or S
401130	Gold of pleasure	N or S
401140	Hempseed	N or S
401150	Castor bean	N or S
401990	Others	
402000	(ii) Oilfruits	
402010	Olives for oil production	S
402020	Palm nuts (palmoil kernels)	W
402030	Palmfruit	W
402040	Kapok	W
402990	Others	
500000	5. CEREALS	
500010	Barley	N+S
500020	Buckwheat	N
500030	Maize	N+S
500040	Millet (Foxtail millet, teff)	N
500050	Oats	N+S
500060	Rice	S
500070	Rye	N
500080	Sorghum	S
500090	Wheat (Spelt Triticale)	N+S
500990	Others	
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	W
620000	(ii) Coffee beans	W
630000	(iii) Herbal infusions (dried)	N or S or W
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	N
800000	8. SPICES	N or S or W
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	N
900020	Sugar cane	W
900030	Chicory roots	N
900990	Others	

(*) Zones of crops distribution:

- N : crops essentially cultivated in Northern France
S : crops essentially cultivated in Southern France
N + S : crops spread throughout the entire territory
N or S : residue data accepted from south and/or north zone
W : crops cultivated outside metropolitan France