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TECHNICAL GUIDELINES¹

ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN

(Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)

¹ This document has been conceived as Technical Guidelines of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

TABLE OF CONTENTS

1. Introduction and scope	4
1.1. Applicability of the revised Technical Guidelines	5
2. General principles	5
2.1. Geographical zones to perform residue field trials.....	5
2.2. Minimum number of residue trials	7
2.2.1. Trials applicable to minor crops	7
2.2.2. ‘< limit of quantification (LOQ) residue’ and ‘Zero residue’ situations	7
2.2.3. Specific cases related to the condition of use	8
2.2.3.1. Indoor uses	8
2.2.3.2. Post-harvest treatments.....	9
2.2.3.3. Empty storage rooms	9
2.2.3.4. Seed treatments.....	10
2.3. Season of the treatment	10
2.4. Principles for combining/pooling/merging of residue trials data sets.....	10
3. Deviations in trial parameters	11
3.1. GAP-compliance: the 25% tolerance rule	11
3.2. Deviations in application rate: the proportionality principle	12
3.3. Deviations in application rate: leaf wall area	12
3.4. Deviations of residue trials regarding the formulation	12
3.5. Deviations in application method	13
3.6. Deviations of residue trials regarding number of applications	13
3.7. Deviations in timing of application: pre-harvest interval (PHI) and interval between applications	14
4. Extrapolation for plant products.....	15
4.1. Main extrapolation principles	15
4.2 Recommended extrapolations.....	16
5. Extrapolation regarding products of animal origin	16
6. References.....	17
 Table 1: List of major crops.....	 19
Table 2: Minimum number of trials.....	21
Table 3: Recommended extrapolations.....	22
Table 4: Addendum to the recommended extrapolations table.....	500
Annex I Clarifications on “old/new” data requirements.....	522
Annex II: Division of France into two geographical zones	544
Annex III: Glossary and abbreviations.....	611

1. INTRODUCTION AND SCOPE

This document provides Technical Guidelines on data requirements for setting maximum residue levels (MRLs), comparability of residue trials and extrapolation of residue data on products from plant and animal origin – hereafter mentioned as “extrapolation guidelines” or “guidelines”. It contains further specifications and clarifications on the data requirements on residue trials of Regulations (EU) No 283/2013, (EU) No 284/2013, (EU) No. 544/2011 and (EU) No 545/2011².

It replaces the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3 and takes into account the provisions of the OECD Guidance Document on crop field trials (ENV/JM/MONO(2011)50/REV1). Recommendations relevant for the assessment of residue trials presented in the EFSA document “Residues trials and MRL calculations” (EFSA, 2015) and Guidance Document 7029/VI/95 have been also integrated.

The Extrapolation Guidelines are intended to be used by applicants who prepare their dossiers and by EU/national risk assessors and risk managers for the approval of active substances and the authorisation of plant protection products (PPPs) under Regulation (EC) No 1107/2009 and for setting MRLs in the framework of Regulation (EC) No 396/2005.

In general, residue trials should be representative for the critical Good Agricultural Practices (cGAP). The current document provides detailed illustrations on the data requirements defined in the relevant legislation. Residue situations which are assumed to be comparable on the basis of currently available information are described, and clarifications are made as to the type and minimum number of residue trials which have to be submitted. The Report from the Commission to the European Parliament and the Council on the evaluation of pesticides legislation³ concluded that there is insufficient availability of PPPs for minor uses for a number of different reasons. In order to address this, several actions have been proposed, including a commitment from the Commission to regularly update these Extrapolation Guidelines to facilitate MRL setting for minor crops.

In practice, special cases may be identified which are not fully described in these guidelines, as they would require ad-hoc approaches that cannot be described in a general document. In addition, new scientific knowledge may justify a deviation from the principles of comparability assessment described in the subsequent sections. Such deviations may therefore be acceptable if fully documented and substantiated by data.

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

² For an increasing number of applications, the data requirements defined in Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (“new data requirements”), as amended, are applicable. However, data requirements defined in Regulations (EU) No 544/2011 and 545/2011 (“old data requirements”) continue to apply for certain active substances, as detailed in Article 3 of Regulation (EU) No 283/2013 and in Guidance Document (SANTE/11509/2013– rev. 5) on the interpretation of the transitional measures for the data requirements for chemical active substances and PPPs. Annex I of this document summarises the data requirement in both frameworks.

³ https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_report_2020_en.pdf

1.1. Applicability of the Extrapolation Guidelines

These extrapolation guidelines have been presented to and noted by the representatives of the Member States during the meeting of the Standing Committee on Plants, Animals, Food and Feed (SCPAFF), section Phytopharmaceuticals – Pesticides Residues of 23/24 November 2020

They will be applicable, as from 1 January 2021 and apply to all applications submitted to the competent national authorities after that date (date of receipt of application by the competent authority); they should be used by EFSA for ongoing assessments, i.e.

- for ongoing MRL applications submitted to EFSA after 1 January 2021 (date of the mandate),
- for new and ongoing MRL reviews (call for data launched after 1 January 2021),

In cases where applications are already advanced in the EFSA assessment procedure and use of the new version would delay the overall procedure, no retroactive amendments should be carried out to align with these Guidelines. The same principles apply to the Art. 12 MRL review process.

2. GENERAL PRINCIPLES

MRLs should be set at the lowest achievable level consistent with the Good Agricultural Practice (GAP). The results of supervised residue trials⁴ conducted under conditions representative for the cGAP form the basis for the estimation of MRLs for pesticides in or on products of plant origin. The test conditions (such as maximum number of proposed applications, shortest interval between applications, maximum application rate and concentration, most critical safety intervals with regard to exposure) shall be defined to identify the highest residues which may reasonably arise and shall be representative of the realistic conditions at the cGAP under which the active substance is to be used (Reg. (EU) No 283/2013).

2.1. Geographical zones to perform residue field trials

Residue field trials should be representative for the zones where an EU authorisation is granted or envisaged. With regard to the pesticide residue assessment, the EU is divided into the two geographical zones that are considered to represent comparable conditions:

- **Northern and Central Europe (NEU):** Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France*, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, and Sweden. Iceland, Liechtenstein and Norway, as part of the Northern Zone under Regulation (EC) No 1107/2009 are considered part of the NEU under the EEA Agreement⁵.

⁴ for the meaning of these Guidelines this term is equivalent to “crop field trials” (see glossary for definition)

⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.202.01.0057.01.ENG&toc=OJ:L:2015:202:TOC

- **Southern Europe and the Mediterranean (SEU):** Bulgaria, Croatia, Republic of Cyprus, France*, Greece, Italy, Malta, Portugal and Spain.

(*) France metropolitan territory is divided between the two geographical zones. Annex II illustrates the distribution of the French regions and departments in the zones and the corresponding distribution of crops.

Residue trials should be performed in the geographical zone relevant for the GAP. The use of data from non-EU countries located in the continent Europe should be considered case-by-case, based on their equivalence with EU zones having similar climatic conditions, e.g. Switzerland, the United Kingdom for the NEU zone and Serbia, Bosnia and Herzegovina, North Macedonia, Turkey for the SEU zone.

According to Regulation (EU) No 283/2013, 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:

1. at least 50% of the number of trials in relation to the minimum number of trials required are generated within the EU⁶;
2. the trials are compliant with these EU guidelines and are representative for the intended cGAP;
3. the production and climatic conditions outside of the EU are comparable to the region of the EU for which authorisation is sought;
4. the trials generated outside the EU do not show significant deviating residue levels compared to the dataset generated within the EU (to be verified using statistical tests where appropriate);

Data packages with more than 50% non-EU trials may be acceptable in exceptional cases, e.g. in support of tropical minor crops or minor crops not covered by extrapolation in table 3 if overall uncertainty is not increased. It will be necessary to demonstrate that the agricultural practice use to generate data to define the MRL is defining the worst-case situation.

For import tolerance applications the residue trials should be performed in a geographical region which is expected to reflect the conditions of the country where the GAP is authorised and which is the basis for the application.

Residue field trials need to be performed at different geographical sites/locations to reflect the variability in production system, soil conditions and/or weather conditions. The different sites must be at least 20 km far from one another unless sufficient evidence is available to demonstrate that in shorter-distance sites significant variations occur in relevant conditions e.g. soil types, weather conditions, etc.

⁶ This may include trials performed in non-EU countries located in the continent Europe considered to reflect equivalent conditions and agreed on a case by case basis

2.2. Minimum number of residue trials

Commission Regulation (EU) No 283/2013 and Regulation (EU) No 544/2011 provide the data requirements for active substances, including the minimum number of residue trials required to derive MRL proposals for intended/notified uses of pesticides. Annex I of these extrapolation Guidelines summarises the main differences between the “old” and the “new” data requirement Regulations, providing clarifications in the number of trials required in different circumstances.

As a general rule, the minimum number of trials varies between 4 independent trials per residue zone for a minor crop and 8 independent trials per zone for a major crop. In certain specific circumstances a reduction in the number of trials is acceptable (see below):

2.2.1. Trials applicable to minor crops

According to Regulation (EU) No 283/2013, if the GAP is the same in both residue zones, 6 trials equally distributed in the representative growing zones are normally sufficient for a minor crop.

Under Regulation (EU) No 544/2011, at least 4 trials per zone are required, even if the GAP is the same in both zones.

2.2.2. ‘< limit of quantification (LOQ) residue’ and ‘Zero residue’ situations

According to Regulation (EU) No 283/2013, in the following two situations the number of studies to be performed may be reduced as follows:

- I. ‘<LOQ residue’ situation: is given when the supervised residue trials show that the residue levels in plants or plant products are lower than the limit of quantification (LOQ). In this case, the number of independent trials may be reduced. The number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops.
- II. ‘Zero residue’ situation: shall be predicted from representative plant metabolism studies and/or from studies performed under more critical conditions (supervised residue trials with exaggerated application rates (at least 3 times the envisaged application rate⁷), the number of applications is equal or higher than the envisaged number of applications and the treatment in a comparable growth stage as defined in cGAP) showing no detectable residues (< limit of detection (LOD)). In these situations, **three trials**⁸ shall be performed for **major crops** and **no trials** shall be required for **minor crops**.

Both are situations where residues are expected to be below LOQ at the point of normal commercial harvest. This is often the case with early applications (e.g. applications in autumn or spring) of herbicides, applications of non-systemic insecticides and fungicides on fruits crops prior to flowering, and seed dressings.

⁷ In case of herbicides higher application rates correspond to rates at the border to phytotoxic effects

⁸ For major crops under “zero residue” situation it is recommended to perform three trials per zone.

Results of primary crop and rotational crop metabolism studies, studies investigating the uptake and distribution of the active substance and its relevant metabolites in plants and residue trials in comparable crops with similar application pattern can be used to better understand whether measurable residues (at or above the LOQ) are expected to occur. A justification to support the argument that the crops are comparable should be provided by the applicant

Regulation (EU) No 544/2011 foresees reduction in the number of trials required for the <LOQ residue situation without specifying the amount of this reduction. In order to ensure consistency, the specifications described in Regulation 283/2013, requiring a minimum of three per zone for minor crops and four per zone for major crops in ‘<LOQ residue’ situations and no trials for minor crops and three trials for major crops in ‘zero residue’ situations should also apply to dossiers for which Regulation (EU) No 544/2011 applies (see also Annex I).

2.2.3. Specific cases related to the condition of use

2.2.3.1. Indoor uses

Different types of structures are currently used for protecting crops (i.e. greenhouses with glass or plastic covering, walk-in tunnels, shade houses, plastic shelter, net shelter, low (mini) tunnels or indoor production like production of cultivated mushrooms or forcing chicory). According to OECD Guideline for testing of chemicals (509) “in matters related to residue trial conduct, greenhouse production is defined as a crop grown in its entirety (i.e., planting to harvest) in a completely enclosed structure”. Uses on crops cultivated from planting to harvest in a completely enclosed structure (greenhouses) are considered as indoor/greenhouse GAPs. Therefore, no completely enclosed structures (i.e. net shelters, shade houses) are considered as outdoor GAPs. Moreover, when seedlings are raised indoors and treated during that stage, but planted outdoors afterwards, this should be considered an outdoor GAP.

The results of outdoor trials are normally not representative for indoor conditions/protected crops, because these structures offer varying degrees of protection from environmental conditions which influence the residue behaviour. Hence, if the use of the pesticide under indoor conditions is envisaged, residue trials representative for these conditions need to be provided.

If the same GAP is foreseen for indoor and outdoor conditions, a full package of residue trials is required for both situations, unless clear evidence can be provided, demonstrating that either the outdoor or the indoor use is more critical. In this case, the data for the more critical use are sufficient.

Growing protected crops requires an optimum range in temperature, independent from the geographical region. Therefore, for the purpose of use in greenhouses, one residue zone shall apply across the EU. Part of the trials may be replaced by trials performed outside the EU, under the conditions detailed in 2.1. Although the trials should be performed in different facilities, the requirement on a minimum distance between the trial sites (as defined for crop field trials) is not applicable.

2.2.3.2. Post-harvest treatments

Residues arising from post-harvest treatments are expected to have an inherently higher level of homogeneity and are not affected by climatic conditions. However, differences in residue levels may be associated with the application method/application technique and different store types, resulting in a more or less homogeneous distribution of the applied PPP on the commodities treated. Therefore, residue trials for post-harvest treatments shall be carried out with different application techniques (compliant with the GAP) and at different treatment premises.

Post-harvest treatments are considered as a “single zone” worldwide (see Table 2). Hence, there are no specific provisions on the geographical location of the test sites. Although the trials should be performed in different facilities, the requirement on a minimum distance between the trial sites (as defined for crop field trials) is not applicable.

According to Regulation (EU) No 544/2011 (“old” data requirements), a minimum of four trials is required, independent of the crop (major/minor crop). Under Regulation (EU) No 283/2013, at least 4 trials are required for minor crops and at least 8 trials are required for major crops. Annex I summarises the differences between “new” and “old” data requirements regarding post harvests treatments.

Post-harvest treatments on cereals should generally produce homogeneous and predictable residues. Where the residues are unlikely to be degraded (evidence provided in representative metabolism studies) and where the storage interval is short, the MRL may be set at the application rate without residue trials data.

Since post-harvest treatments (spraying, fumigation, fogging) of potatoes, fruits, vegetables, etc are expected to lead to a less homogeneous distribution of residues than in cereals, residue trials are necessary.

Decline studies are also required for post-harvest uses to investigate whether relevant degradation products are formed over time or whether residues translocate to the edible part of the crop.

2.2.3.3. Empty storage rooms

Similar to post-harvest treatments (section 2.2.3.2) treatments of empty stores are considered as a “single zone” worldwide. Although the trials should be performed in different facilities, the requirement on a minimum distance between the trial sites (as defined for crop field trials) is not applicable.

Residues may occur from certain active substances remaining in the structure of the store. Thus, considerations on the worst-case scenario are required to design the residue trials. The main parameters influencing the magnitude of residues in products stored in places previously treated with pesticides are the ratio of the surface and the quantity of stored products, the surface structure and the cleaning practices applied before the storage room is loaded.

The expected lower variability of residue levels may be reflected by a reduced number of trials. No specific legal provision is in place for the minimum number of required trials for treated storage rooms. Considering the similarity to post-harvest treatments with regard to variability of results, the number of trials shall be identical to those required for post-harvest treatments.

2.2.3.4. Seed treatments

Seed treatments in general lead to lower residues in the harvested crops and often residues are below the LOQ.

When a systemic active substance is applied to seeds, residue trials representative for the use need to be provided. The general rules on the number of trials and the geographic location where the residue trials are performed apply. If residue trials show that the residue levels in plants or plant products are lower than the LOQ, the number of trials to be performed may be reduced (<LOQ residue situation; see Section 2.2.2 and Table 2).

When a non-systemic active substance is applied to seeds, no quantifiable residues are expected in plants or plant products (zero residue situation; see Section 2.2.2 and Table 2). However, special consideration should be given to the occurrence of toxicological relevant soil metabolites that are taken up by the plant and to root and tuber vegetables for which a contamination from the treated seed could occur. In these cases, a zero residue situation cannot be postulated on the basis of the non-systemic properties of the active substance.

2.3. Season of the treatment

Provided that conditions are comparable and that trials are widely spread over different locations, according to Regulation (EU) 283/2013 it is sufficient to carry out field trials over one growing season.

For cases where Regulation 544/2011 is applicable, residue field trials are required to be performed over two seasons; deviations need to be fully justified. For residue trials reflecting indoor uses, post-harvest uses and treatments of empty storage rooms it is acceptable that they are performed in one year/season only.

For active substances which readily undergo photolytic breakdown the trials should be performed in the season for which less favourable photolysis conditions are anticipated. If the worst-case situation cannot be predicted, it is necessary to provide trials from summer and winter season to prove the worst case season, and provide residue trials under worst-case indoor conditions, in accordance with the envisaged GAP.

2.4. Principles for combining/pooling/merging of residue trials data sets

Since a larger data set provides a more robust basis to derive MRL proposals, FAO and OECD guidelines recommend the merging of residue data sets, provided that trials were conducted according to the same GAPs.

Indoor and outdoor trials should not be combined, due to greater inherent variability.

Under the conditions described below it is appropriate to combine data sets to increase the number of individual residue trial results.

1) Combining NEU and SEU residue trials to derive an MRL proposal **for one crop/commodity**:

- The trials are representative for the GAP;
- The data sets must belong to the same statistical population tested by using appropriated statistical tools (as Mann-Whitney U-Test). It is noted that the power of statistical test is limited in case of small data sets (<5) and for data sets containing a high amount of results <LOQ.
- The MRL proposals derived for the individual data sets should fall into the same or a neighbouring MRL class.

2) Combining residue trials performed on **different crops**:

In order to derive MRL proposals for a crop group, residue trials on different crops belonging to the same crop group can be combined in accordance with the provisions on extrapolation (see Table 3). In this case a higher variability of residue trials is expected. Hence, combining of residue trials is possible if the following conditions are fulfilled:

- The same GAP applies to the whole group;
- The trials are representative for the GAP.
- The number of trials is in line with the data requirements and the extrapolation rules (Table 2 and Table 3).

In this case, no statistical analysis is required.

It is highlighted that the rules on the minimum number of residue trials required to derive MRL proposals are not affected by the possibility to combine different datasets: hence, data sets cannot be combined to circumvent data requirements for a minimum number of trials per individual residue zone.

3. DEVIATIONS IN TRIAL PARAMETERS

3.1. GAP-compliance: the 25% tolerance rule

As a general principle, trials may deviate by $\pm 25\%$ in no more than one parameter of the GAP, among which:

- application rate (see further provisions on acceptable wider deviations in Section 3.2);
- number of applications;
- interval between applications;
- pre-harvest interval (PHI);

The basis for calculating the acceptable 25 % deviation is the highest application rate or the lowest interval between applications, if in the GAP these parameters are defined as a range. The development stage of the crop at the time of application should also be considered for

deviation in the maximum number of applications. In general, residue trials are considered not representative for the GAP if more than one parameter deviates by more than 25% of the GAP simultaneously.

However, based on an expert judgment, minor deviations on more than one parameter may be accepted in exceptional and specific cases, especially if the deviation is not expected to have a major influence on the residue level in the harvested products (e.g. trial conducted with applications at 1100 g/ha and a 16 day PHI may be considered in compliance with a GAP defined as 1000 g/ha with a 14 day PHI)

3.2. Deviations in application rate: the proportionality principle

The actual application rate tested in residue trials should generally deviate by no more than $\pm 25\%$ of the maximum application rate (see also section 3.1). However, wider deviation of the application rate may be acceptable, if the principle of proportionality can be applied, which postulated a linear relationship between application rates and residue levels. The residue concentrations measured in overdosed or underdosed trials can be scaled down or scaled up by applying scaling factors to predict the residue concentrations expected at the cGAP.

The principles and guidance for application of the scaling approach were proposed by the Codex Committee on Pesticide Residues during the 45th session [Codex, 2013] and adopted at EU level at the Standing Committee on the Food Chain and Animal Health Meeting in September 2013. They are detailed in the OECD guidance document on crop field trials. In May 2017, Member States agreed on several recommendations related to the implementation of the proportionality principle at EU level. These recommendations are detailed in an EFSA technical report on the use of the proportionality approach in the framework of risk assessment for pesticide residues (EFSA, 2018).

The proportionality principle should be used only when not enough data complying with the 25% rules are available.

3.3. Deviations in application rate: leaf wall area

In tall crops like fruit trees or vineyards, which are vertically treated, the application rate normally depends on the surface area of the canopy. For this reason, in former times the amount applied was given in kg ai per hl. In some countries the amount applied is given in kg ai per ha leaf wall area (LWA). In such cases residue trials reports should include detailed information on the dimensions of the crops/orchards (treated crop height, distance between rows, ha LWA/ha soil ratio) and the doses applied should be given in both per ha and per ha LWA. In addition, additional data (e.g. the leaf surface area, crop planting density) should be provided to demonstrate that the trials are representative for the GAP.

3.4. Deviations of residue trials regarding the formulation

In general, residue trials should be performed with formulations equivalent to the formulations related to the GAP. Formulation types can be roughly classified in products that are diluted with water prior to application and those which are directly applied. A complete description of the various types of formulations is detailed in the OECD Guidance Document on crop field trials.

Residue trials that are performed with a formulation type that is not equivalent to the formulation type specified in the GAP under assessment are not acceptable; a complete data set performed with the formulation type defined in the GAP is required, unless comparable residue behaviour can be demonstrated with bridging studies. However, experience shows that emulsifiable concentrates (EC), wettable powders (WP), dispersible granules (WG), and suspension concentrates (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. More detailed information can be found in MacLachlan and Hamilton (2010) and in the OECD Guidance Document on crop field trials.

Bridging studies should be generated for at least three major crop groups (one crop per group), e.g. a fruit, a leafy crop, a root crop, a cereal/grass crop, pulses and oilseeds, etc. It has proved sufficient to carry out four comparative trials on each crop selected. Trials should preferably be carried out on crops that would be expected to show high levels of residues.

Residue trials are considered representative if the application rate is comparable with the GAP, even if the concentration of the active substance in the formulation differs from the formulation related to the GAP.

3.5. Deviations in application method

Different application methods, such as spraying, drenching, dusting, misting and granule spreading, are not expected to produce comparable residue results. Unless the worst case situation can be clearly identified, a set of trials shall be carried out for each application method which must be documented separately as stated in Regulation (EU) No 283/2013.

3.6. Deviations of residue trials regarding number of applications

In order to encompass the least favourable trial conditions, the trials must be carried out with the maximum number of applications defined in the cGAP. Where a PPP is applied in several applications, generally, the last application prior to harvest is the one that has the highest impact on the final residue in the harvested crop. The applications in fruits and fruiting vegetables prior to flowering are most of the time of less importance.

A deviation of $\pm 25\%$ compared to the number of applications defined in the GAP (e.g. 3 or 5 applications instead of 4) is permitted.

Generally, a deviation of the number of applications compared to the GAP is also acceptable under the following conditions:

- I. If the number of applications in the residue trials exceeds the number of applications defined in the cGAP by more than 25% and if information on the residue concentration before the last application provides evidence that the previous applications do not contribute significantly to the total residues. Alternatively, decline studies could be used to demonstrate a rapid decline of residues, which would allow to conclude that the additional applications do not have a significant impact on the final residues measured.

- II. If the number of applications in the residue trials is lower than the number of applications defined in the GAP by more than 25% and if it can be demonstrated that additional applications (e.g. at an early growth stage, rapid decline of residues after treatment) are unlikely to contribute significantly to the final residues.
- III. If the number of applications in the residue trials exceeds the number of applications defined in the GAP by more than 25% and residue concentrations at harvest are <LOQ.

The nature of the crop should also be considered. For example, crops which may be harvested only a few days after flowering; hence residues of a non-systemic pesticide applied before flowering would be expected to be low and the number of applications should have little influence on the residue level. A similar approach is also used by JMPR (FAO, Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed).

3.7. Deviations in timing of application: pre-harvest interval (PHI) and interval between applications

The development stage 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. Residue trials should reflect the most critical conditions defined in the cGAP and therefore should be carried out using the shortest PHI and the minimum interval between applications. Experience has shown that residue results can be assumed to be comparable when deviations from the cGAP PHI are of no more than $\pm 25\%$ on one parameter only (see also section 3.1).

In certain cases, residue levels may increase with a longer PHI (e.g. different commodities used as food and feed at different growth stages such as forage/fodder or cereal grains, sprouts inhibition, systemic active substance accumulation in root crops). Therefore, it is important that samples are also taken at later sampling points than the requested harvest time. To ensure that this information is available, residue decline studies should be carried out in line with the respective regulatory provisions (see Annex I). If higher residues are found at sampling points later than the PHI, the highest residue value should be selected for deriving the MRL proposal/input values for risk assessment.

Deviation should be considered on a case-by-case basis when the application timing is specified by a crop growth stage. In some cases (e.g. cereals, oilseeds), the crop growth stage at application is more important to consider for the selection of GAP-compliant trials while PHI (if specified in the GAP) may be of secondary relevance. Deviations around growth stages 60 to 70 "flowering-development of fruit" are likely to have an important impact, since the final residue level at harvest may be significantly different if the consumable part of the crop was present or not at last application.

4. EXTRAPOLATION FOR PLANT PRODUCTS

Usually, residue trials should be performed on the crop for which the GAP is foreseen. However, residue trials performed on other crops may be accepted to support a GAP, if certain conditions are fulfilled. This practice is also known as “extrapolation of residue trials”

Residue extrapolation is the process by which field trial data from one or several representative commodities are extended to related commodities in the same commodity group or subgroup for which trials have not been conducted. Broader extrapolations are possible and given in Table 3. The representative commodity has the following properties:

- Most likely to contain the highest residues;
- Likely to be major in terms of production and/or consumption;
- Most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

Wider extrapolations are possible on a case by case basis.

Extrapolations can provide solutions also for minor crops, for which often the available residue trials would not be sufficient to derive MRL proposals; Extrapolation however is not limited to minor crops, but can apply for major crops where insufficient residue data for the specific crop are available or for deriving MRLs for crop groups.

Extrapolation of residue data for different crops presumes that the following parameters defined in the GAP are comparable:

- application rate, the time of application, the number of applications, and the interval between applications;
- application methods;
- formulation used and presence of synergists/adjuvants;
- climatic conditions;

4.1. Main extrapolation principles

The main rules on the number of trials necessary to allow extrapolations to target crop(s) for which the MRL should be established are summarised in section 2.2 and Table 2. The first factor which determines the number of trials required to support an MRL request is whether the target crop is considered major or minor; in case of requests to establish a group MRL, the number of trials depends on whether the crop group contains only major crops, only minor crops or a mix of major and minor crops.

The second factor is the moment of the application of the plant protection product (after or before the edible part of the crop is formed, seed treatment or post-harvest treatment).

The main rules on the number of trials necessary to allow extrapolations are summarised in 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. In addition, it is possible to use the Codex extrapolation tables in a case by case basis (Codex CXG 84-2012). In this sense, a harmonised crop grouping system, justified

extrapolations, and maximizing extrapolation possibilities will facilitate the authorisation of minor uses according to Article 51(3) of Regulation 1107/2009.

Commission Regulation (EU) No 283/2013 has clarified the numbers of studies to be performed if residue levels in plant or plant products are lower than the LOQ or in case of a 'zero' residue situation (see section 2.2.2).

Results of residue trials performed on a crop in Part B of Annex I to Regulation (EC) No 396/2005 can be considered for extrapolation to Part A commodities, if :

- a) a sufficient number of residue trials are available (4 or 8 depending on the crop in Part A) and
- b) the proposed MRL on the basis of these trials is sufficiently protective for consumers.

4.2 Recommended extrapolations

The list of recommended extrapolations is reported in table 3.

Depending on the time of the application of the plant protection product, four different cases for extrapolations are defined:

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

The extrapolation options for the four cases are reported in the corresponding columns of Table 3.

The "Addendum to the recommended extrapolations (Table 4)" explains in more detail the general terminology used in Table 3.

5. EXTRAPOLATION REGARDING PRODUCTS OF ANIMAL ORIGIN

The results from studies on lactating goats, lactating cows/other ruminants and laying hens can be extrapolated to other animal species, taking into account the EFSA document "Estimation of animal intakes and HR, STMR and MRL calculations for products of animal origin" (EFSA, 2015) and the OECD guideline on residues in livestock (505). In some cases, it is necessary to adjust the MRL proposed on the basis of an individual dietary burden calculation.

6. REFERENCES

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Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance

Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances Text with EEA relevance

Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products Text with EEA relevance

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Guidance Document: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRL. SANCO 7525/VI/95 Rev. 10.3

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OECD Guideline for the testing of chemicals (No 501): Metabolism in Crops (2007)

OECD Guideline for testing of chemicals (No 505): Residues in livestock (2007)

OECD Guideline for testing of chemicals (No 509): Crop Field Trials (2020)

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. Text with EEA relevance.

Report from the Commission to the European Parliament and the Council: Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides

Other scientific references:

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Lundeñ, J.-R., Nolting, H.-G., Parnemann, H., Siebers, J., Aßhauer, J., Krebs, B., Timme, G. and Walter, H.-F. (1990): Untersuchungen zur Prüfung der Vergleichbarkeit des Rückstandsverhaltens von ausgewählten Pflanzenschutzmittel-Wirkstoffen an verschiedenen Erntegütern. In: Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft, Heft 263, Juli 1990, Kommissionsverlag Paul Parey, Berlin und Hamburg.

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TABLE 1: LIST OF MAJOR CROPS.

The content of TABLE 1 was not reviewed in detail during the preparation of document SANTE/2019/12752 and will be updated in further future revisions provided that sufficient and recent data for classification crops as minor/major will then be available.

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

Group of crops	Major crops	Region		
		N	S	W
1. Fruits (0100000)				
(i) Citrus fruit (0110000)	Grapefruits (0110010) Oranges (0110020) Lemons (0110030) Mandarins (0110050)		X X X	X X X
(ii) Tree nuts (0120000)				
(iii) Pome fruits (0130000)	Apples (0130010) Pears (0130020)	X X	X X	X X
(iv) Stone fruits (0140000)	Apricots (0140010) Cherries (0140020) Peaches (0140030) Plums (0140040)	X X	X X X	X X X
(v) Berries and small fruits (0150000)				
(a) Table and wine grapes (0151000)	Table grapes (0151010) Wine grapes (0151020)	X	X X	X X
(b) Strawberries (0152000)	Strawberries (0152000)	X	X	X
(c) Cane fruit (other than wild)(0153000)				
(d) Other small fruits and berries (0154000)				
(vi) Miscellaneous fruit (0160000)				
(a) Miscellaneous fruit - edible peel (0161000)				
(b) Miscellaneous fruit - inedible peel, small (0162000)	Kiwi (0162010)		X	X
(c) Miscellaneous fruit - inedible peel, large (0163000)	Bananas (0163020) Pineapples (0163080)			X X
2. Vegetables (0200000)				
(i) Root and tuber vegetables (0210000)				
(a) Potatoes	Potatoes (0211000)	X	X	X
(b) Tropical root and tuber vegetables (0212000)				
(c) Other root and tuber vegetables except sugar beet (0213000)	Beetroot (0213010) Carrots (0213020)	X X	X	X X
(ii) Bulb vegetables (0220000)	Onions (0220020)	X	X	X
(iii) Fruiting vegetables (0230000)				
(a) Solanacea (0231000)	Tomatoes (0231010) Peppers (0231020)	X X	X X	X X
(b) Cucurbits - edible peel (0231000)	Cucumbers (0232010) Courgettes (0232030)	X	X	X X
(c) Cucurbits - inedible peel (0233000)	Melons (0233010) Watermelons (0233030)	X	X X	X X
(d) Sweet corn (0234000)				
(iv) Brassica vegetables (0240000)				
(a) Flowering brassica (0241000)	Cauliflower (0241020)	X	X	X
(b) Head brassica (0242000)	Head cabbage (0242020)	X		X
(c) Leafy brassica (0243000)				

Group of crops	Major crops	Region		
		N	S	W
(d) Kohlrabi (0244000)				
(v) Leaf vegetables and fresh herbs (0250000)				
(a) Lettuce and other salad plants including Brassicacea (0251000)	Lettuce (0251020)	X	X	X
(b) Spinach and similar (leaves) (0252000)				
(c) Vine leaves (0253000)				
(d) Water cress (0254000)				
(e) Witloof (0255000)				
(f) Herbs (0256000)				
(vi) Legume vegetables (fresh) (0260000)	Beans (with pods) (0260010) Peas (without pods) (0260020)	X X	X X	X X
(vii) Stem vegetables (fresh) (0270000)	Leek (0270060)	X		X
(viii) Fungi (0280000)				
(ix) Seaweeds (0290000)				
3. Pulses, dry (0300000)	Beans (0300010) Peas (0300030)	X X	X X	X X
4. Oil seeds and oilfruits (0400000)				
(i) Oilseeds (0401000)	Peanut (0401020) Sunflower seed (0401050) Rapeseed (0401060) Soya bean (0401070) Cotton seed (0401090)	 X X X X	 X X X X	 X X X X X
(ii) Oilfruits (0402000)	Olives for oil production (0402010) Palm nuts (0402020)		X	X X
5. Cereals (0500000)	Barley (0500010) Maize (0500030) Oats (0500050) Rice (0500060) Rye (0500070) Sorghum (0500080) Wheat (0500090)	X 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 (0600000)				
(i) Tea (<i>Camellia sinensis</i>) (0610000)	Tea (<i>Camellia sinensis</i>) (0610000)			X
(ii) Coffee beans (0620000)	Coffee beans (0620000)			X
(iii) Herbal infusions (0630000)				
(iv) Cocoa (fermented beans) (0640000)	Cocoa (0640000)			X
(v) Carob (st john's bread) (0650000)				
7. Hops (0700000)				
8. Spices (0800000)				
9. Sugar plants (0900000)	Sugar beet (0900010)	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: MINIMUM NUMBER OF TRIALS

This table indicates the required minimum number of trials to set MRL by extrapolation in target crop/target crop group, depending on type of use, legal framework and residue situation (residues >LOQ, <LOQ situation, zero residue situation)

Target crop or crop group according to table 3	N° of trials needed to allow extrapolations		
	After and before forming of the edible part; seed treatments	Uses in greenhouses (single zone)	Post-harvest and empty storage treatments (single zone)
Major crop (residues > LOQ)	8 per zone	8	4 (Reg. 544/2011) 8 (Reg. 283/2013)
Crop group containing major crops (residues > LOQ)			
Minor crop (residues > LOQ)	4 per zone (Reg. 544/2011) 6 across both zones ^(a) (Reg. 283/2013)	4	4
Crop group containing only minor crops (residues > LOQ)	4 per zone 6 across both zones ^(a) (Reg. 283/2013)	4	4
Major crop (<LOQ situation)	4 per zone	4	4
Crop group containing major crops (<LOQ situation)			
Minor crop (<LOQ situation)	3 per zone	3	3
Crop group containing only minor crops (<LOQ situation)			
Major crop (zero residue situation)	3 per zone	3	3
Crop group containing major crops (zero residue situation)			
Minor crop (zero residue situation)	No trials	No trials	No trials
Crop group containing only minor crops (zero residue situation)			

^(a) If the GAP is the same in NEU and SEU zone. Trials should be equally distributed in the representative growing zones.

TABLE 3: RECOMMENDED EXTRAPOLATIONS

The content of TABLE 3 was not reviewed during the preparation of document SANTE/2019/12752 and will be updated in further future revisions. In case of discrepancies between Table 3 with the text of the guidelines and/or the content of Table 2, the content of the text and Table 2 should prevail.

- 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).
- For extrapolations to individual crops a mixed data set of trials in the crop for which a MRL is requested plus trials mentioned in the column "*trials available*" would be also acceptable. E.g. for setting a MRL in lemons, it would be acceptable to have a mixed data set with lemons and mandarins. It is not necessary that only mandarin trials are provided.
- If the setting of a group tolerance based on a data set defined in the column "*trials available*" is possible, it should be also allowed to use the data set to set MRLs for individual crops listed in the crop group. E.g. trials on apples would be acceptable to set an MRL for the group of pome fruit. Hence it would be also acceptable to set a MRL just for pears or for quinces.

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	4 trials in total on 2 or more representatives of the group Tree nuts (120000), except coconuts (0120050)	→	Whole group Tree nuts (0120000)	YES (1)	YES		
		trials on brazil nuts (0120020) and/or cashew nuts (0120030) and/or hazelnuts/cobnuts (0120060) and/or pistachios (0120100)	→					YES (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)		YES		
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)		YES		
		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*
0150000	Berries and small fruits	4 trials on strawberries (0152000) + 4 trials on any representative of the subgroups: - (a) grapes, - (c) cane fruits, - (d) other small fruits and berries	→	Whole group Berries and small fruits (0150000)		YES		
0151000	Subgroup (a) grapes	table grapes (0151010) and/or wine grapes (0151020)	↔	table grapes (0151010)	YES	YES		
			↔	wine grapes (0151020)	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		
		two or more representatives 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 any representative of the subgroups: - (a) grapes (0151000); - (d) other small fruits and berries (0154000) with a minimum of 2 trials on currants	→		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) and/or sweet potatoes (0212020) and/or yams (0212030)	→	Whole subgroup (b) tropical root and tuber vegetables (0212000)	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) and/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) and/or courgettes (0232030)	→	Whole subgroup (b) cucurbits with edible peel	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) (or 4 on cauliflower and 4 on broccoli)	→	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*) and/or escaroles/broad leaves endives (0251030) and/or Roman rocket/rucola (0251060) and/or chards/beet leaves (0252030)	→	roman rocket/rucola (0251060)	YES	YES		
			→	escaroles/broad leaved endives (0251030)	YES	YES		
			→	red mustards (0251070)	YES	YES		
			→	baby leaf crops (including brassica species) (0251080)	YES	YES		
0252000	Subgroup (b) spinaches and similar leaves	Spinaches and/or lettuces (0251020) (trials from open leaf varieties*)	→	Whole subgroup (b) spinaches and similar leaves (0252000)	YES	YES		
		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	spinaches (0252010) and/or lettuces (0251020) (trials from open leaf varieties*) and/or 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		
		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		
		celerics (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) and/or peas (0300030)	→	Whole category PULSES (0300000) (2)	YES			YES
		beans (0260010, 0260020, 0300010) and/or peas (0260030, 0260040, 0300030)	→	Whole category PULSES (0300000) (2)		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)				
		sunflower seeds and/or rapeseeds and/or soyabeans and/or cotton seeds) (8 trials in total on two or more crops)	→	all minor oilseeds* 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); -	YES		YES	YES
		any representatives of the group Oilseeds*, except peanuts/groundnuts (0401020)	→	Whole group Oilseeds (0401000), except peanuts/groundnuts (0401020)				
		8 trials on any representatives of the group Oilseeds* except peanuts/groundnuts (0401020) + 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) and/or oat (0500050) and/or rye (0500070) and/or 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*
		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

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).	→					
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
		any representative of the groups: - Bud spices (0850000); - Flower pistil spices (0860000); - Aril spices (0870000).	→					
		lettuces (0251020)	→			YES		
		lettuces (0251020) (trials from open leaf varieties)* (5)	→		YES		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

*	<p>For the explanation of the terms:</p> <ul style="list-style-type: none"> - 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; <p>see the Addendum to the recommended extrapolations table (Table 4).</p>
(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. 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> <p>In case of root, stem (except asparagus), flowering brassica, bulb and tuber vegetables, 'before forming of the edible part' must be intended as before BBCH 19.</p> <p>For oilseeds, a significant part of the edible part is present from full blossom (BBCH 65) onwards.</p>
3	Post harvest	Post harvest treatments can be authorized for: - 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	Immature maize (harvested at BBCH 75). Results of residue trials on maize can be used for extrapolation if maize samples were taken before BBCH 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	The oilseeds which are major crop in NEU zone, in SEU zone, in both zones or in the world: - peanuts/groundnuts (0401020); - sunflower seeds (0401050); - rapeseeds/canola seeds (0401060); - soyabeans (0401070); - cotton seeds (0401090).
9	Minor oilseeds	The oilseeds which are not major crops in NEU zone, in SEU zone, in both zones or in the world: - 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).

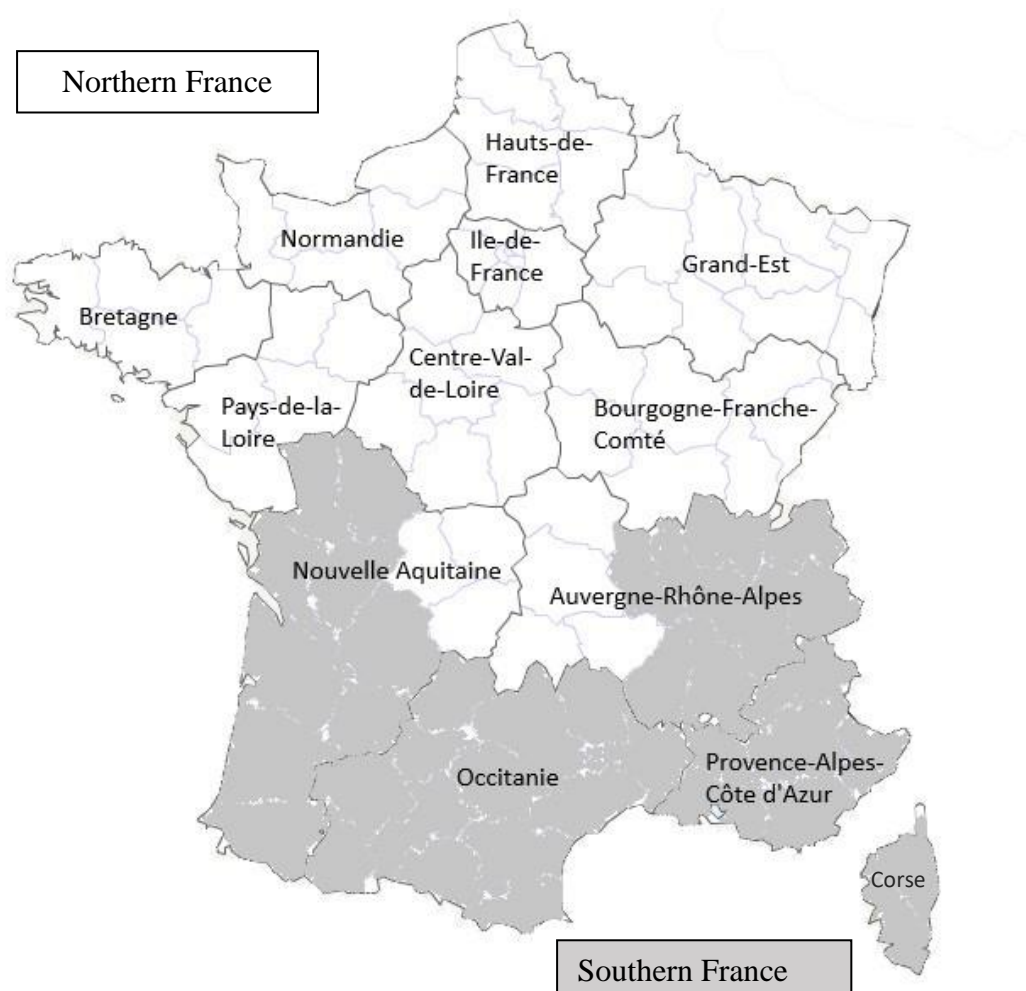
ANNEX I CLARIFICATIONS ON “OLD/NEW” DATA REQUIREMENTS

“Old” Data Requirements (Regulation (EU) No 544/2011)	“New” Data Requirements (Regulation (EU) No 283/2013)	Clarification
<p>Field trials: 2 growing seasons, deviations need to be fully justified.</p> <p>Indoor uses and post-harvest uses: 1 growing season.</p> <p>1 growing season if non-relevant residues (<LOQ)</p>	<p>Field trials: 1 growing season</p> <p>Indoor uses and post-harvest uses: 1 growing season</p>	<p>The differences need to be respected, because they are set out in Legislation.</p>
<p>Post-harvest uses:</p> <p>Min. 4 trials preferably in different locations; trials of 1 season would be enough (this means that 4 trials would also be sufficient for major crops)</p>	<p>Post-harvest uses:</p> <p>No provision on reduced number of trials for post-harvest (min. 8 trials for major, 4 trials on minor crops), the trials shall be performed in different location.</p>	<p>For the old data requirements the number of trials is lower (for major crops); in addition, the provisions for the different locations of the trials are less strict.</p>
<p>Number of trials for major crops (except for post-harvest uses):</p> <p>Min. 8 trials per zone (NEU, SEU, non-EU, indoor)</p> <p>The number of studies per growing season to be performed can be reduced if it can be justified that the residue levels in plants/plant products will be lower than the limit of determination</p>	<p>Number of trials for major crops:</p> <p>8 trial for major crops per zone,</p> <p>Exemption: if residues are below LOQ, 4 trials (per zone) would be enough. Zero residue situation, 3 trials (recommended 3 trials per zone)</p>	<p>The exact reduction in the number of trials is not established in <LOQ and zero residue situations in old data requirements. However, the provisions for <LOQ and zero residue situations provided in the new data requirements should be also used for old data requirements.</p>
<p>Number of trials for minor crops:</p> <p>4 trials for minor crops per zone</p>	<p>Number of trials for minor crops:</p> <p>4 trials per zone,</p> <p>If residues are < LOQ, number of trials is reduced (3 trials per zone)</p> <p>Zero residue situation: no trials are needed.</p> <p>If GAP is the same in NEU and SEU, 6 trials would be sufficient (equally distributed over the two zones).</p>	<p>The reduced number of trials for the same GAP in NEU and SEU would not be acceptable for the old data requirements, because it clearly contradicts the provisions on the number of trials.</p>

<p>Decline studies: 50% of residue trials should be decline studies if a significant part of the consumable crop is present at the time of application.</p>	<p>50% of residue trials should be decline studies, if the consumable part is exposed during application of the plant protection product under the proposed conditions of use.</p> <p>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.</p> <p>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).</p>	<p>The specific provisions for decline studies provided in the new data requirements should be also used for old data requirements.</p> <p>For roots and tubers, stem vegetables, flowering brassica, oilseeds and cereals the growth stage (BBCH) when the consumable part of the crop is formed was not reflected in Reg (EU) No 283/2013 and should be defined (refer to proposal in Table 4)</p>
<p>Geographical location of trials: It is not clearly specified, where the trials should be performed; just general provisions that the trials need to reflect on climatic conditions and growing areas.</p>	<p>Part of the trials may be replaced by trials performed outside the Union, provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable.</p>	<p>The concept of geographic zones was introduced with the first version of the guidance document 7525/VI/96. Hence in the past this concept was also relevant under the old data requirements. A risk management decision should be taken and reflected in this guidance document whether the provisions of the new data requirements that part of the residue trials can be replaced by trials from 3rd countries also apply for cases of the old data requirements.</p>

ANNEX II: DIVISION OF FRANCE INTO TWO GEOGRAPHICAL ZONES

(as described in section 2.1)



Regions and Departments of France (continue on the next page)

Northern France			Southern France		
Regions		Departments	Regions		Departments
Ile-de-France	75	(Ville-de-)Paris	Nouvelle Aquitaine	16	Charente
	77	Seine-et-Marne		17	Charente-Maritime
	78	Yvelines		24	Dordogne
	91	Essonne		33	Gironde
	92	Haute-de-Seines		40	Landes
	93	Seine-Saint-Denise		47	Lot-et-Garonne
	94	Val-de-Marne		64	Pyrénées-Atlantiques
	95	Val-d'Oise		79	Deux-Sèvres

Northern France			Southern France		
Regions		Departments	Regions		Departments
Grand-Est	08	Ardennes	Occitanie	86	Vienne
	10	Aube		09	Ariège
	51	Marne		11	Aude
	52	Haute-Marne		12	Aveyron
	54	Meurthe-et-Moselle		30	Gard
	55	Meuse		31	Haute-Garonne
	57	Moselle		32	Gers
	67	Bas-Rhin		34	Hérault
	68	Haut-Rhin		46	Lot
	88	Vosges		48	Lozère
Hauts-de-France	02	Aisne	Auvergne-Rhône-Alpes	65	Hautes-Pyrénées
	59	Nord		66	Pyrénées-Orientales
	60	Oise		81	Tarn
	62	Pas-de-Calais		82	Tarn-et-Garonne
	80	Somme		01	Ain
Normandie	14	Calvados		07	Ardèche
	27	Eure		26	Drôme
	50	Manche		38	Isère
	61	Orne		42	Loire
	76	Seine-Maritime		69	Rhône
Centre-Val-de-Loire	18	Cher		73	Savoie
	28	Eure-et-Loire		74	Haute-Savoie
	36	Indre	Provence-Alpes-Côte-d'Azur	04	Alpes-de-Haute-Provence
	37	Indre-et-Loire		05	Hautes-Alpes
	41	Loir-et-Cher		06	Alpes-Maritimes
Bourgogne-Franche-Comté	45	Loiret		13	Bouches-de-Rhône
	21	Côte-d'Or		83	Var
	25	Doubs		84	Vaucluse
	39	Jura	Corse	2A	Corse-du-Sud
	58	Nièvre		2B	Haute-Corse
	70	Haute-Saône			
	71	Saône-et-Loire			
	89	Yonne			
	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			
Nouvelle Aquitaine	19	Corrèze			
	23	Creuse			
	87	Haute-Vienne			
Auvergne-Rhône-Alpes	03	Allier			
	15	Cantal			
	43	Haute-Loire			
	63	Puy-de-Dôme			

Annex II (continued):

Distribution of crops in France⁹

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
154030	Currants (red, black and white)	N
154040	Gooseberries (Including hybrids with other ribes species)	N or S
154050	Rose hips	N or S

⁹ 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)
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, Brazilian 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 or S
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	N
213100	Swedes	N
213110	Turnips	N

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
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
252020	Purslane (Winter purslane, garden purslane, common purslane, sorrel, glassworth)	N or S

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
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, Flageolets, 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 or S
270020	Cardoons	N or S
270030	Celery	N or S
270040	Fennel	N or S
270050	Globe artichokes	N
270060	Leek	N
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
401080	Mustard seed	N

Code number	Groups and examples of individual products to which the MRLs apply (a)	Zone* (N, S, N+S, N or S, W)
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 Camellia sinensis)	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

ANNEX III: GLOSSARY AND ABBREVIATIONS

To enhance the usability of this guideline, definitions/descriptions of relevant terms were taken from other documents (available at the date of publication of this guideline) and are copied below. Final user is invited to review the source documents for potential updated versions of definitions. Terms are presented in alphabetical order.

Application rate

Amount of product and/or active substance used. The application rate should be expressed according to the treatment. Examples are

- per unit surface area (e.g., kg a.i. per hectare or kg a.i. per hectare LWA),
- per volume (e.g., g/m³ sometimes connected to a time interval),
- per mass of seed (e.g., ml/100 kg seeds)

Bridging studies

Bridging studies provide an essential tool in a harmonized approach to formulation changes, new formulations, and different application methods. A bridging study normally involves a comparison of different formulations or application methods for the purpose of data extrapolation, but may or may not involve side-by-side comparisons. If bridging trials are deemed necessary and a pesticide is used on a wide range of crops, data should be generated for at least 3 major crop groups (one crop per crop group), e.g., a leafy crop, a root crop, a tree fruit, a cereal grain, an oilseed. The trials should be carried out on crops that would be expected to show high levels of residue (often those with applications at or near harvest). If a bridging study is conducted and residues are significantly higher with a new formulation or different application method for example, generation of a complete data set may be necessary. (OECD Guideline 509)

Critical GAP (cGAP)

According to Reg. (EC) No 396/2005 good agricultural practices are *nationally recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed, in line with the principles of integrated pest control in a given climate zone and using the minimum quantity of pesticides*

The critical GAP is the *GAP which gives rise to the highest acceptable level of pesticide residue in a treated crop and is the basis for establishing the MRL* [Reg. (EC) No 396/2005].

The cGAP comprises test conditions when commodities are harvested [FAO, 2016]:

- after the authorised minimum pre-harvest intervals (PHI)

And following the maximum number of proposed applications:

- at the permitted minimum intervals
- at the permitted maximum dose rates.

In some cases the time of application is well defined by the growth stage (BBCH; a decimal code system, which is divided into principal and secondary growth stages²). In this case setting of a PHI is not necessary (OECD, 2016)

Crop field trials

Crop field trials are residue trials conducted on crops, typically according to the principles of Good Laboratory Practice (GLP), in order to assess the magnitude of the residues under the conditions of the critical Good Agricultural Practice (GAP) [OECD, 2009].

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

- To quantify the highest likely residue levels of all components of the different residue definitions for monitoring and risk assessment in treated crops, at harvest or outloading from store, in accordance with the proposed GAP, and
- To determine, where appropriate, the decline rate of plant protection product residues in plants.

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

When establishing a supervised residue trial programme, factors such as main growing areas and the range of conditions, likely to be encountered in the main growing areas concerned shall be considered [Reg. (EU) No 283/2013].

For the purpose of these guidelines the term is synonymous with supervised residue trials.

Greenhouse/glasshouse

Protected crop scenarios such as greenhouse (glass or plastic covering), plastic tunnel, shade house, etc. which offer varying degrees of protection from environmental conditions. In matters related to residue trial conduct, greenhouse production is defined as a crop grown in its entirety (i.e., planting to harvest) in a completely enclosed structure (OECD, 2009).

The different scenarios are described and identified with the help of EPPO descriptors (<https://gd.eppo.int/PPPUse/3CROLK>)

Independent supervised residue trials

According to OECD (2016), the following factors should be considered separately to decide whether supervised residue trials are independent:

- Geographical location and site – Trials at different geographic locations are considered independent (see also Section 2.1. Geographical zones).
- Dates of planting (annual crops) and treatments – Trials involving significantly different planting dates or treatment dates (> 30 days apart) are considered independent.

Additional factors may influence the independence and may be taken into consideration on a case by case basis:

- Crop varieties – Some varieties may be sufficiently different (e.g. different size at maturity, rough vs. smooth surface, different amount of foliage) to influence the residue and could be considered independent.
- Formulations – Trials conducted with different formulations should not be considered independent.
- Application rates and spray concentrations – Trials at different application rates and spray concentrations should not be considered independent.
- Treatment operations – Trials using the same spray operation are not considered independent.
- Application equipment – Trials using different equipment are not considered independent.
- Addition of adjuvants – A trial with the addition of an adjuvant should not be considered independent. If an adjuvant will be routinely recommended or included in the marketed formulation, then the trials should use the adjuvant. If the use pattern includes mid-season to late season foliar application, consideration should be given to including appropriate adjuvants in a portion of the trials.

For trials being considered independent the measured residue is used to derive the MRL proposal and the risk assessment values.

For those trials being considered as not independent the measured residues should be treated as being replicates. See also replicates.

Limit of quantification (LOQ)

The lowest concentration or mass of the analyte that has been validated with acceptable accuracy by applying the complete analytical method and identification criteria ((SANTE/12682/2019: Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed).

This term is also known as Limit of Determination, but it should be differentiated to Limit of Detection (LOD) which is defined as the lowest concentration of a pesticide residue in a defined matrix where positive identification can be achieved using a specified method.

Major crops

The following criteria were used for classifying a crop or a product as 'major' in the EU:

- 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.

Minor crops

“All crops not defined as ‘major crops’ according to the criteria outlined above. For the purpose of these guidelines, when applied to crops intended to be used as food, this term is used indistinguishably as “insignificant in diet”. However for crops used as feed, as alfalfa or pasture, the criteria for classification should be Cultivated area and Production.

Post-harvest treatment

Treatment of plants or plant products after harvest in an isolated space, for example in a warehouse [Reg. (EC) No 1107/2009].

Pre-harvest interval (PHI)

Time interval in days between the last application of a pesticide to a crop and harvest to meet the relevant maximum residue limits for a particular crop (OECD, 2009). In the case of post-harvest treatments it can also be defined as withholding period or storage period.

Residue decline trials

Supervised residue trials that show how the residue level changes over time. In general, it consists of five sampling stages, two of which are frequently set to coincide with the time of application and the harvest respectively. The recommended Pre-harvest Interval must be declared in every case.

Replicates

According to the OECD Guidance document on Crop Field Trials (OECD, 2016), various scenarios may apply when several residue values are described as "replicates" such as when there are:

- Replicate analysis samples from one laboratory sample (duplicate analysis).
- Replicate laboratory samples obtained with sub-division from one field sample.
- Replicate field samples analysed separately (each sample is taken randomly from a plot which was treated as a whole).
- Replicate plots or sub or split-plot field samples are analysed separately (the whole trial is subject to the same spraying treatment, but it is divided into two or more areas that are sampled separately).
- Replicate trial samples are analysed separately (trials from the same site that are not independent may be considered as replicate trials).

Results from those replicates are not independent and therefore the mean value of replicates should be normally used as the representative value for that field trial. In case where single valid results from replicate samples exceed the MRL estimated from the use of mean values, the highest value of the replicates should be used to calculate the MRL and to derive the HR

for the dietary risk assessment. For more details, see OECD Guideline for testing of chemicals (No 509): Crop Field Trials

Replicates are often reported as "duplicates". In order to avoid confusion, the terms as described above should be used (see also in the glossary the entry on *independent supervised residue trials*).

Seed treatment

Application of pesticides to the seeds of crops prior to planting or sowing, which may occur at a seed treatment facility or in the field immediately prior to planting or sowing [OECD, 2009].

Systemic/non-systemic

Active substances (and the toxicologically relevant metabolites) capable of being translocated to plant sites other than where it was absorbed (IUPAC, 2006) and moved around in its tissues in the vascular system of the plant (in the phloem and/or the xylem) are considered systemic. Indications on the systemic properties of an active substance and its metabolites can be found in metabolism studies or studies on the magnitude of residues in primary crops or rotational crops.

Abbreviations

cGAP: critical Good Agricultural Practices

EC: emulsifiable concentrates

GAP: Good Agricultural Practices

GLP: Good Laboratory Practice

LOD: limit of detection

LOQ: limit of quantification

LWA: leaf wall area

MRL: maximum residue levels

N: North

NEU: Northern and Central Europe

PPP: plant protection products

PHI: pre-harvest interval

S: South

SEU: Southern Europe and the Mediterranean

SC: suspension concentrates

W: world

WG: dispersible granules

WP: wettable powders