Section 5
Other Test Guidelines

Test Guideline No. 506

Stability of Pesticide Residues in Stored Commodities



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OECD Guidelines for the Testing of Chemicals

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OECD GUIDELINE FOR TESTING OF CHEMICALS

Stability of Pesticide Residues in Stored Commodities

INTRODUCTION

1. When compiling magnitude of residue (MOR) data from commodities of plant origin (raw and processed) and animal origin, it is essential to ensure that the residues of all components being part of the residue definitions for risk assessment and enforcement of an MOR sample remain accurately quantifiable from the time of sampling/harvest to analysis. If MOR samples are not analysed as quickly as possible after collection, chemical changes of components of the residue may take place, which may lead to inaccurate results. Where it is not possible to analyse MOR samples immediately after sampling, they should be stored under suitable frozen conditions until analysis and the effect of storage conditions on the stability of residues has to be investigated.

2. In principle, the same considerations apply to environmental matrices, but providing detailed guidance on how to address stability of residues in soil and water samples is out of scope of this Test Guideline. Further considerations can be found in specific guidance documents, for example in the OECD guidance document for conducting pesticide terrestrial field dissipation studies (1).

3. Guidance on storage stability from Canada (2), the EU (3), the FAO (4) and the United States of America (5) was taken into account when revising this OECD document.

PURPOSE

4. The aim of storage stability studies is that the applicant demonstrates the time period for which residues in representative commodities of plant origin (raw and processed) and animal origin are stable during frozen storage under the tested conditions. MOR samples have to be analysed within the period for which stability has been shown in representative commodities. The MOR studies include, but are not limited to, the following: Primary crop field trials, honey residue studies, field rotational crop studies, livestock feeding studies and processing studies.

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GENERAL CONSIDERATIONS

5. In most MOR studies, samples are stored for a period of time prior to analysis. During this storage period, residues of the active substance and/or its metabolites included in the residue definitions may decline due to processes such as volatilization, hydrolysis and/or enzymatic degradation. Therefore, in order to be certain that the level of residues present in MOR samples at the time of their collection is the same at the time of analysis, controlled studies are needed to assess the effect of storage on residue levels in MOR samples.

6. If MOR samples are analysed within 30 days of frozen storage, applicants can omit conducting a freezer storage stability study unless the substance(s) are known to be instable during that period. Normally, MOR samples should be frozen within 24 hours of sampling or harvest. Where samples are not frozen within 24 hours, the period of ambient or cooled storage should be mimicked in the freezer storage stability study or a second storage stability study should be conducted. It is noted that a 24-hour interval after harvest is not feasible in cases which - according to common agricultural practices - require a drying process in the field which can take more than 24 hours. Samples should, in these cases, be frozen within 24 hours after the end of drying.

7. Under normal circumstances, storage stability data is not required for all commodities since data may be extrapolated within matrix groups (see 1.1.Annex B). A freezer storage stability study is representative for the corresponding MOR study if the storage conditions (especially temperature and matrix form such as ‘whole’ versus ‘homogenised’) are the same in both studies, even when the stability study is not run in parallel, but in a separate freezer commencing on a different date.

8. For pesticides whose residues are known or suspected to be unstable or volatile (including fumigants), consideration should be given to undertaking a freezer storage stability study with all individual components of the residue definitions in advance of the MOR studies. The objective is to determine proper storage conditions and maximum storage times before MOR samples are placed in storage. Otherwise, concurrent recovery studies may be required to ensure that the data on the components of the residue definitions from the MOR studies are acceptable.

TEST PROCEDURE

Introduction

9. Freezer storage stability studies should include sufficient starting material and should have a sufficiently high concentration of residue to allow for any observed decline during storage to be quantified. Samples could either be obtained from crops treated or animals dosed with the pesticide (samples with incurred residues) or from the fortification of control (untreated) commodities with known amounts of each component of the residue definition. With residues being incorporated in the sample matrix, studies using incurred residue samples represent a more realistic scenario than studies with fortified samples and are generally considered as superior compared to studies with fortified samples (see also A-26). Freshly fortified control samples of the stored commodities should be analysed at each of the time points when aged/stored commodities are removed

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from frozen storage for analysis, to allow differentiation of procedural losses and losses due to storage.

10. Control samples used for concurrent recovery (= procedural recovery) determinations should be of the same commodity type as the commodity studied in the storage stability study, but they do not need to be from the same batch as the samples used as storage stability samples. It should be shown that the control sample does not contain the pesticide under investigation at levels at or above the limit of quantification of the applied analytical method. For commodities which are obtained in extremely limited quantities from MOR studies, such as nectar, it may be acceptable to use a surrogate, such as diluted honey or sucrose solution as the control sample for fortification.

11. Samples with incurred residues must be analysed within as short a time period as possible and no more than 30 days after harvest/sacrifice to quantify the Day 0 residue levels. In cases with expected stability issues, even 30 days might be too long and the time period should be chosen as short as technically feasible. There might be cases where initial analysis is not possible within 30 days after sampling, for example, for logistical reasons or due to the need to identify suitable samples (by checking if target analytes are present in sufficiently high amounts in generated incurred samples). Studies with initial analysis taking place more than 30 days after sampling can be acceptable if sufficient justification is provided why an earlier analysis was not possible.

Test Chemical

12. Generally, it is anticipated that the formulation of the plant protection product does not play a significant role in the stability of the residue components in the harvested crop under frozen storage conditions. If there is reason to assume the opposite, the applicant should provide a rationale for the validity of the freezer storage stability results. If the freezer storage stability study uses samples with incurred residues, it has to be assured that all components of the residue definitions are present in the MOR samples and at sufficient levels to allow any decline to be observed. It might not be possible to obtain MOR samples with (sufficient amounts of) all components of the residue definition. Several different samples even from different commodities might be necessary to conduct all required studies. In MOR samples several components of the residue definition are usually present in the same sample. If it is known that one component can be converted to another one, this can be considered in the interpretation of storage stability results, for example by summing up recovered residues of both components (for more details it is referred to Annex A).

13. If test chemicals are added to untreated commodities in the laboratory, it is usually the active substance or relevant metabolites that are added. Where the residue definitions contain more than one component, studies need to be designed to demonstrate stability of each component. Mixed fortification solutions might be used only when a scientific justification based on the metabolic pathway can be made demonstrating that no transformation from one component to another can occur. It is not recommended to use mixed fortification solutions if it could mask such potential transformations. In these cases, the freezer storage stability study should be conducted with separate samples of each commodity under investigation, fortified with the individual components of the residue definitions.

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14. For chiral components, fortification with individual enantiomers/diastereomers should be performed if they are identified separately in the residue definition. Use of a mixture of enantiomers/ diastereomers may mask the degradation of one or more components and thus make interpretation of storage stability results challenging (for example, comparison of peak area ratios can only provide a relative assessment while information on absolute stability would still not be available).

15. For conjugates, often no analytical standards are available and they are captured in residue analyses by methods including cleavage steps to detect respective cleavage products. If MOR samples are analysed using methods with cleavage steps and analytical standards for conjugates cannot be readily obtained (for example not accessible via chemical synthesis), storage stability of conjugates might not need to be addressed separately. Justification should be provided that no reactions other than cleavage of the conjugated moiety, for example, oxidation, occur during storage (this could for example be based on conjugate-specific data from metabolism studies comparing early and late sample extractions). In such cases, storage stability of conjugates can be considered as covered by storage stability data for respective cleavage products.

16. If analytical standards for conjugates are available and conjugates are converted to their respective cleavage products during storage, this conversion can be included in interpretation of storage stability for conjugates by considering the sum of conjugates and cleavage products (for more details it is referred to Annex A).

Analytical Methods

17. Analytical methods used to analyse samples in storage stability studies should be validated as detailed in the OECD Guidance Document on Analytical Methods (6). It is not recommended to use different analytical methods within a storage stability study to avoid complex interpretation of study results maybe originating from the use of different methods. In cases where different analytical methods are used within a storage stability study, storage stability results are acceptable as long as the methods are sufficiently validated. The method used for the storage stability study does not need to be the same as for example the one used for the corresponding MOR studies or animal feeding studies, provided the method is adequately validated. For method validation requirements it is referred to the Analytical Methods Guidance Document (6).

18. Standard solutions used for fortification, concurrent recoveries and calibration should be prepared using certified analytical standards and used within their demonstrated solution stability throughout the study. It is highly advised that solutions are also checked against an independent preparation to verify concentration accuracy prior to use. If samples used for storage are fortified using different solutions and/or at different times, data should be available to show that all fortifications were equivalent.

19. For each sampling point, concurrent recoveries from duplicate control samples freshly fortified at the same nominal fortification level as the stored samples should be included to demonstrate the performance of the method. This does not apply to the Day 0 sampling point (except for incurred residue studies) because the Day 0 storage stability samples will serve as concurrent recovery samples as well.

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20. If common moiety methods are used, it is not possible to measure the stability of each of the individual components of the residue definitions. In addition, a common moiety method in some instances may also detect compounds containing the moiety but which are not included in the residue definitions. This can further mask the decline of residues, which may or may not occur. Consequently, common moiety methods should normally not be used in freezer storage stability studies. However, in exceptional circumstances and with justification, common moiety methods may be used. For example, when the MOR studies have used a common moiety method to quantify the residues, this method may also be used for the determination of the stability of residues during storage.

Fortification levels

21. Samples should be fortified at least at 10x the limit of quantitation (LOQ) of the method used to conduct the storage stability study for each analyte in order to adequately determine the stability of the residues under storage conditions. This will make it less likely that highly variable recoveries prevent the determination of the stability of the residues. These are model studies and should be optimised for the demonstrated range of the analytical method. Fortification should be undertaken in the same way as in the validation of the analytical methods. Where this is not possible, a full justification for the applicability of the data should be provided.

22. Prior to fortification it is advisable to analyse the commodities to be used to reveal any potential interference with other substances or contamination with the test chemicals that may result, in some circumstances, in non-acceptability of the study. It is acknowledged that it is not always feasible to obtain sample material with sufficiently low residue levels. In such cases the use of sample material containing background residues is considered acceptable if justified. Examples include compounds like triazole derivative metabolites or trifluoroacetic acid that are frequently occurring in the environment and commonly found in organic samples due to multiple sources.

23. Where no detectable residues are found in field treated commodities, or residue levels are close to the analytical method's LOQ, fortified control commodities should be employed in the freezer storage stability studies rather than samples with incurred residues. Alternatively, samples with a sufficiently high level of residues can be generated if possible (for example by applying exaggerated rates or applying at later growth stages compared to intended GAP) and then used in an incurred storage stability study.

Sample form

24. The form of the stored commodity, for example homogenate, coarse chop, whole commodity or extract, in a freezer storage stability study should be, as far as possible, the same as what was stored in the corresponding MOR studies (please also refer to paragraph 79 of OECD Test Guideline 509 (7)). Deviations should be justified and potential implications on the storage stability discussed.

25. In some cases, MOR samples are stored as whole commodities, while the freezer storage stability samples are kept as homogenates in order to ensure that the samples can be fortified uniformly. Provided the residues are found to be stable, such studies will normally be accepted since the use of a homogenate in

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the freezer storage stability study is likely to represent a worse case compared to the use of a whole commodity.

26. If samples are to be stored as extracts, extract stability should be demonstrated as detailed in the Analytical Methods Guidance Document (6).

Storage conditions

27. It is recognised that MOR samples almost always require transport from the study site to the laboratory prior to placement into storage until residue analysis. Efforts should be made to keep samples as cold as possible during transport (for example packed with dry ice) and to keep the transport period as short as possible. The freezer storage stability study should then simulate conditions used in the laboratory and/or facility for storage of MOR samples prior to their analysis. Storage temperatures should be -18ºC or lower and samples kept in the dark to eliminate the possibility of photochemical reactions. Standard freezer temperature settings might vary slightly depending on common practice in different regions. Mostly used freezer temperatures are -18°C and -20°C. Generally, storage stability studies conducted at slightly lower temperatures, for example at ≤ -20°C, are considered to cover also residue samples stored at -18°C.

28. For pesticides with known instability, options to reduce this instability in the MOR samples can include storage at lower temperatures, or frozen storage of the extracts in solvent. Furthermore, samples from the MOR studies can be stabilised by the addition of acid or base during homogenisation or by cryogenic milling. Any of these additional steps should also be employed in the freezer storage stability study.

29. Storage conditions should be constantly monitored and recorded to demonstrate maintenance of acceptable storage temperatures. If the storage conditions vary significantly, for example due to freezer breakdown, full details should be provided and data from various time points in the study should be considered to determine if validity of the study has been challenged.

30. As far as possible, sample vessels should be of the same design and of the same inert composition as in the MOR studies. However, if this is not possible, as long as the pesticide is not volatile, studies will not be rejected solely due to the use of different containers.

Frequency and period of sampling

31. It is advisable that at the beginning of the study adequate aliquots of each commodity are stored in the freezer to enable sufficient time points to be analysed covering the storage period of the MOR samples. Additional reserve samples are also recommended in case problems are encountered and repeated analysis is required, or if longer storage periods are needed than anticipated. In all cases, the sampling points should include analysis of samples freshly fortified at each sampling point (using non-fortified stored sample material) to check the performance of the method at all timepoints. For Day 0, no additional fortified samples for checking method performance are required (except for incurred residue studies) because the storage stability samples can serve as such as well. The minimum number of sampling events depends upon the stability of the residues and the maximum length of the storage period for the MOR samples.

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32. Applicants may choose to use just two sampling intervals: Day 0 and for example 12 or 24 months. However, this is at the applicant's risk as a rate of decline cannot be established and extrapolation beyond the time tested may not be possible and thus compromise the MOR studies. It is recommended where residues are considered to be stable, to employ typical sampling intervals of 0, 1, 3, 6 and 12 months. This period may have to be extended if the MOR samples are stored for longer periods, for example up to 2 years. In contrast, if relatively rapid decline of residues is suspected, more frequent sampling intervals such as 0, 2, 4, 8 and 16 weeks could be chosen. If there is no prior knowledge then the choice of intervals could be a combination of the above.

33. Duplicate samples of every commodity at each time point for all components of the residue definitions need to be analysed, while for Day 0 a minimum of 5 independent samples is recommended. However, if results for the duplicate samples from the same time point differ significantly (by more than 20% in terms of absolute %-difference), consideration should be given to analysing additional samples of the commodity from that time point. Replicate analyses of the individual samples are at the discretion of the applicant.

34. The applicant should ensure that all MOR samples are analysed within the time period for which freezer storage stability for all components of the residue definitions has been demonstrated. However, where this is not the case, this does not necessarily compromise the use of the MOR data. In exceptional cases, extrapolation to time points not covered by the storage intervals may be possible where there is no observable decline (see 1.1.Annex A).

35. It is not recommended to conduct so called reverse storage stability studies. In a reverse study, samples are put in the freezer at different time points and collected all at the same time point at study termination, thus covering different storage intervals. This has sometimes been done by applicants to start the study even before an analytical method has been developed. However, if problems arise from fortification or residues are declining in storage, this does not become obvious before the study terminates (or the analytical method becomes available).

COMMODITIES TO BE INVESTIGATED

Plant commodities

36. Based on available storage stability data and the differences seen across commodities, four matrix groups are considered sufficient to accommodate all plant commodities (obtained from primary crop, rotational crop or processing studies). Extrapolation of conclusions on stability within a matrix group is recommended. The matrix groups are as follows:

- high water content matrix group;
- high acid content matrix group;
- high oil content matrix group;
- dry matrix group.

37. For each matrix group a set of representative commodities is proposed on which storage stability studies should preferably be conducted (Table 1). The list of commodities in Table 1 is not a comprehensive list and other commodities may

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be used. It is recommended to use commodities which are important in human/animal diets.

38. Depending on the use pattern of the pesticide and the number of matrix and commodity groups covered in the MOR studies, it is sufficient to conduct the storage stability studies with one, two or three representative commodities per matrix group from the list in Table 1, given that no decline of residues is observed. If data for all four matrix groups have been generated, residues in all other commodities are assumed to be stable for at least the shortest common time period for which stability was shown in any of the four matrix groups. No further freezer storage stability data are required for any matrix, including processed foods. For further details, see Table 1 and the paragraphs below.

39. Many pesticides are registered for use on only a few crops. When storage stability data are not available for all four matrix groups, other rules apply (see Table 1). The applicant should justify their selection of representative commodities for the storage stability studies. One example is presented here: In the case of a pesticide to be applied only to oilseed rape (belonging to the high oil content matrix group) and stone fruit (belonging to the high water content matrix group), freezer storage stability data should be provided on at least one representative commodity of each of the two commodity groups. Tested commodities should be an oilseed such as rape seed or sunflower seed and a stone fruit such as peach fruit or cherry fruit. Results can be extrapolated within the two commodity groups. If the use of this pesticide is extended later to other crops belonging to the high water content matrix group such as leafy vegetables, cucurbits, brassica vegetables and pome fruit, storage stability data would be needed on two further of those high water commodity groups, for example on the commodities cauliflower (head with stem) and lettuce leaves. If freezer storage stability can be demonstrated for commodities from all three commodity groups, this result can be extrapolated to all commodities in the high water content matrix group.

40. If instability is observed after a certain storage period in one or more commodity or matrix groups, the applicant should ensure that any commodity (raw or processed) belonging to these commodity or matrix groups is analysed within the demonstrated period of stability.

41. If more than one study per commodity or more than one study per commodity group is available, which cover different storage intervals but show no signs of instability, the study covering the longest storage interval is selected for the assessment.

42. In contrast to Table 1, Table 5 in Annex B serves the purpose of categorising the most typical commodities obtained from residue studies to identify from which matrix group information on storage stability is needed to cover them.

43. Extrapolation principles as outlined in this document are applicable independent from the chosen study design (fortified or incurred storage stability study).

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Table 1. Representative commodities of plant origin per matrix group

Matrix group	Commodity group	Representative commodities	Nº of commodity groups to be tested within a matrix group, if single matrix groups are investigated and			Nº of commodity groups to be tested within a matrix group, if all matrix groups are investigated
			uses concern one commodity group within the matrix group	uses concern two commodity groups within the matrix group	uses concern >2 commodity groups within the matrix group	
High water content	Pome fruits	Apple fruit, pear fruit	1 Extrapolation to whole commodity group	2 Extrapolation to whole commodity groups	3* Extrapolation to whole matrix group	1
	Stone fruits	Apricot fruit, cherry fruit, peach fruit, plum fruit				
	Bulb vegetables	Onion bulb, leek plant				
	Brassica vegetables	Cauliflower head with stem, Brussels sprouts, head cabbage (head with wrapper leaves)				
	Fruiting vegetables	Cucumber fruit, melon fruit, tomato fruit, pepper fruit				
	Leafy vegetables	Lettuce leaves, spinach leaves, kale leaves				
	Legume vegetables	Peas (green, with pods), beans (green, with pods)				
	Root and tuber vegetables	Carrot root, potato tuber, beetroot, sugar beet root				
	Stalk and stem vegetables	Celery stalk				
	Legume feed products	Alfalfa forage, clover forage				
	Cereal grains and grass feed products	Wheat forage, barley forage, maize forage, grass				
	Miscellaneous Feed Products	Beet leaves or tops, fodder beet root				

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Matrix group	Commodity group	Representative commodities	Nº of commodity groups to be tested within a matrix group, if single matrix groups are investigated and			Nº of commodity groups to be tested within a matrix group, if all matrix groups are investigated
			uses concern one commodity group within the matrix group	uses concern two commodity groups within the matrix group	uses concern >2 commodity groups within the matrix group	
High oil content	Tree nuts	Walnut nutmeat, hazelnut nutmeat, almond nutmeat	1 Extrapolation to whole commodity group	2 Extrapolation to whole matrix group	2 Extrapolation to whole matrix group	1
	(Sub)tropical fruits	Avocado fruit				
	Oilseeds and oilfruits	Rapeseed, sunflower seed, cotton seed, peanut nutmeat, olive fruit for oil production				
	Pulses	Soya bean				
Dry	Pulses	Dry bean seeds, dry pea seeds	1 Extrapolation to whole commodity group	2 Extrapolation to whole matrix group	2 Extrapolation to whole matrix group	1
	Cereal grains	Wheat, rye, barley, oats and maize grain				
	Cereal straw	Wheat, rye, barley and oats straw, maize stover				
	Dried fruits	Raisin				
High acid content	Citrus fruits	Lemon fruit, orange fruit, mandarin fruit	1 Extrapolation to whole commodity group	2 Extrapolation to whole matrix group	2 Extrapolation to whole matrix group	1
	Berries and other small fruits	Strawberry, blueberry, raspberry, currant (berries), table/wine grape (berries)				

* The higher number of required studies compared to the other groups is justified by high consumption figures as well as a high number of commodity groups falling under the high water content matrix group.

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44. Commodities which are – in the context of the Guidance Document on Analytical Methods (6) - categorised as difficult to analyse due to high matrix loads do not require specific considerations with respect to storage stability. They are attributed to one of the four matrix groups mentioned in Table 1 (see Table 5 in Annex B for details of attribution). However, while it is allowed to extrapolate from representative commodities in the respective matrix group to the difficult-to-analyse members, this is not recommended the other way round. The reasoning behind is that only minimal data is available on the storage stability of typical difficult-to-analyse commodities and extrapolation is therefore connected to a higher uncertainty than for data-rich commodities.

45. A processed commodity may also be selected as a representative commodity, if it is made up of a single ingredient like orange juice and is not a composite food like beer or bread. The attribution of processed commodities to the four matrix groups is detailed in Table 5. It is not necessary to provide separate data on processed commodities if sufficient data for the respective matrix group is already available. On the other hand, data on processed commodities can make up a part of but not the whole dataset when extrapolating to the whole matrix group. A minimum of one raw commodity and a maximum of one processed commodity shall be selected to demonstrate stability for one matrix group. They shall belong to different commodity groups. Example: for the high acid content matrix group, it would be acceptable to have storage stability data in fresh lemon fruits and fresh raspberries, or in fresh raspberries and lemon juice, but not in lemon juice and raspberry juice.

46. The plant commodities listed in Table 1 and Table 5 have been assigned to a single specific matrix group. It is recognised that some commodities can fit into more than one matrix group, but as these are model studies, such commodities have been assigned to the most representative group. One commodity cannot be used to cover more than one group. However, storage stability data generated in a single commodity can in principle be used to support trials data generated in commodities belonging to other matrix groups. For example, it could be argued that data generated in apple fruits with a low pH value provide information on the storage stability of residues in high acid content commodities. Another example is spices. Due to the relatively high oil content of some spices and their essential oil composition, stability data generated in a matrix with high oil content may be more adequate in some cases. Where deviations from the matrix group attributions in Table1 and Table 5 are proposed, these must be fully justified and supported by relevant data and/or information on the composition of the commodities in question, the pH, water content, oil content and further relevant information.

47. For crops involving sampling of more than one commodity, more than one matrix group might be concerned. Cereals for example require storage stability studies for the dry commodity matrix group and the high water content matrix group, if grain, straw and forage samples have been taken.

48. Commodities used for the freezer storage stability study could also be obtained from metabolism studies using radiolabelled test substance. In this case, the residues according to the residue definitions should be determined after extraction using the extraction procedure described in the residue analytical method that was employed in the MOR studies or another validated method, coupled with an appropriate radio-chemical detection technique for the analyte(s) of interest. In other words, the freezer storage stability data should not be based

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on simply counting total radioactivity. Qualitatively, stability may be evaluated by comparison of the residue profile (using radio chromatograms) from initial extraction and a later extraction. Quantitatively, %TRR and/or mg/kg data corresponding to individual analytes may be evaluated from initial extraction and later extractions. (NOTE: the discussion in this paragraph is not referring to the residue freezer storage stability data needed to support a metabolism study which is covered separately in corresponding OECD guidelines (8)(9)(10)).

49. Additional storage stability data might also be available from metabolism studies. Within nature of residue studies, the stability of samples is typically demonstrated by a qualitative comparison of the residue profile (for example obtained from chromatograms) from an early and late extraction. Such information may be useful for storage stability assessments in conjunction with data from standard storage stability studies (see also Annex A, section 'Lack of Day 0 Results'). Quantitative data for individual analytes might also be available from metabolism studies. Such information may be used to complement data from typical storage stability studies if needed, for example if a longer storage interval was covered in the metabolism study compared to the standard study. Since samples from metabolism studies contain incurred residues, storage stability information obtained from such samples can be considered as superior compared to data from fortified samples and, hence, can provide valuable information for the assessment of storage stability.

Animal commodities

50. In the case of studies involving animal commodities such as livestock feeding studies, the appropriate commodities should be chosen from Table 2 below, depending on the animal species and the study design.

Table 2. List of commodities of animal origin proposed to be used for storage stability studies

Ruminants/poultry/swine	Fish
- muscle - liver or kidney - fat - milk - eggs	- fish fillet + skin - fish liver* - fish carcass*

* to be included only if analysis of liver and/or carcass is required in the respective MOR study.

51. For fish commodities, it may be possible to address the storage stability of residues in the relevant commodities within the data generation studies rather than include them in a stand-alone animal commodity storage stability study. Results are extrapolated to other fish species.

52. If residues are shown to be stable in muscle of one species (ruminant, poultry, or swine), they are assumed to be stable also in muscle of other ruminants, poultry or swine for the same time period under the same storage conditions. The same is true for the other commodities (liver, fat, etc.) listed in the column "Ruminants/poultry/swine" of Table 2. Further, the stability of residues from MOR studies with mammalian species other than those mentioned above may be

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permissible. Applicants should ensure that all MOR samples of animal origin are analysed within the storage period for which stability has been demonstrated.

Bee Products

53. In the case of studies involving bee products, storage stability studies on honey (and pollen, if applicable) are required and no extrapolation is possible. However, a study on pollen would only be necessary if it has been sampled in a MOR study on honey, which is not mandatory. Separate storage stability data for nectar and flowers are usually not considered necessary, as these commodities are attributed to the high water content matrix group and may be covered by frozen storage stability data generated in representative high water content commodities. In the event that no data are available in this matrix group, separate storage stability studies on nectar/flowers would be needed. It should be noted that a honey storage stability study may require the inclusion of additional analytes, if residue definitions differ. It may be permissible to address the storage stability of residues in the relevant commodities within the data generation study or within a stand-alone storage stability study.

FURTHER DATA CONSIDERATIONS

54. When a storage stability study demonstrates that at least 70% of the initial concentration remains after storage, residues are considered to be stable under the tested storage conditions and for the tested storage duration.

55. During freezer storage stability studies, freshly fortified control samples should be analysed at each of the time points when aged/stored freezer storage stability samples are removed from storage for analysis in order to demonstrate concurrent recovery at the time of analysis. This will allow appropriate interpretation with regard to possible residue decline in case analytical recoveries are variable across the different time intervals. As such, if concurrent recoveries are close to 100%, but stored commodities give low recoveries, then this would suggest decline during storage. However, if recoveries for stored commodities and concurrent recoveries are both low, then this indicates problems with the analytical method and no conclusion on storage stability can be drawn. Examples are discussed in 1.1.Annex A, Table 3.

56. Data from the freezer storage stability study indicating a limited stability does not necessarily compromise the use of the MOR data. The significance of observed decline is dependent upon a number of factors which can include: the rate of decline and whether a plateau is reached (equilibrium); the acceptability of mean concurrent recoveries (usually acceptable between 70 and 120%, see 1.1.Annex A for further examples), as well as how close the tested commodities in the freezer storage stability studies are to the crop used in the MOR trials. Overall, acceptability of studies will be considered on a case-by-case basis taking into account the above factors (see also 1.1.Annex A).

57. In the case of measurable decline in residues, provided sufficient data points are available to construct a suitable graph, the principle of interpolation could be applied to determine the decline at any point in time. For interpretation of an observed decline, results of concurrent recoveries may be taken into account. While quantitative correction for concurrent recovery is discouraged, it is noted that some jurisdictions allow such adjustment. Examples are provided in 1.1.Annex A.

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If a decline is still indicated, the applicant should ensure that all MOR samples are analysed within the time window for which stability of the residues of interest has been demonstrated in the commodity.

DATA REPORTING

58. Reports on freezer storage stability studies should include a detailed description of the commodities that were stored (whether raw or processed, homogenised or whole); the test compound(s); the experimental design and storage conditions such as freezer temperature, length of storage, type of containers, residue analytical method(s) and instrumentation; freezer storage stability results and reporting of the data; statistical analysis; quality control measures/precautions taken to ensure the validity of these operations, including the dates for each step above. To relate the results from storage stability studies to MOR studies, it is important for applicants to describe how MOR samples are prepared (for example coarsely chopped, homogenised, water or buffer added) before being placed into storage.

59. The values for individual recoveries should be reported for all commodities and concurrent recoveries, as opposed to just reporting a mean. Results should be presented as absolute values in mg/kg as well as in % of nominal fortification level. Results for stored commodities should be reported without adjustment by concurrent recoveries. Concurrent recoveries should be provided for all samples and sampling times including Day 0, which is defined as the beginning of the freezer storage stability testing, also when incurred residue samples are used. The Day 0 sample is the same as the initial concurrent recovery (except for incurred residue studies). A suggested tabular format for reporting the results is provided in 1.1.Annex A, Table 3.

Materials

(i) Test chemical

(A) If fortified samples were used, describe the test chemical(s) (chemical/ common/experimental names/CAS numbers, including the determination/check of the purity of the test compounds (all components of the residue definitions) and preparation of standard solutions, including necessary dilutions. Provide certificates of analysis.

(B) If incurred residue samples were used, confirm the presence and the amount of all components of the residue definitions in the sample at Day 0. First analysis for samples with incurred residues should be carried out as soon after harvest/sacrifice as possible and no more than 30 days after harvest/sacrifice.

(C) Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description and identification of the test substances used in freezer storage stability testing.

(ii) Test commodity

(A) Identification of the individual animal or plant commodity, including

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crop, type, variety and botanical name where available.

(B) For plant commodities describe the developmental stage, the general condition such as immature/mature, green/ripe or fresh/dry and the size of the commodity.

(C) Describe the sampling procedure and sample handling for each commodity, for example trimming, cleaning or other means of residue removal, compositing, subsampling, chopping, and extraction.

(D) For incurred samples, describe source of MOR samples, study/trial identification number, flag it as control or incurred residue sample and provide unambiguous sample identity.

(E) Any additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the commodities.

Methods

(iii) Experimental design, such as the number of test commodities and test chemicals, the number and magnitude of test levels, the number of replicate samples per test chemical per test level and the number of sampling intervals and storage times.

(iv) Test procedures

(A) Fortification procedure (if applicable): Detail the manner in which the test chemical(s) was/were introduced to the test commodities.

(B) Storage conditions: Temperature, lighting, container types/size, commodity form (extract/macerate/etc.), sample sizes/weight(s), duration, etc. should be provided.

(C) Sampling: Describe the sampling procedure at Day 0 and at regular intervals thereafter.

(D) Dates and kinds of sample preparation (maceration/extraction/ homogenization etc.), date of fortification or determination of incurred residue (Day 0), sampling intervals, start and end of freezer storage and dates of residue analyses should be provided.

(E) Methods of residue analysis: Concerning the data/information to be included it is referred to the Guidance Document on Analytical Methods (6).

Results/Discussion

(v) Residue results: uncorrected data, details of any necessary dilutions, peak heights/areas, individual concurrent recoveries, formula(e)/standard curves used, individual sample residue levels, recovery, percent decline related to Day 0 (if observed) vs. length of storage, appropriateness of length of freezer storage stability study, etc. should be provided. See 1.1.Annex A, Table 3 for an example of how to report the results. Storage durations should be reported in days.

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(vi) Statistical methods: Describe tests applied to the raw data.

(vii) Other: Any additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the results should be provided.

Conclusion

(viii) Discuss conclusions that may be drawn regarding the stability of the test compound(s) in the test commodities as a function of storage time, and the use of the data for interpolation and extrapolation purposes.

GLP

(ix) The study should be conducted according to GLP principles (11) and relevant certification should be provided.

Tables/Figures

(xi) Tables of data from freezer storage stability testing and a summary table of residue levels in stored samples as a function of commodity and storage time in days should be submitted, see 1.1.Annex A, Table 3 for an example of how to report the results.

(xii) Relevant graphs, figures, flowcharts, etc. should be included. Concerning the analytical method part, it is referred to the provisions of the Guidance Document on Analytical Methods (6).

Appendices

(xiii) Reprints of methods and other studies cited unless physically located elsewhere in the overall data submission, in which case cross-referencing will suffice, should be submitted.

(xiv) Other: Include any relevant material not fitting in any of the other sections of this report.

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Annex A. Guidance on interpretation of study results

A-1. Ideally, (i) samples of all the matrices of interest from storage stability studies are maintained under frozen storage conditions for a duration meeting or exceeding the longest storage period of any sample from a magnitude of the residue study, (ii) data from Day 0 samples confirm the nominal fortification level, (iii) concurrent recoveries are in the acceptable range between 70 and 120% and consistent across all sampling intervals, and (iv) the amount remaining at all sampling intervals is near 100% of the nominal fortification level. When such is the case, there are no confounding conditions and the conclusion can easily be made that residues are stable in the stored analytical sample. When the results of a storage stability study are not aligned with that ideal situation, a deeper analysis may be necessary to determine whether the residues in stored analytical samples from the MOR study are fit for purpose.

A-2. When data demonstrate that residues have dissipated in storage to an extent that less than 70% of the fortification level (see also paragraphs A-9 ff) remains, the general conclusion should be that residues are not stable under the tested storage conditions for durations longer than that for which storage stability recoveries are below 70%. See also paragraph A-19.

A-3. This Annex provides guidance on the interpretation of storage stability study results in an effort to promote consistent conclusions when issues arise, including observed decline of residues during storage, inconsistent results (including within a commodity and/or across different commodities), storage durations for analytical samples that exceed the storage duration covered by the storage stability study, storage freezer malfunctions and thawing of analytical samples, and periods of storage under ambient conditions.

A-4. The issues detailed in this Annex may occur individually or in various combinations. It is beyond the scope of this guidance to address all permutations of issues that may arise. Expert judgement is needed to gauge the importance of any discrepancies, to interpret the interplay of variables, and ultimately to conclude on the stability of residues and the impact on stored samples from MOR studies.

A-5. In discussing the situations detailed in this Annex, it is assumed that all storage stability samples for a given commodity were fortified with the same standard solution and at the same time, or that data are available to support that all fortifications were equivalent if they were made with different standard solutions and/or at a different time (for example, use of internal standards in the fortification solution).

Concurrent recoveries

A-6. Ideally, conclusions on storage stability should not need to rely on quantitative corrections for method performance such as concurrent recovery data; however, some regulatory authorities may quantitatively correct freezer storage recoveries for concurrent recoveries that are <100%. This correction is made according to the following:

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$$Freezer\ storage\ recovery\ at\ time\ (t)_{Corrected} = \frac{Freezer\ storage\ recovery\ at\ time\ (t)_{Observed}}{Mean\ concurrent\ recovery\ at\ time\ (t)}$$

A-7. Regardless of whether quantitative correction is made, concurrent recovery information can be useful in interpreting results from storage stability samples, especially in the case of apparently errant results for a single time point—a low recovery from an analytical sample and a low concurrent recovery may lead to the conclusion that the perceived decline in storage was not real.

A-8. When concurrent recoveries consistently fall outside of the acceptable range for the method being used, it may be prudent to re-evaluate the suitability of the analytical method. The source of the discrepancy should be investigated and reported. An example would be an error in preparation of the concurrent recovery fortification solution. Another situation that requires investigation and explanation of the results is when there is a chronological upward or downward trend in concurrent recovery values (see Example 2, below). Results of that nature may indicate fundamental problems with the analytical method and/or stability of reference substances.

Normalisation to Day 0

A-9. When samples with incurred residues are used to evaluate storage stability, the results from Day 0 analyses are the only reference point that can be used to evaluate stability in storage. In this case, normalisation to results from Day 0 is required, and analysis should be done as soon as possible, preferably within 30 days after harvest of the sample or after sacrifice, if animal samples are concerned. A sufficient number of samples corresponding to Day 0 should be analysed to ensure a robust result; a minimum of 5 independent samples is recommended.

A-10. When control samples are fortified with the analyte(s) of interest, the expectation is that variability associated with fortification (meaning the absolute amount added to the sample) is less than the variability associated with sample analysis; therefore, the preferred reference point for evaluating stability is the nominal fortification level. Nevertheless, the results from Day 0 should still be examined as they provide confirmation that the fortifications were done correctly. In the event that there are discrepancies between the nominal fortification level and the results from Day 0 samples that cannot be accounted for by analytical variability, those discrepancies should be investigated.

A-11. If an explanation can be provided that the discrepancy between the nominal fortification level and the Day 0 results is due to a fortification error, then it is acceptable to correct the nominal fortification level to account for the error. Otherwise, consideration should be given to either restart the storage stability study or normalise results from stored samples and express the residue as a percentage of the amount remaining relative to Day 0. A robust result for residues on Day 0 is needed to support this approach; therefore, a minimum of five independent Day 0 samples is recommended (note that concurrent recovery samples generated to support the Day 0 analysis are, themselves, Day 0 samples).

Lack of Day 0 results

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A-12. Storage stability studies should always include Day 0 samples. These samples provide evidence of the actual fortification level and provide a basis for interpreting results from storage stability samples collected at later time points.

A-13. If Day 0 results are not available, questions may arise as to whether sample fortifications occurred at the nominal fortification level, especially if recoveries from stored fortified samples are considerably greater or less than 100%. In such cases, information from metabolism studies may be useful, if the first profile is generated early in the study. Typically, samples from nature of the residue studies are not stored for long periods of time, as OECD guidelines require analysis of samples within 6 months. Stability of residues is often demonstrated by a qualitative comparison of the residue profile (for example from chromatograms) from an initial extraction with the profile from a later extraction after some longer duration of storage. While not as robust as a proper storage stability assessment, such information can be used in conjunction with recoveries from the storage stability samples to build a weight-of-evidence argument for interpreting stability of residues in analytical samples when data from Day 0 are not available. Data from nature of the residue studies may also help to conclude on stability for short time periods that may not be specifically addressed in the storage stability study.

A-14. Acceptable recovery at a later time point, in the absence of Day 0 results, does not preclude a fortification error and subsequent decline of residues. Therefore, if Day 0 results are not available, then the storage stability study will generally be considered unsuitable for supporting MOR studies. Supporting evidence of accurate fortification and/or short-term stability could be considered on a case-by-case basis.

Decline of residues

A-15. Recoveries from storage stability samples may show a pattern with time similar to one of the following scenarios:

- Recoveries show little, if any, decrease over the entire duration of the storage period. When this is the case, it can be concluded that the residues are stable for *at least* the duration covered by the study.
- Recoveries show a consistent decrease over time. In this case, decline of residues may be an issue, depending on the degree of decline and the storage durations for analytical samples.

    - Analytical samples stored for a period associated with residue instability (<70% recovery) will generally not be suitable for supporting regulatory conclusions.

    - Note, however, that in cases where decline of the residue is accompanied by a quantitative increase in another residue/metabolite AND that residue/metabolite is included in the residue definition for enforcement, the results from the analytical sample may be usable, provided the % recovery of the combined residue, expressed on an equimolar basis, is ≥ 70%. In the case of residue definitions for risk assessment, a similar situation exists, but only if the individual residues in question are

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assessed together and the definition is expressed as the sum of residue without any adjustments for toxicological potency.

- Recoveries show residues to be stable for a given time period, followed by a decrease in % recoveries. In this case it can be concluded that residues are stable up to the duration of demonstrated stability. Samples stored for longer than that duration should not be used to support regulatory decisions (noting the same exception as above regarding quantitative transformation to another residue in the residue definition).

A-16. Some regulatory authorities allow for quantitative adjustment of results from MOR to account for loss of residue in storage. Any such adjustment should be supported by the available data and should be made using a consistent approach for all samples (for example a single-point correction factor vs. interpolation vs. regression equation using all data points; see also A-31). Furthermore, adjustments should be made in a way that introduces the least amount of uncertainty to the MOR results.

A-17. If samples cannot be analysed within the period of demonstrated stability or reliably corrected to account for loss in storage, then data generators should consult with regulatory agencies on how best to proceed under the given situation.

Inconsistent results for one commodity within a study

A-18. It is not uncommon that results from a single time point may raise questions about the stability of residues. Example: 84% recovery at 0 and 6 months followed by a result of 60% recovery at 12 months and then a result of 80% recovery at 18 months. It needs to be determined whether low % recovery values are indicative of actual decline in storage or some other phenomenon. Often, expert judgement will be needed in these cases, and concurrent recovery results may help in interpreting whether the variations in % recoveries are the result of true decline or are from an analytical anomaly.

A-19. It is recommended that low recoveries (<70%) can be disregarded if recoveries greater than approximately 70% are seen for at least two time points after the low recovery (Example 5, below). By extension, a low recovery at the final sampling time should be interpreted as non-stable residues unless other evidence to the contrary is available (Example 6).

A-20. If the data show that less than approximately 70% of the initial residue is remaining for consecutive sampling times and/or a trend toward such loss is observed, then it should be concluded that residues are not stable.

Inconsistent recoveries within a commodity or commodity group in different studies

A-21. Data from multiple storage stability studies may show inconsistent results for the same commodity. Comparison of the study designs (including consideration of the form of the sample), keeping in mind also the details on the storage conditions and durations of storage for the analytical samples, may help to determine if one study is more representative than another. Newer studies should NOT be used preferentially over older studies solely on the basis of the age of the

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study, and neither should newer studies automatically supersede the results of older studies.

A-22. In the case of conflicting results for the same commodity, the shortest period of demonstrated stability should be assumed unless explanation and/or data can be provided which is specific to the residue samples and the associated storage stability study in question. A third study may be helpful to be able to conclude on the stability of residues.

A-23. If studies for commodities in the same commodity group show inconsistent results with respect to stability of residues in storage, then storage stability data may be needed for each commodity in the commodity group for which field trials were conducted.

A-24. For extrapolation to all crops within a matrix group, stability in 2-3 commodity groups has to be investigated. The following example is based on the high-water matrix group where stability in 3 different commodity groups is needed. The duration of the stability studies in the example was different (between 6 and 30 months). It is assumed that residues were **stable for the duration of the study** and that the following conclusions are supported by the results:

- **Study 1 in apple fruits** with storage stability for at least **6 months**;
- **Study 2 in plum fruits** with storage stability for at least **24 months**;
- **Study 3 in cucumber fruits** with storage stability for at least **30 months**;
- **Study 4 in carrot roots** with storage stability for at least **30 months**.

For the entire matrix group, extrapolation to 30 months is not possible since this period is covered by two studies only. Extrapolation to 24 months, however, is possible based on study 2, 3, and 4. It is noted that if the study in apple fruits was conducted for longer than 6 months and showed dissipation concluding that residues are stable for **up to** 6 months, then stability in the entire matrix group could be assumed only for up to 6 months.

A-25. Extrapolation may also be considered within an established commodity group or subgroup (for example, the Codex Group of Root and Tuber Vegetables). Due to the inherent similarity of commodities within a commodity group, in cases with differing results across a matrix group, extrapolation should first be made to commodities within a commodity group or subgroup and then to the matrix group. Thus, for the example above, stability of residues in potato (another high-water commodity and in the same commodity group as carrot) could be inferred for at least 30 months based on the results from carrot, rather than the 24-months limit for the high-water matrix group.

Diverging results from studies conducted on material with incurred residues and on fortified samples

A-26. In case diverging results are obtained from studies conducted on material with incurred residues and on fortified samples and no explanation can be identified from the studies other than the different application of the test substance, the results from incurred residues should be preferably taken, as these reflect actual field samples.

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Storage durations exceeding the demonstrated period for residue stability

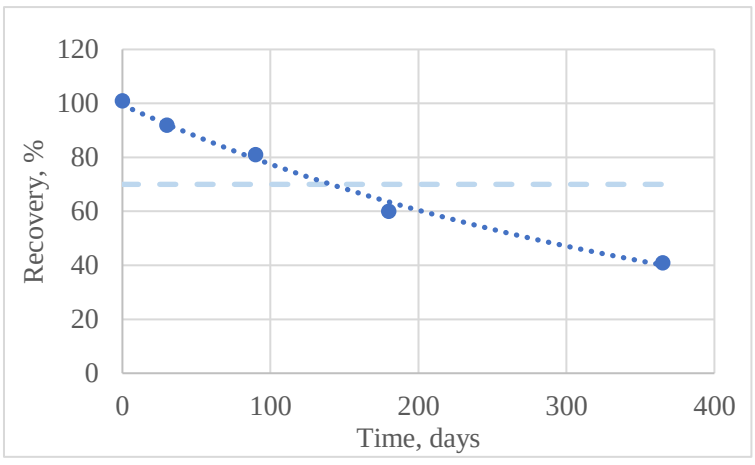
A-27. Analytical samples may be stored for a length of time that exceeds the storage duration of the available storage stability studies.

A-28. If data from a similar commodity in the same commodity group are available showing stability of residues in storage for the period of time relevant to the analytical samples in question, then those data may be used to conclude that residues are stable in the analytical samples. For example, assume storage stability data are available for cucumber fruits (cucurbit fruiting vegetable commodity group) for 7 months showing no decline and for summer squash (also cucurbit fruiting vegetable group) for 18 months showing stability over that time period. If samples of cucumber fruits from field trials were stored for 12 months, then residues can be assumed to be stable based on the results from the cucumber storage stability study with mutual support from the summer squash storage stability study to cover the additional 5 months storage period not directly addressed by the data for cucumber fruits.

A-29. Correspondingly, if data from a similar commodity show a decline in residues over the time period not covered by the storage stability data for the commodity of interest, then it should be concluded that residues are not stable beyond the time period demonstrated by the storage stability study for the commodity of interest.

A-30. If data to support extrapolation from a similar commodity are not available, then the conclusion on stability may be extrapolated beyond the demonstrated period of stability on a case-by-case basis. The degree of extrapolation will depend on the number of time points and the trend observed in the available data. Regardless of trends in the data, empirical data covering the period of storage are preferred. If extrapolation is used, it should be kept to a minimum (generally not more than 10-20%) and at least three time points should be available.

A-31. Related to extrapolating storage stability data to support storage durations exceeding the length of the study, there might be cases where residue recoveries fall below 70% during the course of the study. If that decline follows predictable kinetics, it may be suitable to determine the period of demonstrated stability by interpolation. For example, the data below indicate a period of stability of up to 90 days. The decline follows single first-order (SFO) kinetics with a rate constant of -0.00247 per day (intercept forced through 100%). Based on that value, the estimated time at which the recovery crosses the 70% threshold is approximately 144 days. Depending on the overall situation, a conclusion might be supported that samples stored for up



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to ca. 140 days are suitable for deriving regulatory conclusions, rather than the limit of 90 days that would be derived from the data without using interpolation. Various models may be suitable for interpolation. Selecting a model is beyond the scope of this guidance; regardless, use of this technique should be supported by general modelling principles, including consideration of degrees of freedom and goodness of fit.

Storage time, days	Recovery, % of nominal fortification level
0	101
30	92
90	81
180	60
365	41

Freezer malfunctions

A-32. In the event of a freezer malfunction and thawing of analytical samples, the duration of the malfunction and the impact on temperature must be documented. In cases where there are concurrent storage stability samples that experience the same storage conditions as the analytical samples, the results from pre- and post-malfunction storage stability samples can be used to conclude on the impact of the malfunction on the integrity of the analytical samples. If the malfunction does not result in samples thawing, or samples taken after the malfunction do not show signs of residue decline, then it can be concluded that the malfunction had no impact on the suitability of the study; otherwise, a special study mimicking the conditions during the malfunction may be needed to conclude on the impact of the malfunction.

A-33. If the freezer malfunction occurs such that only storage stability samples are affected and a decline of residues is observed, then the study may need to be repeated.

Examples for reporting and interpretation of study results

A-34. To illustrate the interpretation of results from storage stability studies, some examples are provided below.

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Table 3. Examples for reporting and interpretation of study results

Nominal fortification, mg/kg	Storage time, days*	Stored sample		Concurrent recovery	
		Residue, mg/kg	% of nominal level [mean]	Residue, mg/kg	% recovery [mean]
Example 1: Observable decline of residue in stored samples, good concurrent recoveries					
1.0	0	0.998, 1.03, 1.08, 1.15, 1.18	99.8, 103, 108, 115, 118 [109]	--	--
1.0	30	0.847, 0.963	84.7, 96.3 [90.5]	0.998, 1.02	99.8, 102 [101]
1.0	90	0.745, 0.798	74.5, 79.8 [77.2]	0.921, 0.997	92.1, 99.7 [95.9]
1.0	180	0.678, 0.699	67.8, 69.9 [68.9]	0.889, 0.962	88.9, 96.2 [92.6]
1.0	365	0.678, 0.701	67.8, 70.1 [69.0]	0.899, 0.954	89.9, 95.4 [92.7]
1.0	545	0.645, 0.657	64.5, 65.7 [65.1]	0.911, 0.935	91.1, 93.5 [92.3]
1.0	730	0.654, 0.698	65.4, 69 8 [67.6]	0.921, 0.975	92.1, 97.5 [94.8]
Example 2: Observable decline of residue in stored samples, decline mirrored in concurrent recoveries					
1.0	0	0.992, 0.998, 1.01, 1.02, 1.03	99.2, 99.8, 101, 102, 103 [101]	--	--
1.0	30	0.847, 0.963	84.7, 96.3 [90.5]	0.998, 1.02	99.8, 102 [101]
1.0	90	0.745, 0.798	74.5, 79.8 [77.2]	0.724, 0.785	72.4, 78.5 [75.5]
1.0	180	0.678, 0.699	67.8, 69.9 [68.9]	0.721, 0.744	72.1, 74.4 [73.3]
1.0	365	0.678, 0.699	67.8, 69.9 [68.9]	0.721, 0.744	72.1, 74.4 [73.3]
1.0	545	0.645, 0.657	64.5, 65.7 [65.1]	0.691, 0.711	69.1, 71.1 [70.1]
1.0	730	0.654, 0.698	65.4, 69.8 [67.6]	0.624, 0.712	62.4, 71.2 [66.8]
Example 3: Observable decline of residues in stored samples, good concurrent recoveries, high Day 0 recovery					
1.0	0	1.09, 1.11, 1.12, 1.18, 1.19	109, 111, 112, 118, 119 [114]	--	--
1.0	30	0.963, 0.987	96.3, 98.7 [97.5]	0.998, 1.02	99.8, 102 [101]
1.0	90	0.912, 0.922	91.2, 92.2 [91.7]	0.877, 0.962	87.7, 96.2 [92.0]
1.0	180	0.816, 0.821	81.6, 82.1 [81.9]	0.824, 0.853	82.4, 85.3 [83.9]
1.0	365	0.875, 0.912	87.5, 91.2 [89.4]	0.874, 0.912	87.4, 91.2 [89.3]
1.0	545	0.742, 0.785	74.2, 78.5 [76.4]	0.756, 0.821	75.6, 82.1 [78.9]
1.0	730	0.711, 0.751	71.1, 75.1 [73.1]	0.932, 0.978	93.2, 97.8 [95.5]
Example 4: No decline, good concurrent recoveries, low Day 0 recovery, recovery <70% at two time points					
1.0	0	0.781, 0.802, 0.811, 0.812, 0.830	78.1, 80.2, 81.1, 81.2, 83.0 [80.7]	--	--
1.0	30	0.814, 0.834	81.4, 83.4 [82.4]	0.998, 1.02	99.8, 102 [101]
1.0	90	0.788, 0.834	78.8, 83.4 [81.1]	0.887, 0.932	88.7, 93.2 [91.0]
1.0	180	0.688, 0.723	68.8, 72.3 [70.6]	0.888, 0.954	88.8, 95.4 [92.1]
1.0	365	0.678, 0.699	67.8, 69.9 [68.9]	0.799, 0.854	79.9, 85,4 [82.7]
1.0	545	0.721, 0.786	72.1, 78.6 [75.4]	0.921, 0.941	92.1, 94.1 [93.1]
1.0	730	0.687, 0.708	68.7, 70.8 [69.8]	0.873, 0.882	87.3, 88.2.[87.8]
Example 5: No decline, low recovery at one time point, followed by recoveries greater than 70 % at two subsequent time points, good concurrent recoveries					
1.0	0	0.972, 0.980, 0.991, 1.01, 1.02	97.2, 98.0, 99.1, 101, 102 [99.5]	--	--
1.0	30	0.963, 0.987	96.3, 98.7 [97.5]	0.998, 1.02	99.8, 102 [101]
1.0	90	0.912, 0.922	91.2, 92.2 [91.7]	0.877, 0.962	87.7, 96.2 [92.0]
1.0	180	0.821, 0.864	82.1, 86.4 [84.3]	0.853, 0.913	85.3, 91.3 [88.3]
1.0	365	0.623, 0.654	62.3, 65.4 [63.9]	0.912, 0.942	91.2, 94.2 [92.7]
1.0	545	0.824, 0.836	82.4, 83.6 [83.0]	0.859, 0.912	85.9, 91.2 [88.6]
1.0	730	0.823, 0.853	82.3, 85.3 [83.8]	0.932, 0.978	93.2, 97.8 [95.5]

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Nominal fortification, mg/kg	Storage time, days*	Stored sample		Concurrent recovery	
		Residue, mg/kg	% of nominal level [mean]	Residue, mg/kg	% recovery [mean]
Example 6: No decline, low recovery at final time point, good concurrent recoveries					
1.0	0	0.972, 0.980, 0.991, 1.01, 1.02	97.2, 98.0, 99.1, 101, 102 [99.5]	--	--
1.0	30	0.963, 0.987	96.3, 98.7 [97.5]	0.998, 1.02	99.8, 102 [101]
1.0	90	0.912, 0.922	91.2, 92.2 [91.7]	0.877, 0.962	87.7, 96.2 [92.0]
1.0	180	0.821, 0.864	82.1, 86.4 [84.3]	0.853, 0.913	85.3, 91.3 [88.3]
1.0	365	0.823, 0.853	82.3, 85.3 [82.8]	0.912, 0.942	91.2, 94.2 [92.7]
1.0	545	0.871, 0.886	87.1, 88.6 [87.9]	0.859, 0.912	85.9, 91.2 [88.6]
1.0	730	0.598, 0.637	59.8, 63.7 [61.8]	0.932, 0.978	93.2, 97.8 [95.5]

* Storage periods should always be reported in days to reflect the exact periods covered. The presentation in months is recommended in addition. For conversion of days into months, an average of 30.4 days per month should be used and resulting storage periods be reported with one decimal point using standard ISO rounding rules.

A-35. **Example 1**: Concurrent recovery values indicate that the method worked well throughout the storage stability study. A clear trend of decreasing recovery is seen in the results from the stored samples. The result at Day 0 is somewhat elevated, but probably within the range that would be expected for the analytical method. Based on the available data, it can be concluded that residues are stable for up to 90 days under the tested conditions.

A-36. **Example 2**: Concurrent recovery values are showing a clear trend of decreasing recovery. That trend is also shown in the stored samples. It could be concluded that residues are stable for up to 90 days.

A-37. **Example 3**: Concurrent recovery values indicate that the method worked well throughout the storage stability study. A clear trend of decreasing recovery is seen in the results from the stored samples. The significance of that decline depends on the interpretation of the Day 0 result. As the initial value (mean = 1.14 mg/kg) is suitably similar to the nominal fortification level based on what is known about the performance of the method, it can be concluded that residues are stable for up to 730 days.

A-38. **Example 4**: Concurrent recovery values indicate that the method worked well throughout the storage stability study. Recoveries from stored samples are similar at all time points, but are low. Explanation for low recoveries should be required from the applicant. No trend of loss in storage is observed. It can be concluded that residues are stable for at least 730 days.

A-39. **Example 5**: Concurrent recovery values indicate that the method worked well throughout the storage stability study. Recoveries from stored samples are consistently >80% at all time points except for the result at 365 days (63.9%). Given the results at the two subsequent time points (545- and 730-day sampling times) showing stable residues, the result at 365 days can be disregarded. It can be concluded that residues are stable for at least 730 days.

A-40. **Example 6**: Concurrent recovery values indicate that the method worked well throughout the storage stability study. Recoveries from stored samples are consistently >80% at all time points except for the result at 730 days (61.8%). As

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there are no data beyond the 730-day time point, it should be concluded that residues are stable for up to 545 days.

Storage stability of conjugates

A-41. If analytical standards for conjugates are available, their storage stability behaviour should be assessed. Instability of conjugates might be related to conversion into cleavage products such as the respective aglycons during storage. Such conversion can be considered for storage stability evaluation in case the cleavage products are measured in addition to the conjugates. The sum across conjugate and cleavage product can be used to demonstrate storage stability.

A-42. The example described in Table 4 reflects a case in which the conjugate is stable for up to 90 days of storage and recovery falls below 70% for the remaining storage intervals. At the same time, residues of the respective cleavage product occur >LOQ starting at 90 days. After conversion of residues of the cleavage product to the respective conjugate equivalent and summing up residues across both, storage stability is demonstrated for up to 545 days (sum of recoveries at 720-day interval is <70%).

A-43. The described approach can also be used in any other case in which transformation of a compound to a breakdown product occurs, for example in case of ester cleavage. It is recommended to fortify samples for such storage stability studies at rather high levels to ensure that degradation of compounds can be traced sufficiently.

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Table 4. Example for storage stability of conjugates

		Concurrent recovery conjugate		Concurrent recovery cleavage product		Stored sample conjugate, mg/kg		Stored sample cleavage product, mg/kg		Stored sample sum, mg/kg	
Fortification conjugate, mg/kg	Storage time, days	Residue, mg/kg	Mean % of fortification level	Residue, mg/kg	Mean % of fortification level	Residue, mg/kg	Mean % of fortification level	Residue, mg/kg	Residue, conjugate equivalent, mg/kg*	Residue (sum conjugate + cleavage product)**, mg/kg	Mean % fortificati level
1.0	0	-- , --	--	-- , --	--	0.998 , 1.18	109	<0.01 , <0.01	<0.01 , <0.01	0.998 , 1.18	109
1.0	30	0.998 , 1.02	101	0.932 , 0.982	95.7	0.847 , 0.963	90.5	<0.01 , <0.01	<0.01 , <0.01	0.847 , 0.963	90.5
1.0	90	0.921 , 0.997	95.9	0.896 , 0.913	90.5	0.745 , 0.798	77.2	0.148 , 0.139	0.225 , 0.211	0.970 , 1.01	99.0
1.0	180	0.889 , 0.962	92.6	0.921 , 0.936	92.9	0.621 , 0.589	60.5	0.195 , 0.179	0.296 , 0.272	0.917 , 0.861	88.9
1.0	365	0.899 , 0.954	92.7	0.903 , 0.889	89.6	0.453 , 0.401	42.7	0.286 , 0.299	0.435 , 0.454	0.888 , 0.855	87.2
1.0	545	0.911 , 0.935	92.3	0.914 , 0.923	91.9	0.314 , 0.324	31.9	0.307 , 0.318	0.467 , 0.483	0.781 , 0.807	79.4
1.0	730	0.921 , 0.975	94.8	0.936 , 0.958	94.7	0.295 , 0.287	29.1	0.251 , 0.202	0.382 , 0.307	0.677 , 0.594	63.5

* Residue (conjugate equivalent) = residue (cleavage product) x conversion factor = 1.52 (derived from molecular weights conjugate / cleavage product (830.4 g/mol / 545.8 g/mol))

** for calculation of sum, conjugate equivalent of cleavage product is used. Conjugate equivalent residues < 0.01 mg/kg are not considered for sum.

LOQ (conjugate and cleavage product): 0.01 mg/kg

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Annex B. List of food and feed commodities of plant origin and attribution to commodity groups and matrix groups

Explanations for Table 5

B-1. In Table 5, a colour coding is used to designate the four matrix groups:

high acid content
high water content
high oil content
dry

B-2. Column “R/P” distinguishes between raw commodities (“R”) and processed commodities (“P”). In this context, “processing” includes also the process of separating peel from pulp.

B-3. While Table 5 is organised according to Codex commodity groups for all raw commodities, it was decided not to follow the Codex classifications for processed commodities. Those were rather listed directly beneath the respective raw commodity instead of using the Codex groups 055-059, 065, 067-071. In general, the latest version of the Codex classification has been used (12).

B-4. Directly harvested feed items can be found in the Codex Commodity Groups 050, 051 and 052, which are dedicated to feed-only products. It has to be noted that the parts consumed by humans and harvested from the same crops are contained in other Codex Commodity Groups (for example cereal grains in group 020). Feed items obtained as processing by-products are listed together with the raw food commodities and the entry “feed item” is provided in the column “Comments”. For these entries reference is made to the latest version of the Guidance document on residues in livestock (13).

B-5. The comments "difficult to analyse" and dry/high sugar content are intended as cross-references to the OECD guidance document on analytical methods where these additional groups have been defined. They have no implication for storage stability studies.

B-6. It should be noted, that the table is not complete and further commodities (raw and processed) might be used in storage stability studies that require attribution to one of the matrix groups.

Rules for attribution of further commodities

B-7. Juices, pulps, wet pomaces (see glossary for definition of pulp and pomace), cooked or canned commodities not mentioned in the table should be attributed to the same matrix group as the respective raw commodity.

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B-8. Commodities having undergone a drying process (in the field such as pulses or post-harvest such as dried fruit and vegetables) should be attributed to the dry matrix group, even if they still contain a certain percentage of water. An exception is made for those which retain high oil content after drying, which are attributed to the high oil matrix group.

B-9. pH values vary between commodities, but even between different species of the same commodity. Commodities belonging to or produced from “citrus fruits” or “berries and small fruit” are likely to have a comparably high acid content as the other members of the group should be attributed accordingly. A pH value below 4 may serve as a justification to attribute a commodity to the high acid content matrix group.

B-10. Commodities in the high oil content matrix group typically have a fat/oil content of 20-70 %. “Oil” also includes “essential oils”. Commodities not explicitly mentioned in Table 5, but belonging to “tree nuts”, “oilseeds” or “oil fruits” and commodities used for oil production are always attributed to the high oil content matrix group.

B-11. Commodities not considered as high acid or high oil and which have not been dried are normally attributed to the high water content matrix group.

B-12. Only a few composite foods are mentioned in the table, such as beer. Though it is noted that jam, jelly and marmalade have been frequently produced in processing studies, they are composite foods prepared according to various recipes. Based on the particular composition, the appropriate assignment to a matrix group should be justified on a case-by-case basis. In general, simple processed foods are preferred over composite foods in storage stability and processing studies.

B-13. Dry processed commodities derived from high acid raw commodities require specific attention when samples are prepared for analysis: while being “dry” during storage, in solution the acidic character could become relevant again and determine the analytical method.

Table 5. List of food and feed commodities of plant origin (raw and processed) and attribution to matrix groups

Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
001 Citrus fruits	Lemon fruit	high acid content	R	
	Lime fruit	high acid content	R	
	Kumquat fruit	high acid content	R	
	Mandarin fruit	high acid content	R	
	Orange fruit	high acid content	R	
	Grapefruit fruit	high acid content	R	
	Pomelo fruit	high acid content	R	
	Citrus fruit, canned	high acid content	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Citrus juice	high acid content	P	
	Citrus oil	high oil content	P	
	Citrus peel (see also group 028)	high acid content	P	
	Citrus peel, dried	dry	P	
	Citrus pomace, dried	dry	P	feed item
	Citrus pomace, wet	high acid content	P	feed item
	Citrus pulp	high acid content	P	
002 Pome fruits	Apple fruit	high water content	R	
	Pear fruit	high water content	R	
	Quince fruit	high water content	R	
	Medlar fruit	high water content	R	
	Loquat/Japanese medlar fruit	high water content	R	
	Kaki/Japanese persimmon fruit	high water content	R	
	Pome fruit, canned	high water content	P	
	Pome fruit, cooked	high water content	P	
	Pome fruit, dried	dry	P	dry/high sugar content
	Pome fruit juice	high water content	P	
	Pome fruit puree	high water content	P	
	Pome fruit, wet pomace	high water content	P	feed item
003 Stone fruits	Cherry fruit	high water content	R	
	Plum fruit	high water content	R	
	Peach fruit	high water content	R	
	Apricot fruit	high water content	R	
	Stone fruit, canned	high water content	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Stone fruit, cooked	high water content	P	
	Stone fruit, dried	dry	P	dry/high sugar content
	Stone fruit juice	high water content	P	
	Stone fruit pulp	high water content	P	
	Stone fruit puree	high water content	P	
	Stone fruit, wet pomace	high water content	P	
004 Berries and other small fruits	Blackberry	high acid content	R	
	Dewberry	high acid content	R	
	Raspberry	high acid content	R	
	Blueberry	high acid content	R	
	Currant (berries)	high acid content	R	
	Gooseberry	high acid content	R	
	Elderberries	high acid content	R	
	Cranberry	high acid content	R	
	Strawberry	high acid content	R	
	Berries, canned	high acid content	P	
	Berries, cooked	high acid content	P	
	Berries, dried	dry	P	dry/high sugar content
	Berry juice	high acid content	P	
	Berry puree	high acid content	P	
004 Berries and other small fruits: Grapes	Table grape (fruit)	high acid content	R	
	Wine grape (fruit)	high acid content	R	
	Grape pomace, wet	high acid content	P	feed item
	Grape juice	high acid content	P	
	Must	high acid content	P	
	Raisin	dry	P	dry/high sugar content
	Grape spirit	high water content	P	
	Wine	high acid content	P	
005 Assorted tropical and subtropical fruits - edible peel	Jambolan fruit	high water content	R	
	Table olive fruit	high oil content	R	
	Table olive fruit, fermented	high oil content	P	
	Carambola fruit	high acid content	R	
	Carob pod	dry	R	high matrix load, difficult to analyse

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Fig fruit	high water content	R	
	Fig fruit, dried	dry	P	dry/high sugar content
	Guava fruit	high water content	R	
	Date fruit	high water content	R	
	Date fruit, dried	dry	P	dry/high sugar content
006 Assorted tropical and subtropical fruits – inedible peel	Litchi fruit	high water content	R	
	Logan fruit	high water content	R	
	Avocado fruit	high oil content	R	
	Banana fruit	high water content	R	
	Mango fruit	high water content	R	
	Papaya fruit	high water content	R	
	American persimmon/Virginia kaki fruit	high water content	R	
	Granate apple/pomegranate fruit	high acid content	R	
	Star apple/cainito fruit	high water content	R	
	Breadfruit	high water content	R	
	Cherimoya fruit	high water content	R	
	Durian fruit	high water content	R	
	Pineapple fruit	high acid content	R	
	Pineapple, process waste	high acid content	P	feed item
	Soursop/guanabana fruit	high water content	R	
	Prickly pear/cactus fruit	high water content	R	
	Kiwi fruit	high acid content	R	
	Passion fruit/maracuja fruit	high acid content	R	
	Tropical and subtropical fruit with inedible peel, dried	dry	P	dry/high sugar content

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
009 Bulb vegetables	Garlic bulb	high water content	R	fresh & dry garlic cloves
	Garlic bulb, peeled	high water content	P	
	Onion bulb	high water content	R	
	Onion bulb, peeled	high water content	P	
	Shallot bulb	high water content	R	
	Shallot bulb, peeled	high water content	P	
	Spring onion plant/green onion plant and Welsh onion plant	high water content	R	
	Leek plant	high water content	R	
	Bulb vegetable, dried	dry	P	
010 Brassica vegetables (except brassica leafy vegetables)	Broccoli head with stem	high water content	R	
	Cauliflower head with stem	high water content	R	
	Brussels sprout	high water content	R	
	Head cabbage (head with wrapper leaves)	high water content	R	
	Sauerkraut	high acid content	P	fermented white cabbage
	Sauerkraut juice	high acid content	P	
	Chinese cabbage/pe-tsai (head with wrapper leaves)	high water content	R	
	Kohlrabi globe	high water content	R	
	Brassica vegetable, cooked	high water content	P	
011 Fruiting vegetables: Cucurbits	Cucumber fruit	high water content	R	
	Gherkin fruit	high water content	R	
	Gherkin fruit, canned	high acid content	P	
	Gherkin fruit, fermented	high acid content	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Summer squash/zucchini fruit	high water content	R	
	Summer squash/zucchini fruit, cooked	high water content	P	
	Melon fruit	high water content	R	
	Melon, pulp	high water content	P	
	Pumpkin fruit	high water content	R	
	Pumpkin fruit, cooked	high water content	P	
	Pumpkin, wet pomace	high water content	P	
	Pumpkin, pulp	high water content	P	
	Pumpkin, puree	high water content	P	
	Watermelon fruit	high water content	R	
	Watermelon, pulp	high water content	P	
012 Fruiting vegetables, other than cucurbits	Tomato fruit	high water content	R	
	Tomato fruit, canned	high water content	P	
	Tomato fruit, dried	dry	P	
	Tomato juice	high water content	P	
	Tomato paste	high water content	P	
	Tomato puree	high water content	P	
	Tomato, wet pomace	high water content	P	feed item
	Tomato, dry pomace	dry	P	feed item
	Okra/lady's finger fruit (pods)	high water content	R	
	Sweet pepper/bell pepper fruit	high water content	R	
	Chili pepper fruit	high water content	R	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Aubergine/egg plant fruit	high water content	R	
	Fruiting vegetables other than cucurbits and tomato, fruit canned	high water content	P	
	Fruiting vegetables other than cucurbits and tomato, fruit cooked	high water content	P	
	Fruiting vegetables other than cucurbits and tomato, fruit dried	dry	P	
013 Leafy vegetables (including brassica leafy vegetables)	Chard/beet leaves	high water content	R	
	Escarole/broad-leaved endive leaves	high water content	R	
	Lamb's lettuce/corn salad leaves	high water content	R	
	Lettuce leaves or head with leaves	high water content	R	
	Purslane leaves	high water content	R	
	Spinach leaves	high water content	R	
	Cress leaves and stems	high water content	R	
	Kale leaves	high water content	R	
	Mustard greens (leaves)	high water content	R	
	Roman rocket/rucola leaves	high water content	R	
	Grape leaves	high water content	R	
	Water cress leaves and stems	high water content	R	
	Witloof sprouts	high water content	R	
	Baby leaves	high water content	R	baby crops listed in the leafy vegetable group and harvested up to 8 true leaf stage

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Leafy vegetable, canned	high water content	P	
	Leafy vegetable, cooked	high water content	P	
014 Legume vegetables	Bean (green, with pods)	high water content	R	
	Bean (succulent, without pods)	high water content	R	
	Pea (green, with pods)	high water content	R	
	Pea (succulent, without pods)	high water content	R	
	Legume vegetable, canned	high water content	P	
	Legume vegetable, cooked	high water content	P	
015 Pulses	Bean (dry seeds)	dry	R	
	Cowpea (dry seeds)	dry	R	
	Lupin (dry seeds)	dry	R	
	Lupin, extracted meal	dry	P	feed item
	Pea (dry seeds)	dry	R	
	Lentil (dry seeds)	dry	R	
	Pulses (dry seeds), canned	high water content	P	
	Pulses (dry seeds), cooked	high water content	P	
015 Pulses: Soya bean	Soya bean, dry seeds	high oil content	R	
	Soya bean, extracted meal	dry	P	feed item
	Soya bean, flour	dry	P	
	Soya bean, hulls	dry	P	feed item
	Soya oil	high oil content	P	
	Soya drink	high water content	P	
	Soya sauce	high water content	P	
	Tofu	high water content	P	
016 Root and tuber vegetables	Beetroot	high water content	R	
	Carrot roots	high water content	R	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Celeriac/turnip rooted celery root	high water content	R	
	Horseradish root	high water content	R	
	Turnip-rooted parsley, root	high water content	R	
	Parsnip root	high water content	R	
	Radish root	high water content	R	
	Salsify root	high water content	R	
	Swede/rutabaga root	high water content	R	
	Turnip root	high water content	R	
	Arrowroot	high water content	R	
	Cassava root/manioc root	high water content	R	
	Jerusalem artichoke root	high water content	R	
	Yam root	high water content	R	
	Root and tuber vegetable, juice	high water content	P	
	Root and tuber vegetable, wet pomace	high water content	P	feed item
	Root and tuber vegetable, puree	high water content	P	
	Root and tuber vegetable, cooked/canned	high water content	P	
	Root and tuber vegetable, dried	dry	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
016 Root and tuber vegetables: Sugar beet and chicory root	Sugar beet root	high water content	R	
	Sugar beet, ensiled pulp	high water content	P	feed item
	Sugar beet, molasses	high water content	P	feed item and intermediate in food production
	Sugar beet pulp, dried	dry	P	feed item
	Sugar from sugar beet, refined	dry	P	dry/high sugar content
	Chicory root	high water content	R	
	Chicory root, milled	dry	P	
	Chicory root, roasted	dry	P	
016 Root and tuber vegetables: Potatoes	Potato tuber	high water content	R	
	Sweet potato tuber	high water content	R	
	Potato tuber, peeled	high water content	P	
	Potato tuber, canned	high water content	P	
	Potato tuber, cooked (with or w/o peel, with or w/o microwave)	high water content	P	
	Potato tuber, baked (with or w/o peel)	high water content	P	
	Potato tuber, steamed (with or w/o peel)	high water content	P	
	Potato peel	high water content	P	feed item
	Potato tuber, dried	dry	P	
	Potato flakes/granules	dry	P	
	Potato peel, dried	dry	P	feed item
	Potato pulp, dried	dry	P	feed item
	Potato starch	dry	P	
	Potato crisps (with or w/o peel)	high oil content	P	composite: contains oil
	Potato tuber, fried or deep-fried (with or w/o peel)	high oil content	P	composite: contains oil
017 Stalk and stem vegetables	Cardoon stems	high water content	R	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Celery stalk	high water content	R	
	Florence fennel bulb	high water content	R	
	Rhubarb stems	high acid content	R	
	Rhubarb stems, cooked	high acid content	P	
	Asparagus stems	high water content	R	
	Bamboo shoot	high water content	R	
	Globe artichoke flower head	high water content	R	
	Palm heart stems	high water content	R	
	Stalk and stem vegetable (except rhubarb), canned	high water content	P	
	Stalk and stem vegetable (except rhubarb), cooked	high water content	P	
018 Edible fungi	Cultivated fungi (cap and stem)	high water content	R	
	Wild fungi (cap and stem)	high water content	R	
	Fungi, canned	high water content	P	
	Fungi, dried	dry	P	
020 Cereal grains	Amaranth seeds	dry	R	
	Quinoa seeds	dry	R	
	Rye grain	dry	R	
	Rye, bran	dry	P	
	Rye, flour	dry	P	
	Wheat grain	dry	R	
	Wheat, bran	dry	P	
	Wheat, distiller’s grain, wet	high water content	P	feed item
	Wheat, distiller’s grain, dried	dry	P	feed item
	Wheat, flour	dry	P	
	Wheat, germs	dry	P	
	Wheat, gluten	dry	P	
	Wheat, gluten feed meal	dry	P	feed item
	Wheat, grit	dry	P	
	Wheat, malt	dry	P	
	Wheat, starch	dry	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Barley grain	dry	R	
	Barley, beer	high water content	P	composite: contains malt and hops
	Barley, bran	dry	P	
	Barley, brewer's grain	high water content	P	feed item
	Barley, distiller’s grain, wet	high water content	P	feed item
	Barley, distiller’s grain, dried	dry	P	feed item
	Barley, flour	dry	P	
	Barley, malt	dry	P	
	Barley, malt sprouts	high water content	P	
	Pot/pearl barley	dry	P	
	Barley, spirit	high water content	P	
	Buckwheat grain	dry	R	
	Oat grain	dry	R	
	Oat, bran	dry	P	
	Oat, flour	dry	P	
	Oat, hulls	dry	P	
	Rolled oat	dry	P	
	Rice grain	dry	R	
	Rice, bran	dry	P	feed item
	Rice, flour	dry	P	
	Rice, hulls	dry	P	feed item
	Rice, polished	dry	P	
	Rice, spirit	high water content	P	
	Common millet/proso millet grain	dry	R	
	Sorghum grain	dry	R	
	Sorghum, flour	dry	P	
	Sorghum, starch	dry	P	
	Maize/corn, grain	dry	R	
	Maize, distiller’s grain	high water content	P	feed item
	Maize, extracted meal	dry	P	feed item
	Maize, flour	dry	P	
	Maize, germs	high oil content	P	
	Maize, gluten meal	dry	P	feed item
	Maize, grits	dry	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Maize, oil	high oil content	P	
	Maize, starch	dry	P	
	Sweet corn kernels	high water content	R	
	Sweet corn kernels, cooked	high water content	P	
	Sweet corn kernels, canned	high water content	P	
021 Grasses for sugar or syrup production	Sugar cane	high water content	R	
	Sugar cane, molasses	high water content	P	feed item and intermediate in food production
	Sugar from sugar cane, raw	dry	P	dry/high sugar content
	Sugar from sugar cane, refined	dry	P	dry/high sugar content
022 Tree nuts	Almond nutmeat	high oil content	R	
	Almond hulls	dry	P	feed item
	Brazil nut nutmeat	high oil content	R	
	Cashew nut nutmeat	high oil content	R	
	Chestnut nutmeat	high water content	R	
	Coconut nutmeat	high oil content	R	
	Coconut, dried meat (copra)	high oil content	P	
	Coconut, dried meal	dry	P	feed item
	Hazelnut nutmeat	high oil content	R	
	Macadamia nut nutmeat	high oil content	R	
	Pecan nutmeat	high oil content	R	
	Pine nut nutmeat	high oil content	R	
	Pistachio nut nutmeat	high oil content	R	
	Walnut nutmeat	high oil content	R	
023 Oilseeds and oilfruits	Borage seed	high oil content	R	
	Gold of pleasure seed	high oil content	R	
	Linseed	high oil content	R	
	Mustard seed	high oil content	R	
	Poppy seed	high oil content	R	
	Rapeseed/canola seed	high oil content	R	
	Sesame seed	high oil content	R	
	Safflower seed	high oil content	R	
	Sunflower seed	high oil content	R	
	Cotton seed	high oil content	R	
	Castor bean	high oil content	R	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Grape seed	high oil content	P	
	Hemp seed	high oil content	R	
	Kapok seed	high oil content	R	
	Palm nut/palm kernel nutmeat	high oil content	R	
	Palm kernel meal	dry	P	feed item
	Peanut/groundnut nutmeat	high oil content	R	
	Peanut butter	high oil content	P	
	Peanut, roasted	high oil content	P	
	Pumpkin seed	high oil content	R	
	Oilseed, extracted meal	dry	P	feed item
	Oilseed, hulls	dry	P	feed item
	Oilseed oil	high oil content	P	
	Olive for oil production	high oil content	R	
	Olive oil	high oil content	P	
	Olive, wet pomace	high oil content	P	
	Oil palm fruit	high oil content	R	
	Oil palm fruit, extracted meal	dry	P	feed item
	Palm oil	high oil content	P	
024 Seeds for beverages and sweets	Cacao bean (fermented or dried)	high oil content	R	high matrix load, difficult to analyse
	Cacao bean, roasted	high oil content	P	high matrix load, difficult to analyse
	Cacao butter	high oil content	P	high matrix load, difficult to analyse
	Cacao powder	dry	P	high matrix load, difficult to analyse
	Coffee bean (green)	dry	R	high matrix load, difficult to analyse
	Coffee bean, roasted	dry	P	high matrix load, difficult to analyse
	Instant coffee	dry	P	high matrix load, difficult to analyse
	Coffee, infusion	high water content	P	
027 Herbs	Fresh herbs and edible flowers	high water content	R	
	Herbs and edible flowers, dried	dry	P	high matrix load, difficult to analyse
	Peppermint oil	high oil content	P	

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
028 Spices	Seed spices	dry	R	high matrix load, difficult to analyse
	Fruit or berry spices	dry	R	high matrix load, difficult to analyse
	Bark spices	dry	R	high matrix load, difficult to analyse
	Root or rhizome spices, dried	dry	P	high matrix load, difficult to analyse
	Root or rhizome spices, fresh (for example ginger)	high water content	R	
	Bud spices, dried	dry	R	high matrix load, difficult to analyse
	Bud spices, pickled (for example capers)	high acid content	P	
	Flower or stigma spices	dry	R	high matrix load, difficult to analyse
	Aril spices	dry	R	high matrix load, difficult to analyse
	Citrus peel, dried	dry	P	
	Dried chili peppers	dry	P	
050 Legume feed products	Forage (for example alfalfa, clover, vetch, bean)	high water content	R	feed item
	Vine (for example pea)	high water content	R	feed item
	Silage (for example alfalfa, clover, vetch, beans, peas)	high water content	P	feed item
	Hay (for example alfalfa, clover, vetch, beans, peas)	dry	R	feed item
	Straw (for example alfalfa, clover, vetch, beans, peas)	dry	R	feed item
051 Cereal grains (including pseudo-cereals) and grass feed products	Forage (for example barley, grass, maize, millet, oat, rice, rye, triticale, wheat)	high water content	R	feed item
	Silage (for example barley, grass, maize, millet, oat, rice, rye, triticale, wheat)	high water content	P	feed item
	Hay (for example barley, grass, maize, millet, oat, rye, triticale, wheat)	dry	R	feed item
	Straw (for example barley, grass, maize, millet, oat, rye, triticale, wheat)	dry	R	feed item

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Codex Commodity Group	Commodity (examples from the group including typical processed commodities)	Matrix Group	R/P	Comments
	Stover (for example maize)	dry	R	feed item
052 Miscellaneous feed products	Beet leaves or tops (for example fodder beet, sugar beet, turnip)	high water content	R	feed item
	Fodder beet root	high water content	R	feed item
066 Teas	Tea (Camellia sinensis, dried leaves, stalks and flowers, fermented or otherwise treated)	dry	R	high matrix load, difficult to analyse
	Tea, green, dried	dry	R	high matrix load, difficult to analyse
	Instant tea	dry	P	high matrix load, difficult to analyse
	Tea, infusion	high water content	P	
	Herbal infusion (dried, flowers)	dry	R	high matrix load, difficult to analyse
	Herbal infusion (dried, leaves and herbs)	dry	R	high matrix load, difficult to analyse
	Herbal infusion (dried, roots)	dry	R	high matrix load, difficult to analyse
	Herbal infusion, infusion	high water content	P	
079 Miscellaneous processed foods of plant origin	Hops, green cones	high water content	R	high matrix load, difficult to analyse
	Hops (dried), hop pellets and unconcentrated powder, hop extract	dry	R	high matrix load, difficult to analyse
	Beer	high water content	P	composite: contains malt and hops
	Hop extract (aqueous solution)	high water content	P	high matrix load, difficult to analyse
	Spent hops	high water content	P	feed item; high matrix load, difficult to analyse

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Annex C. GLOSSARY

Ambient temperature
Average temperature of an environment and can be any temperature.

Commodity
A raw or processed agricultural product.

Commodity group
Commodities within a commodity group (for example pome fruits) are intended to have similar residue characteristics and to be suitable for setting group MRLs. Note that a given crop may be included in more than one commodity group. For example, wheat is a crop, and the commodities are grain (cereal grain commodity group) and straw (straw, fodder and forage of cereal grains and grasses commodity group.

Component
An element of a larger whole. In this guideline, component describes an analyte which is part of the residue definition.

Concurrent recovery (= procedural recovery)
A fortification experiment performed in parallel with analysis of the stored samples to determine method performance on a sampling and analysis day.

Day 0
Timepoint at which the amount of analyte was recovered from the matrix directly after fortification by using suitable analytical methods.

Decline
The continuous loss from an initial number. In this guideline the loss of recoverable residues.

Fortification
Adding a known amount of analyte to a matrix.

Freezer
Device which allows deep freezing of samples. Mostly used freezer temperatures are -18°C and -20°C.

Good Agricultural Practice (GAP)
The Good Agricultural Practice in the use of pesticides includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control.

Good laboratory practice (GLP)
The formalised process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data. The U.S. Environmental Protection Agency GLP definition also covers field

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experiments.

Incurred residues
Residues which are present in the commodity resulting from a treatment of the crop with the pesticide.

Limit of quantitation (LOQ)
The lowest concentration of a pesticide residue in a defined matrix where positive identification and quantitative measurement can be achieved using a specified method.

Matrix group
A broad categorization of crop commodities based on macromolecular properties such as moisture content, oil content and pH value.

MOR (Magnitude of Residue) study
Conducted with non-radiolabelled test substance. This type of study encompasses crop field studies, processing studies, field rotational crop studies and livestock feeding studies.

Nominal (fortification) level
The amount of analyte which was added to the matrix.

Pomace
By-product of fruits and vegetables that is generated when they are pressed to obtain juice or concentrates.

Pulp
Edible part of fruit and vegetables after removal of inedible peel and inedible stone.

In the case of root and tuber vegetables, pulp refers to by-products primarily used as animal feed. Sugar beet pulp is the fibrous material left after water extraction of the sugar contained in the root. Potato pulp is a by-product of the starch production and describes the fibrous material of the potato after removal of starch and juice.

Recovery
The amount measured as a percentage of the amount of analyte(s) (active substance and relevant metabolites) originally added to a sample of the appropriate matrix, which contains either no detectable level of the analyte or a known detectable level.

Residue
Any specified substance resulting from a use.

Single First Order (SFO)
A kinetic where constant proportions are eliminated per time

Test substance
The active ingredient or metabolite(s) of a pesticide on which freezer stability is tested.

Total radioactive residue (TRR)

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TRR is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound) and impurities in a sample which is obtained from a study conducted with radiolabelled test substance (nature of residue study).

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