



**REQUIREMENTS FOR ACCREDITED LABORATORIES
APPLYING FOR A FLEXIBLE SCOPE FOR ANALYSIS OF
PESTICIDE RESIDUES IN FOOD AND FEED**

In revision

English translation for information only
French and Dutch version remain the authoritative documents

Applicable from : 15.12.2009

In revision

DOCUMENT HISTORY

Revised	Reason for revision	Impact of revision
BELTEST I15		
0	First document	Not applicable
BELAC 2-104		
0 CC 25.06.2004	Renumbering of the document within BELAC's management system. No change of the content of BELTEST I15 Rev 0	Full document
1 CC 01.07.2006	Revision following coming into force of Royal Decree BELAC	Only formal amendments; no change of the content
2 CC 11.12.2009	Alignment of the document with document SANCO/2007/3131 of the European Commission (including scope of the document: food and feed) Adding examples of scopes for the laboratories	New grouping of parameters and matrices (in compliance with the SANCO document) (3.1.1. and 2) Introduction of 3 possibilities of flexibility for parameters as well as matrices (3.1.1, 2 and 3) Validation requirements in compliance with the SANCO document (3.2)

REQUIREMENTS FOR ACCREDITED LABORATORIES APPLYING FOR A FLEXIBLE SCOPE FOR ANALYSIS OF PESTICIDE RESIDUES IN FOOD AND FEED

1. OBJECTIVES AND REFERENCES TO NORMATIVE DOCUMENTS

This document is intended to specify the requirements that shall apply for laboratories requesting a flexible scope for analysis of pesticide residues in food and feed.

A flexible scope offers the laboratories the necessary flexibility to introduce new, or change existing methods of analysis without referring to BELAC. This will allow the laboratory to react more rapidly to constantly changing economical demands. Obviously, accrediting a flexible scope is subject specific quality requirements.

This document complements the general provisions of the BELAC document 2-101 (including documents EA-2/05 and EA-2/15).

2. RECIPIENTS

With follow up of modifications:

- Members of the Coordination Commission
- Members of the Accreditation Board
- Accreditation secretariat
- Assessors in charge of the evaluation of the testing laboratories in the concerned sector
- Accredited testing laboratories in the concerned sector

Without follow up of the actualization:

- Any external request

3. SPECIFIC REQUIREMENTS

The following text documents the specific requirements with respect to the application and the management of a flexible scope for the analysis of pesticide residues in food and feed.

The general requirements for the application and management of a flexible scope as laid down in BELAC document 2-101 remain valid. It needs to be highlighted that a laboratory can only apply for a flexible scope if it can provide evidence that the analytical techniques to which the request applies are sufficiently mastered, and if experience in development and validation of new analytical methods can be demonstrated.

3.1. Matrices and parameters

3.1.1. Matrices

As far as the matrix subject to testing is concerned, accreditation in the framework of a flexible scope can be applied according to the 3 following paths:

1. for one or more **matrix-subcategories**: e.g. stone fruits, nuts, ...
2. for one or more **matrix-categories**, e.g. vegetable matrices with high water content, meat, ...
3. For one or both matrix-groups 'vegetable matrices' and 'products of animal origin', under the provision that the laboratory is already accredited for a certain number of matrix-categories within these matrix-groups (view also §3.1.3.).

The different possible matrix-subcategories and the corresponding matrix-categories are listed in the following table. Similar to the annex 1 of the European document N° SANCO/2007/3131 ("Method validation and quality control procedures for pesticide residues analysis in food and feed"), they are categorized in one of the two matrix-groups '**vegetable matrices**' or '**products of animal origin**'.

Matrix-category	Matrix-subcategory	Typical representative matrices
MATRIX-GROUP: VEGETABLE MATRICES		
Vegetable matrices with high water content	Pome fruit Stone fruit Bulb vegetables Fruiting vegetables/cucurbits Brassica vegetables Leafy vegetables and fresh herbes Stem and stalk vegetables Forage/fodder crops Fresh legume vegetables Sugar cane Leaves of root and tuber Fresh green tea Fungi	Apples, pears Apricots, cherries, peaches Bulb onion Tomatoes, peppers, cucumber, melon Cauliflower, Brussels sprout, cabbage, broccoli Lettuce, spinach Leek, celery, asparagus Wheat and barley forage, alfalfa Fresh peas with pods, petit pois, mange tout, broad bean, runner bean, dwarf French bean Sugar beet and fodder beet tops
Vegetable matrices with high oil content	Tree nuts Oil seeds Oil Olives Avocados Hops (Fresh) cacao beans (Fresh) coffee beans Spices	Walnut, hazelnut, chestnut Oilseed rape, sunflower, cotton, soybean, peanut
Vegetable matrices with high protein content or high starch content	Dry legume vegetables/pulses Cereal grain Roots of root and tuber Starchy root crops Bread Confectionary products Pasta	Field bean, dried broad bean, dried haricot bean (yellow, white/navy, brown, speckled) Wheat, rye, barley and oat, grain; maize, rice Sugar beet and fodder beet, roots, carrot Potato, sweet potato Wholemeal white, crackers Cake, biscuits, breakfast cereals Spaghetti
Vegetable matrices with high acid content	Citrus fruit Berries, currants Grapes Kiwifruit Pineapple Rhubarb	Lemon, mandarin, tangerine, orange Strawberry, blueberry, raspberry, black currant, red currant, white currant
Unique vegetable matrices (*)	Fermented cacao, coffee and tea Composed feeds	

MATRIX-GROUP: PRODUCTS OF ANIMAL ORIGIN		
Meat	Red meat White meat Fish Offal Fat from meat	Beef, pork, sheep, game, horse Chicken, duck, turkey Cod, haddock, salmon, trout Liver, kidney
Milk and milk products	Milk Cheese Yogurt Cream Butter	Cow, goat and horse milk Cow, goat cheese
Eggs	Eggs	Chicken, duck, quail, goose eggs
Honey	Honey	

(*) No separate accreditation under a flexible scope can be granted for this matrix-category: it can only be requested in addition to another matrix-category or as a part of the matrix-group “Vegetable matrices” (as mentioned above).

A flexible scope can be granted for the matrix group “Vegetable matrices” that consists of 5 matrix categories under the condition that the laboratory is already accredited for at least 3 matrix categories.

A flexible scope can be granted for the matrix group “Products of animal origin” that consists of 4 matrix categories under the condition that the laboratory is already accredited for at least 2 matrix categories.

3.1.2. Parameters

As far as the parameters are concerned, accreditation in the framework of a flexible scope can be applied according to the 3 following paths:

1. For one or more **specific parameters** (pesticides): eg. Chloremequat, inorganic bromide, ...
2. For one or more **main parameters**: eg. Organochlorine compounds, dithiocarbamates, nitrogen compounds, organophosphorus compounds, or other important groups or compounds;
3. For the **parameter-group** ‘pesticides’.

3.1.3. Combination matrix / parameter

The laboratory may choose for one ore more combinations of matrices and parameters. The following provisions need to be taken into account:

- If the laboratory chooses for one or more main parameters (see the second option as mentioned under §3.1.2), it shall be able to detect, in the proposed matrices, the most frequently encountered active substances, permitted and prohibited, that belong to this (these) main parameter(s). The evidence needs to be presented by the laboratory and the technical auditor shall evaluate whether the selection of substances is acceptable.

- If the laboratory chooses for the parameter 'pesticides' (see the third option mentioned under §3.1.2), it shall be able to detect, in the proposed matrices, the most frequently encountered pesticides, permitted and prohibited. The evidence needs to be presented by the laboratory and the technical auditor shall evaluate whether the selection of substances is acceptable.

3.2. Testing methods

Dividing the matrices and parameters as described above implies automatically a certain flexibility with respect to the methods of analysis. In practice; it means that it will be necessary to group similar testing methods around a general analytical technique (e.g. LC-MS, GC-MS, ...). The scope of use and the performance of the currently used analytical techniques were taken into account to decide on the grouping in matrices and parameters.

As far as testing methods are concerned, the flexibility does not go beyond a given analytical technique. Extension of an analytical technique or switching to another one requires a formal application for extension by BELAC.

3.3. Concept of validation

For application and management of a flexible scope, the laboratory shall comply with specific requirements on validation, as specified hereafter.

Two types of validation are taken into account, the **total validation** and the **secondary validation**.

3.3.1. Total validation

A total validation includes the determination of the performance characteristics as mentioned in document SANCO "Method validation and quality control procedures for pesticide residues analysis in food and feed" (document N° SANCO/2007/3131 or a more recent version of this document when available) and compliance with the established performance criteria.

3.3.1.1. Total validation with respect to matrices

When a laboratory applies for a flexible scope for one or more matrix-categories, a total validation in a representative matrix from one of the matrix-subcategories belonging to this (these) matrix-category(ies) shall be performed. 'Representative' means the most frequently analysed matrix in the applicant laboratory, preferably listed in column 3 of the table under §3.1.1.

Each time a laboratory wishes to add a new matrix-subcategory (column 2 of the table under §3.1.1) to a matrix-category (column 1 of the table under §3.1.1) for which it is already accredited, a secondary validation is sufficient (see under §3.3.2.).

In case a laboratory is already accredited for the matrix-group "vegetable matrices" and/or the matrix-group 'products of animal origin', a total validation needs to be performed every time it wishes to add a new matrix-category to the concerned matrix-group under the flexible scope.

Exception: A total validation for the matrix-group 'unique vegetable matrices' is only required when these matrices are frequently analyzed. In case of occasional work, a secondary validation is allowed provided the necessary internal controls for this matrix are included in each series of measurement (see also §3.3.2.).

3.3.1.2. Total validation with respect to parameters

When a laboratory applies for a flexible scope for one or more main parameters, or for the parameter-group “pesticides”, a total validation shall be performed for the (within the concerned matrix/ces) most frequently encountered parameters (pesticides), permitted and prohibited, for the matrix(ces) in question.

When a laboratory is already accredited for one or more main parameters, or for the parameter-group “pesticides”, a total validation needs to be performed every time a new parameter is added under the flexible scope.

3.3.2. Secondary validation

When a laboratory wishes to add a new matrix-subcategory (column 2 of the table listed under §3.1.1) to a matrix-category (column 1 of the table listed under §3.1.1) for which it already has a flexible scope, a secondary validation is sufficient. Obviously, a total validation may be performed as well.

A secondary validation is allowed as well when a laboratory wishes to take up the matrix-category ‘unique vegetable matrices’ for matrices that are analyzed on an occasional basis only. In this case, the necessary checks for this matrix have to be included into each series of measurement.

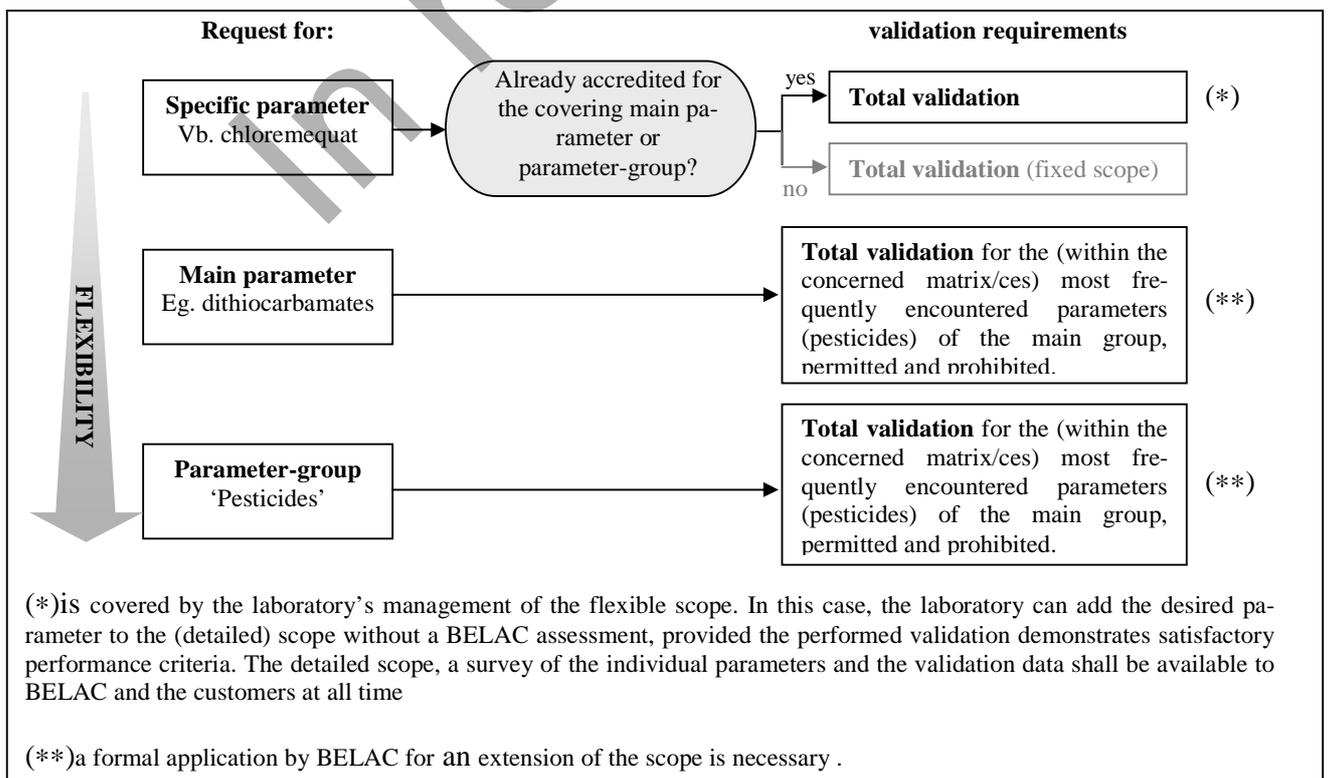
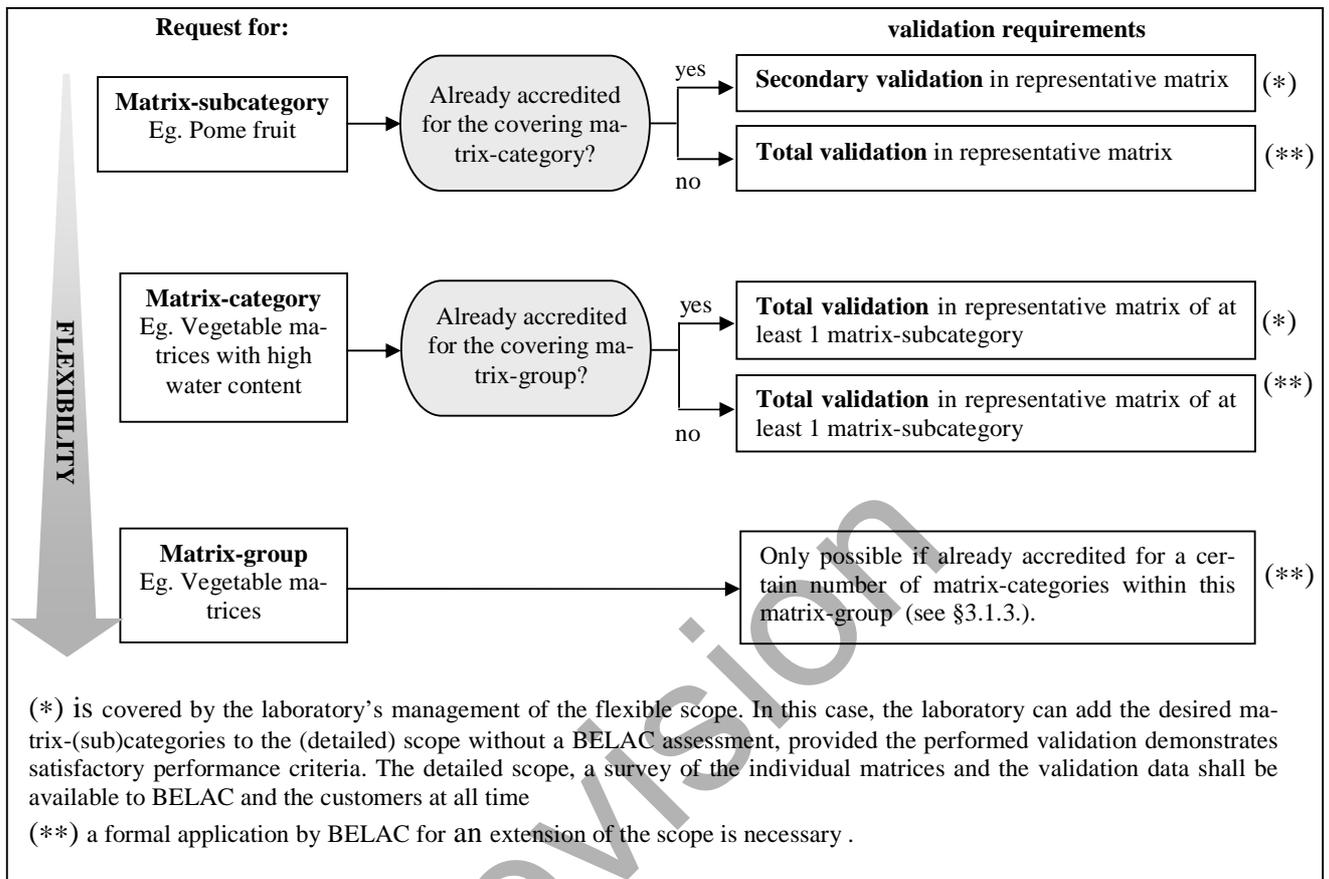
A secondary validation involves the determination of the efficiency and the specificity in this new matrix, using at least:

- 1 blank material;
- 2 spiked samples or samples containing a known concentration (with permitted level of concentration LOQ up to 10 x MRL; eg. 10 x LOQ)

If secondary validation points out that the required performance criteria cannot be met, the laboratory needs to perform a critical analysis and if necessary change the method. A total validation will be performed after the method has been changed. If the laboratory has chosen to switch to a different technique of testing, a formal request for extension of the scope of expansion needs to be submitted to BELAC.

3.3.3. Survey of the requirements for validation with respect to matrices and parameters

A survey of the different levels of flexibility and the associated requirements for validation is presented in the following figures (respectively for matrices and for parameters). The survey mentions as well which cases can be handled under the intern management of the flexible scope (by the laboratory itself) and which cases require a formal request of extension to be submitted to BELAC.



4. TECHNICAL APPENDIX TO THE ACCREDITATION CERTIFICATE

The technical appendix to the accreditation certificate mentions (see also BELAC 2-101 § 5.4):

- One or more combinations of the following matrices:

Matrix		
One or more specific matrix-subcategories		
One or more matrix-categories		
Matrix-group 'vegetable matrices' and/or matrix-group 'products of animal origin'		

- Together with following parameters:

	Parameters:	
	One or more specific parameters	
	One or more main parameters	
	Parameter-group 'pesticides'	

- And the general analytical technique:

		General analytical technique
		Examples: GC-ECD, GC-NPD, GC-MS, LC-MS,

Moreover, there is a clear reference to the concept of flexible scope and to the detailed list of individual matrices and parameters for which total validations and secondary validations are available. The list shall be available to BELAC and to the customer at all time, on request to the laboratory.

Examples:

Example 1: Flexibility is limited to the type of the analyzed matrices

Matrix-category/matrix-group	Measured parameters	General method(s) of testing
Vegetable matrices with high water content and high fat content	Propamocarb	LC-MS
Products of animal origin	DDT	GC-MS

Example 2: Flexibility is limited to the determination of groups of parameters

Matrix	Main parameter/Parameter-group	General method(s) of testing
Berries, currants	Dithiocarbamates	GC-ECD
Citrus fruit	Pesticides	GC-MS

Example 3: Flexibility in the analyzed matrices and the measured parameters:

Matrix-category/matrix-group	Main parameter/Parameter-group	General method(s) of testing
Vegetable matrices with high water content and high oil content	Pesticides	GC-MS and LC-MS
Milk and milk products	Organochlorine pesticides	GC-ECD

A full flexibility for the type of matrices and for the measured parameters can lead to the following description in column 1 and 2:

Matrix-group	Parameter-group	General method(s) of testing
Vegetable matrices	Pesticides	GC-MS and LC-MS
Products of animal origin	Pesticides	GC-MS/MS and LC-MS/MS

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