

## EXTENSION OF THE SCOPE OF METHODS

### Introduction

In the context of the analysis of pesticide formulations the extension of scope of an analytical method can be defined as, the application of a standardized method to a different matrix or concentration range to those for which the method originally was accepted. The need for such an extension usually arises when new formulations are introduced after the collaborative study of a particular compound has been completed; and time and financial constraints make it improbable that new collaborative studies will be conducted for one formulation only. On the other hand, adoption of a method without any testing would be incompatible with the principles of standardization. The procedure described below will prevent important formulations from remaining without standardized methods.

### Definitions

*Acceptability range.* The range from 200 % to 50 % of the concentration of an analyte in a sample studied in a collaborative trial.

*Minor change.* A slight change of the procedure of a method such as a slight change of the procedure for the preparation of the sample solution and/or the chromatographic conditions (e.g. a 10% change of the concentration of the modifier in HPLC).

*Major change.* A change of the basic principles of the method and/or a substantial change of the chromatographic conditions.

*Specificity test.* A test usually carried out using a blank formulation to demonstrate that applying the method, unchanged, to the new formulation will not induce any systematic errors.

*Validation study.* A study in which at least 5 different samples of the 'new' formulation are compared by at least 2 laboratories.

*Full study.* A study in accordance with the standard CIPAC requirements for a collaborative trial.

### Procedure

- Step 1* Check of availability of a CIPAC method for the formulation concerned
- a) CIPAC method available for the formulation → step 2
  - b) no CIPAC method available for the formulation: → step 3

- Step 2* Check whether the concentration of the analyte is inside or outside the acceptability range covered by the samples of the original trial.
- a) concentration inside the range: → step 7
  - b) concentration outside the range: → step 4
- Step 3* Performance of a specificity test
- a) a method accepted for other formulations can be applied and is specific: → step 2
  - b) method is not specific → step 4
- Step 4* Modification of method method has to be changed in order to be specific:
- a) minor change necessary: v step 5
  - b) major change necessary: v step 6
- Step 5* Validation study
- a) repeatability figures comparable to those of original study or at least within the normal range: method can be adopted, → step 7
  - b) repeatability figures deviate from those of original study and/or are outside the normal range: → step 6
- Step 6* Full scale trial
- a) repeatability and reproducibility figures within normal range:
    - method acceptable: → step 7
  - b) repeatability and reproducibility figures outside normal range:
    - method not acceptable
- Step 7* Results to be presented at the CIPAC meeting.

Where there are reasons to deviate from the above schedule it is advisable to present the case to CIPAC.

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