

# **THE EU TESTING METHODS ADOPTION PROCESS**

## **1.- INTRODUCTION**

### **1.1.- General Scope**

This paper tries to summarise the process of adoption of Testing Methods in the EU chemicals legislation, in particular for Annex V to Directive 67/548/EEC, and outline the roles of the different Commission Services involved as well as other partners and the interactions with parallel programmes in other international organisations.

### **1.2.- What Testing Methods**

In the EU, legally recognised standardised Testing Methods to determine the hazardous properties of chemical substances are contained in Annex V of Dir 67/548/EEC on the Classification, Packaging and Labelling of Dangerous Substances. Once included in Annex V, the results obtained with these methods are recognised by the regulators. They play a central role in chemicals control and they are referred to in many other pieces of EU legislation (e.g. those related to dangerous preparations, pesticides, cosmetics and biocides also refer to these methods).

### **1.3.- Why Testing Methods**

The standardised Annex V Testing Methods, on the one hand, are the basic tools to generate data needed for hazard and risk assessment of chemicals. These constitute the basis to attain a high degree of protection for human health and the environment in the EU. On the other hand, they are also important for ensuring the Single Market in the EU allowing the free movement of goods between Member States. The Annex V methods are generally either original or adaptations of internationally recognised standards (e.g. ISO, UN, OECD). When they are adaptations of internationally recognised methods, they also contribute to the free movement of goods at a global level. For this reason, their development is closely linked and co-ordinated, in particular, with the parallel OECD Test Guidelines programme.

## **2. AREAS OF RESPONSIBILITY**

### **2.1.- General**

The Commission has overall competence for the EU policy on Testing Methods. Within the Commission, DG Environment (currently Unit C.3 Chemicals is “chef de file”) has the policy responsibility and the European Chemicals Bureau (ECB) is responsible for the scientific and technical aspects. The Competent Authorities (CAs) for

the implementation of Dir 67/548/EEC are responsible for their Member State's position on all Testing Methods issues. The EU National Coordinators for Testing Methods (NC) have an important role in giving technical and scientific advice and support to the CAs and the Commission.

In particular, adoption and regulatory acceptance of Testing Methods is responsibility of DG ENV and the CAs, following the advice respectively of the ECB and the National Coordinators. In addition to the technical/scientific aspects, when making their decision the Commission and the CAs also take into consideration other aspects as e.g. policy needs, priorities, urgency, costs...

## **2.2.- Policy level**

The Commission (DG Environment, Unit C.3), upon advice of the ECB, proposes to the Member States the methods which should be introduced into Annex V. This is done by an Adaptation to Technical Progress (ATP) of the "mother" Directive 67/548/EEC. For such an Adaptation, the Commission prepares a proposal for a Directive that amends Directive 67/548/EEC by introducing new or updating existing methods in its Annex V, and presents it to the relevant Regulatory Committee. In this Committee, Member States delegates possibly discuss to fine-tune the proposal and then vote on it by qualified majority. In case of a favourable vote, the Directive is subsequently adopted by the Commission<sup>1</sup> and soon afterwards published in the Official Journal.

## **2.3.- Technical Level**

All the technical/scientific work needed to prepare the Commission proposal for Annex V methods is carried out and coordinated by the European Chemicals Bureau (ECB), located in the Joint Research Centre, in consultation with the Group of the National Coordinators for Testing Methods, who are experts from the Member States supported by further experts in their respective countries. The National Coordinators represent the Member States Competent Authorities and advise the ECB on any issues related to Testing Methods. In addition, the ECB may seek advice, when appropriate, from other experts either within the Commission services (e.g. in DG ENV, DG RTD, IES, ECVAM) or even non-Commission experts.

### **2.3.1.- The EU National Coordinators Group**

The National Coordinators Group, as already stated, advises the ECB and the Member States Authorities regarding Testing Methods and has two main functions:

- *Coordination of the EU activities regarding Testing Methods for Annex V to Dir 67/548/EEC.*

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<sup>1</sup> Other Comitology steps are needed for final adoption or in the case of disagreement, but they are not discussed in this document.

*- Coordination of the EU input and priorities into the OECD Test Guidelines Program.*

The EU National Coordinators are expected to represent their Member States views, nevertheless, the final recommendations are taken by the Competent Authorities.

The EU National Coordinators normally meet at least once a year, within the two weeks preceding the corresponding meeting of the OECD WNT (the Working Group of the National Coordinators of the Test Guidelines Programme), in order to ensure an adequate input and efficient coordination with this programme (see below). The meeting of the EU National Coordinators is organised by the ECB and chaired normally by the responsible of the Testing Methods Work Area who is also responsible for communication/coordination with DG Environment regarding Testing Methods issues.

The members of the National Coordinators group are:

- the responsible of the ECB Testing Methods Working Area (who normally chairs the meeting, though for some specific points others may chair).
- the National Coordinators of the EU Member States.
- a representative of DG Environment C.3.

but others may also be invited to take part in the meetings:

- other ECB staff as appropriate.
- representatives of other relevant Commission Services, when appropriate (e.g. DG ENTR, DG RTD, ECVAM ...).
- an observer of the OECD Secretariat of the TGP, if appropriate.
- invited experts, consultants...as appropriate.

For carrying out their work, both the EU NCs and the ECB, when appropriate, may organise working groups, task forces or other meetings and may seek advice from experts from the different MS as well as from other Commission Services (e.g. DG RTD, DG ENV, DG SANCO, ECVAM...) and even non-MS experts. In particular, the advice of ECVAM<sup>2</sup> may be requested when discussing the development of alternative or in vitro methods and their status of validation.

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<sup>2</sup> The European Centre for the Validation of Alternative Methods (ECVAM) was established by a Communication of the Commission with its main duties being: 1) To coordinate the validation of alternative test methods at the European Union (EU) level, 2) To act as a focal point for the exchange of information on the development of alternative test methods, 3) To set up, maintain and manage a data-base on alternative procedures, and 4) To promote dialogue between legislators, industries, biomedical scientists, consumer organisations and animal welfare groups, with a view to the development, validation and international recognition of alternative test methods. ECVAM is advised in its activities by a non-decision-making committee named ESAC (ECVAM Scientific Advisory Committee), whose duties are: 1) To provide advice on the development, validation and acceptance of alternative methods, 2) To make formal recommendations on the scientific validity of alternative methods, 3) To provide advice on, and assistance with, the activities of ECVAM, and 4) To act as the focal point for the exchange of information on the development, validation and acceptance of alternative methods. More detailed information on ECVAM/ESAC activities and procedures can be found in "ESAC 21.01 rev. ECVAM European Centre for the Validation of Alternative Methods. Guidance for Members of the ESAC. Status of 28 May 2004".

### 2.3.2 Introducing methods in Annex V<sup>3</sup>

Whenever a need for a new or updated method<sup>4</sup> is identified either by the Commission Services or the Member States Authorities, it is discussed by the National Coordinators, who advise, either in a meeting or by written procedure on the proposed testing protocol(s), work plan, priorities and preferred approach.

Generally speaking, three possibilities exist:

- a) the coordinators may advise to further develop the method by the ECB (in collaboration with other Commission Services, consultants or other experts) and/or by some leading Member State. This may involve the establishment of working groups or task forces as well as organising expert meetings or workshops. Subsequently, the coordinators may advise
  - a1) to introduce the method into Annex V directly or
  - a2) to propose it to the OECD TG Programme. Following adoption in the OECD the method is included in Annex V to Directive 67/548.
- b) In other cases, the coordinators may advise that any further development of the method be carried out in the frame of the OECD Test Guidelines Programme and, when the corresponding guideline has been adopted there, introduce it in Annex V as well.

Based on this advice, the appropriate policy decision on the approach to be followed is taken by the Commission in consultation with the CAs. In general, to avoid duplication of work, path b) is favoured. Nevertheless, in case of urgent or high priority matters, or particular policy needs (as methods aimed to solve a specific EU problem or alternative/in vitro methods), path a1) may be chosen.<sup>5</sup>

In any case, care is taken that Annex V Testing Methods are equivalent in all their technical and scientific parts to the corresponding OECD Test Guidelines or other standards (e.g. ISO, UN), if the methods originated from there. Methods are written in a standard format and additional guidance (specific for EU needs) may be introduced if the National Coordinators so advise and the Competent Authorities agree. The ECB is charged to prepare the draft of the proposed methods and to forward them to DG ENV so they can prepare the official Commission proposal. The final version, translated in all the official languages of the EU, is then proposed by the Commission in the ATP process, as described in a previous section.

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<sup>3</sup> See Appendix 1 for a general scheme of the process.

<sup>4</sup> Or other related activity as e.g. developing guidance. In this case a similar process, *mutatis mutandi* can be followed

<sup>5</sup> Normally, when the method has been adopted at EU level following this path, it can afterwards be proposed to the OECD Test Guidelines Programme, if appropriate, to ensure a wider international harmonization.

If the direct introduction into Annex V is followed (path a1 above) the full process from initial proposal to adoption may take 6 months. In other cases, time may be longer, in particular if difficulties are encountered that involve reiterated consultations with experts or the coordinators.

### **3.- COORDINATION WITH OTHER PROGRAMMES**

The main programme related with the development of testing methods for chemicals is the OECD Test Guidelines Programme (TGP)<sup>6</sup>, accordingly, this section concentrates exclusively on this.

#### **3.1.- Collaboration with the OECD Test Guidelines Programme**

As explained in the introduction, the collaboration with the OECD TG Programme (TGP)<sup>7</sup> is considered crucial to ensure mutual acceptance of data related to chemicals as well as their free trade at a global scale.

The Commission participates in all the activities of the OECD Working Group of the National Coordinators of the Test Guidelines Programme (WNT). There is not a common EU representative but each Member State participates as a separate entity, with their own right to vote. The decisions in this OECD WNT are taken by consensus. The work of the WNT is supervised by the OECD Joint Meeting that is the policy body which has ultimate responsibility on guiding and endorsing the work of the TGP.

Regarding the distribution of responsibilities within the Commission, DG Environment (C.3) again has the policy responsibility and represents the Commission in the OECD Joint Meeting, while the European Chemicals Bureau (ECB)<sup>8</sup> has the responsibility for technical aspects, representing the Commission at the WNT.

The activities of the Commission (the ECB) in this forum are centred in two aspects:

#### *1- Coordination of the EU input and views in the OECD TG Programme.*

This ensures consistency of the opinions expressed by the COM and the MS with regards the needs and priorities at EU level while, at the same time, providing an enhanced impact of the EU positions. A coordinated EU position has an extra weight in

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<sup>6</sup> Other related programmes that eventually could be used as initial source for developing Testing Methods are e.g. the ISO standards or the UN Recommendations on the Transport of Dangerous Goods.

<sup>7</sup> Explanations on the procedures of the OECD TGP can be found in "Guidance Document for the Development of OECD Guidelines for Testing of Chemicals. Environment Monograph No. 76 OCDE/GD(95)71. Paris 1995.

<sup>8</sup> By delegation from DG ENV.

the WNT, whose decisions are taken by consensus. Nevertheless, this activity has to be carried out in strict respect of the sovereignty of the EU MS, as, in this forum, the Commission has no mandate to represent them. This coordination is normally attained in the annual meeting of the EU National Coordinators Meeting mentioned before. The discussions normally concentrate on coordinating the EU priorities regarding Test Guidelines development and other projects in the OECD, in relation to the EU needs, coordinating the positions on particular issues related to the TGP, the approach for presenting them and bringing them to implementation.

*2- Representing the Commission in the OECD Test Guidelines Programme.*

The responsible of the ECB Testing Methods Working Area is nominated, by delegation from DG ENV, to represent the Commission in the OECD TG Programme, acting as the “National” Coordinator of the Commission. In this role, the Commission “National” Coordinator is the focal point for communication between the OECD Secretariat and the Commission on any technical/scientific matters related to Test Guidelines. The ECB responsible for Testing Methods attends the annual meeting of the WNT and ensures at the Scientific/Technical level the COM contribution to the programme. In this role he/she

1- Supervises the activities of the Commission relevant to Testing Methods/Test Guidelines development, in particular, those for which the Commission has a leading role, and provides input to the OECD Secretariat regarding relevant developments for the TGP.

2- Collates and coordinates the position of the different Commission services regarding issues related to the TG programme as e.g. proposals of Test Guidelines, draft Detailed Review Papers, Guidance Documents or other documents circulated by the OECD Secretariat for review and comment. For doing this he/she consults the appropriate experts within the Commission services or elsewhere and participates in relevant workshops/meetings of the program or nominates adequate experts.<sup>9</sup>

3- Prepares and presents the official position of the Commission in the OECD TG Programme, after consultation with DG ENV for policy related matters.

4- Briefs and advises the Commission representative to the OECD Joint Meeting on any issues related to the TGP

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<sup>9</sup> Depending on the kind of meeting, these nominated experts may in some cases participate in their personal capacity only or, in other cases, they should also be able to present the Commission views on the subjects discussed. These should be in harmony with the views communicated to the Secretariat via the “National” Co-ordinator.