Directive 86/609/EEC on the Protection of Animals Used for Experimental and Other Scientific Purposes[1]

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Summary — *Directive 86/609/EEC* regulates the use of animals for experimental and other scientific purposes in the EU. The Directive seeks to improve the controls on the use of laboratory animals, and to set minimum standards for housing and care, and for the training of personnel handling these animals and supervising the experiments. It also aims to reduce the numbers of animals used for experiments, by encouraging the development and the validation of alternative methods to replace animals methods. Since the scientific basis of the Directive dates back at least 15 years, the Commission is planning on an in-depth revision of the Directive. The Commission aims to have a first draft proposal ready by the end of 2003.

Key words: *alternative method, animal experimentation, animal welfare,* Directive 86/609/EEC*, expert working group, Protocol of Amendment, revision, Three Rs, two-step approach.*

Directive 86/609/EEC (1) on the protection of animals used for experimental and other scientific purposes has been in place in the European Union (EU) since 1986. The Directive is based on Article 95 (old Article 100) relating to the good functioning of the Internal Market. Animal welfare, on the other hand, is the responsibility of the Member States. Therefore, a Directive on the basis of animal welfare under EU competency, was not possible, and is still not possible.

The scope of the Directive covers animals used in the development, production and safety testing of drugs, foodstuffs and other substances and products. It also covers testing to protect both the environment and the health and welfare of man and animals. However, because of the legal basis of the Directive, animals used in forensic enquiries and in education and training are not included within its scope.

The Directive sets minimum standards for the acquisition and care of the animals and for the staff involved in experiments. It sets requirements for the authorisation and control of the establishments where animals are bred, kept and used. The Directive further requires that certain species, such as non-human primates, dogs and cats, must be individually identified and their life-long records be kept, and that statistical data must be collected and forwarded to the European Commission for EU-wide compilation and publication.

What is of main relevance in the light of the subject of this seminar, is that the Directive also calls for active application of the Three Rs (*reduction, refinement* and *replacement*) in its Article 7, albeit not verbatim, and for the development and validation of alternative methods.

The Directive and ECVAM

Article 23 of the Directive states that the Commission and the Member States should encourage research into the development and validation of alternative techniques. The Commission acted on that Article in October 1991 by announcing the establishment of ECVAM in a communication to the Council and the Parliament (2).

Since 1991, ECVAM has succeeded in establishing in the EU, as well as internationally, the concept of prevalidation and validation of alternative methods.

How does the link between the Directive and ECVAM work in practice? The Directive calls for the development of alternative methods. Once a method has been developed and has enough potential to successfully pass a validation study, ECVAM takes the method on board. The prevalidation phase tries to find out whether the method is likely to succeed in a validation exercise and to optimise its chance of success. This ensures that valuable resources are not spent on methods that are unlikely to succeed, with the consequence that successful results are achieved more rapidly.

Once a method has successfully been validated, it needs to be accepted for regulatory purposes. An officially agreed protocol on how the method is to be applied has to exist for it to be "reasonably and practicably available", as required by the Directive.

ECVAM has a crucial role in assisting regulatory acceptance, not only in the EU, but also internationally. In the area of chemicals testing, the main player in the EU for establishing regulatory acceptance is the Environment Directorate General.

[1]*The talk was presented at the seminar by Jürgen Vogelgesang.*

However, without the scientific and technical support of ECVAM, this work would be extremely difficult.

Regulatory acceptance is an area where precious time could be saved. A solid scientific demonstration of the relevance and reliability of a method paves the way to faster regulatory acceptance. The role of ECVAM is thus crucial.

The first three alternative methods validated by ECVAM were included in the EU chemicals legislation in 2000 (3, 4). These methods test phototoxic potential and skin corrosivity. Their international acceptance at the level of OECD is expected in 2002. It is hoped that international regulatory acceptance will be somewhat smoother in the future, following the experience gained with these first three methods.

Chemicals testing is only part of the testing performed on animals. An important number of animals are used in the area of biologicals. "Regulatory acceptance" in the eyes of the Directive goes beyond just EU legislation. In the case of biologicals, for example the production and potency testing of vaccines, the required testing methods are laid down in the *European Pharmacopoeia*. The first validated methods involving ECVAM, on the potency testing of tetanus vaccine for human use (5, 6), are expected to be formally included in the *European Pharmacopoeia* in the very near future.

Closing the circle, *Directive 86/609/EEC* clearly states that an alternative method, once it is "practicably and reasonably available", shall replace the respective animal method.

The Directive provides a strong base for the existence of ECVAM. At the same time, the work and results provided by ECVAM assist in achieving the goals set up by the Directive.

In-depth Revision of the Directive

In recent years, it has become clear that *Directive 86/609/EEC* needs to be fully revised in order to incorporate improvements in the welfare of laboratory animals and to further promote the development of alternative methods. Important progress has been made in science, and new techniques are being applied which could not be imagined at the time of the drafting of the Directive.

Parallel to that, there are developments in the field of laboratory animal welfare at the level of the Council of Europe. There is a 1986 Council of Europe Convention on the protection of vertebrate animals used for scientific purposes (7). The Community has been a party to the Convention since 1998.

Under the auspices of the Council of Europe, a Working Party is currently reviewing the housing and care guidelines for laboratory animals covered by the Convention. The scientific basis of the guidelines was first established 15–20 years ago, and a great deal has been learnt since then. The revision will incorporate the latest available scientific knowledge into the Convention.

The Council of Europe intends to adopt the necessary amendments by using a "simplified procedure" which is not yet formally provided for by the Convention. Consequently, the Council of Europe has opted to first ratify a *Protocol of Amendment* that will incorporate a "simplified procedure" into the Convention.

The Commission is tackling these challenges by a two-step approach. In step one, in November 2001, the Commission adopted two proposals, which are currently with the European Parliament and the Council. The first proposal is to conclude a *Protocol of Amendment*, and in the second proposal, the Commission provides for a Regulatory Committee Procedure to be incorporated into *Directive 86/609/EEC*. The existence of such a procedure within the Directive is a prerequisite for ratification by the EU of the *Protocol of Amendment* of the Council of Europe.

As a second step, an in-depth revision of the Directive is under preparation. This will require expert discussions and considerable input from all the stakeholders. The discussions at the level of the European Parliament and the Council are expected to be complicated. Therefore, it is crucial that the in-depth revision is carried out as a separate step.

Issues that need to be considered during the in-depth revision of the Directive include questions on the existing legal base to cover animals used in basic research and education and training, and on how routine production, such as the production of vaccines, is covered.

Furthermore, consideration should be given to how the welfare of animals that are killed for their tissues and organs can be protected and safeguarded, how commercial breeding can be covered, and what species are currently used, the use of which was not foreseen 20 years ago.

In looking at the provisions of the Directive, some definitions clearly require greater precision. The Commission also intends to incorporate provisions to improve the control and welfare of certain species, such as non-human primates, dogs and cats. The Commission also has to carefully consider how genetic modification and cloning is to be taken into account.

The requirements for authorisation of the animal experiments and inspection of the establishments need to be revisited. Statistical requirements will be under scrutiny, and what is clearly lacking is the role of ethical reviews. Back in 1986, nobody was concerned about ethical committees. Today, several Member States have incorporated compulsory ethical reviews into their national legislation. The Directive needs to ensure that at least the minimum ethical considerations are taken on board.

The above are just some examples of the questions that need to be looked at and carefully considered during the in-depth revision of the Directive.

ECVAM and the Revision

How does the work of ECVAM fit into this picture? One of the main questions for the in-depth revision is how to better incorporate the principles of the Three Rs into the core of the Directive.

Article 7.2 will need to be revisited, and greater precision and clarity incorporated into it. Here, there is also room to define the role of ECVAM in the process of making alternative methods "practicably available". References to the work of ECVAM have already been proposed in other parts of Community legislation, such as the Draft 7th Amendment to the Cosmetics Directive. How this should be tackled in *Directive 86/609/EEC* is clearly a matter of great importance to ECVAM and needs to be discussed with ECVAM.

Are there other ways of improving the practical application of Three Rs? Furthermore, how can *Directive 86/609/EEC* better contribute to the development and validation of alternative methods? The EU White Paper on *Strategy for a Future Chemicals Policy* (8) called for more resources for the development of alternative methods within the Commision's research budget. How should *Directive 86/609/EEC* handle this issue?

These are important questions, which cannot be easily answered. If the revision of the Directive is to be successful, there must first be sufficient dialogue and consultation with the various stakeholder groups. Some organisations have already contributed to this process, and more contributions are expected in the near future. It is important that the opinions of all interested parties are heard and carefully considered.

What progress has been made until now? The first two proposals are expected to be finalised by the European Parliament and the Council before the end of 2002. At the same time, the background work for the in-depth revision of the Directive has already started. An Expert Working Group will be convened to tackle the most technical and scientific questions. The Commission is currently identifying organisations for participation in the Expert Working Group. In this way, the Commission aims to have a first Draft Proposal ready by the end of 2003.

With these measures, the Community will be able to make a giant step forward in the protection and the welfare of laboratory animals.

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