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A new partnership to reduce Animal Testing

Check Against Delivery
Seul le texte prononcé fait foi
Es gilt das gesprochene Wort

EP - Conference on Animal Testing

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Introduction/Objectives of the Conference

Janez Potočnik and I take great pleasure in welcoming you to the Conference on “Alternative Approaches to Animal Testing”.

We have organized this conference with three important objectives in mind:

- Firstly, we would like to demonstrate that the European Union continues to place animal welfare high on the political agenda with the objective to remain the world leader in animal welfare.
- Secondly, our intention is to show progress made in the development of alternative methods to animal tests at the national, European and international level.
- Thirdly, we are aiming at identifying further possibilities to improve development and validation of alternative methods.

We have invited, and I am delighted to see here present today, quite a number of high-level representatives and experts from industry, animal welfare organisations, academia and national, European as well as international institutions.

Today's conference will allow you to join us in discussing the challenges and the ways forward in promoting alternative approaches to animal testing. The subject is highly sensitive, very technical and at the same time political, touching on different societal aspects, such as ethics, health, economics and science.

Challenges ahead

The use of animals in experiments has always been a focal point of concern. The importance attached to animal welfare continues to evolve in terms of ethical concerns. This has already become a “cultural attitude for European society”.

Asked whether “scientists should be allowed to experiment on animals if this can help resolve human health problems” respondents in the European Union seem somewhat divided: Although a relative majority, 45 %, appears to be in favour. 34 % indicate that they disagree while, 18 % say that they neither agree nor disagree (EUROBAROMETER 2005).

In Europe, about 11 million animals are used in experiments or for scientific purposes per year. At present, the world-wide use is estimated to be 100-150 million vertebrates per annum.

Roughly 25 % of the tests carried out on animals in Europe can be considered as regulatory testing. These animal tests are performed due to the high safety requirements that we have come to expect in the areas of pharmaceuticals, chemicals, cosmetics, biotechnology, medical devices as well as food and feed. Products and substances of these sectors cannot be placed on the market if they are unsafe.

I can assure you that I am personally committed to animal protection. But as a Member of the European Commission I am also committed to the protection of consumers, workers and patients.

As long as scientists tell me that animal tests are still needed in the various industrial sectors to assess risks to human health, we have to continue our efforts in identifying alternative methods. The challenge, therefore, is not whether we need to carry out these tests. The challenge is whether we can do it also by using alternatives.

REACH

We are currently discussing with the Council and the European Parliament a new legal framework for chemicals – REACH (Registration, Evaluation and Authorization of Chemical Substances).

The REACH proposal was triggered by the general lack of information about the dangerous properties of chemicals on the market. More than 99 % of the entire tonnage of such chemicals, the so-called “existing” substances – these are substances placed on the market before 1981 – are not subject to the standard information requirements prescribed for “new” substances.

The testing requirements for so-called new substances – these are substances placed on the market after 1981 – give us a current picture of their dangerous properties. Thus their risks can be reliably assessed when considering the exposure of man and the environment.

For existing substances, however, knowledge about the dangerous properties is generally very limited. Therefore, it is nearly impossible to know whether they represent serious risks for humans and the environment, including animals.

Consequently a substantially improved knowledge of the dangerous properties of such chemicals is necessary. To remedy this knowledge gap, the REACH proposal suggests making available any and all information on the dangerous properties or hazards of substances.

The REACH-system seeks to balance the potentially serious threats to human health and the environment against animal welfare considerations.

Therefore, a number of elements have been developed with a view to keeping animal testing to a minimum:

- Existing information on the toxicity and ecotoxicity of substances, including epidemiological studies, results from computer calculations and international sources, will be taken into account before deciding whether additional testing is necessary;
- Substances which are similar may be grouped, where appropriate, in order to minimise testing;
- For substances produced or imported in quantities between 1 - 10 tonnes per year and per manufacturer or importer, testing should generally be limited to *in vitro* methods.

Against this background it is not justified to criticize the REACH-proposal because of its possible impact on animal testing. Such criticism ignores the needs for a revision of chemicals legislation to improve protection of human health and the environment as well as the overall efforts to reduce animal testing and to develop alternative methods.

Where have we come from?

The first animal protection movement, the Victoria Street Society, was established in 1875 in London. In time, several other countries founded similar societies utilising different policies to achieve their goals. Some of them emphasised political lobbying, others organised public campaigns and protest demonstrations.

Activities of the animal protection movement have undoubtedly contributed to legislative regulations for protection of animals used for experimental purposes:

- A number of European Member States have prohibited animal testing on their territory.
- At the European Union level, the Protocol on Protection and Welfare of Animals, annexed to the EC-Treaty, was adopted in 1999. It aims at ensuring improved protection and respect for the welfare of animals as sentient beings. In formulating and implementing the Community's policies, the Community and the Member States shall pay full regard to the welfare requirements of animals.
- In 1986, the Community adopted the Laboratory Animals Directive 86/609/EEC. It integrates the so-called "Three R" approach - Replacement, Reduction and Refinement - into a Community regulatory framework. According to this Directive, alternative methods to animal testing have to be applied where these methods are practically available.
- In this regard, the Cosmetics Directive provides the most ambitious approach of all industry sectors. It establishes a prohibition on the testing of finished cosmetic products and cosmetic ingredients on animals (the testing ban), and a prohibition to market, in the European Community, finished cosmetic products and included ingredients which were tested on animals (the marketing ban). The testing and marketing bans apply fully in 2009 and 2013 respectively, irrespective of the availability of non-animal tests.
- The development of new alternative testing methods using fewer or no animals is fostered under the Community Framework Programmes for Research and Technological Development. Researchers submitting suitable projects for such methods will be funded from the Programme. My colleague, Janez Potočnik, will expand more on this.
- At international level, the harmonisation of test guidelines led to a significant reduction of the number of animals being tested. In 1982, the OECD was the first international organisation to agree harmonised guidelines for the testing of animals. And it is a major success that OECD adopted, for the first time in 2004, alternative methods aimed at replacing animal tests (skin absorption, skin corrosion and phototoxicity).

The Way Forward

Although a number of initiatives have been launched promoting alternative methods at national, European, international, public and private level, it will not be possible to fully replace animal testing by alternative methods in the short or medium term without endangering our high safety standards.

Unfortunately the process of developing, validating and legally accepting alternative methods is slow and, to some extent, uncoordinated due to the setting of different priorities in the sectors concerned.

Against this background a coordinated approach might help in our view to overcome obstacles. A coordinated approach would furthermore avoid duplication of work and create positive synergies between industrial sectors, without compromising competitiveness of European industry.

A coordinated approach would finally demonstrate that research in the development of alternatives is not only beneficial for animal welfare but also encourages the development of new markets for these methods.

Alternative methods have the potential to increase the credibility and accuracy of tests as well as the safety of human beings. In fact, sometimes human cell models are better in predicting human health effects than the animal model.

The development and validation of new methods and strategies will also increase competitiveness of European industry. The alternative method developed to replace the so-called rabbit pyrogen test for bacterial impurities in drugs has proved a major commercial success, and has a world-wide market volume of 200 million Euro.

Action

We have explored, together with other stakeholders, and in particular representatives of industry, animal welfare and the European Parliament, various avenues forward that would be both appropriate and pragmatic. A significant outcome from this collaboration was the agreement to set up a “European Partnership to Promote Alternative Approaches to Animal Testing”.

I am very happy that the European Commission and industry representatives will today be able to agree on a declaration and an action programme, including activities and timetables, aimed at refining, reducing and replacing animal use and to apply advanced methodology from biosciences and medicine to develop novel approaches to assessing safety.

It is a significant success that for the first time different industry sectors will cooperate together on these common goals, despite different economic and legal situations, interests and experiences.

Concluding Remarks

Science and Research over the last two decades has moved almost completely away from animal experimentation to alternative approaches. Animal use has more than halved over the last two decades. This development demonstrates that we are on a good track. But let's try to be more ambitious and promote this development further. The “European Partnership to Promote Alternative Approaches to Animal Testing” shows the way and the right direction.

Thank you for your attention and I hope you will enjoy and profit from the conference.