



July 2013

EUROPEAN CONSENSUS
PLATFORM FOR ALTERNATIVES

Directive 2010/63/EU

Directive 2010/63/EU on the protection of animals used for scientific research, adopted on 22 September 2010, replaces the previous 20-year old EU Directive 86/609/EEC. The Directive aims to ensure high standards for housing and care of animals, to regulate the level of pain, suffering, distress and lasting harm that may be caused to animals. The authorization of animal experiments is also dependent on the balance between discomfort and potential research benefits.

The new Directive foresees retrospective evaluation and regular inspections, and aims at improvement of the transparency through publication of non-technical project summaries inter alia. The new Directive, which centres around the 'Three Rs', foresees beside the implementation of 'Animal Welfare Bodies' within institutions and establishments (animal suppliers, breeders) also the introduction of responsible administrative infrastructures and appointment of responsible laboratories, contact points, advisory committees and competent authorities on the national level.

Directive 2010/63/EU came into force on 1 January 2013 across Europe, i.e. all Member States have had to translate the Directive into national legislation by 10 November 2012 (§ 61, 2010/63/EU), ensuring their application as of 1 January 2013. Whereas all Member States have already appointed authorities in accordance to Directive 2010/63/EU and [National Contact Points](#) according to § 59, 2010/63/EU, the transposition of the Directive is delayed in many Member States.

At the moment there are notifications regarding the transposition of Directive 2010/63/EU from Austria, Bulgaria, Czech Republic, Denmark, Estonia, France, Ireland, Latvia, Lithuania, Luxemburg, Slovakia, Spain, Sweden, and the United Kingdom. The notification regarding the full transposition of the Directive is still awaited from Belgium, Cyprus, Finland, Germany, Greece, Hungary, Italy, Malta, The Netherlands, Poland, Portugal, Romania and Slovenia.

As the noncompliance with the transposition deadline represents an infringement, there have been discussions and contentions from different interest groups about the legal consequences and penalties. Notably, The European Commission has already initiated infringement procedures against two Member States due to non-compliance with the transposition deadline: against Hungary on 30 May - its notified transposition was found incomplete - and against Malta on 20 June.

It is expected that the European Commission will initiate infringement procedures against other Member States, which did not comply with the deadline and against Member States with incomplete translation of the

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Won't you join us?

Joint Information Day on
"High Content Imaging
Technology in Safety
Sciences"
24 October 2013
Mainz, Germany
Details will soon be available
here. For registration
contact.

ecopa meetings

ECOPA Board Meeting
24 September 2013
Charlottenlund, Denmark

ECOPA General
Assembly
23 October 2013
Mainz, Germany

Other coming events

International Congress of
Toxicology
30 June - 4 July 2013
Seoul, Korea

Science in the Service of
Animal Welfare: Priorities
around the world
4 - 5 July 2013

Directive into the national legislation. Moreover, the decisions on legal consequences of the infringement are expected shortly, as these are thought to provide the necessary incentive for implementation of the Directive on a national level.

Mardas Daneshian

Status of the implementation of the EU Directive 2010/63 in Belgium

Activities before 2013

In Belgium several provisions of Directive 2010/63/EU were already in application before its publication in 2010 (Authorization of users, breeders and suppliers; Consideration of the 3Rs and single point of contact on alternatives; Preliminary evaluation and authorization of projects and procedures by local ethical committees; AWOs in all institutions; Adoption of housing and care dispositions of annex 3 of 2010/63 - compulsory for all new establishments from 15 May 2010 and compulsory for all establishments from 15 May 2015; Education and training of personnel).

On 1 January 2013, in function of Article 2 of the EU Directive 2010/63, all national actions before the 9 November 2010 which go further than the EU Directive to promote animal health have to be shared with the EU:

1. Royal decree of 30 November 2001 (and Amendments) which imposes a prohibition to conduct some animal experiments:
 - o Prohibition to conduct skin corrosivity and phototoxicity tests. Skin corrosivity testing was adopted to REACH in 2009.
 - o Prohibition to produce monoclonal antibodies via the ascites method (2004).
 - o Prohibition to test ingredients and final products of cosmetics (2005).
 - o Prohibition to use great apes for experiments (2009). This is a complete prohibition which goes further than the EU Directive.
2. The law of 14 August 1986 on the protection of animals and animal welfare needed to be modified to partly implement some new (definitions, scope etc.) provisions of Directive 2010/63. That law has been modified by the law of 27 December 2012 (Loi portant des dispositions diverses en matière de bien-être animal, Cites, santé des animaux et protection de la santé des consommateurs/ Wet houdende diverse bepalingen inzake dierenwelzijn, CITES, diergezondheid en bescherming van de gezondheid van de gebruikers) that was published on 31 December 2012.
 - o Art 23 §2 compelled that the expert in animal welfare must be a veterinary surgeon for test animals like dogs, cats, monkeys and farm animals.
 - o Art 26 §1 requested that the responsible scientists for animal experiments must have a university degree.
3. The royal decree of 6 April 2010 on the protection of animals used for scientific purposes was also modified to implement the

Barcelona, Spain

Mondial Research Group:
Reduced Animal Testing
25 - 26 July 2013
Zurich, Switzerland

BEHAVIOUR 2013
4 - 8 August 2013
Newcastle, UK

Newcastle Consensus
Meeting 2013
9 August 2013
Newcastle upon Tyne, UK

Sixth Cell Stress Society
International Congress
18 - 22 August 2013
Sheffield, UK

Toxicology and
Environmental Health (a
short course)
19 August 2013
Utrecht, The Netherlands

Symposium on Social
Housing of Laboratory
Animals
22 - 23 August 2013
Bethesda, MD, USA

Eurotox 2013
1 - 4 September 2013
Interlaken, Switzerland

Workshop on Laboratory
Animal Anaesthesia and
Peri-operative care
9 - 11 September 2013
Newcastle Upon Tyne, USA

EUSAAT's 2013 Congress
and Symposium
13 - 18 September 2013
Linz, Austria

Course on Animal
Welfare Science, Ethics
and Law
8 - 20 September 2013
Cambridge, UK

Environmental
Mutagenesis and
Genomics Society 44th
Annual Meeting
21 - 25 September 2013
Monterey, California, USA

rest of the Directive.

- o Addendum 3: the general part concerning the housing of animals is much more demanding than required in EU Directive 2010/63.
 - o Art 35 foresees a timeframe until 2015 to comply with the housing standards. In exceptions housing standards should be adopted at latest by 2017, which is the date foreseen by the EU Directive 2010/63.
4. Authorization of users, breeders and suppliers.
 5. Consideration of the 3Rs, PARERE.
 6. Preliminary evaluation and authorization of projects and procedures by local ethical committees that include a member of the Federal Department of Health.
 7. AWOs in all institutes.
 8. Education and training of personnel (animal care, carrying procedure, design of project)

Activities in 2013

The Council of State examined the Royal decree of 6 April 2010 on 17 January 2013. The decree will be adapted to the remarks of the Council.

Philippe Vanparys



Norecopa: Norwegian Consensus Platform for Alternatives to Animal Experimentation

Resources available from an International Consensus Meeting on Agricultural Animals

Norecopa, the Norwegian consensus-platform for the 3Rs, arranges international consensus meetings on specific areas of research involving animals. The latest meeting was held in September 2012 entitled *Harmonisation of the Care and Use of Agricultural Animals in Research*.

All the presentations from this meeting and a compilation of relevant guidelines are now available for download from the meeting's [website](#). The site also contains a 12-page consensus document describing the participants' views of tasks that should be carried out to increase implementation of the 3Rs in this area. Among other topics, the meeting addressed the consequences of the new EU Directive and described the new edition of the US FASS Guide for the Care and Use of Agricultural Animals in Research and Teaching.

Norecopa hopes that the resources on this website may be useful for the continuing professional development of all those involved in the use of farm animals in research. Norecopa started an e-mail discussion forum after the meeting for those interested in this subject. This forum is open to people

Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)
24 - 25 September 2013
National Institute of Environmental Health Sciences
Research Triangle Park, NC

29th Workshop of SSCT, Frontiers in Cell Toxicity Testing
25 - 27 September 2013
Charlottenlund, Denmark

International Conference on Alternatives to Animal Model (ICAAM-2013) – New Trends and Current Progress
3-4 October 2013
Kuala Lumpur, Malaysia

Synthesis of evidence in animal experimentation; from information to knowledge through systematic reviews
4 October 2013
Nijmegen, The Netherlands

Scientific Workshop on Translational Alternative Models and Biomarkers Predictive of Drug or Chemical Cardiovascular Risk
10 - 11 October 2013
Research Triangle Park, NC, USA

INVITROM Symposium: "In Vitro Models: The Cell is the Limit?"
16 October 2013
Breda, The Netherlands

LATINFARMA 2013: 3Rs Alternatives in Pharmacology, Toxicology and Teaching Workshop
21 - 25 October 2013
La Habana, Cuba

Joint Information Day on "High Content Imaging Technology in safety sciences"

who were not at the meeting following nomination by one of the participants.

Norecopa has also arranged international consensus meetings on the care and use of wildlife and fish in research, from which all presentations are available on the [internet](#). For more information, please contact Norecopa's secretary, [Adrian Smith](#).

Nordic animal welfare organisation sponsors the further development of the NORINA database

The NORINA database contains information on nearly 4,000 products that may be used as alternatives or supplements to animals or animal material in teaching and training, at all levels from junior school to university. The database is available free on the [internet](#) and was developed by [Karina Smith](#).

Norecopa has received funding from the Nordic Society against Painful Experiments on Animals for three years so that Karina may continue the work of updating and enlarging this database. She also manages [TextBase](#), which contains information on over 1,500 books of relevance to laboratory animal science and the 3Rs.

Implementation of the Directive 2010/63/EU

Norway is not part of the EU, but as a member of the European Economic Area (EEA) it is in the process of writing new legislation that will implement the Directive in the course of 2013. At the same time, the system for approving and monitoring animal experiments in Norway is being radically changed, so this will be a challenging year for the laboratory animal community. Norecopa is collaborating closely with the Norwegian authorities and animal facilities in this matter.

Norecopa's 3R prize and annual seminar

Norecopa awards an annual prize of NOK 30,000 (approx. €4,000) to individuals or groups who have made significant contributions to the development or implementation of 3R-alternatives. This prize is awarded during Norecopa's annual seminar, which in 2013 was held in Oslo on 3 June. This year's prize was awarded to Dr. Goril Eide Flaten, who has developed a model membrane (PVPA: phospholipid vesicle-based permeation assay) for simulating the passage of molecules over a membrane, to replace in vivo work on, in particular, chemicals that cross the skin and intestines.

Adrian Smith

24 October 2013
Mainz, Germany
For registration contact.

AALAS 2013 National Meeting
27 - 31 October 2013
Baltimore (MD), USA

LASA's 50th Anniversary Meeting
26 - 28 November 2013
London, UK

6th International Symposium on Nanotechnology, Occupational and Environmental Health
28 - 31 October 2013
Nagoya, Japan

ASCCT 2nd Annual Meeting
31 October 2013
Rockville, MD, USA

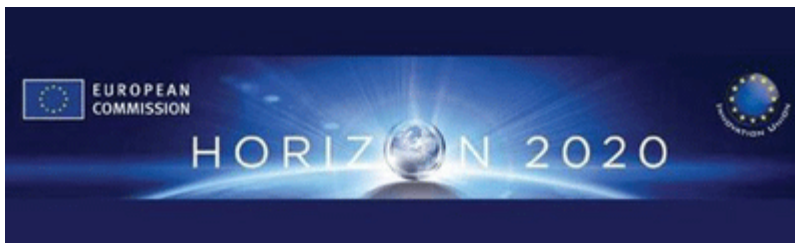
6th International Workshop on Genotoxicity Testing - Satellite meeting of the International Conference on Environmental Mutagens (ICEM)
31 October - 2 November 2013
Foz du Iguaçu, Brasil

11th International Conference on Environmental Mutagens
3 - 8 November 2013
Foz du Iguaçu, Brasil

In Vitro Medical Device Testing Symposium
10 - 11 December 2013
Baltimore (MD), USA

Fourth International Conference on Alternatives for Developmental Neurotoxicity Testing (DNT)
12 - 14 May 2014
Philadelphia, PA, USA

ESTIV2014
10 - 13 June 2014
Egmond aan Zee, The



Horizon 2020

On 30 November 2011 the European Commission introduced "Horizon 2020", the framework for research and innovation (2014 - 2020) as the successor programme of the current EU research framework FP7, which finishes at the end of 2013. This upcoming European R&D flagship programme will encompass three research foci: I) "Excellent Science", II) Industrial leading role ("Industrial Leadership") and III) "Societal Challenges". In addition, the Joint Research Centre (JRC) will contribute with its research projects to II) and III) and will also be funded as the forth pillar of Horizon 2020, i.e. the Non-nuclear Direct Actions of the JRC.

Horizon 2020 will merge the research framework programme, the innovation-promoting parts of the Competitiveness and Innovation Framework Programme (CIP) for enterprises and for SMEs as well as the European Institute for Innovation and Technology (EIT). The latter will be established outside the specified programme core and shall be funded with about €3 billion from the Horizon 2020 budget.

After a long period of negotiation and a final marathon spurt on 25 June 2013 the European Council and the European Parliament finally agreed on the total budget for the implementation of Horizon 2020, which amounts to € 70 billion. This financial package needs to be agreed on by different institutions within the EU's overall budget, which can be expected in autumn 2013. However, the agreed research budget differs significantly from the initial demand of the Parliament, which was € 100 billion. The strenuous struggle for the decision-finding can be best characterized by the statements of Kurt Deketelaere, Secretary-General of The League of European Research Universities (LERU):

"The Parliament finally gave up on the unrealistic demands of different funding rates for different projects and the Council showed a lot of flexibility in agreeing with the Parliament on almost everything else. It really was time to wrap up the negotiations in order to have a smooth transition from Framework Programme 7 to Horizon 2020. It was unthinkable that we would have to go to a second reading of the texts."

In a nutshell, Horizon 2020 will simplify the support of the European Union for research considerably. For example, European researchers are to get a part of their costs refunded flatly, i.e. they do not have to provide evidence for them any longer. Also, the researchers can expect a faster processing of their applications, i.e. the decision is to be made within eight months - presently it takes on average 12 months. However, the benefits of the novel simplified accounting model are not undisputed, as some institutions may get less compensation for the utilization of their technological infrastructure.

Mardas Daneshian

Netherlands

9th World Congress on
Alternatives & Animal
Use in the Life Sciences
24 - 28 August 2014
Prague, Czech Republic

Open consultations

Consultation on the
modification of the
REACH Annexes on
Nanomaterials
Deadline: 9 September 2013

Farm animal welfare
codes reform
Deadline: 8 August 2013

National consensus platforms throughout Europe

Austria
Belgium
Czech Republic
Denmark
Finland
France
Germany
Hungary
Ireland
Italy
The Netherlands
Norway
Poland
Spain
Sweden
Switzerland

Policy corner

European Union Strategy for the Protection and Welfare of Animals 2012-2015.

[Read more >](#)

EU new cosmetic regulation (EC) No 1223/2009 will take effect from July 2013.

[Read more >](#) [Read more >](#)

New EU Biocidal Products Regulation 528/2012 coming into force in September 2013.

[Read more >](#)

Draft guideline on the declaration of the quantitative composition / labelling of biological medicinal products that contain modified proteins as active substance.

[Read more >](#)

Regulatory frameworks for nanotechnology in foods and medical products.

[Read more >](#)

EU-wide restrictions on pesticide use.

[Read more >](#)

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