12th *ecopa* Annual Workshop
"THE FUTURE OF THE 3Rs – FROM INNOVATION TO VALIDATION"
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Inconsistencies in EU data requirements

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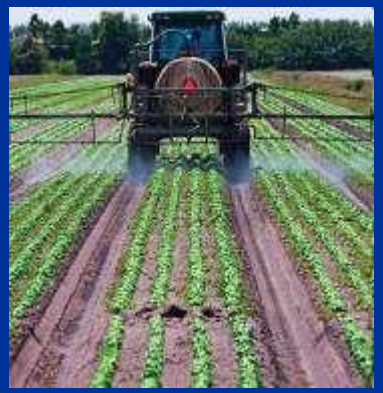
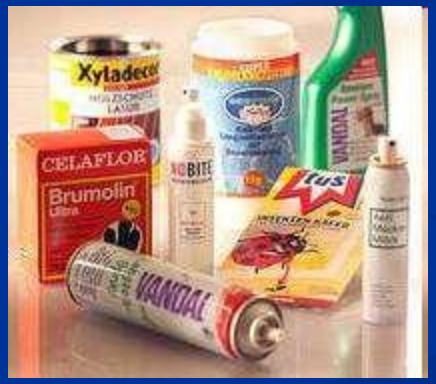
EU legislation that involves animal testing

- REACH
- Plant protection products regulation
- Biocidal products regulation
- Novel Foods regulation
- Food safety (marine biotoxins, etc.)
- Cloning, GMO foods
- Pharmaceuticals



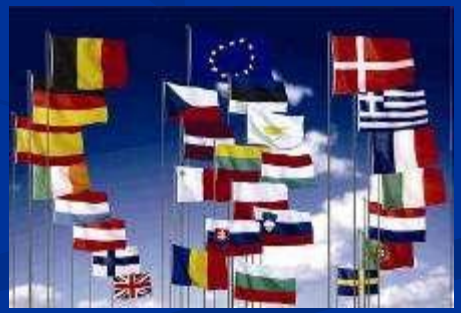


Protection of animals in the EU

Animal Welfare:

- Treaty on the Functioning of the European Union (TFEU), amended 2009:

"In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, ***since animals are sentient beings, pay full regard to the welfare requirements of animals****, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage."*



Animal experiments - legal situation

- Directives 86/609/EEC and 2010/63/EU
- European Convention ETS 123
- Animal Welfare Acts of the EU Member States

Common basic principles:

- Each experiment has to be essential for a given purpose
- The number of animals as well as pain, suffering and harm have to be reduced to a minimum
- Pain, suffering and harm caused to the animals have to be ethically justifiable

Directive 86/609/EEC

Article 7

2. An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.

Article 22

1. *In order to avoid unnecessary duplication of experiments for the purposes of satisfying national or Community health and safety legislation, Member States shall as far as possible recognize the validity of data generated by experiments carried out in the territory of another Member State unless further testing is necessary in order to protect public health and safety.*

Directive 2010/63/EU

Recital 11:

[…] Where no alternative method is recognised by the legislation of the Union, the numbers of animals used may be reduced by resorting to other methods and by implementing testing strategies, such as the use of in vitro and other methods that would reduce and refine the use of animals.

Recital 12:

[…] The use of animals for scientific or educational purposes should therefore only be considered where a non-animal alternative is unavailable. […]

Recital 42:

[…] It is necessary to introduce specific measures in order to increase the use of alternative approaches and to eliminate unnecessary duplication of regulatory testing. For that purpose Member States should recognise the validity of test data produced using test methods provided for under the legislation of the Union.

Article 13 'Choice of methods'

1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.

Analysis of EU legislation – work stages

1. Identification of data requirements that involve testing on animals within EU legislation. Collection of available data, literature research

2. Analysis and comparison of data requirements in the different regulations

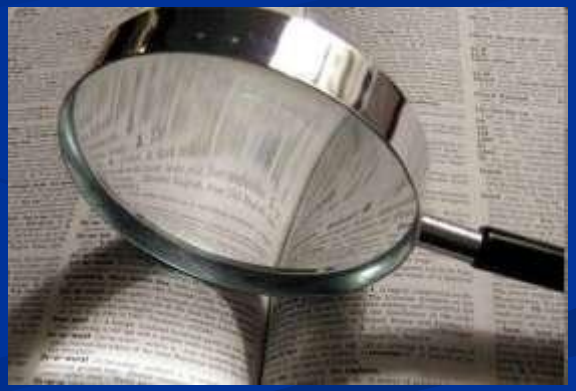
3. Identification of inconsistencies + other problems

4. (Drafting of a homogenous strategy for compilation of data requirements)

Analysis of EU legislation – what did we look for?

- Analysis of data requirements of EU legislation that involves testing on animals:

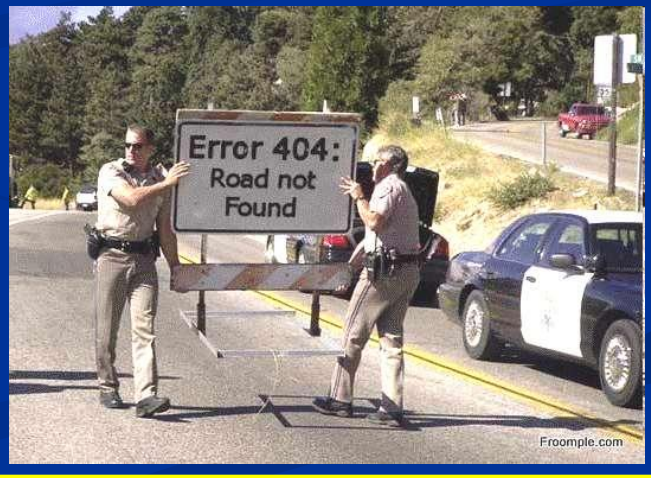
  - Are accepted alternatives considered/included/referred to?
  - How are data requirements structured?
  - Waiving criteria?
  - Rules for adaptation?
  - Consistency of legislation/data requirements?



Analysis of EU legislation – what did find?

- 40 internationally accepted alternative methods available but not considered in most data requirements
- Structure of data requirements is non-uniform from legislation to legislation
- Also varying language, wording and reference to waiving criteria and rules for adaptation

→ Lacking consistency of legislation/data requirements



Case study 1: eye irritation

- AM available (can partly replace *in vivo* test)
- AM not directly included in Test Methods Regulation (440/2008/EC)
- AM only described in regulation 1152/2010 amending Test Methods Regulation (440/2008/EC)
- reference to AM still lacking in respective data requirements (Biocidal Products Regulation or the Plant Protection Products Regulation)
- *In vivo* testing still required, consideration of 3Rs only via reference to a "Sequential Testing Strategy for Eye Irritation and Corrosion" (appendix to *in vivo* eye irritation and corrosion test method (B.5.) of 440/2008/EC)
- Testing strategy developed in 1996, "not an integral part of testing method", does not mention specific AMs ("validated and accepted *in vitro* or *ex vivo* tests"").

Case study 2: skin irritation and corrosion

- Skin irritation (and corrosion) usually required as standard information for hazard identification
- Accepted alternative methods (AM) available (can either partly or fully replace respective *in vivo* test)
- AM already included in Test Methods Regulation (440/2008/EC), but reference still lacking in respective data requirements (Biocidal Products Regulation; Plant Protection Products Regulation)
- There, *in vivo* testing still required, consideration of 3Rs only via reference to "Sequential Testing Strategy for Skin Irritation and Corrosion" (appendix to *in vivo* skin irritation and corrosion test method (B.4.), 440/2008/EC)
- Testing strategy under B.4., 440/2008/EC developed by OECD in 1998, "not an integral part of testing method", only refers to accepted AM in references

- **Update of testing strategy necessary to include newly accepted AM**
- **Restructuring of data requirements necessary**
- **Only the REACH regulation *clearly* refers to *in vitro* testing**

Regulation 440/2008/EC - Problems

- Lays down test methods for REACH, Biocidal Products Regulation, Plant Protection Products Regulation
- Only regulation that is adapted to technical process on regular basis

But:

- Adaptation carried out by separate Regulations to amend 440/2008/EC
  → new methods not included into text of 440/2008 as an update, but in separate regulation document
- Register of test methods lists alternative methods last (e. g. *In vivo* skin irritation is B.4., in vitro methods are only listed as B.40., B.40.bis and B.46.)
  →If scientists are unaware of new methods, they can easily miss the updates and method descriptions

Conclusions 1 – Analysis of data requirements

- accepted alternative methods not referred to or included in data requirements (also true for reprotox EOGRTS, dermal absorption, and others)
- lacking or insufficient advice on how to replace, reduce or refine animal tests
- waiving criteria and rules for adaptation of data requirements differing significantly between the compared legislations
- information and data required for the same endpoint varying from legislation to legislation
- no homogenous or consistent strategy for data requirements

Reasons

- Flood of information
- Requirements to protect animals vs. requirements to ensure consumer safety
- Lack of trust in alternative methods (safety, applicability, significance)
- Tangle of competences: several DGs responsible
- Lack of communication
- Process of adaption to technical process often inert

Conclusions 2 – Outlook

Solution to the aforementioned problems by strategy for drafting future data requirements:

- Need to improve communication between EU institutions, competent authorities and applicants
- Suggestion to create one central organ responsible for drafting data requirements
- Homogenous structure of data requirements (wording, waiving criteria, rules for adaptation)
- General guidance document on how to avoid unnecessary animal testing (e. g. like Practical Guide 10 by ECHA) for all EU legislation that involves animal testing

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Thank you for your attention!

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Description of project:

http://www.stiftung-set.de/projects