How REACH promotes the use of alternative approaches

EP Intergroup on the Welfare & Conservation of Animals
17 December 2015
Strasbourg

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The EU chemical legislation REACH

- Regulation (EC) 1907/2006 concerning the registration, authorisation and restriction of chemicals
- Places responsibility on manufacturers/importers to prove safety of chemicals
- States "promotion of alternative methods" amongst aims
- Contain explicit cross-reference to principles laid down in Directive 86/609/EEC (now replaced by 2010/63/EU on protection of animals used for scientific purposes)
- Implements 3R and "last resort" principle
- Establishes a Regulation on test methods

REACH and test methods

- REACH offers a very flexible approach to methods that can be used
- REACH Annexes VII-X specify information requirements depending on production volume and (sometimes) applicable test methods
- Annex XI gives possibilities to "adapt" standard information requirements by a wide array of other methods/approaches
  - Existing data (from non-standard tests, non-GLP-compliant tests, human data)
  - Weight of evidence
  - Structural characteristics ((Q)SAR)
  - In vitro testing
  - Grouping/read across
  - Exposure-driven waiving

REACH promotes reduction of animal use and application of alternative methods/approaches

- Testing on animals as last resort only/avoidance of duplicate testing
  - Registrants: joint submission and data sharing
  - Registrants: collect and examine existing data before performing new tests
- Prominent role for non-animal methods and approaches
  - Commission: follow developments, update REACH Annexes and TMR to reduce animal testing
  - Registrant: generate information by means other than animal testing whenever possible,
  - Test methods: possibility to replace in vivo data by in vitro test results
  - REACH even allows use of "sufficiently well developed" methods that have not (yet) reached regulatory acceptance on a case-by-case basis
  - Far-reaching provision to waive testing by using non-testing/in silico approaches: grouping, read-across, QSAR

Test Method Regulation

- Commission Regulation (EC) 440/2008
- Established in REACH as tool to "recognise" test methods as appropriate
- Not a new concept: already the preceding chemical legislation contained a listing of applicable test methods (Annex V of Directive 67/548/EEC on dangerous substances)
- Takes up OECD TG in EU law
- Provides full-text version of test methods in all EU languages
- Necessary to provide legal certainty

Limitation of TMR as tool for regulatory acceptance

- Inherently slow process
  - Administrative steps connected to updating legal instruments
  - Translation of long technical texts (Amendments of >500 pages)
- Resource intensive - number of new and updated methods that can be processed is limited

⇨ not well suited as the main tool to bring new alternative methods into regulatory use

⇨ Only feasible for methods that have already reached widespread acceptance

Other means for regulatory acceptance

- REACH: "…recognised by the [..] agency…" (= European Chemicals Agency, ECHA)
- Important tool: ECHA Guidance on information requirements for REACH– provides detailed and comprehensive information on the use of conventional and alternative methods and approaches, integrated testing strategies (guidance development: formalised process involving MS/stakeholders and including several consultation steps)
- Closing the gap: ECHA webpage on OECD and EU test guidelines – provides interim short information on possible application of new methods for REACH purposes, quick update possible after OECD adoption of new methods (informal process)

REACH – how is it working?

- According to currently available information: animal use far below initial estimates (but no final numbers yet)
- Extensive use of non-testing approaches (data sharing, existing data, read-across…) in dossiers
- Caveat: in most cases acceptability of approaches not (yet) assessed
- Number of new tests performed rather small
- Established in vitro approaches (skin/eye irritation) are being used, but not enough
- Little information on use of alternative testing methods not having OECD TGs

Challenges for the use of alternatives under REACH

- Shift from "one endpoint-one test" principle on whole organisms/organ systems to more flexible testing approaches
- More complex to set information requirements (what type/how much information is needed?)
- Complex decision-making for regulatory uses (classification, risk assessment)
- Requires technical knowledge by registrants
- Places high demand on resources, technical knowledge and assessment expertise in Member States
- Requires offer of tests and consultancy by contract laboratories ("all-inclusive" offers including data interpretation)

The bigger picture -EC activities to promote alternatives

- REACH: major driver for developments in the area of alternatives
- Concerted efforts of numerous Commission services
- Embedded in extended EU/international network

EC activities to promote alternatives

- Research in alternative methods/approaches
  - Funding (DG RTD programmes, Life+)
  - Direct involvement in development of test method and *in silico* tools (COM-JRC)
- Assessment of regulatory relevance, validation and evaluation of new methods (EURL-ECVAM, PARERE, ESAC, NETVAL)
- Guidance for regulatory use of endpoint-specific test methods and alternative approaches (ECHA)
- EPAA - European Partnership for Alternative Approaches to Animal Testing: public-private partnership enhancing cooperation between regulators and various industry sectors

EC activities to promote alternatives-contd.

- Dissemination of information
  - DG ENV Animals website
  - ECVAM DataBase Service on ALternative Methods (DB-ALM), Tracking System for Alternative Test Methods Review, Validation and Approval (TSAR)
- Training on the use of new methods (EURL-ECVAM, MS)
- International collaboration to streamline method development and harmonise data requirements (OECD, JRC-ICATM, EC-sector-specific groups)

Thank you for your attention

– looking forward to a lively discussion!