REACH – The new Chemicals Regulation

Maria do Carmo Palma, 7th November, C3P-NASA Workshop

AGÊNCIA PORTUGUESA DO AMBIENTE

Ministério do Ambiente, do Ordenamento do Território e do Desenvolvimento Regional

REACH – The new Chemicals Regulation

- REACH :
  - Regulation for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals
    - One single system for new and existing substances;
    - Entry into force: 1st June 2007
    - Streamline and improve the former legislative framework on chemicals of the European Union (EU), replacing more than 40 pieces of legislation
    - Places greater responsibility on industry to manage the risks that chemicals may pose to the health and the environment
    - No data, no market
    - Promotes the development of alternative methods for the assessment of hazards of substances.

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- REACH :
  - Legislative framework:
    - Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
    - Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

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- Aims of REACH:
  - Improve the protection of human health and the environment from the risks that can be posed by chemicals
  - Enhance the competitiveness of the EU chemicals industry, a key sector for the economy of the EU
  - Promote alternative methods for the assessment of hazards of substances
  - Ensure the free circulation of substances on the internal market of the European Union

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- Scope:
  - Applies to the manufacturing, import, placing on the market and use of substances, on their own, in preparations or in articles and to the placing on the market of preparations;
  - Some exemptions for certain substances/uses or substances;
  - Reduced obligations for R&D (research, product and process related research and development (PPORD)), polymers and intermediates;

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- Key elements:
  - Registration of substances (quantities ≥ 1 tonne per year)
  - Evaluation of some substances by Member States
  - Authorisation only for substances of very high concern
  - Restrictions – the safety net

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- Registration (Manufacturers/Importers):
  - Pre-registration phase: from 1 June until 1 December 2008
  - Registration (quantities ≥ 1 tonne per year)
  - Import: registration by EU-importer or the "only representative" of the non-EU company
  - Chemical Safety Report (CSR): for substances ≥ 10 tonnes per year
  - Information requirements according to tonnage
  - Data sharing - reduces testing on vertebrate animals and costs to industry
  - SIEF formation:
    - **SIEF = Substance Information Exchange Forum**
    - Platform to share data , to agree on C&L and prepare for the Joint submission (possible Joint Submission for the same substance)

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- Registration (Manufacturers/Importers):
  - Registration of non-phase in substances
    - Submit inquiry dossier before registration
    - Registration before manufacture or import (3 wks)
  - Registration of phase-in substances
    - Requires pre-registration (1 June –1 December 2008)
    - Deadlines depending on tonnage and properties
  - Phase-in substances:
    - Substances on EINECS (existing substances)
    - Manufactured but not placed on the market (1 June 1992 –1 June 2007)
    - 'No longer polymers'

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- Registration (Manufacturers/Importers):
  - Basic elements of Pre-registration
    - company and contact information;
    - name of the substance, EINECS and CAS number or, if not available, any other identity codes;
    - the envisaged deadline for the registration and the tonnage band;
    - specification of possible “read-across”substances

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- **REACH implementation timeline (key dates)**
  - 1 June 2007: REACH entry into force
  - 1 December 2008: Deadline for all companies intending to register a substance to notify their intention to the EU chemicals Agency (pre-registration)
  - 1 December 2010: Registration deadline for manufacturers/importers supplying a substance above 1,000 tonnes per year, or a CMR cat.1 or 2 substance above 1 tonne per year, or an R50-53 substance above 100 tonnes per year
  - 1 June 2013: Registration deadline for manufacturers/importers supplying a substance above 100 tonnes per year
  - 1 June 2018: Registration deadline for manufacturers/importers supplying a substance above 1 tonne per year

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- Communication in the Supply Chain
  - Downstream user (definition)
    - any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.

  1. Communication down the supply chain (from suppliers to customers)
     - REACH requires manufacturers and importers of a substance on its own or in a preparation to communicate how their substances or preparations can be used safely for humans and environment.
     - Main instrument: Safety Data Sheet (SDS).

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- Communication in the Supply Chain
  - 2. Communication upstream (from customers to suppliers)
    - Mandatory in a number of situations: communication of new information on the hazardous properties that become available as well as of information that may call into question the appropriateness of the risk management measures recommended by the supplier;
    - Distributors have a general obligation to pass on information received to the next actor in the supply chain;
    - Downstream users have a right to make their use known to the supplier and in doing so have to provide sufficient information to prepare an exposure scenario - important role in the preparation of a chemical safety report, including exposure scenarios if required, as a part of the registration dossier;

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- Classification and Labelling
  - No criteria or obligations on classification and labelling – D. 67/548/EEC and 1999/45/EC;
  - To be replaced by a new Regulation on Classification, Labelling and Packaging of substances and mixtures (introduces GHS in the EU);
  - Specifies obligations for dangerous substances and preparations - making available a Safety Data Sheet or conducting an exposure and risk assessment during a chemical safety assessment.
  - Submission of a notification of the hazard classification by IND to the Agency at the latest by 1 December 2010 unless already submitted as part of a registration – Inclusion of this information (by the Agency) in a classification and labelling inventory - **create pressure to remove possible divergences.**
  - Harmonisation of EU classifications - for carcinogenic, mutagenic, toxic to the reproduction or respiratory sensitisers (other possibilities if justified) - Member States can make such proposals submitting an Annex XV dossier.

- Evaluation:
  - Dossier evaluation: the Agency will do a quality check of the registration dossiers:
    - Compliance check: the Agency may check the compliance of registration dossiers with the requirements laid down for registration in the Regulation.
    - Checking of testing proposals: the Agency will check the testing proposals submitted as part of the registrations before such tests are performed, in order to prevent unnecessary animal testing, i.e. the repetition of existing tests, and poor quality tests. The Agency will also invite third parties to submit information that would avoid the need for vertebrate testing.

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- Evaluation:
  - Substance evaluation: The Agency in co-ordination with the Competent Authorities of Member States may clarify suspicions of risks to human health or the environment by requesting further information from industry.
    - To promote a consistent approach, the Agency will, in co-operation with the Member States, develop guidance on the prioritisation of substances for further evaluation.
    - The Agency will publish a Community rolling action plan on its website identifying the Member State who shall carry out the evaluation of those priority substances.

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- Authorisation:
  - For substances of Very High Concern:
    - Identification of SVHC (Substances of Very High Concern)
      - Substances which are:
        - CMR category 1 and 2,
        - PBT, vPvBs, and
        - identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters
    - Checking of test proposals

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- Restriction (entry into force: 1 June 2009):
  - Minor changes compared to existing system;
  - Any substance on its own, in a preparation or in an article may be subject to restrictions if it is demonstrated that risks need to be addressed;
  - Member States are allowed to maintain their own existing and more stringent restrictions until 1 June 2013;
  - Proposals for restrictions - by Member States or the Agency on request of COM in the form of an Annex XV dossier (comments by Interested parties) .
    - Annex XV dossier - demonstrate that there is a risk to human health or the environment that needs to be addressed and identify the most appropriate set of risk reduction measures.
    - Annex XVII: list of all restricted substances and uses (existing restrictions were carried over).

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- Actors:
  - European Commission
  - European Chemicals Agency (ECHA)
  - Member States

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- ECHA
  - to be operational 12 months after entry into force
    - Management Board (The General Director of the Portuguese Environment Agency is the national representant),
    - Executive Director (recently elected),
    - Committee on risk assessment and Committee on socio-economic analysis,
    - Member State Committee,
    - Forum for exchange of information on enforcement activities,
    - Secretariat (technical, scientific and administrative support for the Committees),
    - Board of Appeal, that will consider any appeals against the decisions of the Agency.

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- European Commission
  - guidance (Conclusion of RIP Projects and handover to the Agency)
  - review of REACH regulation
  - propose and instigate implementation measures, e.g. fee regulation and testing methods
  - comitology decisions
  - key role in the authorisation and restriction processes

- Member States
  - Implementation
    - Appoint one or more Competent Authorities for co-operation with the Agency and the European Commission and for carrying out their tasks under REACH;
    - Establish national helpdesk(s) to provide advice on responsibilities and obligations to manufacturers, importers and downstream users as well as any other interested party;
    - Enforcement
    - Representation at the Agency Committes
    - Participation at REACH Committee and Competent Authorities Committee

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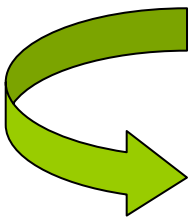
- National developments:
  - Competent Authorities:
    - Portuguese Environment Agency (APA)
    - General Directorate for Health (DGS)
    - General Directorate for Economical Activities (DGAE)



Decree-law that executes this regulation at national level is under preparation

- National helpdesk (coordinated by DGAE)
- Enforcement

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- For further information:
  - http://ec.europa.eu/enterprise/reach/index en.htm
  - http://ec.europa.eu/comm/environment/chemicals/reach.htm
  - http://ecb.jrc.it/REACH/
  - http://ec.europa.eu/echa/home en.html

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- Contacts:

Maria do Carmo Palma
Portuguese Environment Agency
Environmental Risks and Emergencies Unit
carmo.figueira@apambiente.pt

Thank you!