Royal HaskoningDHV
Enhancing Society Together

Chemicals legislation:

Should I care?
I am into the IVDR and MDR !

Jean-Marc Abbing
Consultant Chemicals management,
Environmental and Occupational Health

Charlotte van Daele
Consultant Chemicals management

Pakhuis de Zwijger
MDR and IVDR implementation – have you got it sorted out?
Axon Lawyers, Amsterdam
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Structure in this regulatory jungle

The Chemical (horizontal) Laws:

- REACH & CLP basics
- BPR basics

Chemical references in your (vertical) law:

- IVDR - Annex I
- MDR - Annex I

REACH: safe use of Chemicals

Requirement & processes:

- **Registration** of all chemicals including its use in the EU (=> no use outside registration);
- **Restriction or authorisation** of the most hazardous ones; (after placing on the ***candidate list***);
- **Identification** and information in the supply chain of chemicals on the candidate list > 0,1% w/w in an article.

Specific mention in REACH of IVD/MD/AIMD:

- Exemption from Authorisation if on candidate list based on Human Health hazards only (safety assessment patient & user considered to be done within MDD / IVDD);
- Other exemption in Q&A: used in R&D, IVD and Q&A testing (Triton x-100) if < 1 ton and under strictly controlled conditions (SCC)

Impact on MDD / IVD: direct & Indirect:

- Registration: Continuity of supply and use of your production chemicals
- Authorisation in production and in products (e.g. Triton x-100, not exempted, based on ENVI hazards) or (NMP in production- pending restriction or authorisation)

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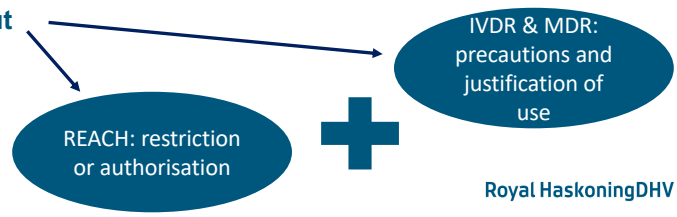
CLP: Classification, Labeling, packaging of dangerous substances

- Classification rules:
  Defines the “danger” of the substance
- May change over time (new data and insights in registration dossiers)

- “Up”classification to CMR 1a/1b, PBT, vPvB, or endocrine disrupting properties (Environment or Human Health)

= > watch out



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Biocidal Product Regulation

- BPR applies to products and treated articles
- 22 product types divided into 4 main groupes:
  1) Disinfectants
  2) Preservatives
  3) Pest control
  4) Other biocidal products

Exemption from BPR:

- Product used ***in*** products under Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC; (IVDD, MDD and AIMD, reference requires updating)

  If used in EU Manufacturing of IVD/MD only (and not in end product) => in scope

Main groups applicable to IVD/MDR: Disinfectants & Preservatives

Use in manufacturing as biocidal product, not in end product ***and*** supplier registered under REACH: switch to other supplier (that registered under BPR)

Summary REACH & BPR impact

Regulatory assessment of each used substance, focus on:

- Hazard:
  - CMR - Carcinogenic, Mutagenic Reprotoxic
  - ED - Endocrine disruptor (HH-Human Health or ENVI-Environment)
  - = > risk of regulatory phase out
- Use:
  - in manufacturing process
  - in end product
  - Use as biocide (BPR) ***or*** as process chemical (REACH)
  - other sectors in wide dispersive uses (high on priority list)
  - Societal attention
- Substitution potential (publicly known)
- Suppliers reliability (Registration & Authorisation & Use)
- Suppliers commercial interest & your dependency / vulnerability

Requirements in Vertical Legislation

IVDR

Annex I: General safety and performance requirements

Chapter II: Requirements regarding performance, design and manufacture

10.4. Risks posed by substances or particles

MDR

Annex I: General safety and performance requirements

Chapter II Requirements regarding design and manufacture

10.4: Substances

23.4: Information in the instructions for use

IVDR

ANNEX I 10.3

Reduce ***as low as reasonably practicable*** the risks posed by substances or particles, including wear debris, degradation products and processing residues, that ***may be released*** from the device:

- all substances

"Special attention" to:

- 'CMR', 1 and 2 in accordance CLP (harmonized) (# >1000)
- 'ED' substances (endocrine disrupting) listed on candidate list REACH (≈10s)

Precautions related to materials incorporated into the device:

- CMR substances
- EDs
- Substances that could result in sensitisation or an allergic reaction by the patient or user

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NO guidance or definition for *"reasonably practicable", "Special attention"* or *"precautions".*

IVDR – what approach?

Top Down (from material to exposure):

Required: Full Material Composition

1. Any CMR/ED & sensitizers present => No: no special attention and precaution

Yes =>

2. Any release of these substances and interaction with patient or user? No: no special attention and precaution => No: risks release other substances?

Yes=>

3. Special attention and precautions related to these substances

Bottom Up (from exposure to material):

1. IVDR in contact with patient or user => No: no special attention and precaution

Yes =>

2a. Select part IVDR in contact with patient or user

2b. Any release of substances and/or interaction with patient or user? No: no special attention and precaution

Yes=>

Any CMR/ED & sensitizers present in that part that require special attention or precaution?

Requirements in the MDR
Annex I. 10.4 specific on (chemical) substances

Political compromise:

Initially European Parliament: all CMRs and EDs in Medical Devices ***"should be banned"***

Result: article 10.4. on Substances in MDs (with a risk based approach):

Specific scope:

Devices, or those parts thereof or those materials used therein that:

- invasive ***and*** come into direct contact with the human body
- (re)administer medicines, body liquids or other substances, including gases, to/from the body,
- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

"identify the MD (or part) where there is a risk of transfer of chemicals to the patient"

Restriction or justification:

Shall not contain any CMR's (1a/b) and ED's (targeted), unless justified (guidance To Be Defined)

Communication:

If substance present and justified => 0,1% => labeling

MDR substances “encore”

General substance requirements in (article 10)

“Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that ***may be released*** from the device”.

- Ingress of materials from the device
- Special attention to Nanomaterials

Out of the blue: general precautions the Instructions For Use (article 23.4)

Precautions related to materials that contain:

- CMR substances
- endocrine-disrupting substances
- Substances that could result in sensitisation or an allergic reaction by patient or user

Challenges Substances requirements MDR

1. **Identification** MD, part MD or material thereof;
2. **Information from the supply chain** on presence of the targeted substances;
3. **Transitition times** (REACH & CLP train is moving): more substances are being “up” classified (to CMR 1a/b or ED) and come into scope MDR; (there is no transition time in the MDR);
4. **Justification** (study of alternatives and assessment of risks), guidance on phthalates to be developed by the SCHEER (Scientific Committee of Health, Environment and Emerging Risks), ready in 2019 (MDR).

Takeaways

REACH / BPR: supply chain communication

- Supply chain registration and assurance by user
- Alertness of phase out (regulatory or commercial) of specific substances
- Are you aware of regulatory status of process chemicals and composition of your product?

IVDR / MDR: Product assessment

General: is there any release or interaction of substances to patient or user?

IVDR:

- broad “precautions”, broad range of substances, CMRs and EDs

MDR:

- specific product requirements & justification of use of specific chemicals
- Broad “precautions” broad range of substances, CMRs and EDs CMRs and EDs

Thank you!

jean-marc.abbing@rhdhv.com +316 1509 3011