Regulatory fitness check of CLP and related chemicals legislation (excluding REACH)

Chemical Watch Conference

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Summary

- **Aim**: Identify and evaluate the impact and consequences of implementing the CLP and examine the way it interacts with other chemical legislation
- **Specific objectives**: The study involved four key tasks:
  1. Evaluate the implementation of the CLP
  2. Evaluate horizontal links between different pieces of EU legislation on hazard identification and communication
  3. Evaluate the vertical links between the CLP and relevant EU and national downstream legislation identifying risk management measures based on hazard classification
  4. Support the Commission in organising a public consultation and workshop

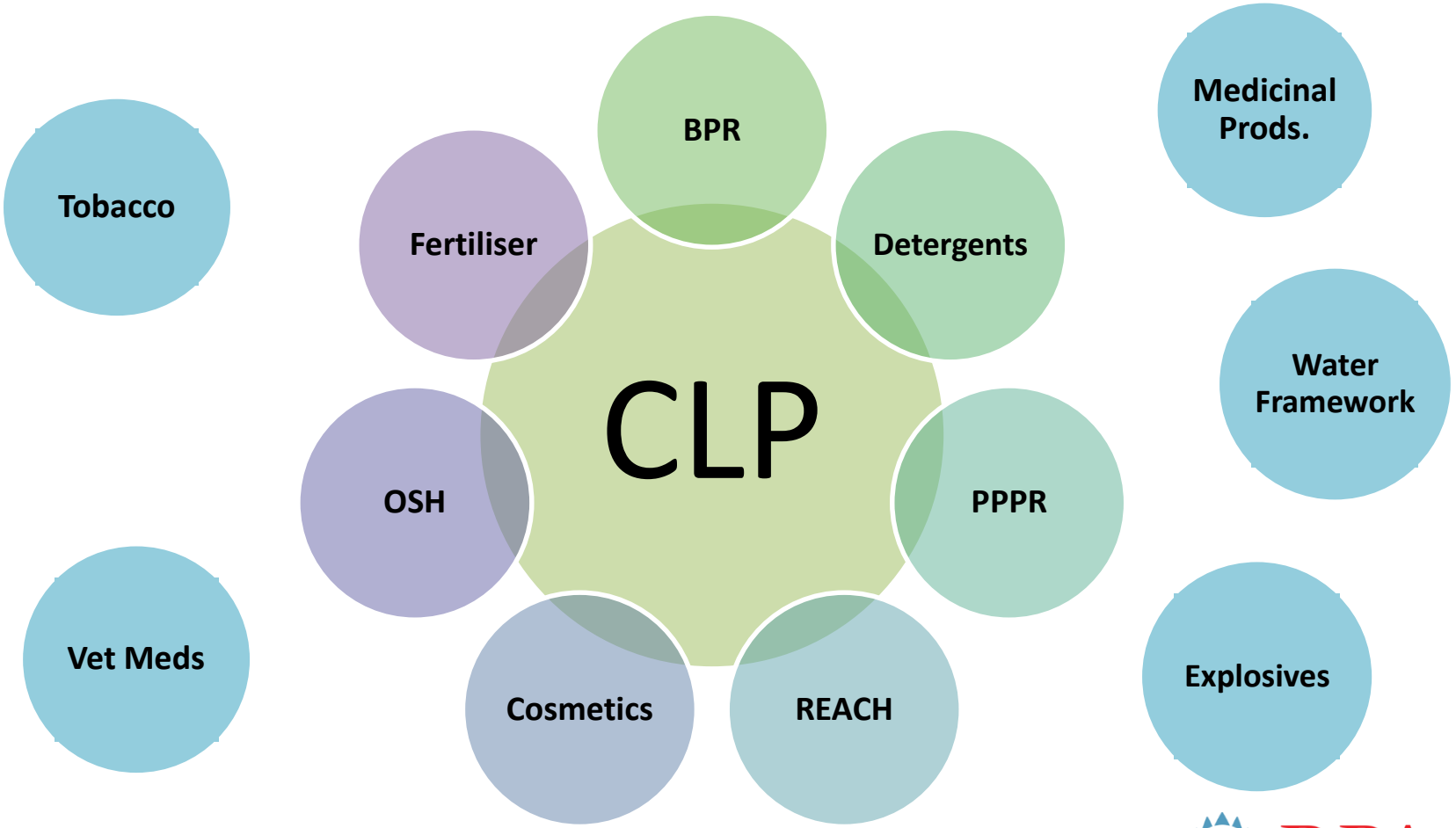
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Legislative mapping

- Scope included **41 pieces of legislation** although focused in the end on a subset
- Horizontal mapping for – **15 pieces of legislation**
  - Identification of properties of concern
  - Hazard communication requirements
  - Packaging requirements
- Vertical mapping for reliance on CLP for triggering risk management – **21 pieces of legislation**
  - Risk management triggered automatically
  - Risk management only triggered after further assessment
  - Risk management is subject to further implementation steps

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Linkages on properties and communication



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CLP specific findings

- On balance, CLP contributes towards a high level of protection
  - Identifying properties of concern and hazard communication
  - Acting as the basis for downstream risk management
  - Quality and reliability of data used for classification
- But, there is room for improvement
  - Bridging principles for mixtures and acceptability of different approaches by national authorities
  - Extent to which rules reflect bioavailability for metals
  - Information overload on labels
  - Lack of differentiation between certain hazards / some pictograms are not well understood

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CLP specific findings

- Classification criteria for terrestrial toxicity and immunotoxicity
- Quality of some of the data notified to the CLI is poor
  - There is no means for removing data of poor quality
  - But authorities and others are using CLI as a source of information
- Not enough progress on agreeing CLH proposals
  - Focus on PPPs and BPs not industrial chemicals
  - Parallel procedure with EFSA on PPP
  - Mixed views on transparency of the process and stakeholder participation



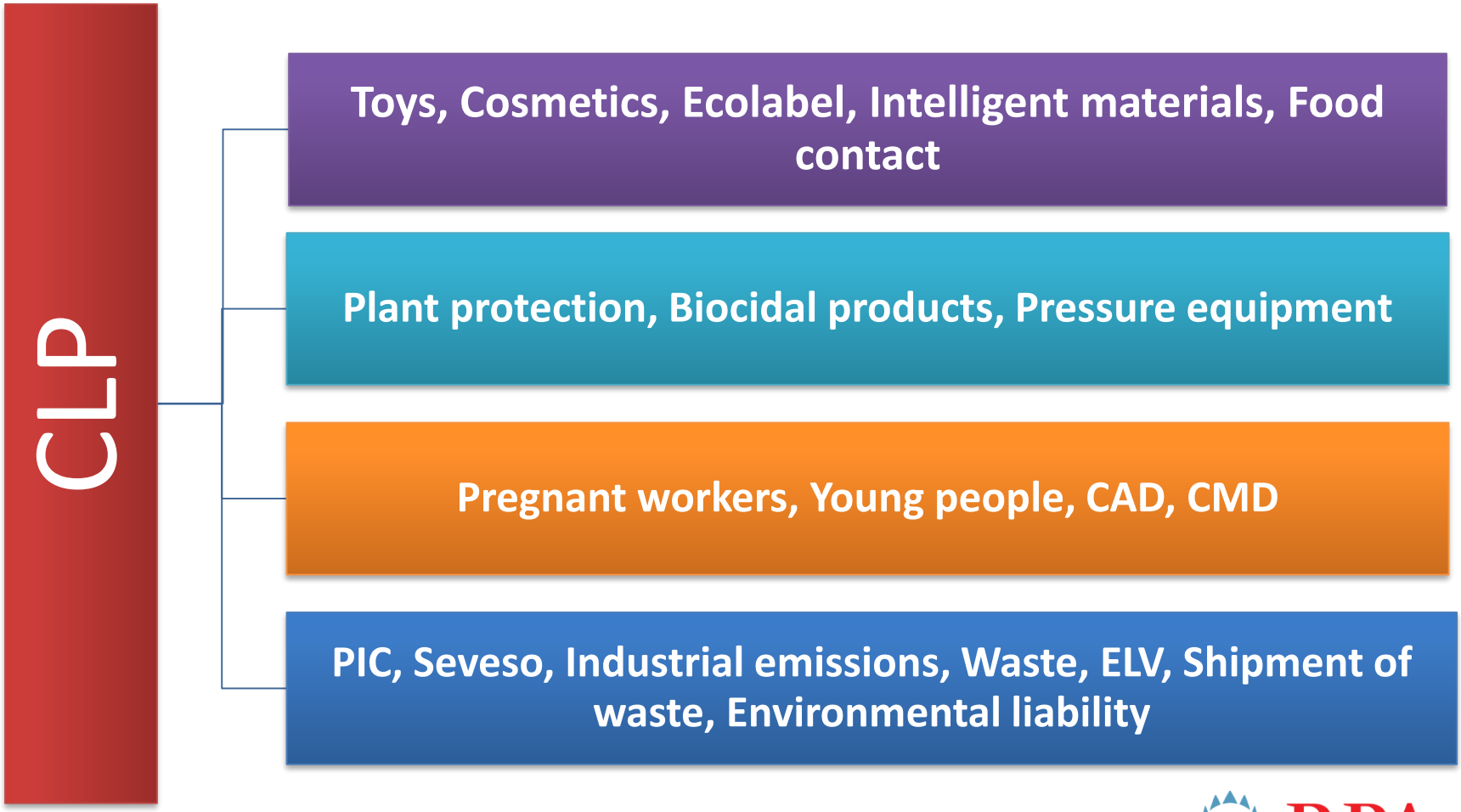
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CLP specific findings

- CLP implementation costs for industry = €1.3 billion, excluding poison centre costs
- Estimated CLP transition costs = €1.6 billion (central figure, and depending on numbers of mixtures)
- Costs of on-going adaptation to GHS = €205 million (ATP 02 & 04, impacting an estimated 95,500 substances based on CLI)
- Annual value of reductions in poisoning incidents, occupational skin and respiratory disease and occupational cancers is estimated at:
  - Since 2008: between €217 – 338 million per year
  - Figures exclude reduction in impacts on consumers and society more generally and environmental impacts

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Linkages for risk management purposes



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Linkages with specific chemicals legislation

- Consumer and professional products legislation has a consistent, harmonised approach to the risk management of CMRs through the use of generic risk considerations (*hazard-based triggers*)
  - Bans and use restrictions as the primary form of risk management for PBTs/vPvBs, EDCs and CMRs does reduce emissions and exposure
- A positive impact on access to and use of substances / products with a more favourable hazard or risk profile (view of most MS)
- A lack of data sharing across the legislative framework is an issue and stakeholders believe that it should be encouraged in order to prevent unnecessary replication of testing (and costs)
- Issues with labelling requirements under legislation in communicating certain hazards to workers / consumers
  - Issues raised, in relation to the Toy Safety Directive, Cosmetic Products Regulation, Biocidal & Detergent Regulation

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Linkages with specific chemicals legislation

- Potential for unnecessary burdens from linkages to CLP based on generic risk considerations in the BPR, PPPR and TSD
  - Evidence is mixed
  - Potential for significant benefits but also regrettable substitution and unintended consequences
  - Particular concern where no potential for derogation or exemption on the basis of technical feasibility or an SEA
- Existence of parallel hazard assessment processes under CLP and PPPR (also effectiveness and coherence)
- Constraints on resources and expertise within Member State Authorities impacts on level of activity on harmonised classifications (also impacting on effectiveness)

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Legislative framework

- The objectives of the legislation continue to be relevant
  - Data used and labelling requirements are appropriate
  - Regulation still necessary for protection and single market
- Some needs remain:
  - GPSD lacks an effective means of addressing the safety of products
  - Lack of methods for assessing combination effects and multiple routes of exposure leads to a gap in protection
  - Potential for use of more innovative communication approaches to reduce information overload or the provision of additional information



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Legislative framework

- Framework is generally coherent in terms of objectives of the legal acts and in the actions required under them
- Gaps and inconsistencies:
  - Lack of consistency in implementation and enforcement has a negative impact on single market
  - Classification criteria for terrestrial toxicity and immunotoxicity
  - Good coherence on identification of PBT properties but lack of coherence for allergens (including labelling)
  - Animal test data under REACH etc. but not cosmetics
  - Differences in derogations under sectoral legislation – in particular under BPR and PPPR as an inconsistency
  - Gaps in the protection of professional users under the Cosmetic Products Regulation and Regulation on food additives

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Legislative framework

- Chemicals legislative framework operating at the EU level (rather than the national level) provides added value
- Harmonisation at the community level is necessary to meet objectives of the legislative framework
- EU-level intervention helps ensure effectiveness and efficiency
  - Helps avoid barriers to trade due to national differences
  - Reduces the costs compared to separate systems operating at national level
  - Enables cooperation across MS in taking regulatory and enforcement actions

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Thank you

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