Joint action plan to tackle REACH compliance

Webinar: Improving the quality of your REACH registration dossier – what authorities are planning and how you can prepare

26 November 2019

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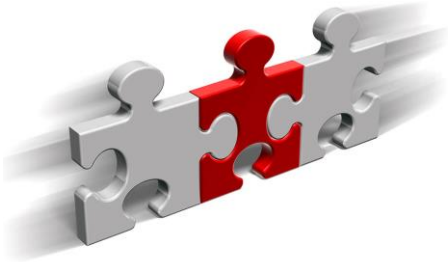
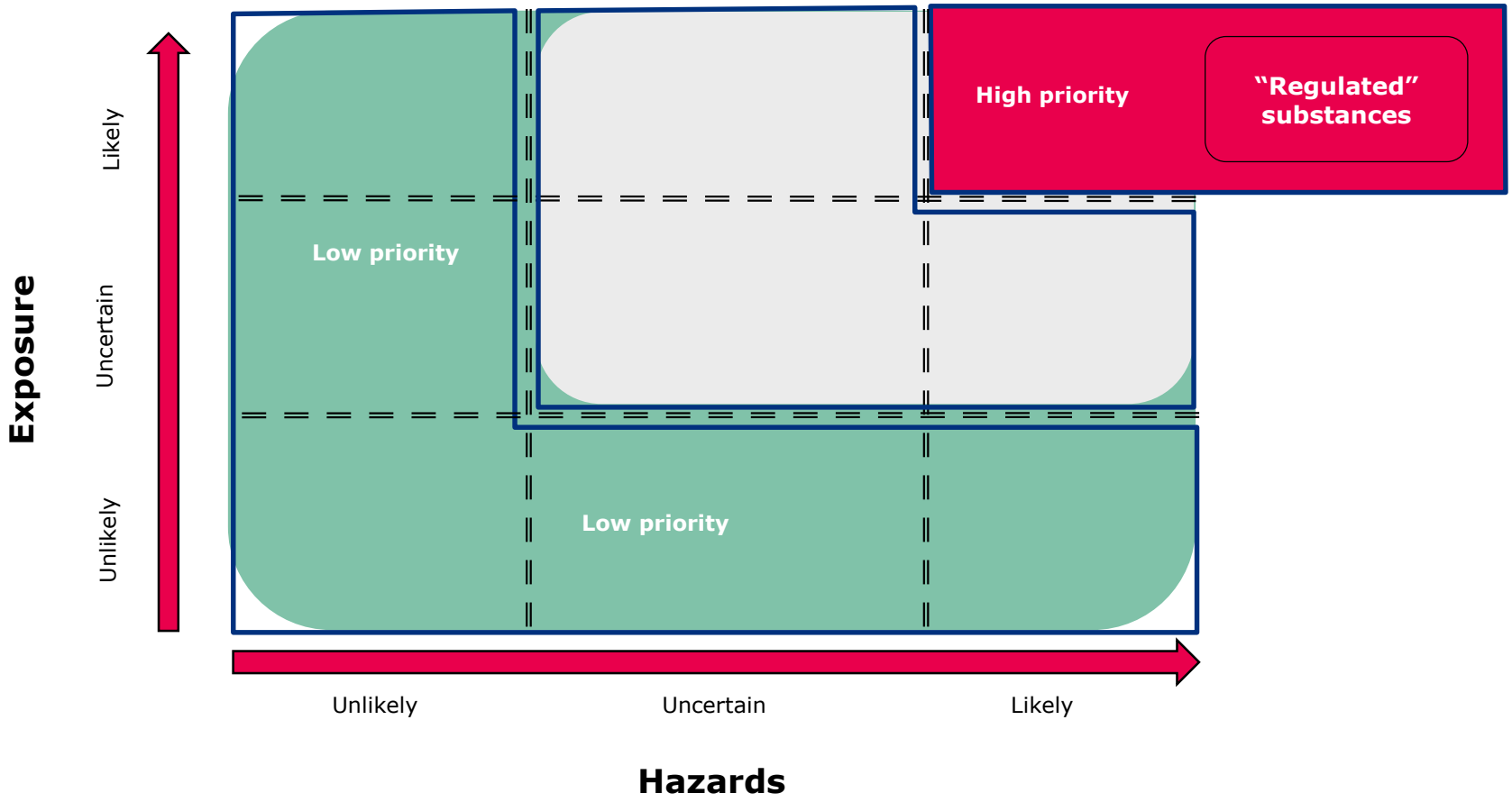
Objectives 2019-2027

- **By 2023** for substances in tonnage bands over 100 tonnes/year and
- **By 2027** for substances in the 1-100 tonnage bands/year,
- ECHA will have:
  - **screened all registration dossiers** submitted by the 2018 deadline, and
  - **performed a compliance check** for all substances **where needed**: data gaps prevent from concluding whether there is a concern or whether substance is of low priority for further regulatory action

How we prioritise?





15 Actions, 5 areas

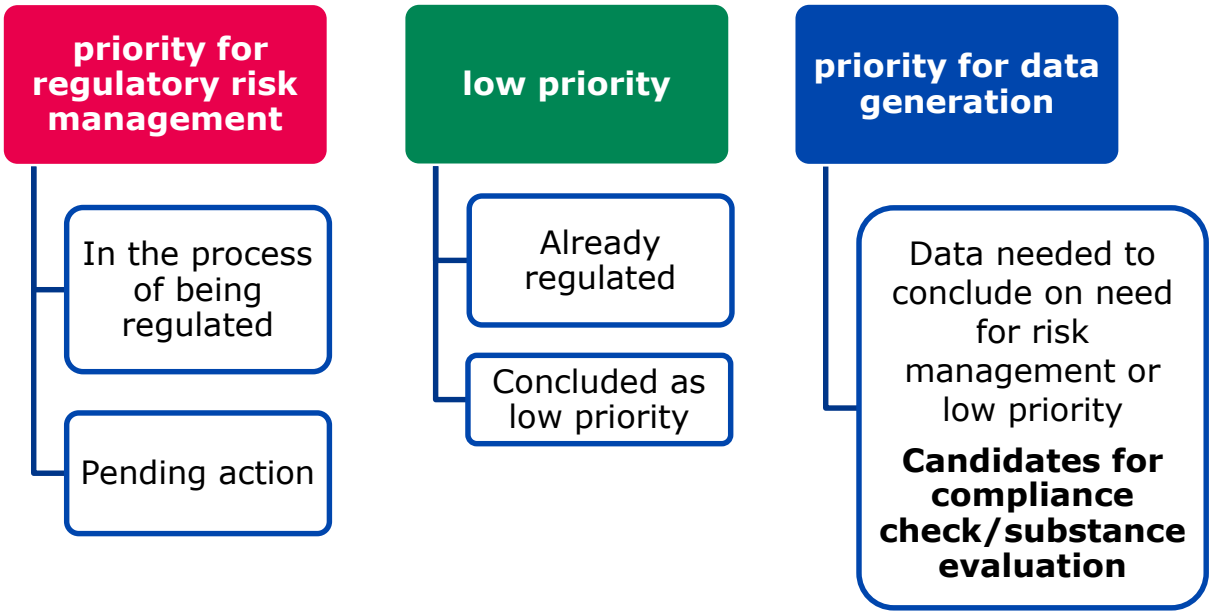
Area	Actions
1. Address all substances	Targets and timelines
2. Improve clarity of legal provisions	REACH annexes and decision-making
3. Accelerate compliance check decision-making	Simplify decisions, standard texts, alignment with Member States, better integration of dossier and substance evaluation
4. Improve follow-up and enforcement of ECHA evaluation decisions while keeping dossiers compliant	Enforcement matters
5. Industry to take on the compliance challenge	Working arrangement

Address all substances - Actions 1-4

	When	Actor	Action
1.	By mid-2019	Commission	Propose amendment of Article 41(5) of REACH to raise from 5% to 20% of dossiers selected for compliance check
2.	By end 2020	ECHA	For all substances above 100 tonnes per year, conclude if they: 1. are a priority for regulatory risk management; 2. are a low priority for further regulatory action; or 3. need more data for a judgement to be made. (These are candidates for further compliance check or substance evaluation) ➢ Conclusions published and clearly communicated to stakeholders
3.	By end 2021	ECHA	Develop a similar approach to draw similar conclusions for all substances registered in lower tonnage bands (under 100 tonnes per year)
4.	By end 2023 & 2027	ECHA	For all substances registered by 31 May 2018, conclude: 1. whether substances are a priority for regulatory risk management; 2. whether substances are a low priority for further regulatory action; or 3. ECHA has requested information under compliance check

Address all substances

- New compliance check targets
  - Implementing regulation published: 20% of dossiers per year
  - In line with our integrated regulatory strategy, "substances that matter most"



Improve clarity of legal text
Actions 5-7

	When	Actor	Action
5	By end 2019	Commission	Assess need to amend Annexes VI to X to clarify standard information requirements
6	By end 2019	Commission	Assess need to amend Annex XI for better justifications for adaptations to standard information requirements
7	By end 2019	Commission	Assess need of possible implementing regulation to efficiently put into effect the evaluation decision-making process

- ✓ ECHA proposals to EU Commission in July, further discussed in August
  - Priority 1 changes: proceed quickly
  - Priority 2 changes: for further discussion

Accelerate decision making

Actions 8-10

	When	Actor	Action
8	By end 2019	ECHA	Simplify compliance check decisions and improve statement of reasons to be clearer and more focused
9	By end 2019	ECHA	Organise workshops with Member States, also bilaterally, with the aim of resolving underlying differences of view. Result to be presented to the Member State (MS) Committee Continue, as far as possible, to identify and plan discussions on more generic issues that may arise in upcoming compliance checks
10	By end 2019	ECHA	Make a refined proposal to CARACAL on how to better integrate substance evaluation and compliance check

- ✓ MSC chair met MSC members individually to resolve divergences
- ✓ ECHA proposals discussed with Member State Competent Authorities early November

Dossier evaluation decisions
What changes?

- Support collaboration and data/cost sharing within joint submission
  - SIEFs ended on 1 June 2018
- Improve compliance and data quality
  - Greater certainty and clarity on regulatory obligations for all
  - Help ensure everyone can comply
  - Opt-outs addressed more systematically: level playing field

Dossier evaluation decisions
What changes?

- Latest registration dossier available = basis for draft decision
  - Dossier updates taken into account until sending draft decision
  - After draft decision, factual basis for evaluation cannot change during decision-making process, unless cease of manufacture or import of your substance
  - New information provided only with comments
- Support avoiding unnecessary animal testing
  - Tests and information requested to support compliance across whole joint submission
- Ensure all registrants get timely information to make business decisions on their portfolio

Increased dossier evaluation efficiency in 2019

We continue	We changed
1. Priorities and focus: • Substances that matter (tonnage, uses, data gaps) • Endpoints critical for identifying substances of concern (CMR /PBT)	1. Addressee of decisions • Bring whole joint submission into compliance (lead registrant/ opt-out) • All registrants obliged to comply with respective testing or required information
2. Efforts to induce dossier updates • Enhanced completeness checks • Sector collaboration	2. Structure of the decisions • Requests valid at each Annex • Focused reasoning • Obligations clearer vs. recommendations
3. Commitment to transparency	3. Visibility of which substances are under assessment • Expectation that dossier is up-to-date
4. Safeguarding your procedural and legal rights	4. Dossier and substance evaluation in parallel as far as possible

Be proactive

Increasing number of compliance checks = increased chance to receive a compliance check decision

- All substances will be addressed and 2/3 are non-compliant

1. Keep dossier up-to-date
   - Update is a legal obligation (Article 22) but also proof for safe use of chemicals => Implementing Act - to stimulate dossier updates
   - Not only uses, tonnages, classification
   - Also new data generated e.g. under authorisation process

Be proactive (2)

2. Remove information that is no longer relevant
    - Submit testing proposals, if data lacking - especially if read-across/category approaches not justified
    - Testing proposals can include a testing strategy to save animals/costs
        - Supporting tests can be initiated immediately (e.g. toxicokinetics, screening studies)
3. Get organised if you need to generate further studies/data
4. Agree on information generated after receiving an ECHA decision
    - Test material representative of joint registrants
    - One test only: Share costs and submit requested information jointly by the deadline
    - Testing proposals or new testing strategies
        - **Do not** address data gaps or remove incompliances

Support

- Updated since 2018:
  - Practical guides on dossier and substance evaluation
  - Practical guide on information requirements and adaptations, e.g. not acceptable in any circumstances, such as QSAR predictions on higher tier endpoints
  - Q&As
  - Recommendations to registrants
- Dossier evaluation status to monitor your substances
- CoRAP, PACT and other material for information on authorities' priorities and plans

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