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REACH and the protection of consumers:

The view from the Commission

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Commission services and REACH

- Lead on proposal: DG Environment and DG Enterprise
- Lead on technical and scientific implementation: DG Joint Research Centre
- Other services (closely) involved, e.g.:
  - DG SANCO
  - DG EMPL
  - DG MARKT
  - DG TRADE
  - DG TAXUD
  - Legal Service

Role of the JRC

- (technical) Support during drafting of legislation and the negotiation process
- Development of guidance documents and IT-tools
- Provide support (incl. human resources) to setting-up the Agency in Helsinki
- Provide scientific support to the Agency once established

Contents

- Basics of REACH and improvements in consumer protection
- Data availability and information generation
- What is Risk Assessment in REACH?
- What is the Commission doing to prepare for REACH?

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- **Basics of REACH and improvements in consumer protection**

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WHY do we need REACH?

Problems

Current chemicals management system is inefficient

- Difficult to identify risks – difficult to address risks:
  - Lack of information about most substances on the market
  - Burden of proof on public authorities
  - No efficient instrument to deal with problematic substances
- Lack of incentives for innovation

Solution: A New EU Chemicals Policy

Objectives

- Sustainable Development
  - Protection of human health and the environment
  - Maintain/enhance innovation/competitiveness
  - Maintain the Internal Market
  - Increased transparency and consumer awareness
  - Integration with international efforts
  - Promotion of non-animal testing
  - Conformity to WTO obligations

Substitution and precaution underpin system

Registration: general

AIM:

➔manufacturers and importers obtain information on their substances and

➔use this knowledge to ensure responsible and well-informed management of the risks these substances may present

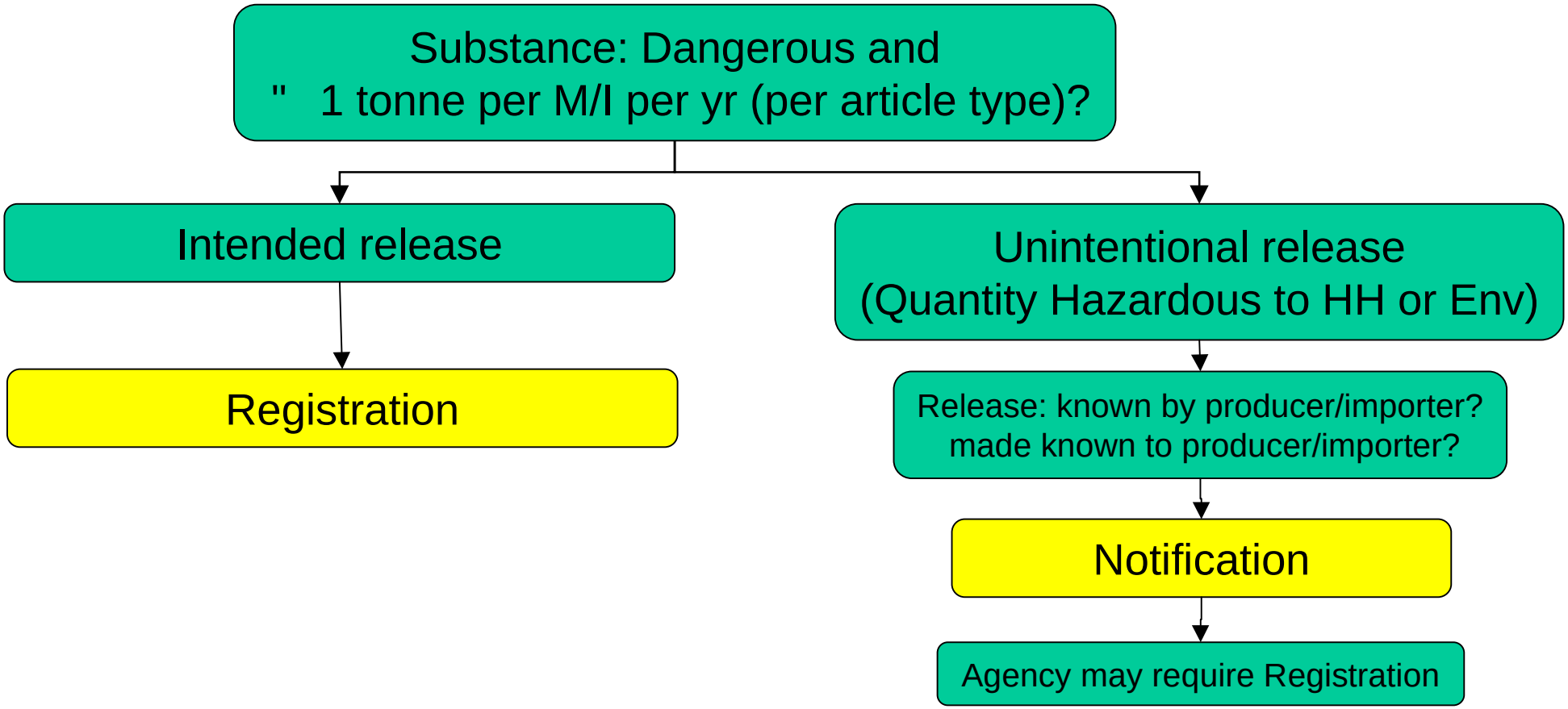
Registration Dossier = Documentation

➔ Technical Dossier: starting at 1 tonnes per year

➔ Chemical Safety Report: starting at 10 tonnes per year

No formal acceptance - industry retain responsibility

Registration: Substances in articles



NB 1: The producer/importer does not have to register or notify substances in articles that have already been registered for that use up the supply chain (i.e. as part of CSR)
NB 2: Article 6 enters into force 11 years and 3 months after REACH enters into force

Evaluation

Provide confidence that industry is meeting obligations

Prevent unnecessary testing

Dossier evaluation

Check test proposals

Compliance

Substance evaluation

Examine any information on a substance

Output:

- Further information decisions
- Info to other parts of REACH/other legislation

Authorisation

Ensure risks from substances of very high concern are properly controlled or that the substances are substituted.

- CMR, PBT, vPvB, ‘serious and irreversible effects’;
- Prioritised (progressively authorised as resources allow);
- Applicant to show:
  - adequate control of risks, or
  - social and economic benefits outweigh the risks

Restrictions

Safety net

- Community wide concern
- MS/COM initiated
  - CMR substances for consumers - fast track possible.
- Agency Committees examine:
  - the risks, and
  - the socio-economic aspects involved
- Commission - final decision through comitology
- Carry-over of existing restrictions (76/769/EEC)

Information through the supply chain

Improve risk management

- What:
  - Expanded SDSs with information from Chemical Safety Reports (exposure scenarios)
  - Information on authorisations, restrictions, registration number etc.
  - Obligation to provide information up the supply chain on new hazards
- Result?
  - more information on risks
  - downstream users benefit
  - dialogue up/down the supply chain-encouraged/stimulated

C and L Inventory

- Inventory :
  - contains C and L info for all marketed substances (no tonnage limit)
  - managed by Agency based on submissions from industry
  - deadline – 3 years
- Industry needs to co-operate to resolve differences in C&L
- EU harmonisation:
  - CMRs
  - respiratory sensitisers

Benefits

- Systematic collection and sharing of available information
- Systematic assessment of risks
- More harmonisation of C&L
- Communication of conditions for safe use through the supply chain
- Authorisation of the most hazardous substances
- Faster restrictions procedure as a safety net

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2. Data availability and information generation

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IUCLID data availability for HPV-substances

- ≥ Base-set 14 % (of 2465 HPVs)
- < Base-set 65 %
- No data 21 %

Data availability for ~25 000 non-HPVs (1 –1000 tpa):

???

Probably less data available, ……..but how much information is in the drawers?

Lessons Learned from existing legislation

New Chemicals:

- substantial and reliable data is generated as the basis for assessing and determining appropriate risk management measures for a substance;
- few chemicals need additional risk management measures imposed by 'authorities' intervention

Existing chemicals:

- encouraging industry to submit previously unknown data, thereby preventing unnecessary tests being performed
- risk management decisions based on Classification & Labelling, the results of Risk Assessment and/or the holistic approach to risk management measures can render requirements for further testing unnecessary.

Design of Registration under REACH

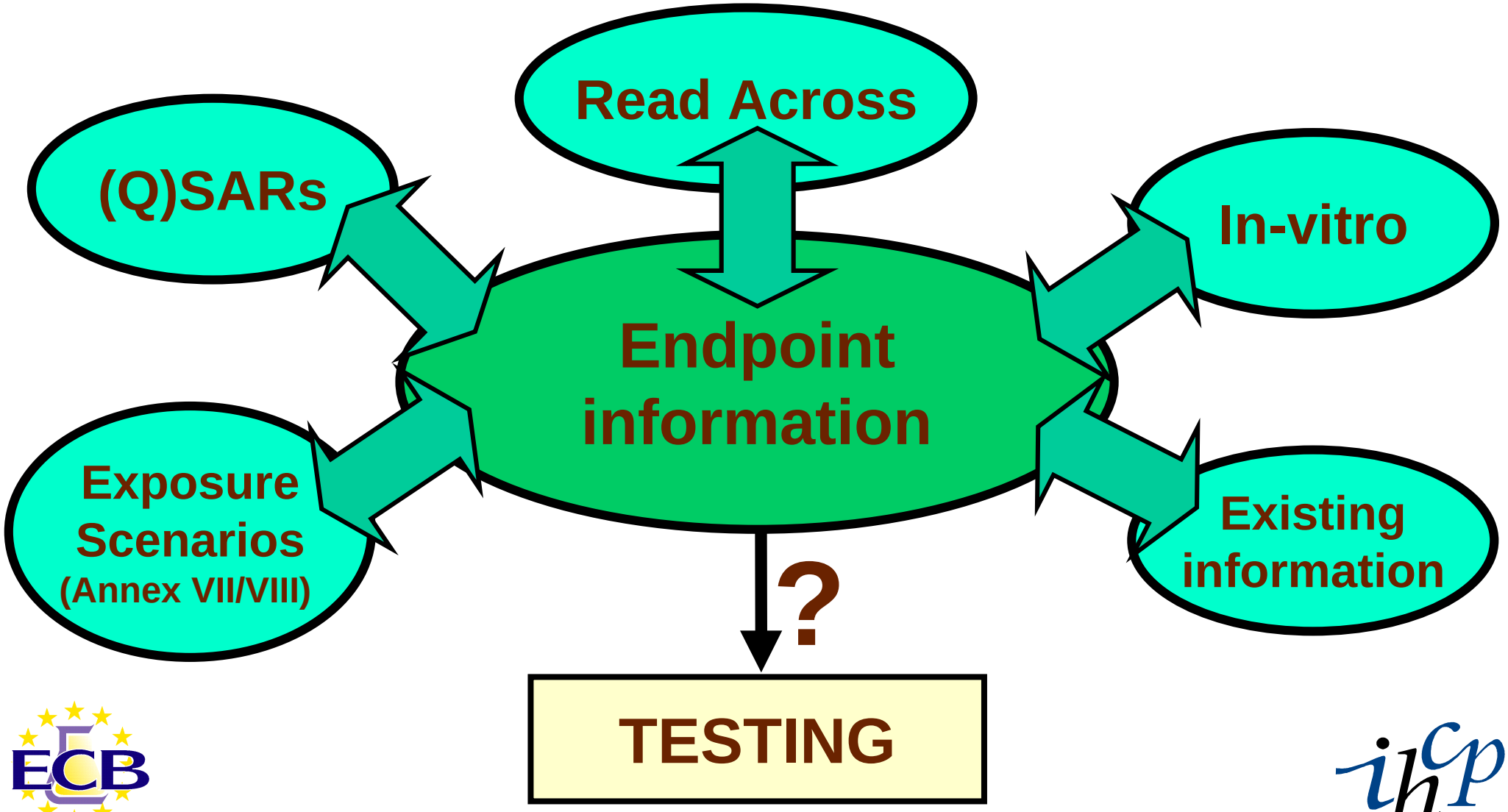
- Minimum information set needed in REACH to enable a risk assessment to be carried out;
- Additional information should be required using a “top down approach”;
- Industry should make the proposals of which additional information is needed;
- But……..
- Information needs to be adequate for C/L and Chemical Safety Assessment (no box-ticking)

REACH and the use of test animals

- Testing on vertebrate animals shall be undertaken only as a last resort (art. 23)
- Information may be generated by other means than tests, in particular through (Q)SARs and read-across (art 12)

→ Legislative text + guidance should limit use of animals and prevent box-ticking

Intelligent Testing Strategies (ITS)



3. What is Risk Assessment in REACH?

What is Risk Assessment in REACH?

- Industry: Tool used in REACH to determine which risk management measures are sufficient for protecting (wo)man and the environment.
- MSs: Tool used in REACH to indicate that the currently implemented risk management measures are not sufficient for protecting (wo)man and the environment.

Exposure Scenario (ES)

- An exposure scenario sets out, for a given use, how the substance can be used in a way that risks are adequately controlled by describing:
- Conditions for use:
  - Process descriptions (incl. quantity used)
  - Operational conditions (incl. frequency and duration of specified operations)
  - Risk Management Measures (process and emission control, personal protective equipment, good hygiene, etc.)
- Other relevant information

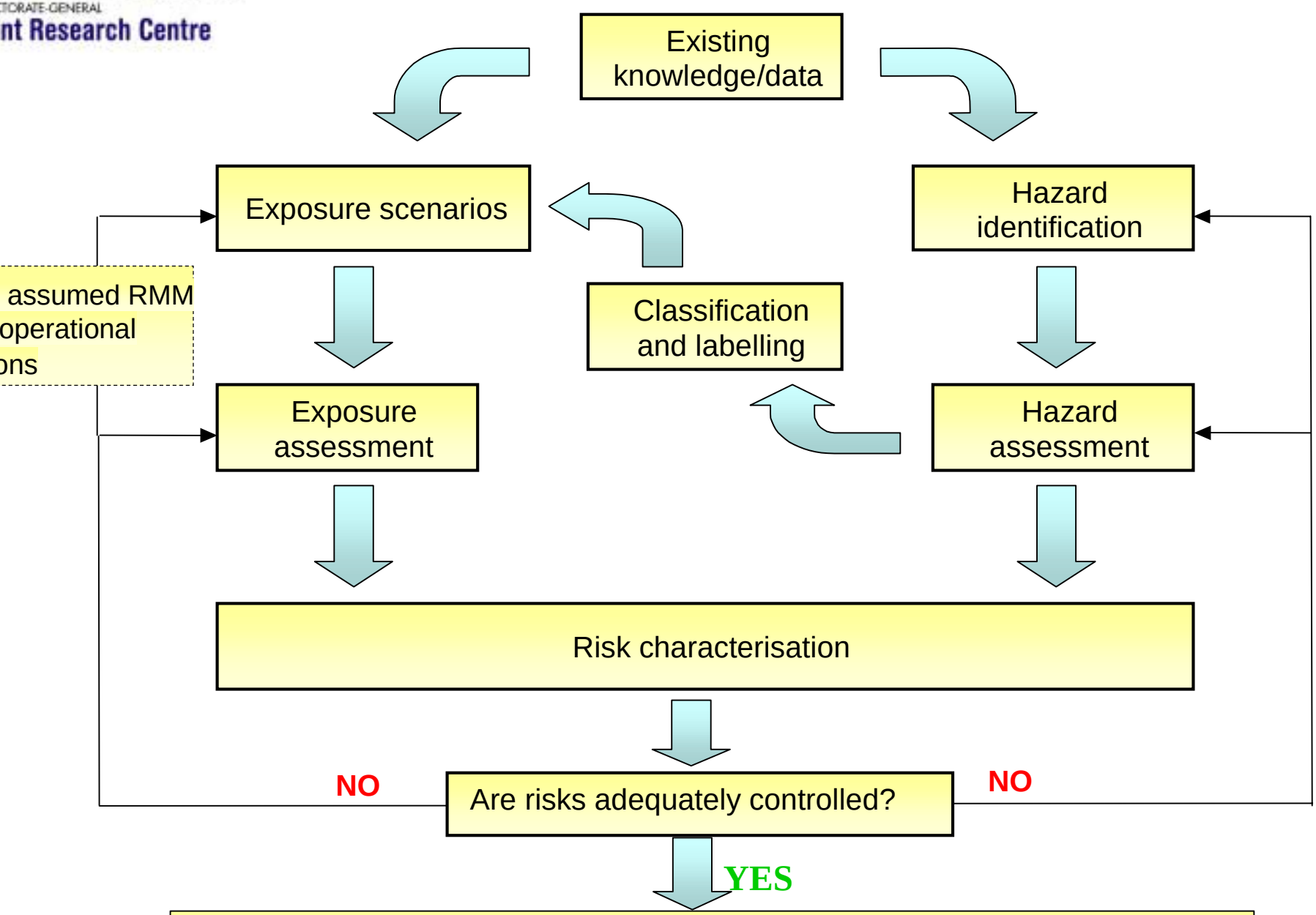
Core tools under REACH

- The Chemical Safety Assessment (CSA) is the tool used to **determine**
- The Chemicals Safety Report (CSR) is the tool used to **record/document**
- The Safety Data Sheet (SDS) is the tool used to **communicate**

Conditions for use (for sufficiently protecting human health and the environment):

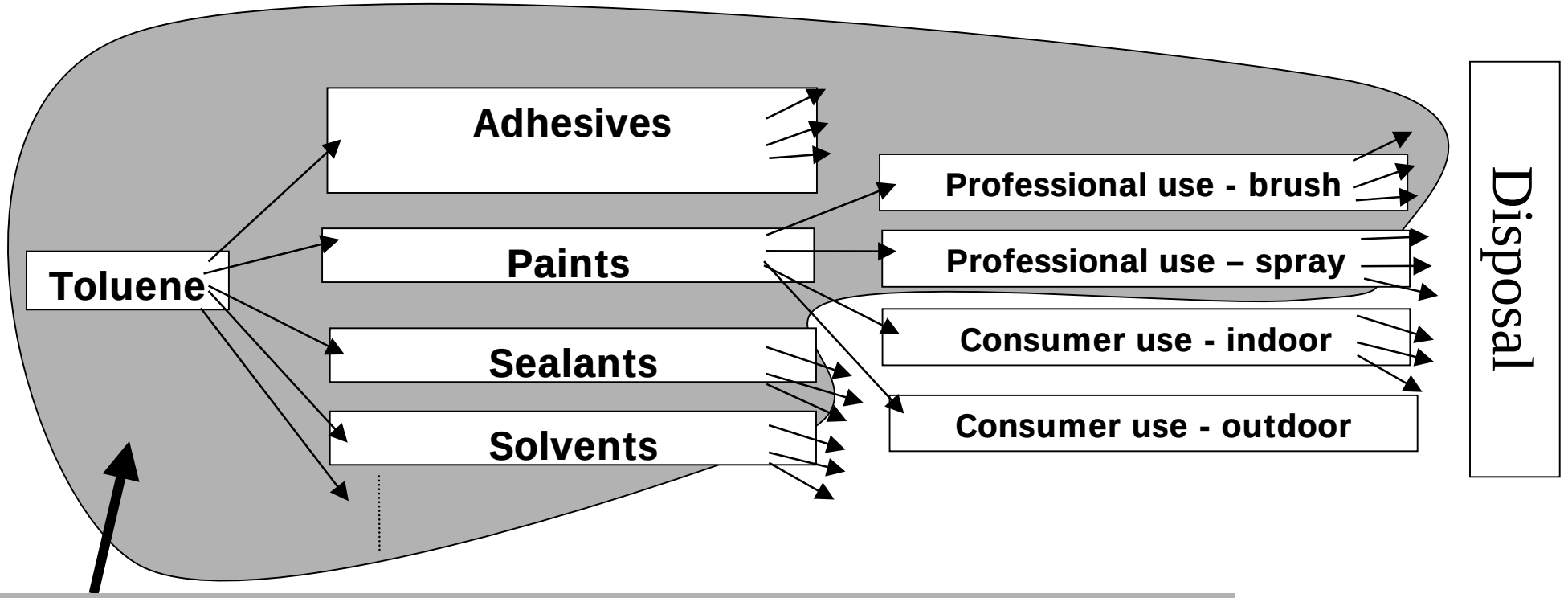
- **risk management measures**
- **operational conditions**

} **ES**



Chemical life cycle

Must be covered in a Chemical Safety Assessment



Downstream uses = requirements for information exchange

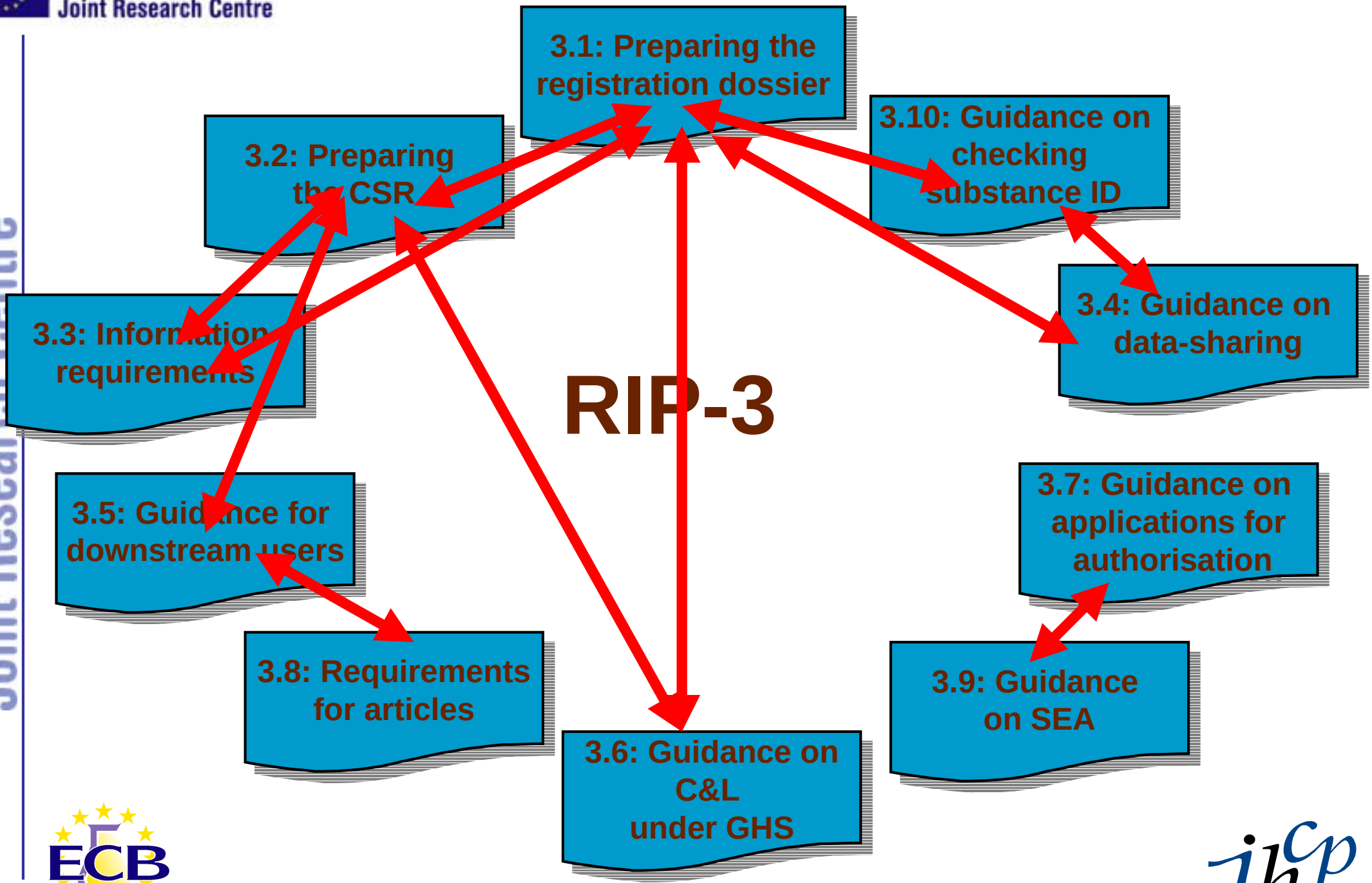
SDS

Identification of uses

4. What is the Commission doing to prepare for REACH?

REACH Implementation Projects (RIPs)

- RIP 1: REACH Process Description;
- RIP 2: REACH – IT;
- RIP 3: Technical Guidance and Tools for Industry;
- RIP 4: Technical Guidance and Tools for Authorities;
- RIP 5/6: Setting up the (Pre-)Agency


3.1: Preparing the registration dossier
3.2: Preparing the CSR
3.10: Guidance on checking substance ID
3.3: Information requirements
3.4: Guidance on data-sharing
RIP-3
3.5: Guidance for downstream users
3.7: Guidance on applications for authorisation
3.8: Requirements for articles
3.9: Guidance on SEA
3.6: Guidance on C&L under GHS

Guidance on preparing a chemical safety report (CSR) (RIP 3.2)

- Develop guidance for manufacturers, importers and down-stream users of chemicals on how they can:
  - carry out the chemical safety assessment (CSA)
  - how they could document the CSA in the CSR, including listing of the exposure scenarios
  - how they can communicate information using the safety data sheet according to REACH.

RIP 3.2-1A (Scoping study)

- Overall workflow – CSA, CSR, SDS
- Focussed on further development of the exposure scenario (ES) concept – framework and examples
- How to incorporate ESs into SDSs ?
- Targeting the chemical safety assessment
- Options for software development
- Tools and methodologies for SMEs – e.g. simpler but more conservative approaches

Information requirements (RIP 3.3)

- Objective
  - Guidance for industry on how they can fulfil the information requirements on intrinsic properties (Annex IV to IX)
- Work will start with a scoping study developing the framework for ***'Intelligent Testing Strategies'***
- Keywords
  - Existing information, QSAR, in-vitro, read-across, exposure based waiving
- Consider how to help SMEs in their decision-making

RIP 3.8 on fulfilling article requirements

Further guidance on REACH Article 6:

- Evaluation of current experiences
- Operationalisation of terms (e.g. ‘article type’, ‘intended to be released’, ‘likely to be released’)
- Guidance for producers and importers of articles on when and how to notify and register
- Exemplification

Conclusions

- Consumer use of substances on their own, in preparations and in articles should be part of the M/I's Chemical Safety Assessment and Report
- After EiF of REACH article 6 (11 years and 3 months) substances in articles not already tackled will be registered or notified ('closing the gap')
- REACH will substantially improve the knowledge on substances giving a better basis for the assessment of the risks from consumer use of substances

Challenges:

- Identification of substances in consumer products
- Development of ESs for consumer use
  - How are consumer products used?
  - Which RMMs can be assumed to be applied?
  - How to best communicate to consumers?

Further information on RIPs

http://ecb.jrc.it/REACH/