Annual Chemicals Regulation Seminar

Welcome

April 1, 2015

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

Steptoe
STEPTOE & JOHNSON LLP

Steptoe & Johnson LLP - Overview

- International law firm focused on regulatory issues and litigation
- Over 500 professionals in the US, EU, China
- Chemical Regulation, Environment and Life Sciences practice is a core focus
  - Largest practice in Brussels, widely recognized for accomplishments
  - Well known in Washington for antimicrobials, pesticides and environmental litigation
  - Unique practice in Beijing focused on regulatory evolution to facilitate market access
- Team includes lawyers, scientists, regulatory and technical advisors

Chemical Regulation, Environment & Life Sciences Practice

- Broad range of Substantive Areas
  - Chemicals
  - Nanotechnology
  - Antimicrobials/Biocides/Pesticides
  - Cosmetics
  - Medical devices
  - Food contact materials and foods
  - Consumer products
- Create efficiencies for clients through cross-jurisdictional work

Our EU Chemical Regulation, Environment & Life Sciences Team

- **Unique litigation experience:** in proceedings related to EU chemicals legislation before the ECHA's Board of Appeal and before the European Courts
  - Five appeals filed in 2014 and four legal cases currently pending before the European Courts
- **Depth in the chemicals regulatory sphere:** REACH, CLP, biocides, plant protection products (agrochemicals) and nano - we have been active in all of these areas since the respective EU regimes were first proposed and worked at all stages of their implementation
- **Capacity:** the largest environment and life sciences regulatory practice of any law firm in Brussels - 10 full time professionals
- **Recognition:** consistently ranked by legal directories in the top tier for Chemicals and Environment

Our US Chemical Regulation, Environment & Life Sciences Team

- **Unique litigation experience:** unparalleled breadth of practice, *e.g.,* challenges to EPA regulations; defending California Prop. 65 claims; defending NGO litigation on endangered species and pesticides; environmental remediation litigation
- **Depth in the chemicals regulatory sphere:** biocides and pesticides regulation, data compensation, food contact materials, enforcement defense
- **Capacity:** 10 full time professionals in DC, with additional specialized litigation capability in DC and CA
- **Recognition:** preferred legal services provider for American Chemistry Council, known for biocides experience

Our Beijing Chemical Regulation, Environment & Life Sciences Team

- **Unique government affairs capability:** Achieve client goals during the rapid evolution of regulatory requirements
- **Broad knowledge of regulatory requirements:** Successful projects in biocides and food contact materials areas.

Resources – *Chemical Watch*

- Steptoe works closely with the online journal to gather and disseminate the latest global developments on chemical legislation.
  - Asia Hub
    - Reform of China's Disinfectant Regulatory System: Are You Ready? (April 2014)
  - Biocides Hub
    - Transitioning to the BPR: what will become of the Manual of Decisions? (February 2015)
    - SMEs and the BPR (December 2014)
  - *Chemical Watch* Conferences
    - *Biocides Symposium 2015* (May 2015) Darren Abrahams, Anna Gergely
    - "Antimicrobials Update on US Legislation," *Biocides 2014 Conference* (December 2014)
    - "Treated Articles – What's New?" *Biocides 2014 Conference* (December 2014)

Resources – Steptoe Client Updates

- CEQ Issues Revised Draft Guidance for Evaluating Climate Change Impacts in NEPA Reviews (February 2015)
- What to Expect from the New European Commission 2014-2019 (November 2014)
- USFWS Eagle Act Permit Rule Update (November 2014)
- DC District Court Issues Key Clean Water Act Opinion in *Mingo Logan Coal Company Inc., v. EPA, Case No. 1:10-cv-00541-ABJ* (October 2014)

Resources – Chinese Chemical Regulation Updates

- The Chinese regulatory system is constantly changing and Steptoe is committed to helping our clients keep up with the latest developments that will affect their business or industry.
- We publish concise, weekly updates which highlight newly issued regulations involving hazardous chemicals, China REACH, biocides, food safety and cosmetics.
  - www.steptoe.com/chinesechemicalupdates

Resources – Webinars

- Environmental Review & the Food Contact Notification Process (April 2, 2015)
- Litigation Under EU Chemicals Legislation Webinar Series: Part 3 (March 19, 2015)
- Litigation Under EU Chemicals Legislation Webinar Series: Part 2 (February 24, 2015)
- Data Sharing: Lessons for REACH, Biocides & Agrochemicals (January 15, 2015)
- Litigation Under EU Chemicals Legislation Webinar Series: Part 1 (December 16, 2014)

Upcoming chemicals legislative challenges for downstream users in Europe: REACH Authorisation

Lorenzo Zullo
Coordinator, Chemicals & Environment Legislation and Advocacy

Content

1 - REACH LEGISLATIVE CHALLENGES

What should chemicals downstream users be worried about?

2 - NEW FAST TRACK REGULATORY DYNAMICS

New fast track regulatory dynamics

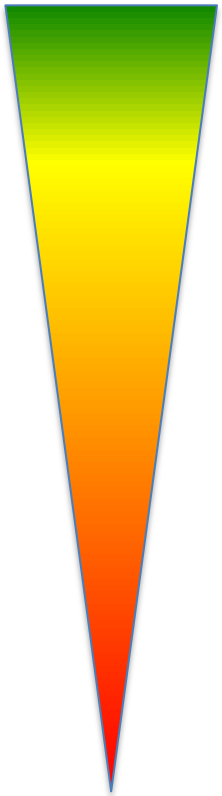
3 - REACH AUTHORISATION

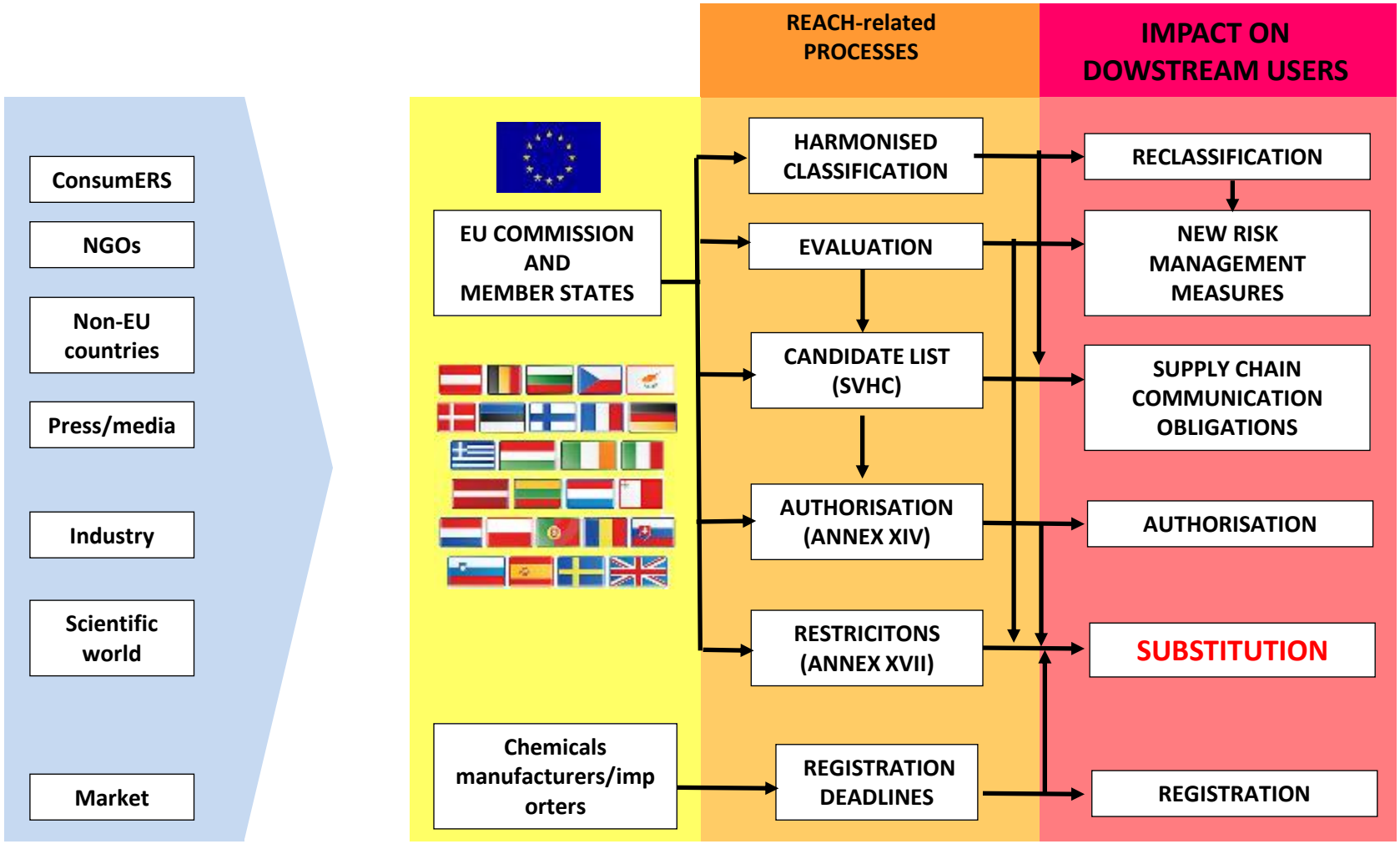
Case study: ADCA

4 – KEY INDUSTRY CONCERNS and WAY FORWARD

ECHA and EU Commission ongoing activities

Major upcoming challenges for chemicals downstream users



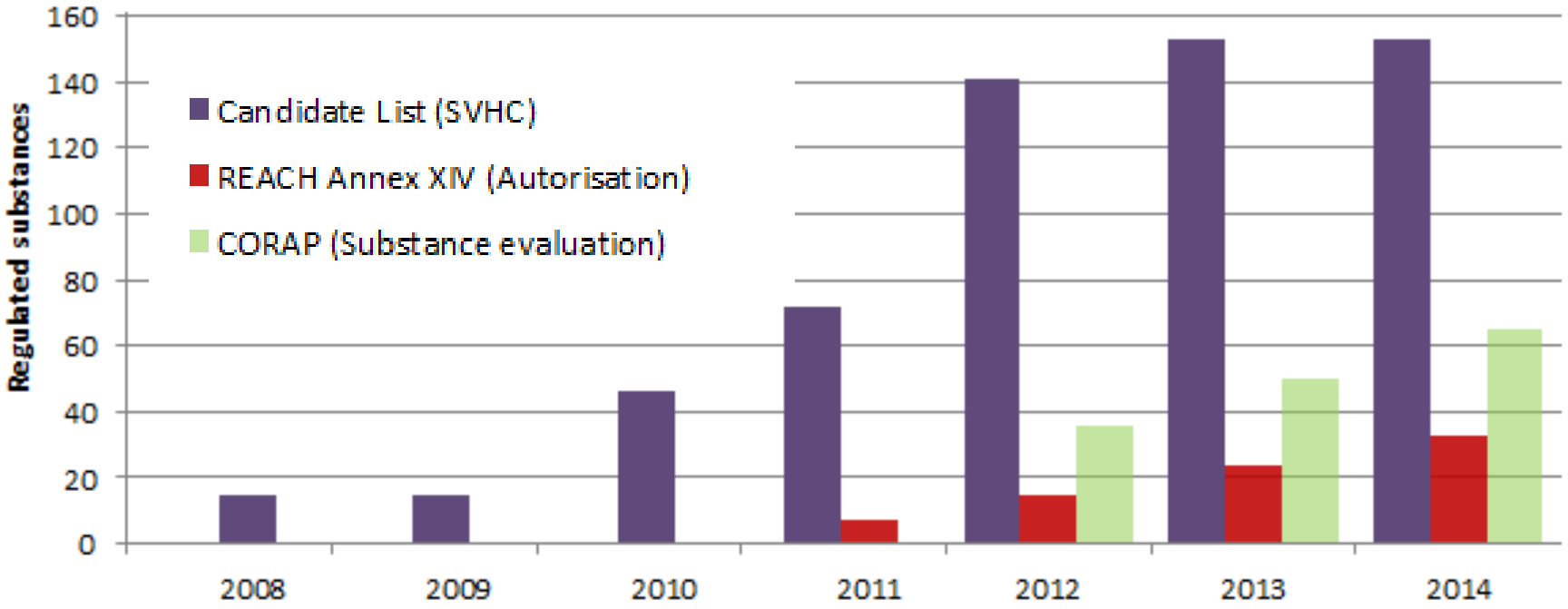

ConsumERS
NGOs
Non-EU countries
Press/media
Industry
Scientific world
Market
REACH-related PROCESSES
IMPACT ON DOWSTREAM USERS
EU COMMISSION AND MEMBER STATES
Chemicals manufacturers/importers
HARMONISED CLASSIFICATION
EVALUATION
CANDIDATE LIST (SVHC)
AUTHORISATION (ANNEX XIV)
RESTRICITONS (ANNEX XVII)
REGISTRATION DEADLINES
RECLASSIFICATION
NEW RISK MANAGEMENT MEASURES
SUPPLY CHAIN COMMUNICATION OBLIGATIONS
AUTHORISATION
SUBSTITUTION
REGISTRATION

2007 — REACH entered into force

2010 — 1st registration deadline

2013 — 2nd registration deadline

2018 — 3rd registration deadline



Case study:

AZODICARBONAMIDE
- ADCA -

EUROPEAN TYRE & RUBBER
manufacturers'association

www.etrma.org

RUBBER APPLICATIONS FOR WHICH ADCA IS CURRENTLY USED

- Sealing gaskets
- Sealing components
- Expandable mastic for insulation and soundproofing
- Foam filler for (certain) tyres
- Parts of anti-vibration rubber components

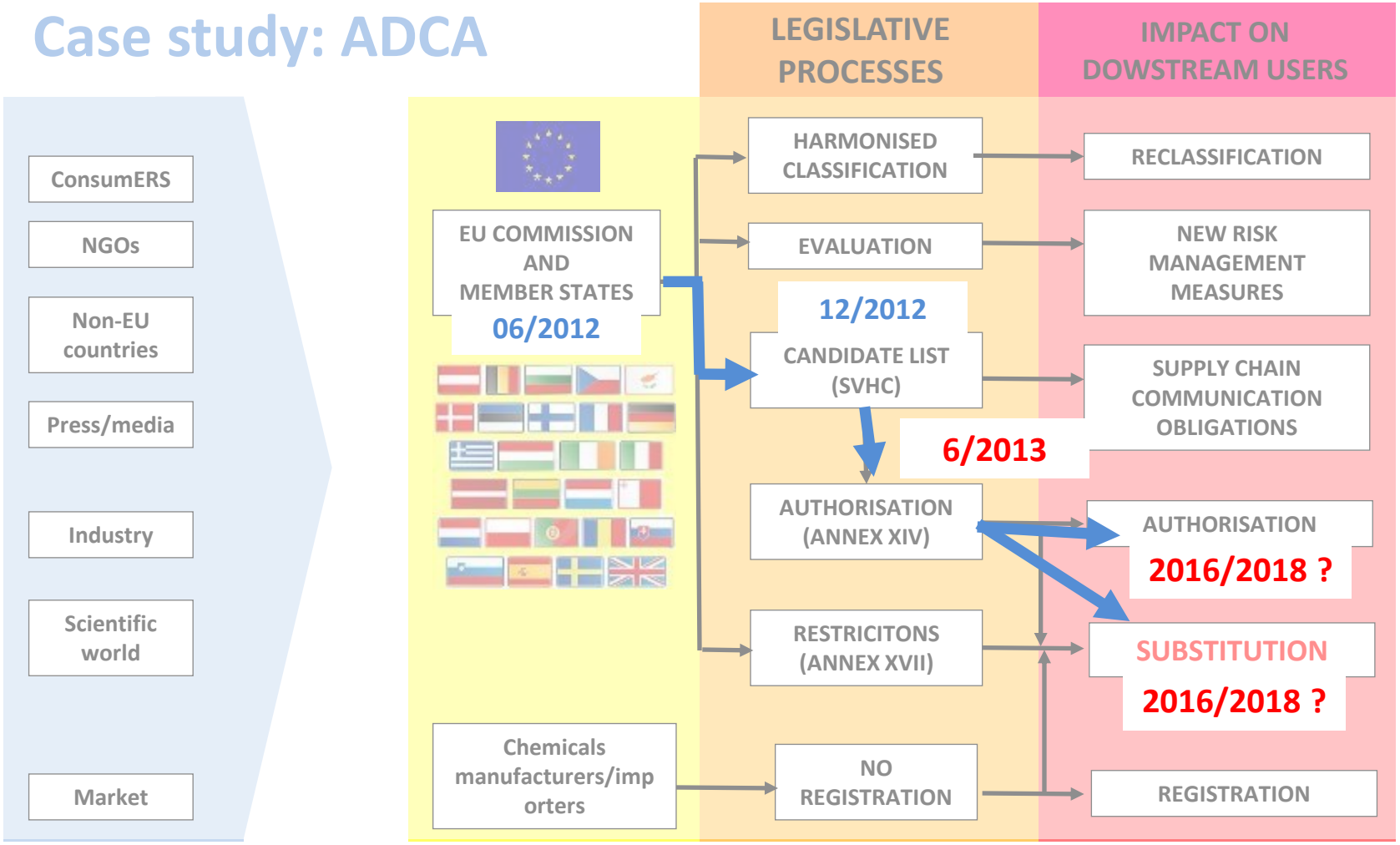
EUROPEAN TYRE & RUBBER manufacturers'association

www.etrma.org

CASE STUDY: ADCA

22/06/2012	Substance entered in the registry of "Current SVHC Intentions"
06/08/2012	Substance entered in the registry of "Submitted SVHC Intentions"
03/09/2012	Beginning of the 45-days consultation on the proposal for identification as SVHC
18/10/2012	End of the 45 days public consultation
19/12/2012	**Substance entered in the candidate list.**
16/05/2013	Chemical industry getting ready for worst case scenario: authorisation
24/06/2013	**ECHA recommends inclusion of ADCA in Annex XIV** (Authorization): 3 months public consultation
???	Annex XIV (Authorisation) → 3 year after inclusion (2016?)

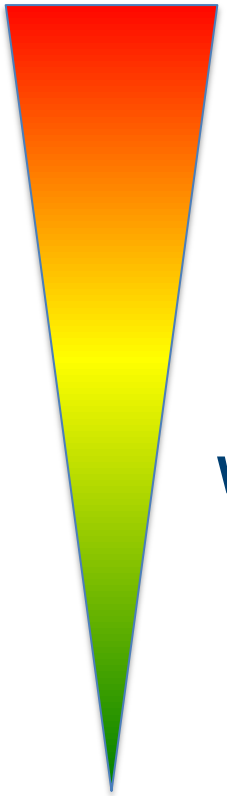
Case study: ADCA



EUROPEAN TYRE & RUBBER
manufacturers'association

www.etrma.org

KEY CONCERNS FOR DOWNSTREAM USERS



WHAT ECHA AND EU COMMISSION ARE DOING?

Workshop: Authorisation

Avoiding the pitfalls, arriving successfully

Elke Van Asbroeck
Managing Director

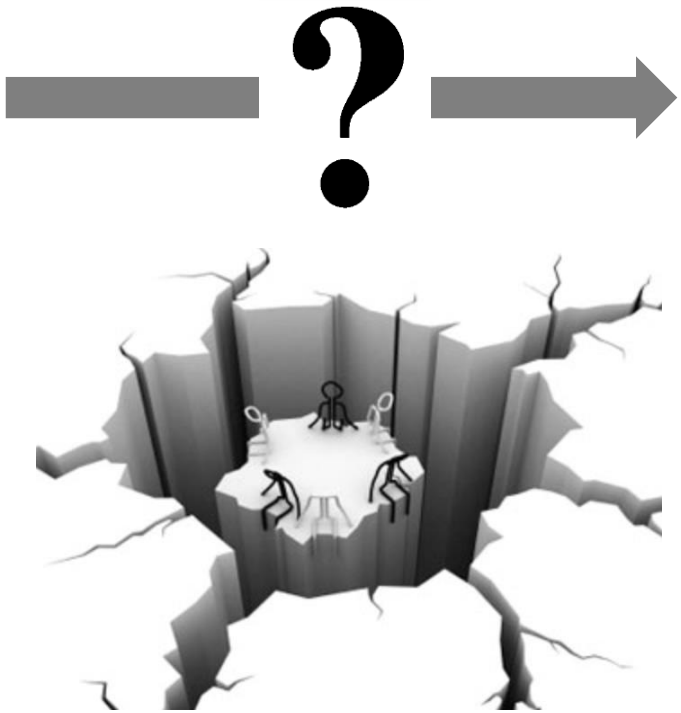
Apeiron
where Strategy, Science and Efficiency meet

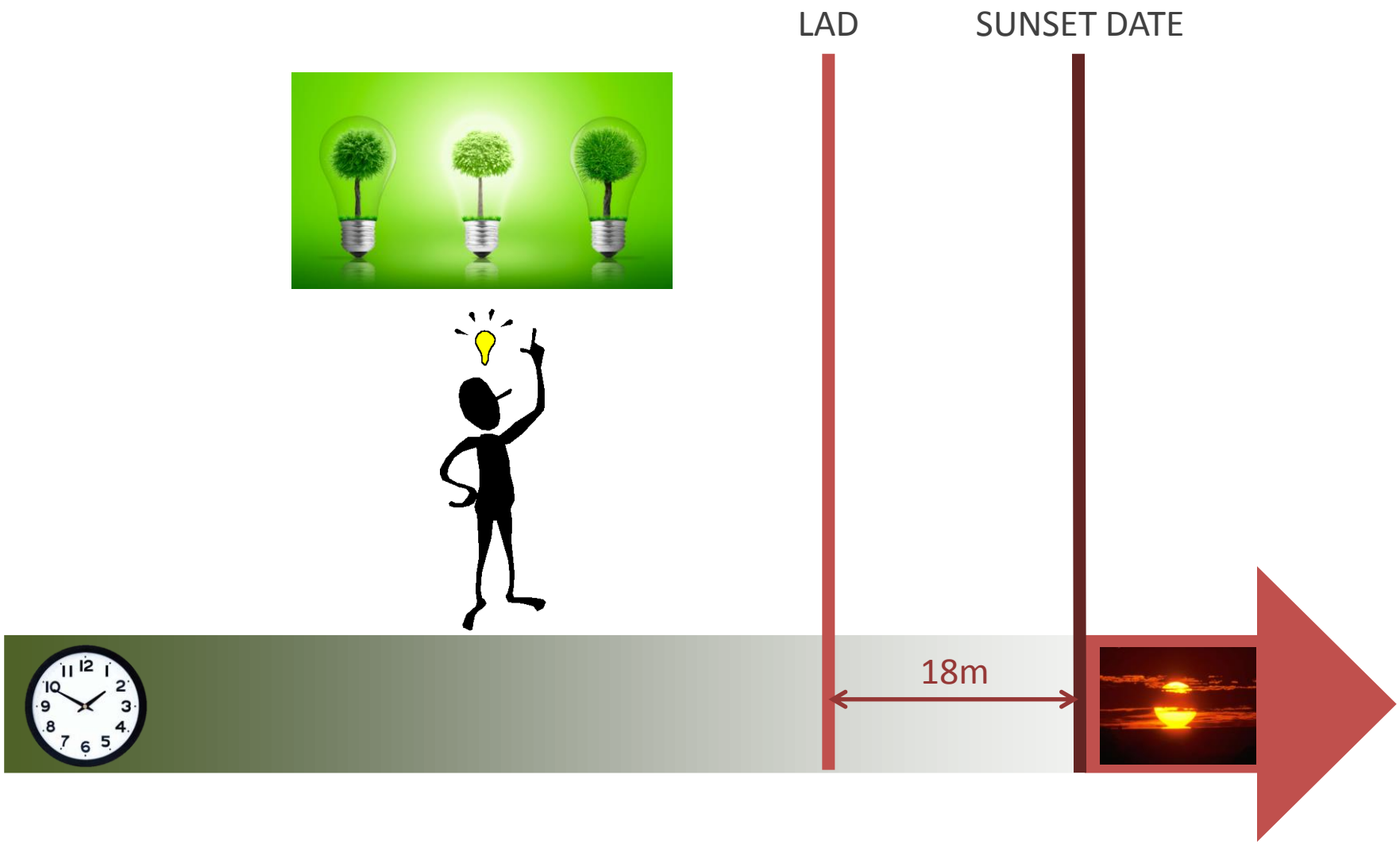
AUTHORISATION

CSR

AoA

SEA




LAD
SUNSET DATE
18m

How safe is the use?

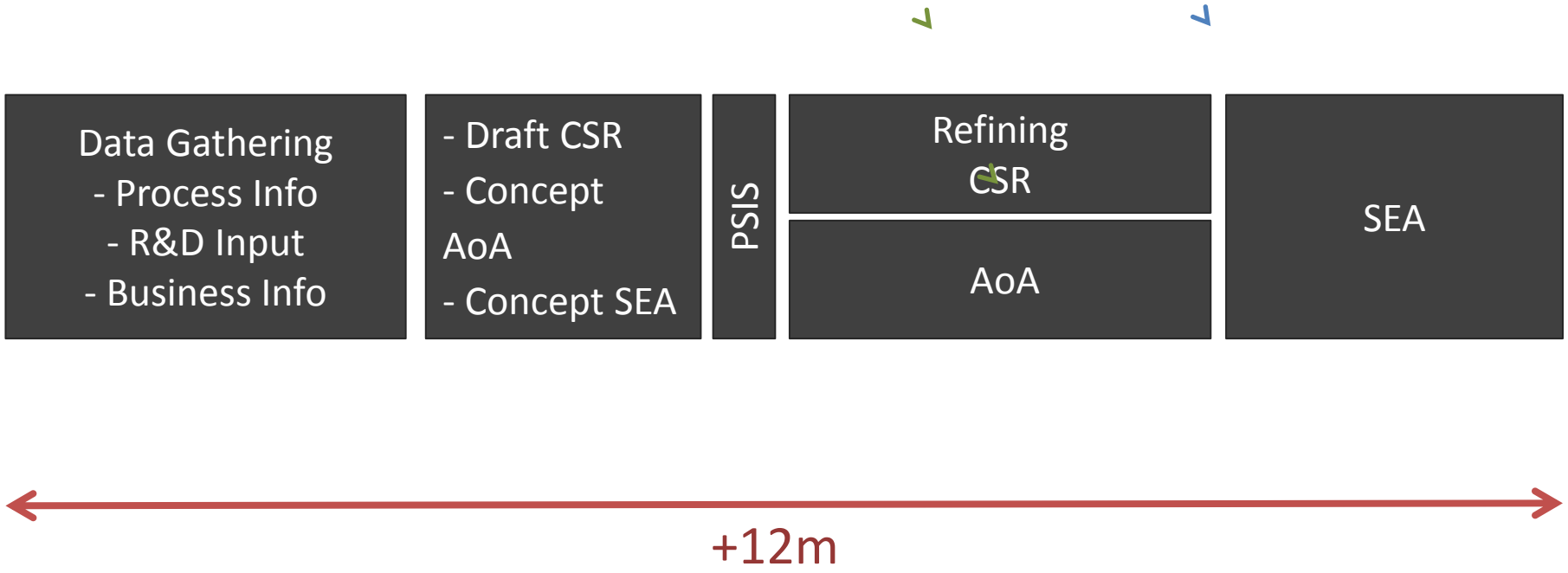
Evidence of research to alternatives?

Do the benefits outweigh the risks?

How safe is the use?

Evidence of research to alternatives?

Do the benefits outweigh the risks?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- Process Info
- R&D Input
- Business Info
- Draft CSR
- Concept
AoA
- Concept SEA
PSIS
Refining
CSR
AoA
SEA
+12m


Applicant
Technology
Data Gathering
AoA
SEA
Refining SSR
AoA
SEA
Risk Assessor
Economist
Consultant

Applicant

Data Gathering	- Draft CSR - Concept AoA - Concept SEA	PSIS	Refining CSR AoA	SEA

Apeiron

Data Gathering
- Process Info
- R&D Input
- Business Info

Data Gathering
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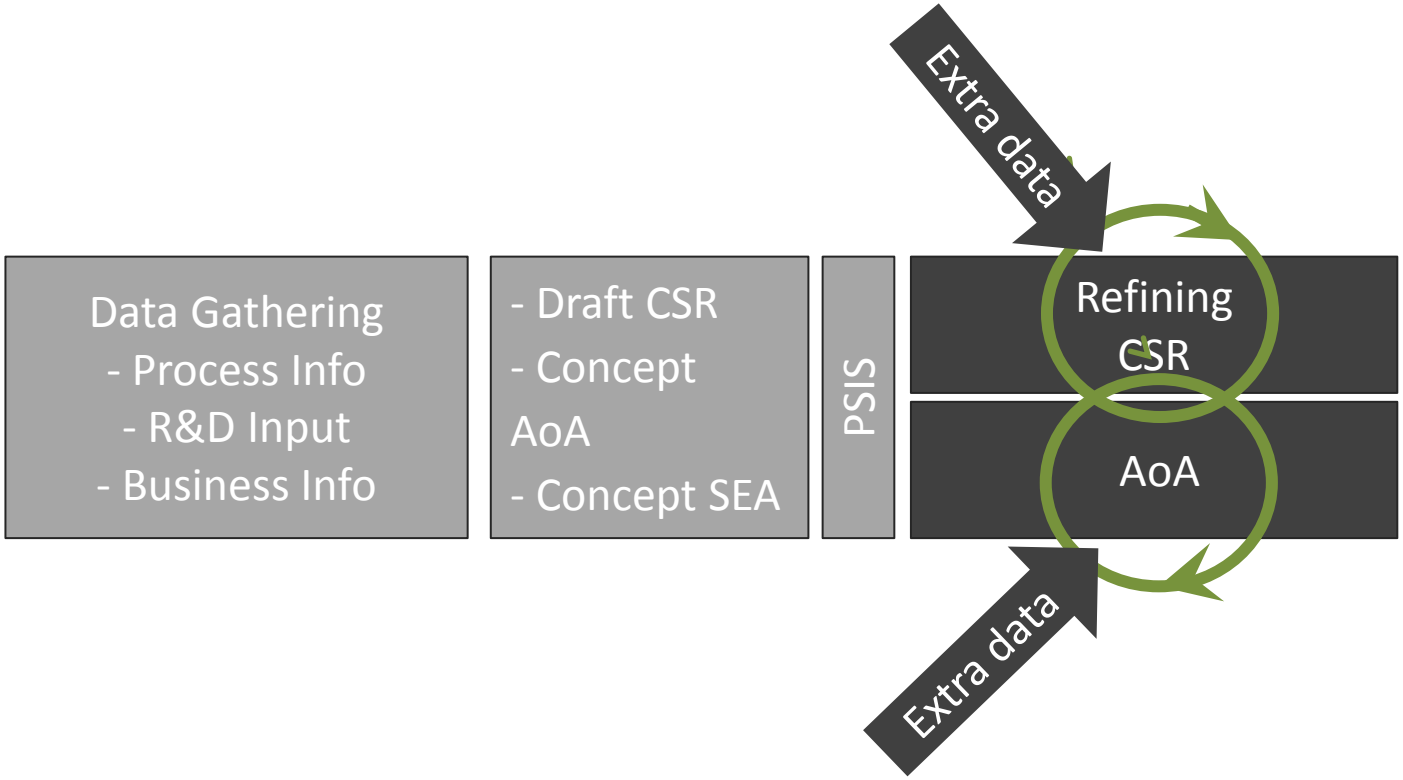
- Business Info

- Draft CSR
- Concept

AoA

- Concept SEA

ECHA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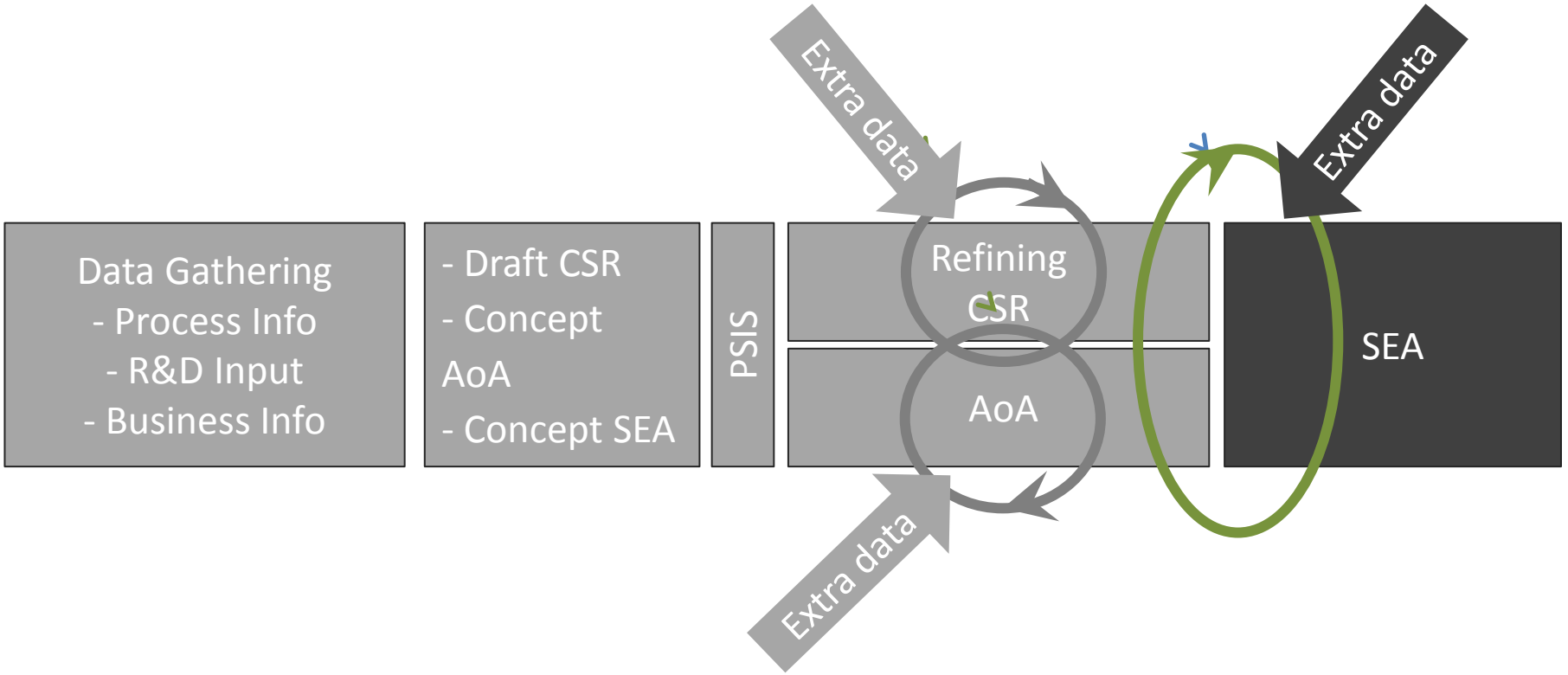
PSIS
Extra data
Refining CSR
AoA
Extra data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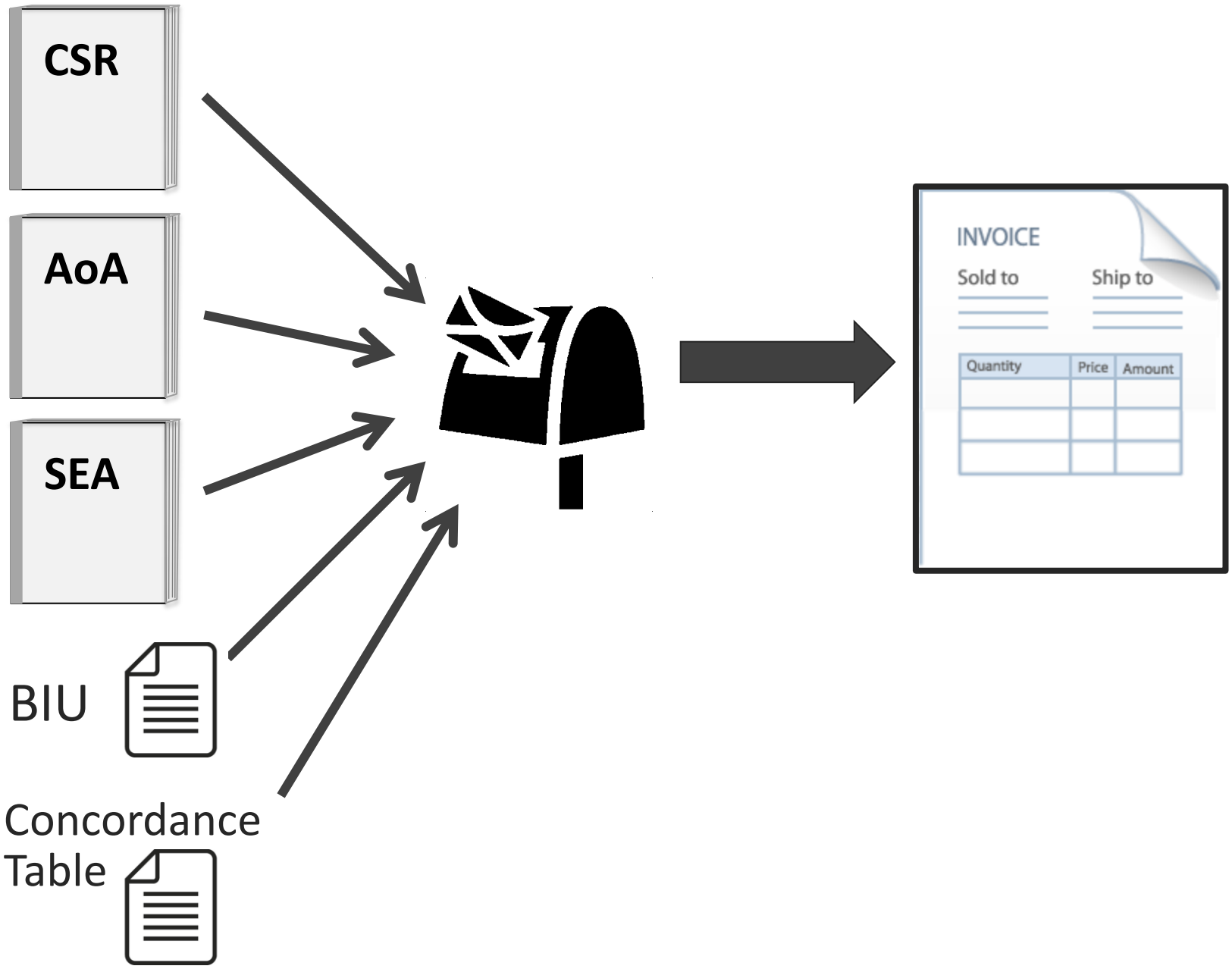
CSR
AoA
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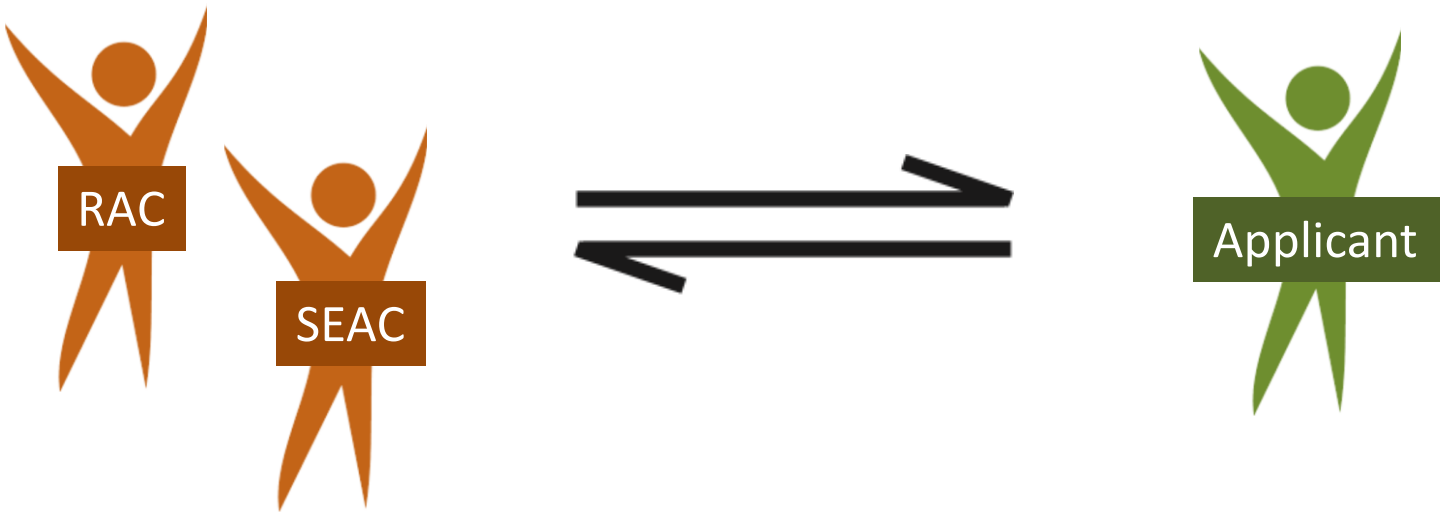
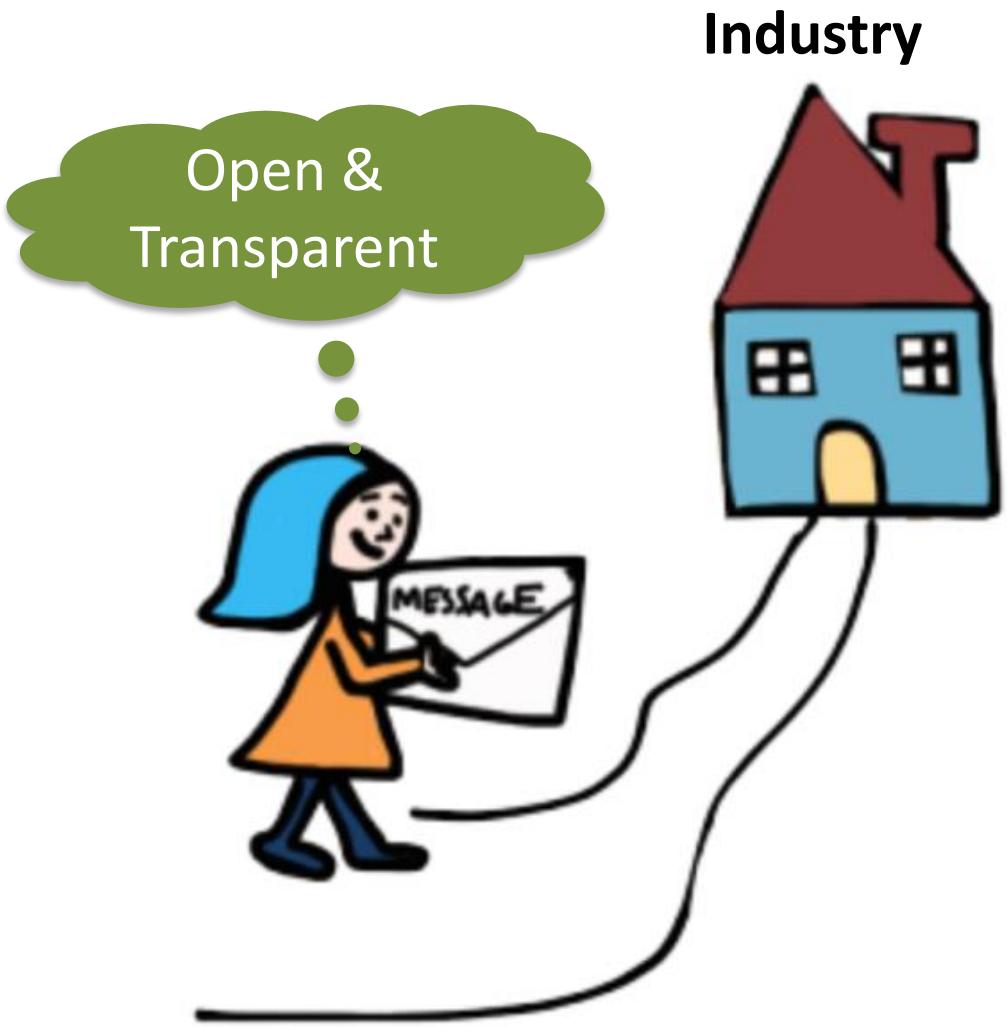
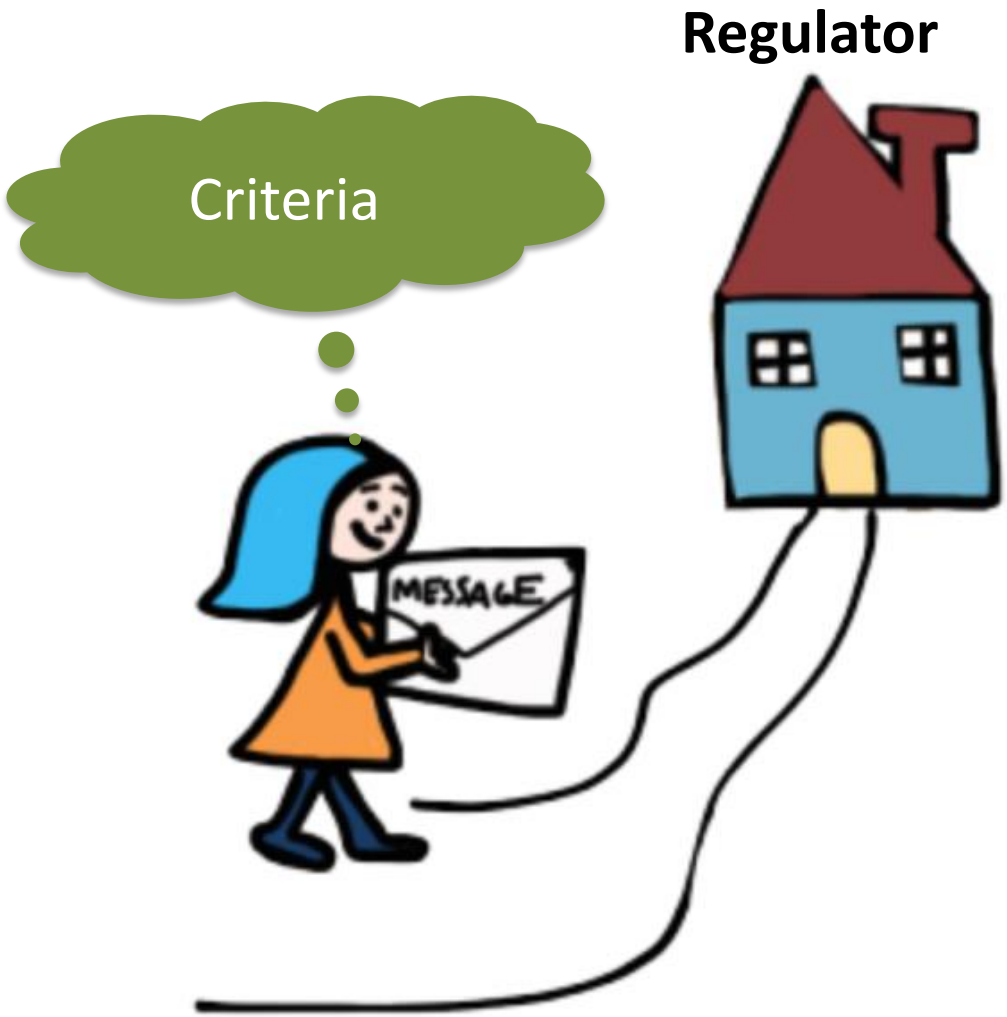
Sold to
Ship to
Quantity
Price
Amount


RAC
SEAC
Applicant


Applicant


Industry
Open &
Transparent
MESSAGE


Regulator
Criteria
MESSAGE

where Strategy, Science
and Efficiency meet

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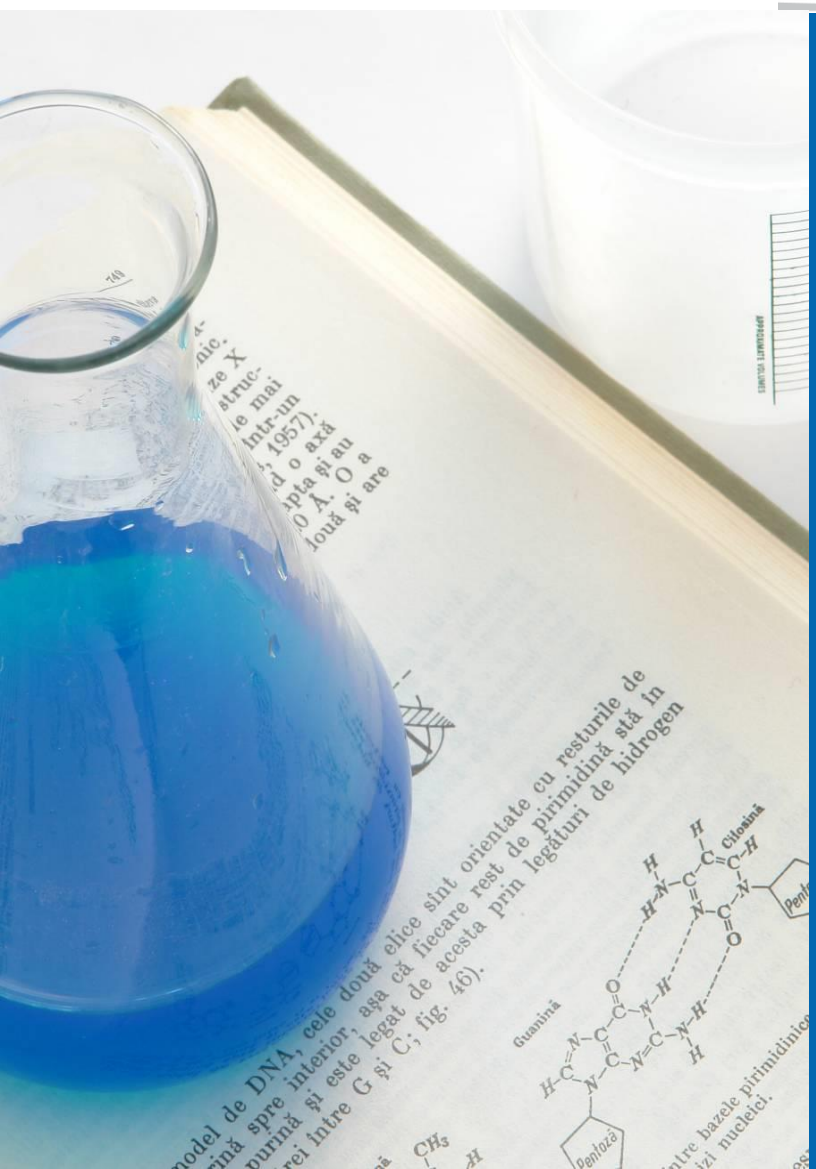

European Commission

The future of REACH authorisation: proposed simplification

Annual Chemicals Regulation Seminar
Steptoe & Johnson LLP
Brussels, 1 April 2015

Anna Borràs
Unit I1 - REACH
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
European Commission

Presentation overview

1) COM reflection on how the authorisation process works

2) Streamlining and simplification initiatives

3) Next steps

What do we want to achieve with REACH authorisation?

Article 55 REACH:

1) Proper control of risks from use of SVHCs
2) Progressive replacement of SVHCs by by suitable alternatives where technically and economically viable

Ultimately:
SUBSTITUTION

Challenges of the authorisation requirement for operators

- Broad scope (no volume threshold, all uses, wide range of operators covered)
- New, relatively broad and demanding information obligations (CSR, AoA, SEA):
  - Some elements not regulated in detail (AoA, SEA)
  - External expertise may be needed (for some operators)
  - Supply chain coordination is a must
- Applicant not necessarily a M/I of chemicals → not necessarily acquainted with REACH
- Not much experience / reference cases

COM reflection on the authorisation process

- **REFIT Communication – June 2014**

  New measures considered in the medium-term to improve the authorisation process to make it more predictable for business, including:

  - reducing the frequency of Annex XIV amendments;
  - considering more strongly socio-economic impacts when including substances n Annex XIV;
  - **simplifying the authorisation process for some specific low-risk cases.**

- **CARACAL 15 (July 2014)**
  - First ideas for improvement presented to MSCAs
  - Setting up of a **TF for improving the workability of the AfA process**
- **Public consultation on first proposed measures (low volumes and legacy spare parts): Feb-Apr 2015**

Streamlining and simplification initiatives

Two types of initiatives under consideration:

- **Simplification of AfAs in specific cases:**
  - **low volumes**
  - **legacy spare parts**

  } **Public consultation (Feb-Apr 2015)**

    - **uses in products subject to type-approval requirements**
    - **essential biological elements**
    - **process chemicals**
    - **recycled substances)**

- **General streamlining of AfAs**:
  making AfAs fit-for-purpose

Simplification of AfAs in specific cases: low volume uses

- **Rationale**: possible disproportionality between cost of a full-scale application and potential benefits for human health/environment
- **Public consultation** (http://ec.europa.eu/yourvoice/consultations/index_en.htm):
  - *Scope of "low volume" cases*:
    - volume limit per substance and per legal entity/year
    - limited to applications for own uses
    - exclusion of cases with potential consumer exposure in substance lifecyle
  - *Simplified information requirements* (within framework of Article 62 REACH): draft CSR, AoA and SEA templates developed by Task Force

Simplification of AfAs in specific cases: uses in legacy spare parts

- **"Legacy spare parts":**
  Spare parts intended for articles produced and placed on the market before the sunset date
- **Two-step approach**:
  - one-time extension of LAD/SD and
  - (in parallel) development of a simplified AfA
- **Public consultation**:
  - definition and scope (e.g. also mixtures for repair of articles?)
  - which Annex XIV substances / volumes are concerned in practice
  - length of one-time extension of LAD/SD

Other specific cases?

- Cases being considered for simplification but no proposals under consideration yet
- **Uses in products subject to a type-approval / certification procedure:**
  - type-approval / certification requirement is a clear element to be considered in SEA and in the calculation of the review period
  - COM has proposed to consider such cases under general streamlining of AfAs
- **Uses as biological essential elements:**
  - not yet of concern for existing Annex XIV substances but of possible concern in the future

Other specific cases?

- **Uses as process chemicals in quasi-closed systems**
  - Suggested as a possible case at the February 2015 "Lessons learnt" workshop on the basis of low exposure and no consumer exposure
  - COM has proposed to consider such cases under general streamlining of AfAs

- **Uses of recycled substances:**
  - Requested by some industry sectors during CARACAL 17
  - No COM position yet

General AfA streamlining

- **CSR**:
  should it be limited to the elements needed for risk assessment? (e.g. remove sections related to hazard assessment if applicants use the DNEL or dose-response curve recommended by the RAC for the substance)
- **AoA**:
  is the Guidance sufficient / fit-for-purpose?
- **SEA**:
  is the Guidance sufficient / fit-for-purpose?

Next steps

- **Low volume uses: Implementing act**
  concerning streamlining and simplification of application procedure + reduction of fees
- **Legacy spare parts uses**:
  one-time extension of transitional arrangements for Annex XIV substances concerned and future simplification of application procedure
- **Other specific cases and general streamlining**:
  MSCAs to comment on COM proposals

Thank you

Disclaimer

All views expressed are purely personal and should not be considered as representative of the European Commission's official position. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information provided.

Nanomaterials under REACH

Dr. Anna Gergely

Annual Chemicals Regulation Seminar
Product Defense for REACH and Biocides
April 1, 2015 - Brussels

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

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Content

1. Current Regulatory Framework – Horizontal and Vertical Regulations
2. Scope of the REACH Regulation
3. The Definition Question
4. National initiatives (Member States and beyond)
5. Further Developments

- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

General EU Legal Framework

- **Horizontal Legislation**: (applicable, but not nano specific)
  - General Product Safety and Product Liability Legislation
  - Workers' Protection Legislation
  - Environmental Legislation
  - Chemicals Legislation (REACH and CLP)
- **Vertical (application specific) Legislation**: (more and more nano-specific)
  - Food / (Novel Food) / Food contact / Cosmetics / Biocides / RoHS / Medical Devices etc.
- **Guidelines**: (not legally binding) such as EFSA on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain; ECHA Guidance on Information Requirements and Chemical Safety Assessment; – more to come

Horizontal Legislation: Product Liability Directive (85/374/EEC)

- (Article 1) The producer shall be liable for damage caused by a defect in his product
- (Article 4) The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage
- (Article 6) A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
  - (a) the presentation of the product
  - (b) the use to which it could reasonably be expected that the product would be put
  - (c) the time when the product was put into circulation
- (Article 7) The producer shall not be liable as a result of this Directive if he proves:
  - (e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered**; - "State of the art" defense**

Horizontal Legislation: REACH (Regulation (EC) No 1907/2006)

- Covers all chemical substances; also in their nano forms
  - Substance: *means a chemical element and its compounds in the natural state or obtained by any manufacturing process* [..] Article 3(1)
  - Current interpretation: Nano-forms of existing bulk equivalents are not "new" substances under REACH; hence no registration requirements until relevant phase-in deadlines for total volumes (Last tier: 1-100MT/year/legal entity: June 2018)
  - No Registration requirement if < 1MT/year (together with bulk equivalent)
  - But other REACH provisions (Authorization, Restriction, CLP) apply

Nano Under the REACH Regulation

- Nano is not explicitly mentioned in REACH

But: Extensive implementation projects (RIP-oN)

  - **oN1)** Substance identification: to identify nanomaterials based on relevant parameters in existing case studies (CNT; nAg; nTiO2; nCaCO3); no agreement whether nano is an identifier or characterizer

  CEFIC: Impact assessment of RIP-oN1. The amount of all possible substances produced in nano-form and all possible surface treatments covered by the regulatory definition is in the range of 500 – 2,000

  - **oN2)** Information requirements: final guidance documents
  - **oN3)** Chemical Safety Assessment: final guidance documents

- **Need for legal clarity**
- **REACH review: Modifying Annexes and Guidance Documents**

Nano Under the REACH Regulation

- REACH Review (Feb 2013): …*REACH sets the best possible framework for the risk management of nanomaterials…*
- No changes to the enacting terms of REACH is proposed
- Commission Consultation on policy options for the modification of technical provisions of the REACH Annexes
- 5 Options reviewed for Cost, Safety and Efficiency:
  - 1. Baseline option (as today)
  - 2. Clarity option (add guidance but no added obligations)
  - 3. Soft law option (new, non binding measures – may produce legal effects)
  - 4. Test data based on ECHA's advice (new binding measures)
  - 5. Considerations based on drive for reduced burden for REACH compliance
  - 6. Very detailed characterization requirements to reduce uncertainty
- Deadline for input was 13 September 2013…

Nano Under the REACH Regulation

- Updated ECHA work plan on nanomaterials for 2014-15
- Four strategic objectives:
  1. Maximize the availability of high quality data to enable safe manufacture and use. Solving key challenges on:
     i. substance identification/characterisation
     ii. risk assessment (hazard and exposure)
     iii. grouping/read across
  2. Mobilise authorities to use data intelligently to identify and address chemicals of concern
     i. harmonise the views of ECHA and MS experts re dossier and substance evaluation
     ii. informal discussions with industry – improve "best practices"
  3. Establish ECHA as a hub for regulatory and scientific support on NM
  4. Resource optimisation

Recommended Nano Definition (FINAL)

- **EU Commission Recommendation** (18 October 2011)
  - Consists of natural, incidental or manufactured particles, in an unbound state or as an aggregate or agglomerate with one or more external dimensions in the size range 1nm – 100nm for more than 50% of their number size distribution, in specific cases between 1-50%
  - ~~Has internal or surface structures in one or more dimensions in the size range 1nm-100nm.~~ Fullerenes, graphene flakes and SWCNT with one or more external dimensions below 1 nm are nanomaterials
  - Has a specific surface area by volume greater than 60m^2/cm^3, but number size distribution prevails
  - Particle: means a minute piece of matter with defined physical boundaries (ISO 146446:2007)

Recommended Nano Definition (FINAL)

- Member States, Union agencies, and economic operators are invited to use the definition
- The recommendation should not prejudge nor reflect the scope of application of any Union legislation
- The definition should be reviewed by December 2014!
- **Not harmonized with the US (or other jurisdictions)**
- **No legal certainty**

Conflict with Existing Legal Framework: Food Contact Materials

- **Regulation (EU) No 10/2011 (Plastics Regulation)**
  - Whereas 23: "*New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at larger scale, e.g. nanoparticles*." The article further states that "…*authorizations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles*."
  - Art.9(2) provides, that "S*ubstances in nanoform shall only be used if explicitly authorized and mentioned in the specifications in Annex I*."
  - The positive listing of a substance may not be claimed to also cover its nanoform
  - Substances in nanoform are treated the same way as CMRs
  - "Nanoform" is not defined

Conflict with Existing Legal Framework: Food Contact Materials

- **Active and Intelligent Packaging Regulation (EC No. 450/2009)**
  - Excludes "nanoparticles" (defined as: "*substances deliberately engineered to particle size which exhibit functional physical and chemical properties that significantly differ from those at a larger scale*") from the exemption to authorize substances behind a Functional Barrier
  - Iron (II) modified bentonite (FCM Substance No 1003) intended to be incorporated in monolayer or multilayer packages or in sachets for absorbing oxygen from the food environment –
  - EFSA opinion: no safety concern for the consumer when used as oxygen absorber incorporated without compatibilizers in polyolefin layers of food packages at levels up to 15% w/w

Conflict with Existing Legal Framework: Food Information

- **Regulation (EU) No 1169/2011 on the provision of food information to consumers**
  - Definition: *'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100nm but retain properties that are characteristic of the nanoscale*
  - All ingredients present in the form of engineered nano materials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets

Conflict with Existing Legal Framework: Biocidal Products

- **Biocidal Product Regulation (EU) N° 528/2012**
  - **Definition**: *a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100nm* (almost identical to Commission Recommendation)
  - **Positive list**: The approval of an active substance does not cover the nanoform, unless explicitly mentioned
  - **Labelling**: if nanomaterials are contained in a product it should always be listed with "nano" in brackets
  - **Authorization**: where nanomaterials are used in a product, the risk to human health, animal health and the environment has to be assessed separately
  - **In force since 1 September 2013!**

Conflict with Existing Legal Framework: Cosmetics Products

- **Cosmetics Regulation (EC) No. 1223/2009**
  - Specifically addresses nano materials – Substances listed in Annexes III-VI (approved/restricted to be used in cosmetics) do not cover nanomaterials, unless it is specifically mentioned
  - Intention to place a product containing nanomaterials on the market must be the subject of additional notification to the Commission 6 months in advance
    - except where they have already been placed on the market by the same responsible person before 11 January 2013 (should have been notified before 11 July 2013)
    - except if they are used as colorants, UV-filters or preservatives (can be listed in main cosmetic product notification)
  - Definition for nanomaterials as "*insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure on the scale of 1 to 100nm*" (no particle number distribution limit)
  - "Moving" definition; it creates difficulties in interpretation and enforcement while acknowledging the need to align it with other regimes
  - Specific data call for ingredient: styrene/acrylates copolymer (nano): comments by 30/06/2015

National Initiatives: French Nano Decree

- **Décret n°2012-232 (17 February 2012) and Arrêté 6 August 2012** concerning the yearly declaration of substances in nanoform. In force since 1 January 2013 (sanctions from 1 July 2013)
- Mandatory: covering all manufacturers, distributors and importers above 100g/year – Declaration by 1 May each year, covering the previous year
- Definition: as "substance" under REACH; manufactured intentionally to be in nano-form, containing minimum 50% of unbound particles between 1-100nm or their aggregates and agglomerates
- Reporting obligation on substance identity; quantity; uses and supply chain – issues of treatment of confidential information and of enforcement for the first year
- As a measure potentially restricting trade between EU Member States, French decree was notified to the EU Commission, however, without the sanctions chapter.

Other Advanced National Initiatives

- **Belgium**:
  - Bill notified to the EU Commission in February 2014, the draft does not apply to chemicals or materials already regulated, such as biocides, cosmetics, food, medicinal products, etc.
  - Applicable to substances on 1/1/2016, and to mixtures and articles on 1/1/2017.
  - Pre-marketing declaration for >100 g; yearly updates on 31 March, including on volulmes actually marketed the previous year
  - Identification of substance, (B2B) customers and uses, estimated volumes for the reporting period
- **Denmark**:
  - Existing data base for products which either contain nanomaterials or are claimed to be a nano product
  - In July 2013: Danish Environmental Protection Agency launched consultation on relevance of register for mixtures and consumer products that contain or release nanomaterials, based on annual declarations (B2B exempt, products falling within scope of other regulations exempt). Operational in 2014 (first year to be reported)

Other Advanced National Initiatives

- **Canada**:
  - Proposed approach to address nanosclae forms of substances on the Domestic Substances List (DSL) – February 2015
  - New substances: under the New Substances Notification Regulations for pre-market assessment: 20 nanoforms assessed
  - Criteria: cumulative: size (1-100 nm) **and** nanoscale properties/phenomena
  - Declaration: >100 g; excludes: polymers, organic and organo-metallic pigments, naturally occurring or incidentally manufactured nanoforms, biological materials
- **USA:**
  - EPA Proposed Rule for Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements – March 2015
  - One-time reporting for existing nanoscale materials – to inform EPA's decision making
  - Criteria: cumulative: size (1-100 nm) **and** nanoscale properties; three factors in combination: (i) change in the process; (ii) change in mean particle size by min. 10% and (iii) 7 fold measured change in at least one of the following properties: zeta potential, specific surface area, dispersion stability or surface reactivity.

Potential Further Developments in the EU

- Some MS (Austria, Belgium, Croatia, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden) have asked the Commission to propose legislation on registration and market surveillance of nanomaterials and products containing nanomaterials
- Amending the Annexes and updating Technical Guidance documents is not considered sufficient by these countries
- They call for lowering tonnage bands for nano registration under REACH
- They call for binding nano definition under REACH
- They call for revisiting workers exposure limits
- Call for mandatory inventories based on the French model
- Calls for discussions on labelling
- **Addressed by impact assessment suggested by the Commission**

Questions?

Classification, Labelling and Packaging: Process & Practice

Darren Abrahams

Ruxandra Cana

Annual Chemicals Regulation Seminar

Product Defense for REACH and Biocides

1 – 2 April 2015, Brussels

ChemicalWatch
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Topics for Today

1. Timelines
2. Procedures
3. Opportunities to Challenge
4. Some Conclusions
5. Q & A

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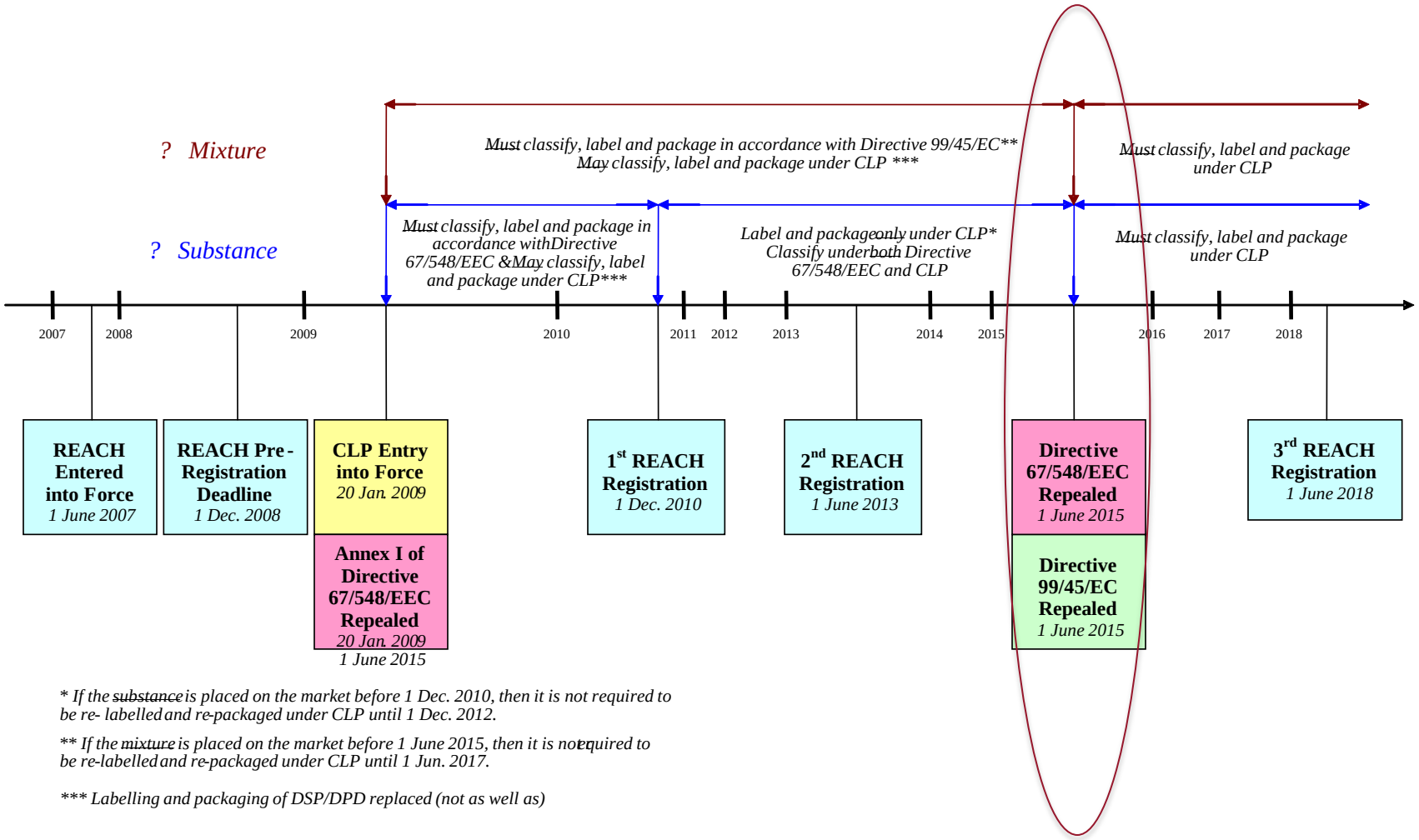
CLP Timelines

CLP Regulation Timelines



** If the ~~substance~~ is placed on the market before 1 Dec. 2010, then it is not required to be re- labelled and re-packaged under CLP until 1 Dec. 2012.*

*** If the ~~mixture~~ is placed on the market before 1 June 2015, then it is not required to be re-labelled and re-packaged under CLP until 1 Jun. 2017.*

**** Labelling and packaging of DSP/DPD replaced (not as well as)*

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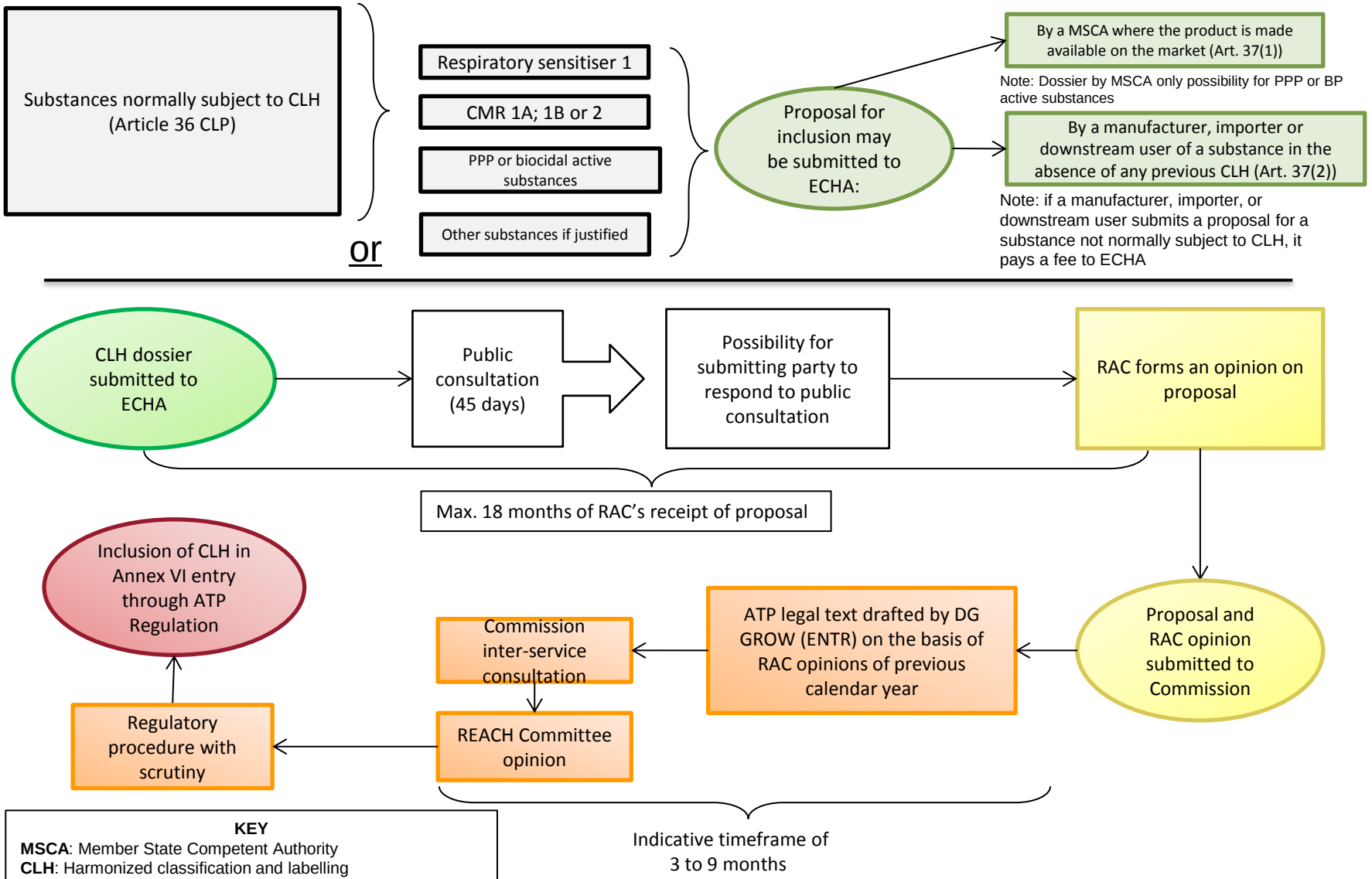
CLP Regulation Timelines

- 1 June 2015 deadline – see Article 61 of the CLP Regulation – what does this mean?
  - For classification, labeling and packaging of mixtures
  - For Safety Data Sheets for mixtures
  - For stocks

CLP Procedures

Procedure for establishing harmonized classification and labelling (CLH)
Article 37 Regulation (EC) No. 1272/2008 (CLP)[1]



KEY
MSCA: Member State Competent Authority
CLH: Harmonized classification and labelling
ECHA: European Chemicals Agency
RAC: Risk Assessment Committee of ECHA
ATP: Adaptation to Technical Progress
EP: European Parliament

[1] See also ECHA "Guidance on the preparation of dossiers for harmonized classification and labelling" (August 2014)
[2] Must be in format specified in second paragraph of Art. 37(2)

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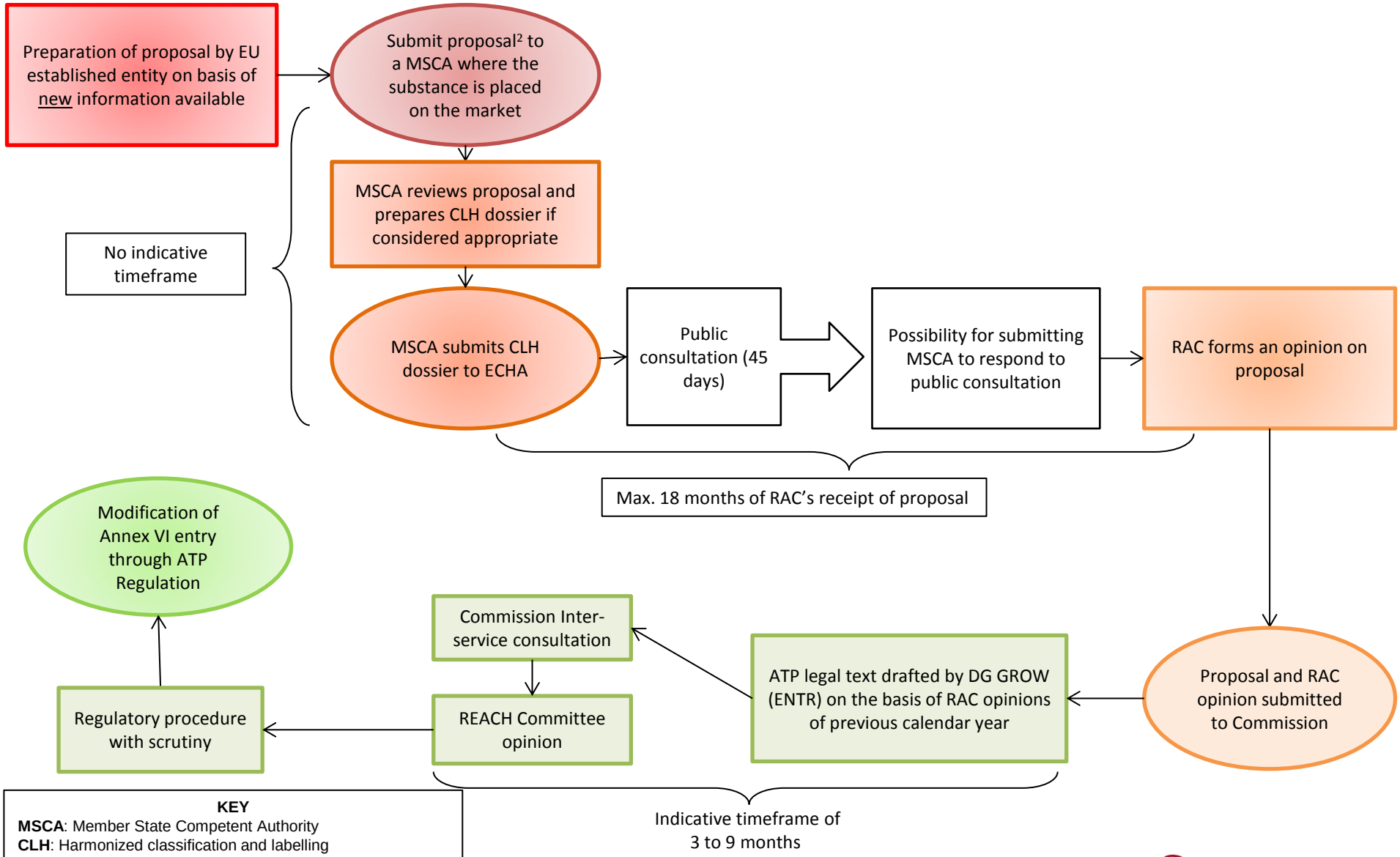
Procedure for revision of harmonized classification and labelling
Article 37(6) Regulation (EC) No. 1272/2008 (CLP)[1]



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Use of Article 37(6) CLP Regulation

- (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate; Bisphenol A Diphosphate; Bisphenol A Polyphosphate
  - Proposal for reclassification, September 2011, UK MSCA
  - RAC opinion, 28 November 2012
- Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate
  - Proposal for reclassification, March 2012, UK MSCA
  - RAC opinion, 30 November 2012
  - 6th ATP introduced by Commission Regulation (EU) No 605/2014 of 5 June 2014
- 1,2-epoxybutane
  - Proposal for reclassification, January 2013, MSCA Germany
  - RAC opinion, 11 September 2013
- Tinuvin 123
  - Proposal for reclassification, MSCA Germany
  - RAC opinion, 6 June 2014
- Iodomethane
  - Proposal for reclassification, November 2013, UK MSCA
  - RAC opinion, 12 Septembre 2014

Opportunities to Challenge

Classification Procedures

- **The CLP Regulation** (EC) no. 1272/2008 has detailed procedures for adoption of:
  - harmonised classifications (Annex VI inclusion)
  - re-classiffications (Modified Annex VI inclusion)
- **Consider <u>which</u> stages are apt for legal advocacy and which may <u>also</u> be susceptible to legal challenge:**
  - MSCA submits CLH proposal (admin. conduct review by national courts + ECJ)
  - ECHA launching of public consultation
  - RAC opinion (Case T-311/06, *FMC Chemical SPRL v EFSA*)
  - REACH Committee opinion
  - ATP Regulation (Direct annulment action)

  Issues of "legal effects" and "ripeness" to be considered.

Case T-532/08, *Norilsk Nickel* (Nickel Compounds)

- **Direct Annulment Action against 30th ATP, a Commission Directive. Inadmissible (under pre-Lisbon Art. 230) - no "individual concern":**
  - **Dir. 67/548 gave no expressly guaranteed procedural rights** during adoption of the contested classifications to distinguish the Applicants individually i.e. "*all those concerned (manufacturers, importers, national authorities) with methods of classifying…*". Contrast with competition, State aid or dumping, where express rights of defence.
  - **Participation in process** by which EU measure adopted ≠ distinguishing individually unless provision has been made under EU rules for procedural guarantees in his favour (e.g. a procedural right to be heard). Applicants conceded this was not the case.
  - **Under the CLP**, any procedural guarantees provided for (Art 37) would apply only in the event of a national authority or a manufacturer, importer or downstream user submitting a CLH proposal (Applicants had not made such a proposal in this case).
- **Same result in Case T-539/08 against 30th ATP (Borates):**
  - **Possibility of suffering** serious economic disadvantage ≠ individual concern.

Case T-532/08, *Norilsk Nickel* (Nickel Compounds)

- **Same inadmissibility result in Case T-539/08 against 30th ATP (Borates):**
  - **Possibility of suffering** serious economic disadvantage ≠ individual concern.
- **Good news is that the admissibility issues are not the same under a post-Lisbon regime:**
  - Classification is a process which results in a "regulatory act" (not based on Article 289 TFEU procedure) but adopted via *comitology* (resulting in an amending Regulation)
  - So there is only a need to be directly concerned and not individually (much lower threshold).

Case C-14/10, *Nickel Institute* (Nickel Compounds)

- **Preliminary Ruling on validity of against 30th & 31st ATP (both Directives) and 1st ATP to CLP (a Regulation):**
  - **Read across method is permissible in context of assessment of intrinsic properties**
    - even though thought not expressly provided for under Dir. 67/548, it is under REACH and CLP and was used following years if expert scientific discussion
    - application is not manifestly flawed because is within the limits of Commission's discretion when relying upon expert advice
    - "*in this complex technical and legal context, which in essence is in a state of flux, Directive 67/548 gives the Commission, in respect of the substance of the assessment, a broad discretion as to the scope of the measures to be taken to adapt the annexes to that directive to technical progress …*
    - *where the European Union authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion… the…judicature cannot substitute its assessment of scientific and technical facts for that of the institutions…*"

Case C-14/10, *Nickel Institute* (Nickel Compounds)

- **Preliminary Ruling on validity of against 30th & 31st ATP (both Directives) and 1st ATP to CLP (a Regulation):**

  - **Assessment of intrinsic hazards linked to intrinsic properties must not be limited to specific circumstances of use (contrast with a risk assessment)**

  - **Reasons given to support a classification must be sufficient but not exhaustive and varies to degree:**
    - *"…requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations…"*
    - "*…the scope of the obligation to state reasons depends on the nature of the measure in question and that, in the case of measures of general application, the statement of reasons may be confined to indicating the general situation which led to the adoption of the measure and the general objectives which it is intended to achieve… if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made …*"

Case T-291/04, *Envirotech* (N-Propyl Bromide)

- **Direct Annulment Action against 29th ATP - Inadmissible (under pre-Lisbon Art. 230) - no "individual concern":**

  - **Same analysis as in *Norilsk Nickel*. Extreme limits of Individual concern underlined:**
    - "*… if it were proved that the applicants were the only operators to have focused their economic activity on the marketing of an nPB-based cleaning solvent, which is particularly affected by the contested classification on the ground that it is 95% composed of that substance, that fact would also not be sufficient to distinguish them individually as long as there are other operators producing and/or marketing similar solvents or other nPB-based products and the number and identity of those operators are not defined, that group may even change after the entry into force of that classification…and that classification affects their products in the same way as it affects the applicants' products*".

  - **However, in the context of a damages claim the Court examined various arguments (all rejected so no illegality to found non-contractual liability).**

General Principles for Classification

- **General Principles of EU law ultimately apply before and after a challengeable decision is adopted**:
  - duty "*to **examine carefully and impartially** all the relevant elements of the individual case*"
  - must verify "***whether the evidence relied on is factually accurate**, reliable and consistent but also whether that evidence **contains all the information** which must be taken into account in order to assess a complex situation and **whether it is capable of substantiating the conclusions drawn from it***"
  - "*[take] **into account of all the relevant factors and circumstan**ces of the situation the act was intended to regulate*"
  - **non-retroactivity** - cannot anticipate a legal regime/thresholds which does not yet apply. If not done - puts final decision in peril.

Good decision-making is a benefit to all stakeholders.

Some Conclusions

- Decisions on classification and labeling, authorization (broadly speaking) have clear effects on business and result in market disruption
- The EU legal system offers legal remedies, mainly as direct challenges before the EU Courts
- So far the EU Courts acted conservatively, reluctant to rule on substance ("manifest error of assessment" standard in "complex technical and scientific matters")
- Good precedents on procedural grounds
- Further cases can be expected
- **Companies have to prepare legal arguments and legal strategy early**
  - Use legal arguments during preliminary stages before adoption
  - Be prepared to use legal arguments in court actions
  - Introduce court actions timely, when justified and when useful

Questions?

REACH - Substance and Dossier Evaluation

Indiana de Seze

Ruxandra Cana

Dr. Anna Gergely

Annual Chemicals Regulation Seminar

Product Defense for REACH and Biocides

April 1, 2015 - Brussels

ChemicalWatch
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Contents

- 1. Types of evaluation - process
- 2. Procedural challenges – right to comment, right to update before adoption of final decision, participating to meetings, update during the deadline in the final decision, and consequences
- 3. What is “concern” in the context of substance evaluation?

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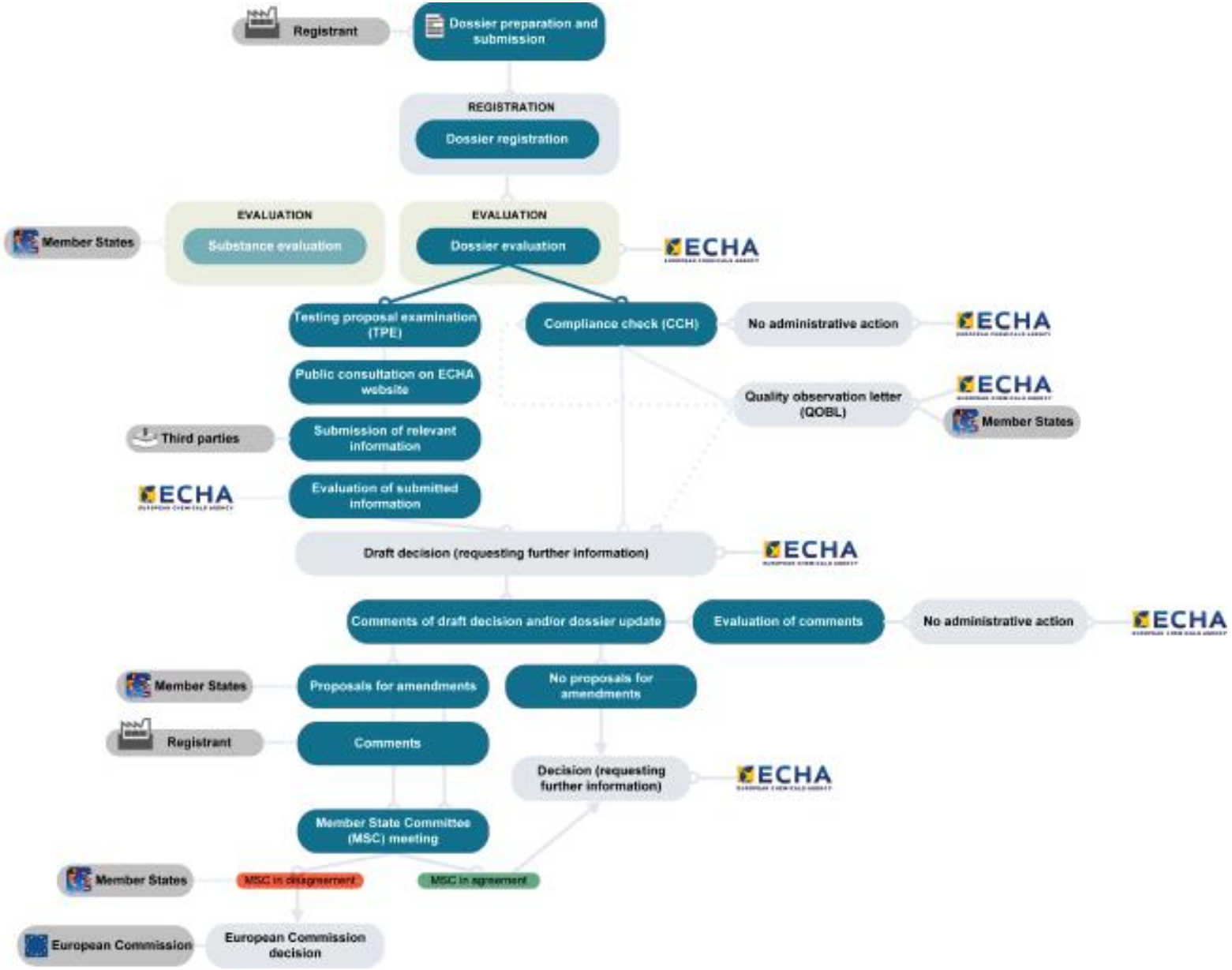
rEach

- Types of evaluation
  - Dossier
    - Compliance check (Article 41 REACH)
    - Testing proposals (Article 40 REACH)
  - Substance (Articles 44-48 REACH)
- Process
  - Leading to draft decision
  - Leading to final decision

Evaluation Process



Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

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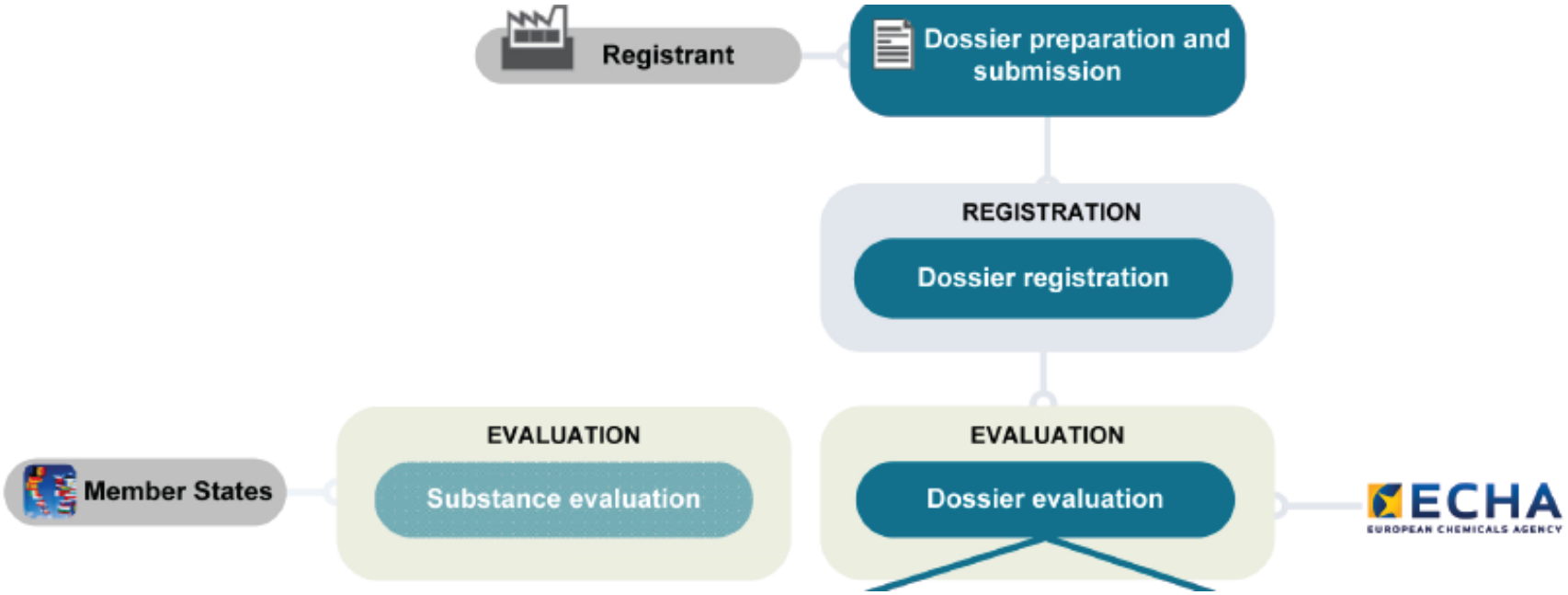
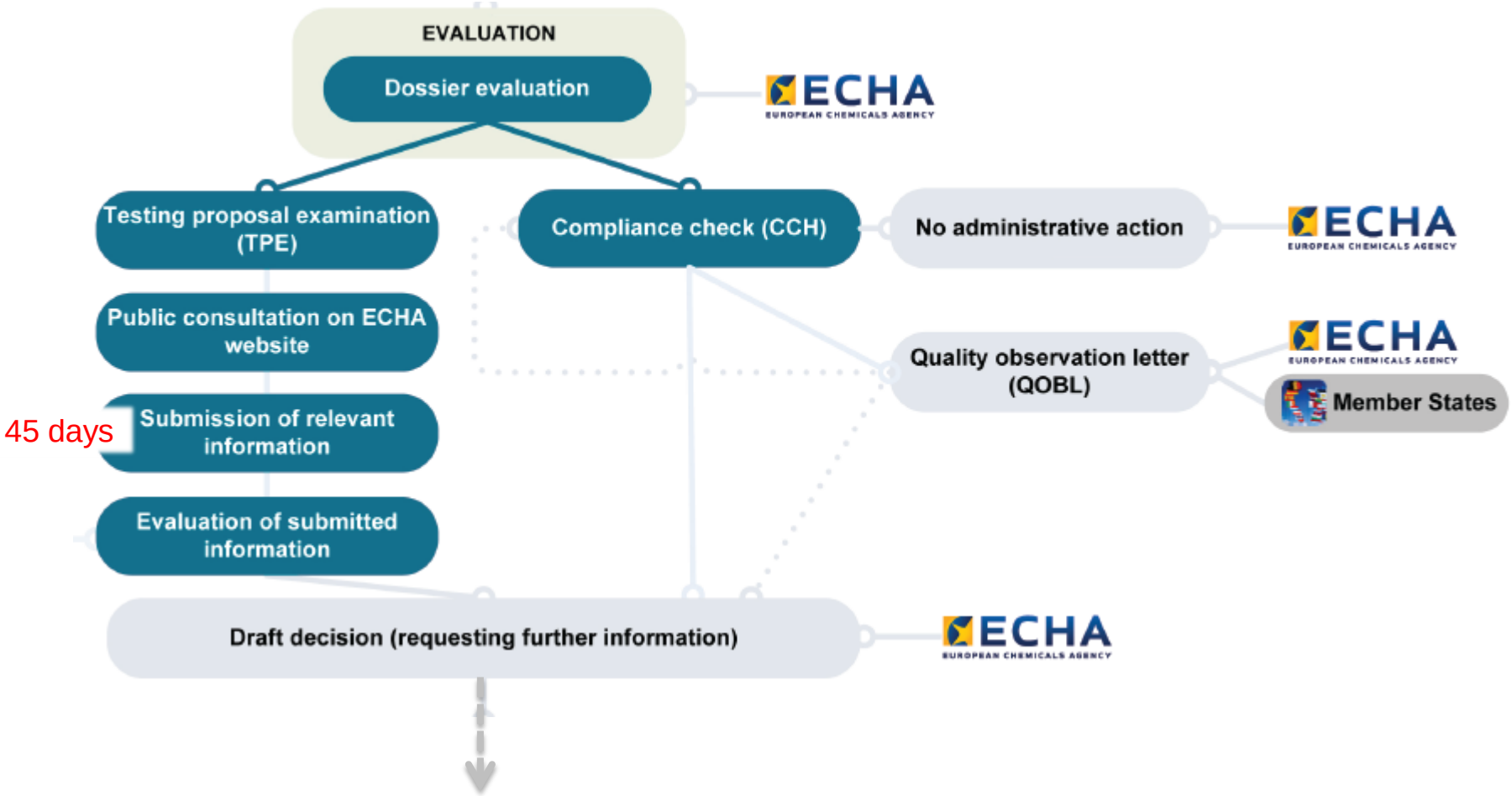
Dossier Evaluation / Substance Evaluation: Actors Involved



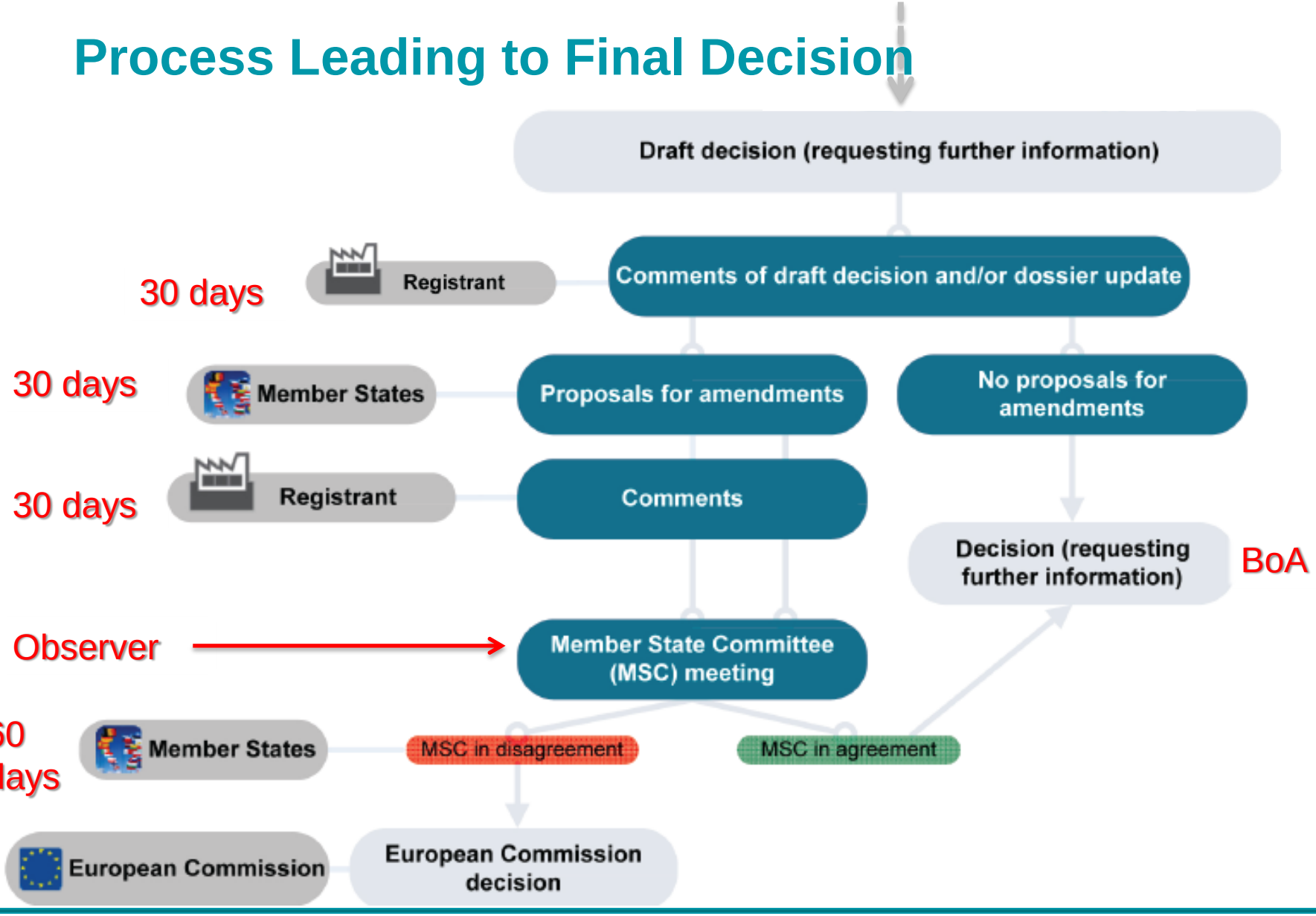
Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

TPE/CCh: Process Leading to Draft Decision



Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure and Steptoe & Johnson LLP

Process Leading to Final Decision



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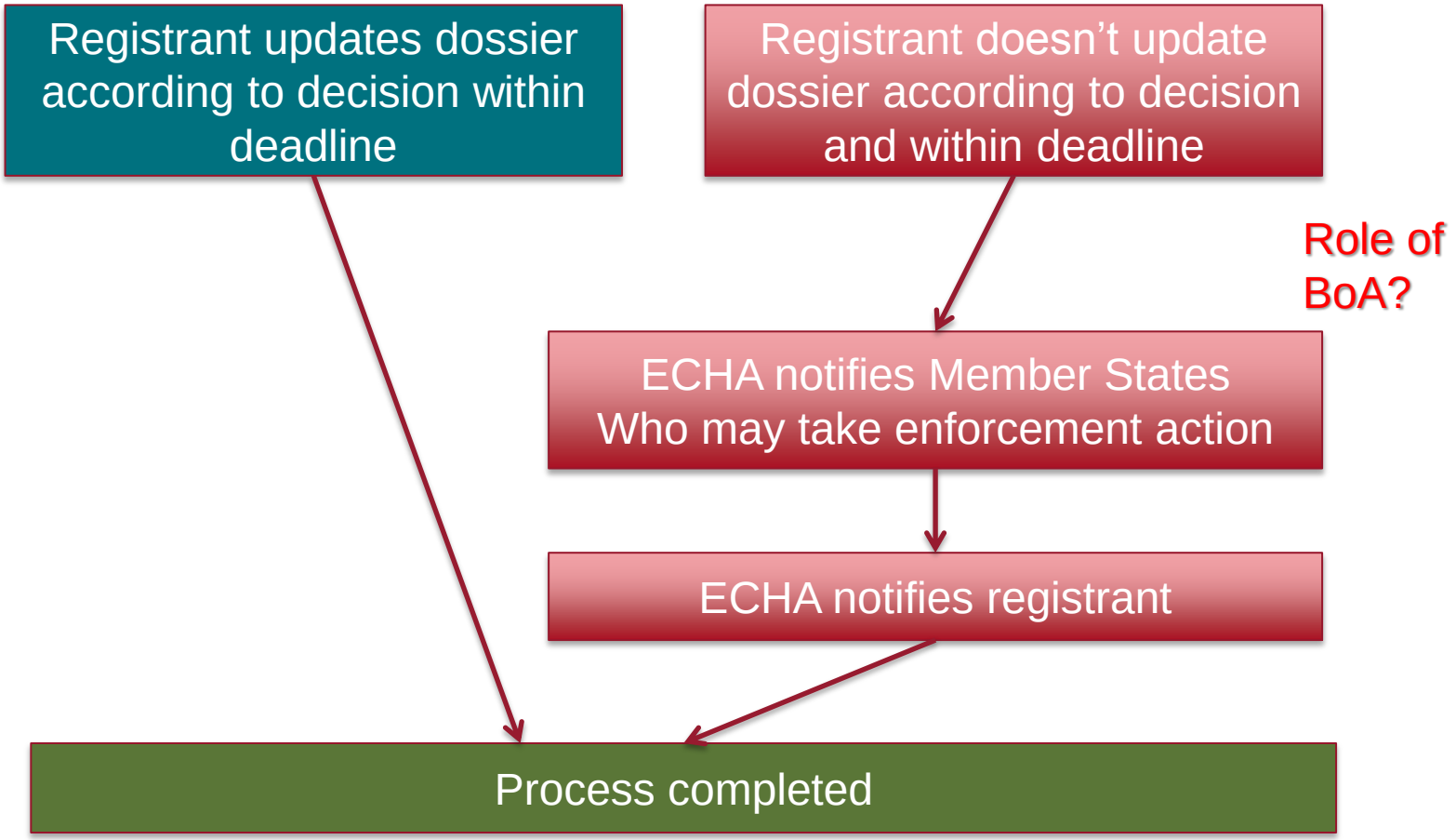
Outcome of Dossier Evaluation



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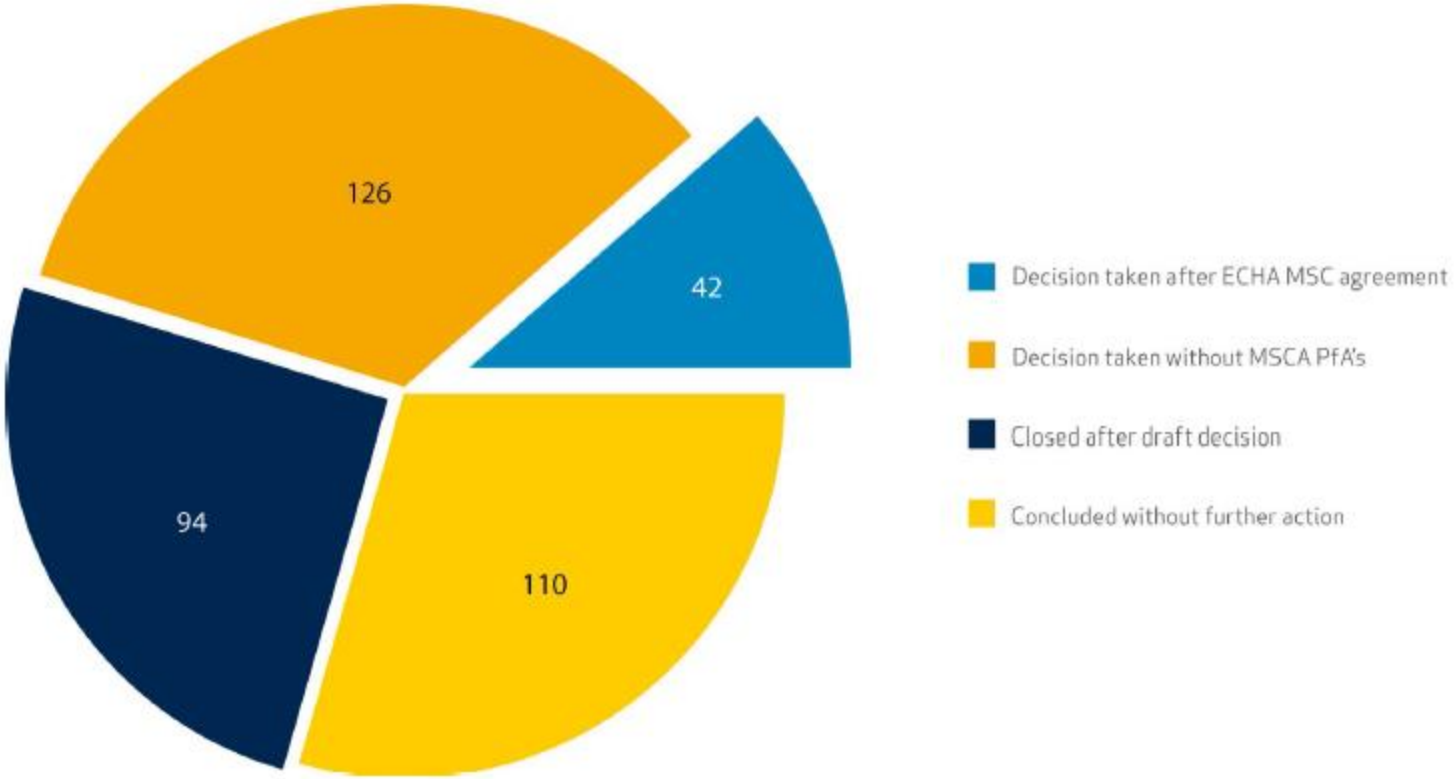
Dossier Evaluation Outcome

Targets of Compliance Checks

- Substance identity issues (often necessary before initiating a testing proposal examination).
- Areas of concern: endpoints considered highly relevant to risk management and chemical safety.
- Substances listed in the Community rolling action plan (CoRAP).

Outcome of “Targeted” Compliance Checks

- Outcome of the 372 ‘targeted’ compliance checks performed in 2014



Source: ECHA’s Evaluation report 2014

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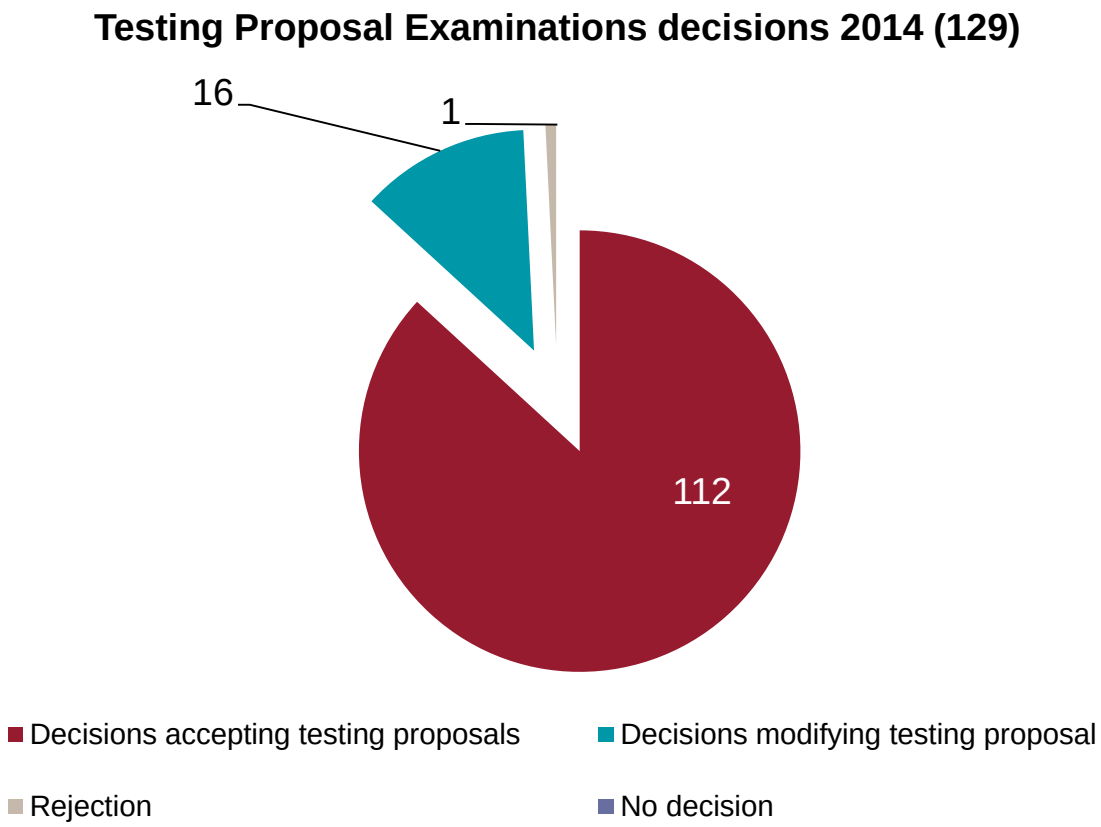
Outcome of TPE Evaluation



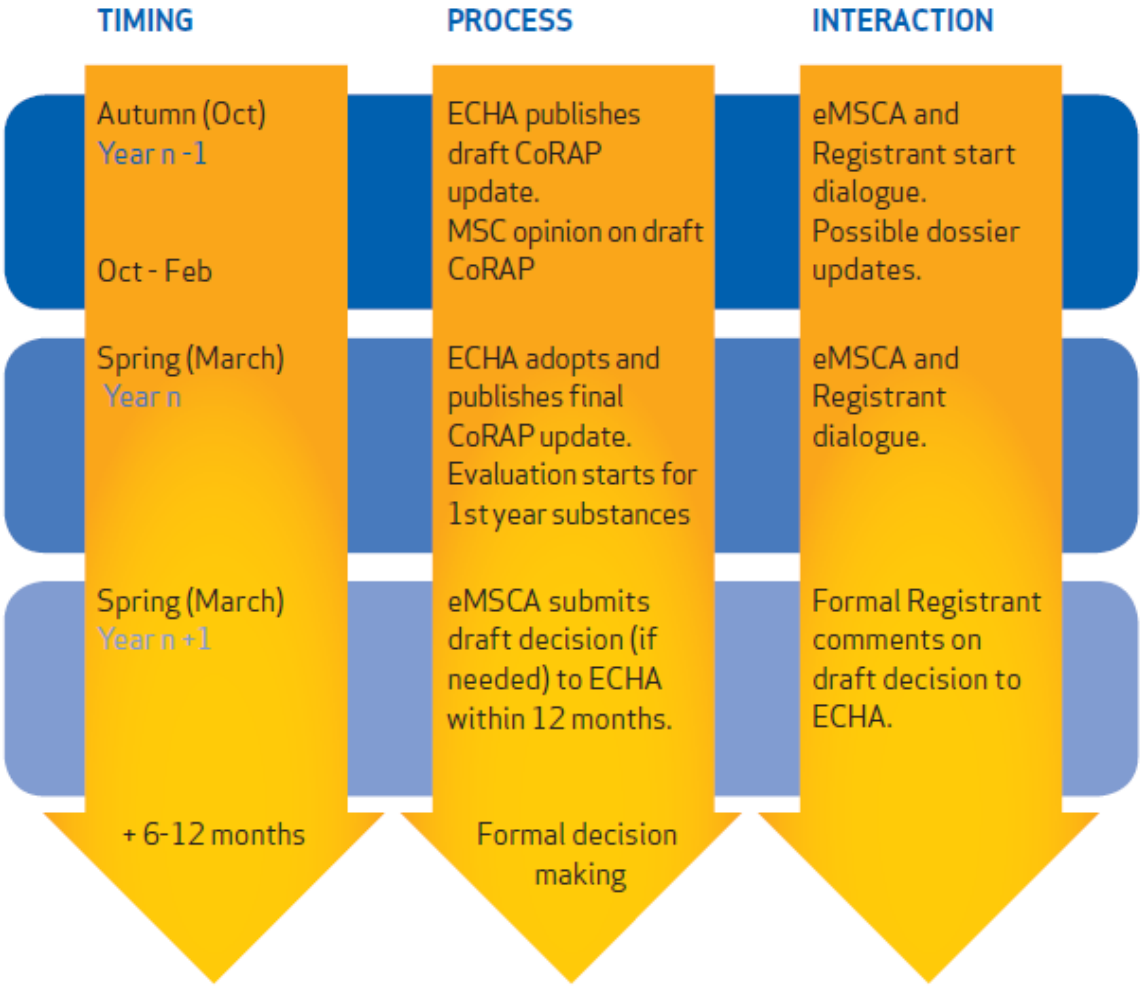
Source: ECHA and Steptoe & Johnson LLP

Substance Evaluation

Substance Evaluation

- Evaluation of substance throughout registrants' dossiers for the "same" substance, to clarify whether the manufacture or uses of a chemical substance poses a risk to human health or the environment
- Community Rolling Action Plan
  - Prioritisation of substances: criteria of Article 44(1) REACH
  - Proposals by Member States
  - Legal impact
  - Latest CoRAP list update: 17 March 2015 for 2015-2017
  - 48 substances are being evaluated in 2015 by 20 Member States
- Carried out by the Member States, while ECHA has a coordinating role in the substance evaluation process and remunerates the Member States for the task

OVERVIEW OF SUBSTANCE EVALUATION PROCESS



Source: Echa

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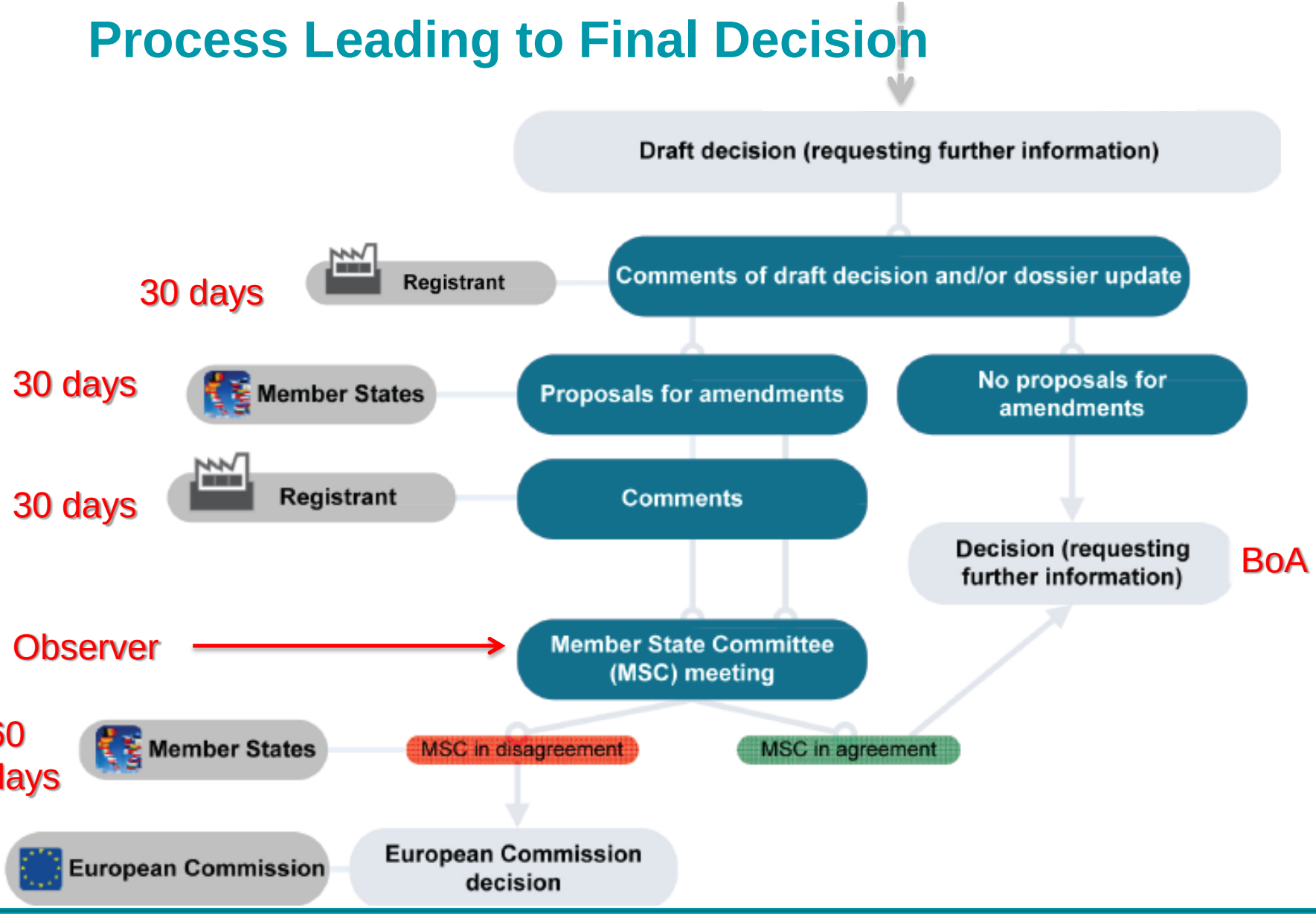
Process Leading to Final Decision



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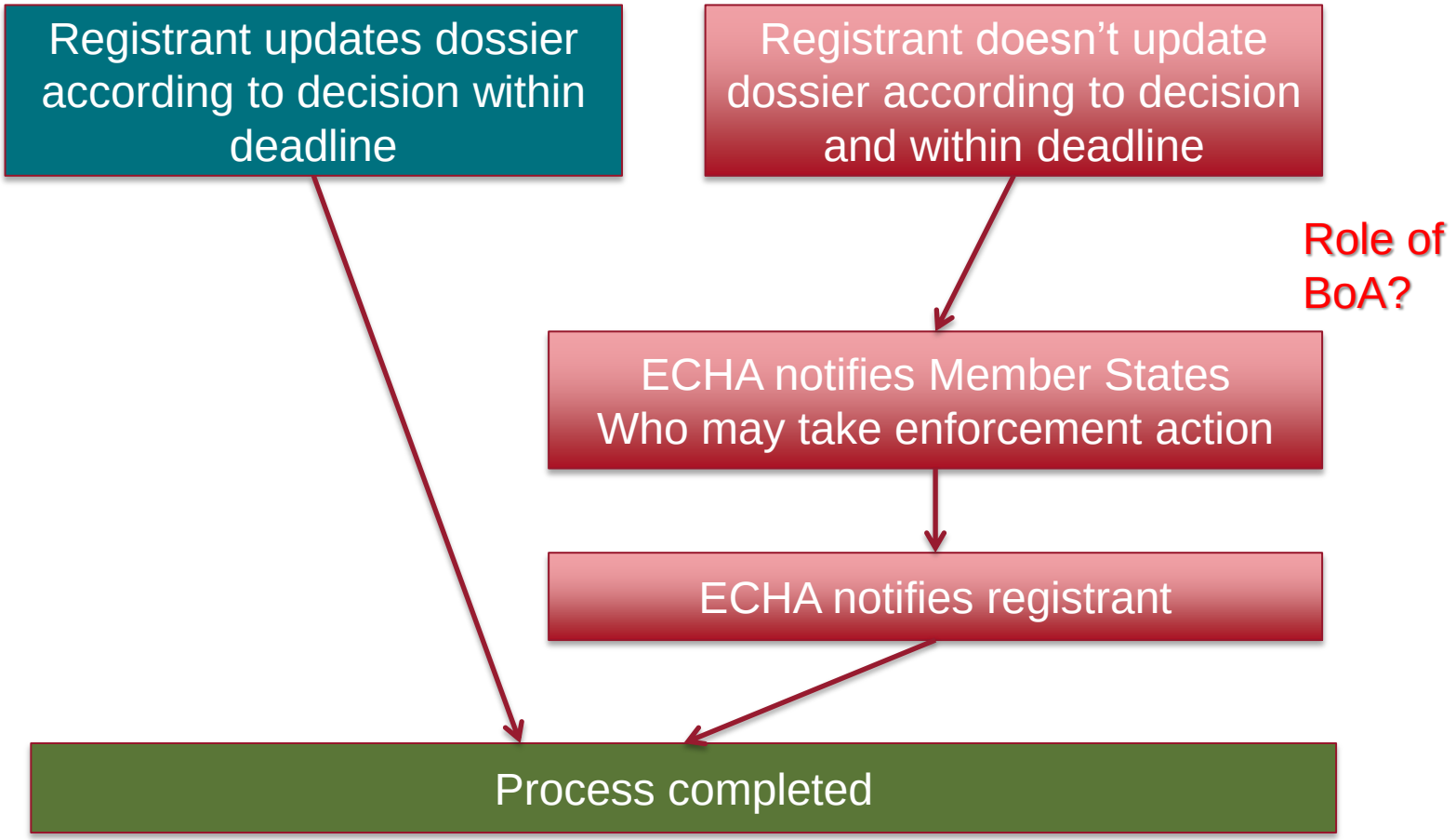
Outcome of Substance Evaluation



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Outcome of Evaluation

- Additional information requested:
  - Limited to REACH annexes in case of dossier evaluation
  - May result in a decision ordering additional testing beyond standard REACH information requirements in substance evaluation
- Information used
  - For other evaluation processes, e.g. for substance evaluation
  - For harmonised classification
  - For restrictions or authorisations
- New concerns identified

How Do the 3 Processes Interlink?

- The processes are independent of each other but are interlinked with regard to scope and procedure. Furthermore, these processes may run in parallel.
- ECHA has indicated that it intends to conduct compliance checks for all substances included in the CoRAP.
- Compliance checks may be open for various types of concern, in sequence.
- In cases where substance evaluation and testing proposal examination would run in parallel, the latter could be suspended by ECHA, pending the conclusion of the substance evaluation process.

Procedural Challenges

Procedural Challenges

- Right to comment
- Right to update the registration dossier
- Participating to MSC meetings
- Actions after receipt of the final decision – consequences
- Interactions with other registrants

Right to Comment

- Accepted in relation to the draft decision
  - Informal discussions may be organized with ECHA desk officers
- Accepted in relation to Proposals for Amendments (if any)
- Not accepted for
  - Revised draft decision
  - Comments of Member States during the MSC meeting
- Depends on discretion and practice of individual Member States during the 12 months period of assessment by MS during substance evaluation

Right to Update the Registration Dossier

- Throughout the procedure, but are updates taken into account?
  - Practice before end of January 2015

  (see ECHA information on 28 January 2015)

  - Practice after end of January 2015 - consequences

Participating to MSC Meetings

- Who participates?
- Formalities
- Discussions with Member States
- Follow-up – minutes, confidentiality

Actions After Receipt of the Final Decision - Consequences

- Informing ECHA of agreement as to the company performing the tests
- Undertaking the test
- Updating the dossier
  - Test results / Improved waiver, read-across
- ECHA actions
  - Possible statement of non-compliance, consequences

Interactions with Other Registrants

- Informing co-registrants throughout the process
- There is no imposed mechanism for cost sharing after a requested study is conducted and submitted by the Lead registrant as a result of an ECHA evaluation decision
  - What if co-registrants refuse payment? ECHA actions
- The contribution by co-registrants to costs of requested studies may differ for dossier *v* substance evaluation

Specific Observations – Initial Grounds for Concerns

- Criteria for Substance Evaluation – ECHA and Member States shall cooperate to develop them – harmonized approach, based on:
  - Hazard information (properties of concern)
  - Exposure information
  - Aggregate tonnage
- Substances meeting the criteria get prioritized for Evaluation - Risk based approach
- Final Community Rolling Action Plan (CoRAP) is based on opinion of the Member State Committee – annual updates covering three years
- Any substance not on the CoRAP list could be recommended for Evaluation by a MS – prioritization based on opinion of the Member State Committee
- During Evaluation further information can be required – if justified

Specific Observations – Initial Grounds for Concerns

- Substance Evaluation is based on all relevant information submitted on that or a structurally related substance
- (Draft) Agency Decision justifies the need for further information
- Registrant shall submit the information by the deadline set – or appeal
- If information is submitted the evaluation is finished in 12 months
- The indication of the initial grounds for concern does not limit the evaluation made by the Member States, since the Member States may also focus their assessment into other concern areas they find relevant during the evaluation. Yes, but:
- **Can further information be required for other (newly defined) concerns in case the initial concern on the substance, triggering CoRAP prioritization has not been confirmed?**

Specific Observations – Communication with Registrants

- Interaction between the registrant and the evaluating Member State is encouraged by ECHA.
- Individual Member States may have different practices; however:
- It is crucial to document discussions and potential agreements during these dialogues

CoRAP Update for Years 2015 – 2017

- Lists 134 substances for evaluation by the Member State Competent Authorities under the substance evaluation process.
- The plan contains 66 newly allocated substances and 68 substances were already published in the previous CoRAP in March 2014.
- 48 substances are being evaluated in 2015 by 20 Member States
- Many suspected PBT/vPvBs, CMRs and sensitizers with potentially wide, dispersive uses.

Questions?

PBT's and vPvB's: Properties of Concern under REACH

Eléonore Mullier

Annual Chemicals Regulation Seminar
Product Defense for REACH and Biocides
April 1, 2015 – Brussels

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Overview

- Concept and Specificities of PBT and vPvB properties
- PBT's and vPvB's as Properties of Concern throughout REACH
  - Registration
  - Evaluation
  - Authorisation
  - Restriction
- Take Away Messages

- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

Concept of PBT and vPvB Properties

- Definition
- Annex XIII REACH
  - Criteria
  - Information
  - Weight-of-evidence approach
  - Incl. PBT/vPvB properties of
    - Relevant constituents
    - Relevant transformation and/or degradation products
  - Excl. inorganic substances
- ECHA Guidance
  - Chapter R.11 of the Guidance on Information Requirements and Chemical Safety Assessment
  - Updated on 25 November 2014

Specificities of PBT and vPvB Properties

- New concern category
- PBT Expert Group

	Number of substances
On-going assessments (including CORAP substances)	99
Substances discussed by the PBT Expert Group (meetings 1 – 8)	121 [1] (incl. 3 biocides)
Outcomes of the assessments for discussed substances:	
Sufficient information available - the substance is PBT/vPvB	5
"Not PBT" based on present information	24
Potential PBT/vPvB, further information needed but follow-up not relevant at present	1 [2]
Refine assessment/More details on the available information needed/Testing or other new information needed	91 [3]

(1) This is the total number of substances for which it is known that the PBT/vPvB assessment is on-going. A small part of these substances have not been discussed in the PBT EG.
(2) This is the total number of substances which have been discussed by the PBT EG, including substances, for which the assessment has already been finalised or is still on-going. Additionally, for several substances counted under the last row the initial assessor has ceased the assessment.
(3) Registered only as intermediate, or similar situation (assessment postponed)

Registration of PBT's and vPvB's

- Registrants of substances manufacturing or importing in quantities ≥ 10 tonnes (Art.14(3) REACH)
- PBT and vPvB assessment (Section 4 of Annex I of REACH)
  - Step 1: Comparison with Annex XIII criteria
  - Step 2: Emission Characterisation
  - Section 8 of CSR
- Exposure Assessment (Section 5) + Risk Characterisation (Section 6)
  - Implementation
  - Communication
  - DU obligations
- SDS (Art.31 REACH)

Evaluation of PBT's and vPvB's

- Substance evaluation
  - Art.44 REACH + selection criteria for prioritisation
    - Suspected PBT and vPvB's
    - « PBT-like substances »
    - « Known PBTs/vPvBs »
  - CoRAP update 17 March 2015
    - main initial ground of concern

➢ Request for further information

Evaluation of PBT's and vPvB's

- Dossier evaluation
  - Testing proposals (Art.40 REACH)
    - *« priority shall be given to registrations of substances which have or may have PBT, vPvB (…) properties »*
  - Compliance checks (Art.41 REACH)
    - Compliance of CSA / CSR with Annex I
    - New Compliance Check Strategy
    - List of substances potentially subject to compliance checks + CoRAP

➢ Request for further information

Follow-up to Evaluation of PBT and vPvB's

- Art.42(2) of REACH:
  - *« The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4). The Agency shall use the information obtained from this information for the purposes of Article 44. »*

    - Substance evaluation
    - Authorisation
    - Restriction

Authorisation of PBT's and vPvB's

- SVHC Candidate List
  - Art.57(d) REACH (PBT) + Art.57(e) REACH (vPvB)
  - 20 substances on Candidate List
  - SVHC Roadmap to 2020 (23 March 2015)
    - Common screening process
    - Assessment
    - Risk Management Option Analysis (RMOA)

Authorisation of PBT's and vPvB's (cont.)

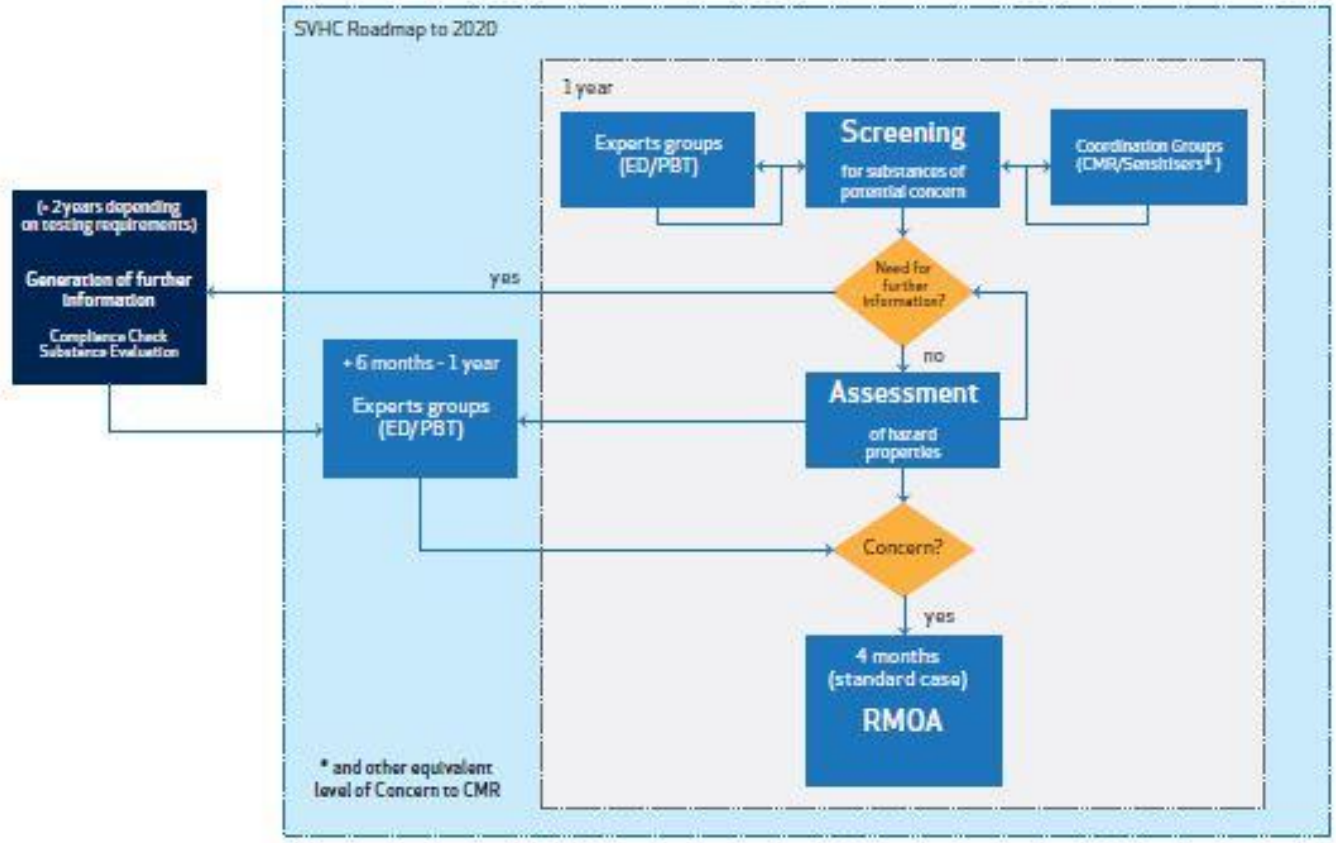

Figure 1: Overview of activities under the Roadmap with indicative timelines and links to closely related activities (compliance check, substance evaluation).

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Authorisation of PBT's and vPvB's (cont.)

- Prioritisation for inclusion on the Authorisation List
  - Highest inherent property score
- Authorisation List (Annex XIV REACH)
  - 1 PBT, 1 vPvB
    - HBCDD
  - 2 PBT's/vPvB's in Draft 6th recommendation
- Application for Authorisation
  - Art.60(2): *« an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled »*
  - Not applicable to PBT/vPvB substances
  - Art.60(4): *« an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies »*

Restriction of PBT's and vPvB's

- No specific provision for PBT/vPvB's
- PBT/vPvB assessment part of Annex XV restriction dossier
- Applied: 2 ongoing processes
- Confirmation of PBT/vPvB properties?
  - Restriction following/in parallel to Authorisation
    - *« The final conclusion and confirmation on the PBT and ED properties can only be achieved through the SVHC identification process. »* (SVHC Roadmap)
- Assessment criteria?
  - *« When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis »* (Art.68 REACH)

Take Away Messages

- PBT/vPvB properties trigger obligations and processes throughout REACH
- Regulatory focus
- Processes feed into one another – build up a consistent scientific/technical/legal argumentation early on
- Opportunities to comment and remedies are available

Questions?

Endocrine Disruptors – Developments in EU Law

Ruxandra Cana

Annual Chemicals Regulation Seminar
Product Defense for REACH and Biocides
April 1, 2015 – Brussels

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

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Content

- **Status quo**
- **Developments so far**
- *Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.*

Status Quo

Status Quo

- Endocrine disruptors are referred to in four legal acts under EU law
  - REACH ((EC) No 1097/2006)
  - EU Plant Protection Products Regulation (PPPR) ((EU) No 1107/2009)
  - EU Biocidal Products Regulation (BPR) ((EU) No 528/2012)
  - EU Cosmetics Regulation ((EU) No 1223/2009)
- These are legislative acts (adopted by the European Parliament and EU Council (composed of Member States representatives))

Status Quo

REACH

- **Article 57(f):** "*The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:* […] *(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59" (emphasis added).*

- **Article 138(7):** "*By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals*" (emphasis added).

Status Quo

EU Plant Protection Products Regulation

- **Article 23(1):** *"For the purpose of paragraphs 2 to 6, a basic substance is an active substance which: ([…];(b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects"* (emphasis added).

- **Section 3.6.5 of Annex II on the procedure and criteria for the approval of active substances, safeners and synergists**

- *An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005.* ***By 14 December 2013, the Commission shall present*** *to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4). Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008,* ***as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties****. In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as* ***toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered*** *to have such endocrine disrupting properties" (emphasis added).*

Status Quo

EU Biocidal Products Regulation

Article 5(1) on exclusion criteria: "*Subject to paragraph 2, the following active substances shall not be approved: (d) active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties*" (emphasis added).

- **Article 5(3):** "***No later than 13 December 2013, the Commission shall adopt*** *delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties. Pending the adoption of those criteria, active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as* ***carcinogen category 2 and toxic for reproduction category 2 shall be considered*** *as having endocrine-disrupting properties. Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as* ***toxic for reproduction category 2 and that have toxic effects on the endocrine organs may be considered*** *as having endocrine-disrupting properties*" (emphasis added).

- **Article 19(4):** "*A biocidal product shall not be authorised for making available on the market for use by the general public where:* […] *(d) it has endocrine-disrupting properties*"

Status Quo

Cosmetics Regulation (EU) No 1223/2009

- **Article 15(4):** "*When Community or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015,* ***the Commission shall review this Regulation*** *with regard to substances with endocrine-disrupting properties*".

Status Quo - Conclusions

- The European Parliament and the EU Council have requested the European Commission to adopt “delegated acts” relating to endocrine disruptors
  - To adopt the definition for pesticides (agricultural and non-agricultural) – by December 2013
  - To decide whether ED should be restricted automatically under REACH – by June 2013
  - To review the EU Cosmetics Regulation – if scientific consensus, or at the latest by January 2015
- What has the European Commission done so far?

Developments So Far

Developments So Far

- Scientific bodies / advisors to the European Commission
- The European Commission
- Member States

Developments So Far

Scientific bodies/advisers to the European Commission

- March 2013: Scientific Opinion by EFSA
  - Endorsing WHO definition, recognizing the possibility of threshold effects
- 18 June 2013: Letter to Ann Glover, Chief Scientist to the European Commission President Barroso
  - Letter signed by 70 scientists highlighting the lack of consultation of scientists in defining a regulatory framework for endocrine disruptors
- 24 October 2013: Minutes from meeting between Ann Glover and experts
- 16 December 2014 Memorandum by Scientific Committee on Consumer Safety (in the framework of the EU Cosmetics Regulation)

Developments So Far

Scientific bodies/advisers to the European Commission (cont'd)

- ECHA Endocrine Disruptors Working Group (independent experts)

2014

- 1st meeting: 13-14 February 2014
- 2nd meeting: 22-23 May 2014
- 3rd meeting: 11-12 November 2014

2015 – Upcoming meetings

- 4th meeting: 24-25 February 2015
- 5th meeting: 3-4 September 2015 (tbc)
- 6th meeting: 21-22 October 2015 (tbc)

Developments So Far

European Commission

- April 2014 European Commission conclusions on the opportunity of reviewing the REACH Regulation to include non-threshold concept for EDs (no review necessary at this stage, see minutes of Caracal meeting of 2-3 April 2014)

- June 2014 European Commission Roadmap for criteria for EDs for Plant Protection Products and Biocidal Products
  - Public consultation open from September 26, 2014 to January 16, 2015.

Developments So Far

Member States

- June 2014: France urges action from Commission on EDC in a Council document (supported by the Swedish and Danish delegations)
  - Explaining the importance of endocrine disrupting properties in France

- 4 July 2014: Legal action introduced by Sweden against the European Commission, before the EU General Court, for failure to adopt ED criteria under the EU BPR – pending

- October/November 2014: Open letter by Sweden and other Nordic State to the Commission urging for action on endocrine disruptors.

Questions?

Science For A Better Life

Endocrine Disruption – what's happening in Europe

March 2015

Agenda

- Endocrine Disruption – sounds bad, but what does it mean?
- How does the EU plan to regulate EDs?
- The EU Impact Assessment
  - Roadmap
  - Industry proposal
  - Public consultation and impact assessment
- A way forward?

Endocrine Disruption – what does it mean?

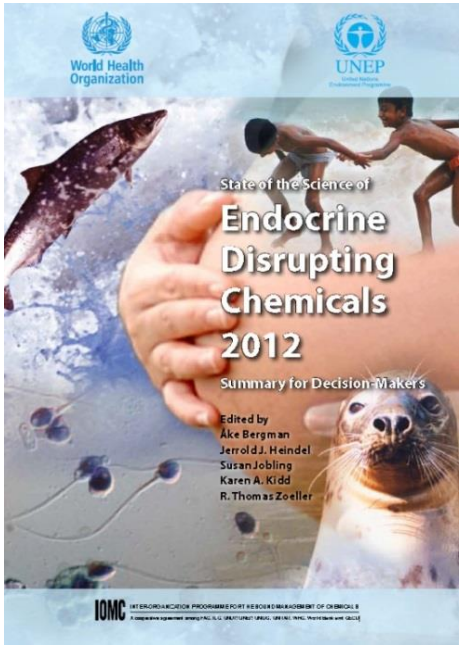
- We rely on our endocrine system to keep our bodies developing and working properly
- Our hormone levels are constantly fluctuating, for various reasons, some normal, some unexpected and transient – everything from daily cycles, puberty, menstrual cycles, stress, fear, excitement ….
- The problems arise when something interacts to cause an irreversible adverse effect, perhaps via an acute exposure at a particular time in embryonic development, or alternatively via chronic exposure over many years – but the effect(s) may not actually appear until many years later
- We maintain that the chronic and multi-generation studies that form part of the data requirements for pesticides are appropriate for detecting ED effects. And we actively contribute to the development of new guidelines as our knowledge continues to improve.

Cause and effect?

WHO/UNEP report in 2002 provided a state of the art view on health concerns, diseases, that might have some link to endocrine disrupting chemicals

The 2012 update raised global concerns on ED chemicals

- Many ED-related human diseases are on the rise
  - Notably diabetes, autism, breast cancer, prostate cancer, testicular cancer, obesity ..
- Past observations of endocrine related effects in wildlife populations
- Numerous laboratory studies support the idea that chemical exposures contribute to endocrine disorders
- Internationally agreed and validated test methods capture only a limited range of the known spectrum of ED effects
- (or do they??)



Pesticides - an easy target

- Diseases/conditions such as various cancers, diabetes, obesity are certainly increasing in prevalence. Indeed WHO considers the issue of overweight children and adults is reaching the scale of a Global epidemic.
- The WHO campaign focus is on sugar-rich foods/drinks and fast-food diets, with insufficient exercise. Lifestyle matters …. and life expectancy continues to increase ..
- But some have ED in their sights ….. with pesticides, generally, and multinationals, especially, to blame!

If the real concern is health, then placing too much focus on pesticides is probably barking up the wrong tree at an easy target. Still, we (and the regulators) have a responsibility to ensure that correct use of our products does not endanger health or the environment!!

An Endless List of EDs?
Illustration using Everyday Life Chemicals

In vitro ED screen
- ER/AR binding
- hER transcriptional activation
- **Steroidogenesis**
- Aromatase
- …

In vivo ED screen
- Uterotrophic
- Herberberger
- Pubertal male & female
- Amphibian metamorphosis
- FLC

Apical toxicity studies
- Chronic & Cancer bioassays.
- Reproductive toxicity studies
- Subchronic studies

Paracetamol	Positive		**Reduced AGD & fetal testicular testosterone**
Gingerol	Positive	**SAT Weight changes; ↑ testosterone**	
Caffeine	Positive	**Changes in SAT Weights (M), estrus cycle effects, delay in puberty (F)**	**↑ Incidence of Leydig cell hyperplasia, mammary tumors, pituitary adenomas**
Capsaicin	Positive		
Eugenol	Positive		
Cinnamaldehyde	Positive		**↑testes & epdidiymis weights, ↑sperm motility**
Resveratrol	Positive		
Curcumin	Positive		
Cuminaldehyde	Positive		
Naringine, obacunone	Positive		
Quercitin	Positive		
Theobromine	Weak Positive		
Vitamin C	Weak Positive	**↑ Testosterone**	**↑ Epididymal sperm count**
Echinacoside	Weak Positive		
Saccharose	Negative		
Ibuprofen	Negative		
Vitamins B9, 6, 3	Negative		
Lipoic acid	Negative		
Gingkolide A	Negative		
Allyl sulfide/disulfide	Negative		

- From 24 randomly selected everyday chemicals several are
- endocrine active (*in vitro/in vivo*) and some induce adverse
- effects in long term studies.

How does the EU plan to regulate EDs

- A need to discriminate between chemicals with the potential to interact with the endocrine system, and those that can actually cause harm ("irreversible, adverse effects"), since many chemicals in everyday foods can have endocrine activity
- Plant Protection and Biocides Regulations in EU will deal with endocrine disruption as an exclusion criterion ("cut-off")
- Under REACH (currently) which regulates industrial chemicals and US EPA EDSP, a substance can be identified as ED (Substance of Very High Concern, SVHC for REACh) and then authorised (or not) via risk assessment with appropriate mitigation measures, taking account of expected exposure and socio-economic impact. **1107 and 528 do not allow for this**, since the cut-off applies before any risk assessment, therefore we need to integrate these elements into the criteria that identify an ED ***for regulatory purposes***
- ***Criteria that are set for pesticides and biocides are then supposed to be applied to industrial chemicals and cosmetics in future. Industrial chemicals have much less data per dossier than pesticides (room for "doubt") and cosmetics are not allowed to conduct animal,*** *in vivo*, ***tests***

A need for focus, prioritisation

BPD-BPR began a 10 year program in 2000, received half the dossiers expected, and has extended the program to 24 years, already. The US EPA's Endocrine Disrupter Screening Program has 10,000 chemicals to screen! We need criteria that help us focus on regulating/removing the substances of real concern.

Roadmap – what are the options?

Criteria:

Option	Details/Comments
1	No criteria specified; the interim criteria for PPPR to apply (C2 and R2 or R2 with adverse endocrine effects)
2	A single category ('known or presumed') based on the WHO/IPCS definition.
3	A multiple category approach based on the WHO/IPCS definition. • Category 1: endocrine disruptors ; Category 2: suspected endocrine disruptors; Category 3: endocrine active substances;
4	WHO/IPCS definition to identify EDs and inclusion of potency as an element of hazard characterization (hazard identification and characterization)

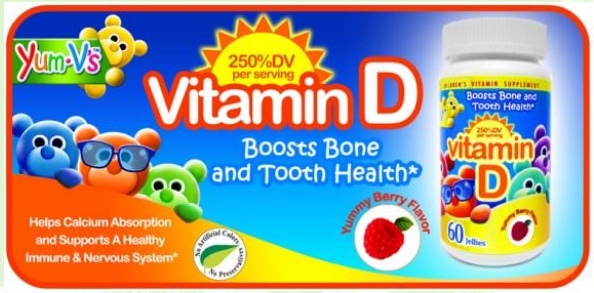
Regulatory decision-making

Option	Details/Comments
A	No policy change required (Baseline). The hazard based provisions in 1107 on regulatory decision making are not changed.
B	Introduction of elements of risk assessment into sectorial legislation as opposed to basing on hazard alone. Introduction of negligible risk to replace negligible exposure?
C	Introduction of further socio-economic considerations, including risk-benefit analysis, into sectorial legislation. Exemption from the ban for cases where not approving the substance would have a disproportionate negative impact on society?

The Risks of the Hazard-Based Approach

- Vitamin D3 is a substance with endocrine activity and potential for disruption and ***it is absolutely essential for proper bone development!!!!!***
- However, it also has uses in rodenticide baits since **high doses** cause hypercalcemia and death
- Current proposals based upon intrinsic hazard could result in a total ban for biocide use, or at least a ban on use by non-professionals in Europe

Meanwhile health authorities encourage us to feed it to our children every day at the right dose for them – and that's good!!



How could a natural ED be approved for biocide use?

When Cholecalciferol was evaluated for biocide uses, the hormonal mode of action was recognised, and the initial classification proposal was C2, R2.

Fortunately, some common sense prevailed and, in spite of the ED potential, it was recommended for approval:

approval could be achieved via derogation « necessary to prevent or control a serious risk to public health » which is not available for PPPs and does not apply to amateur uses under biocides.

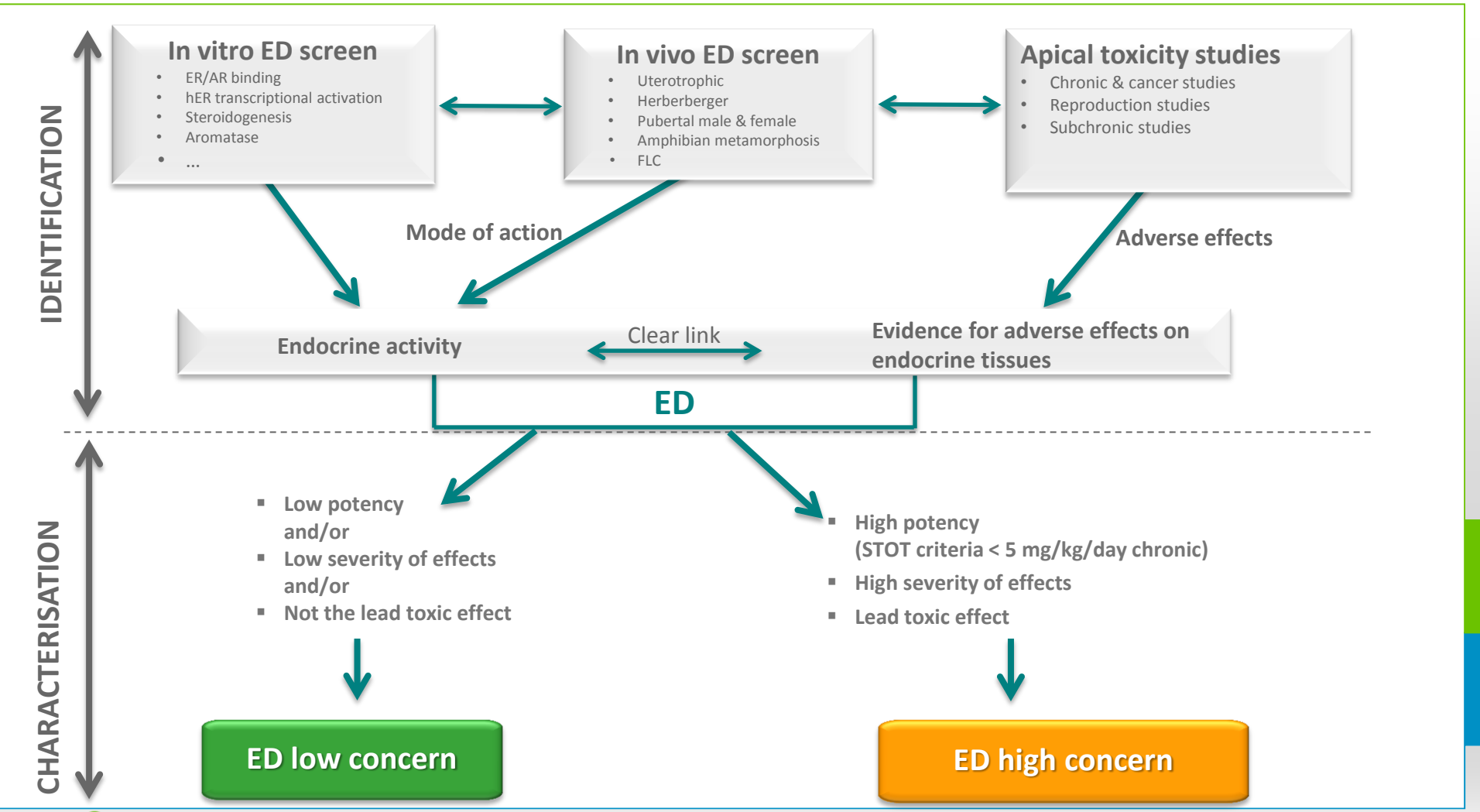
estimated exposure is considered acceptable (not negligible) and within current tolerable upper intake level (i.e. there is an established a threshold)

use might be considered acceptable if sufficient risk reduction measures are applied

use is important as an alternative to anti-coagulant rodenticides (resistance, secondary poisoning issues)

PS. These are the proposals from KEMI (Sweden is Evaluating Member State for cholecalciferol)

ECETOC proposal for criteria based on full hazard assessment



Some of the PC Comments …

- It seems bizarre that triazole fungicides when applied to crops are more harmful than a lady with thrush applying the fungicide to her vagina. (agricultural producer – organization/association)
- Endocrine disrupting chemicals must be regulated extremely carefully, fully adopting the precautionary principle, because their unchecked use could actually threaten the future of humanity and our ability to reproduce. (journalist).
- In this scientific day and age I think banning a chemical purely on a hazard based criteria without further risk assessment of the chemical taking place is living in the dark ages (agronomist).
- Your questions are NOT made to permit normal citizen to tell you what they know: that the risk is huge and precaution should prevail over lobbies
- If we have something which is potentially useful, the object should be to see if it is possible to make it safe, not to ban it.

Impact Assessment Process

1) Substance by Substance Evaluation (JRC, Q4 2014 – Q3 2015)
   - 700 Substances to be checked against the 4 Options from Roadmap (all pesticides and biocides plus approx 200 „representative“ industrial chemicals)

2) Socio-Economic Impact Assessment (External contracter, Q3 2015 – Q3 2016)
   - Assessing the socio-economic impact that the implementation of one the different options may have

But beware – pesticides have data-rich dossiers and it would cost a small fortune (plus overwhelming test lab facilities) to conduct chronic and multi-generation tox tests on all the industrial chemicals that might be « suspected » EDs due to lack of evidence!!

Science For A Better Life

Thank you!

Workshop: The Board of Appeal for REACH & Biocides

Darren Abrahams

Ruxandra Cana

Indiana de Seze

Moderator Carmen Paun, Chemical Watch

Annual Chemicals Regulation Seminar

Product Defense for REACH and Biocides

April 1, 2015 – Brussels

ChemicalWatch
GLOBAL RISK & REGULATION NEWS

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Topics for Today

1. Procedural considerations
2. Decisions so far – any conclusions on the merits?
3. Focus on data sharing
4. The BoA and the BPR
5. Practical considerations – why introduce an appeal?
6. Expected forthcoming issues in the near future
7. Some Conclusions
8. Q & A

Disclaimer: The contents of this seminar are provided for information purposes only. They are not intended as legal advice and should not be relied upon as such.

Procedural Considerations

What is the BoA?

- BoA: a body of the European Chemicals Agency (see art. 76 REACH), established by art. 89 REACH (Regulation No 1907/2006)
- Chairman, the members and alternates are appointed by ECHA's Management Board, for five years (extendable once)
  - appointed on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates adopted by the Commission
  - One Chairman (Chairwoman), one technically qualified member, one legally-qualified member
- Independent members, may not be removed from office, unless serious grounds: Commission decision upon opinion of Management Board
- Members cannot take part in appeal proceedings if they have any personal interest therein: replaced by an alternate

Nature of BoA Proceedings

- Appeal against ECHA decisions exclusively, under REACH or BPR
- Administrative review of decisions: written procedure, with a possibility of oral hearing
- After consultation with Chairman, Executive Director may rectify ECHA's decision (art. 93(1) REACH)
- Powers equivalent to ECHA's decisions: it may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action (art. 93(3) REACH)
- Decisions on admissibility may be taken either after 30 days of lodging the appeal – or with the final decision
- If appeal is admissible the BOA may annul and refer back to ECHA for renewed decision
- Possibility of challenge before the General Court or the Court of Justice of the EU, to contest BoA decision or for failure to act

Activities of the BoA

Decision date	# appeals	#decisions	#withdrawals	#pending
2009	1		1 rectification	
2010	1	0		
2011	6	1 annulled 1 dismissal	2 withdrawals 2 rectification	
2012	8	0	1 rectification	
2013	22	3 annulled 2 dismissals 1 inadmiss	2 withdrawals	4
2014	18	1 inadmiss 4 dismissals 2 annulled	1 rectification 2 withdrawals 12 settlements	14
TOTAL	**56**	**15**	**23**	**18**

What Decisions Can Be Challenged Before the BoA?

Type of REACH decision:	15	Type of BPR decision: 0
Data sharing:	1	Data sharing
Substance evaluation:	6 pending	Active substance approval (and renewal)
Examination of testing proposals:	3	Assessment of the technical equivalence of active substances
Compliance check of registrations / intermediate:	10 + 6 pending (1 intermed)	Union authorisation (and renewal) of a biocidal product
Rejections of registrations (SMEs / appropriate fee)	13	
PPORD exemption	0	

Implementing Texts

- Procedure: Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency – OJEU L 206 of 2.8.2008
- REACH appeal fees: Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) – OJEU L 107 of 17.4.2008 – amended by Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013 – OJEU L 79 of 21.3.2013
- BPR appeal fees: Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products – OJEU L 167 of 19.6.2013

ECHA Fees for Appeals Before the BoA (REACH)

Fees for appeals under Article 92 of Regulation (EC) NO 1907/2006

Table 1

Standard fees

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	EUR 2 356
Article 27 or 30 of Regulation (EC) No 1907/2006	EUR 4 712
Article 51 of Regulation (EC) No 1907/2006	EUR 7 069

Table 2

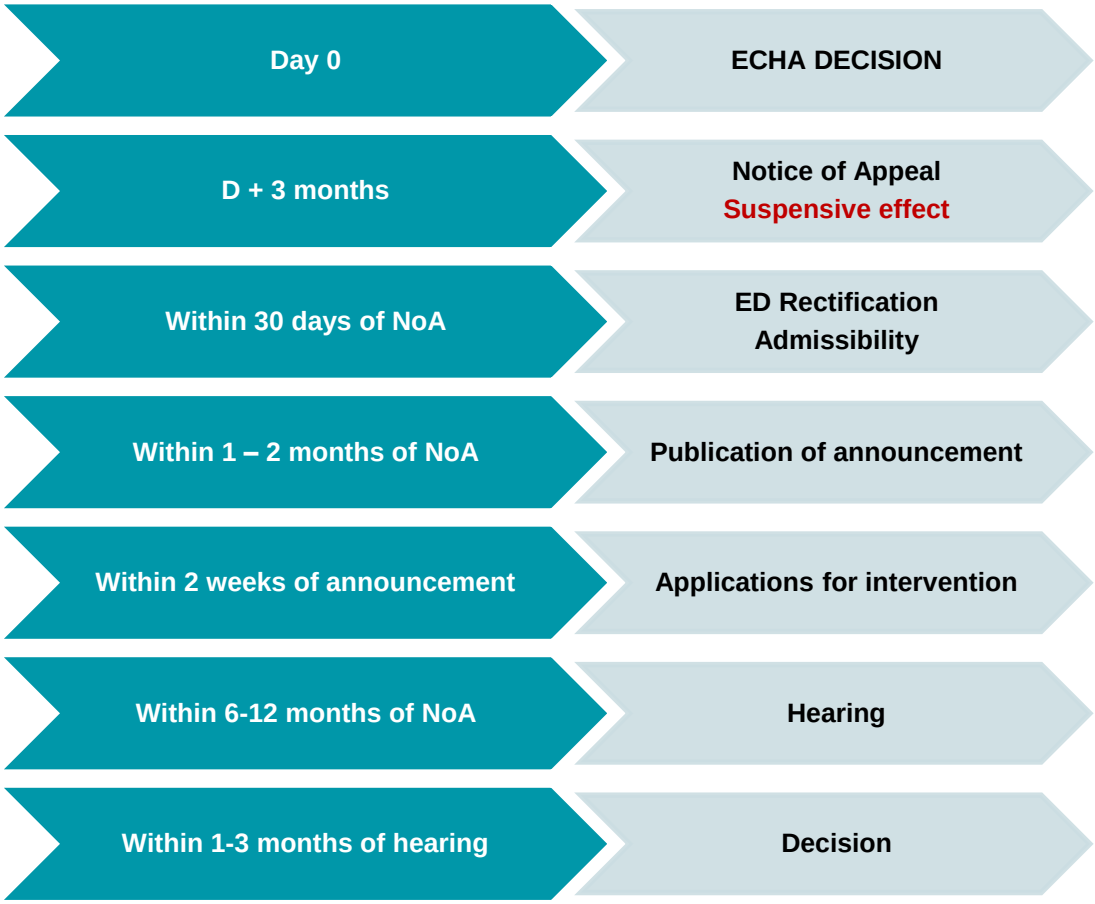
Reduced fees for SMEs

Appeal against decision taken under:	Fee
Article 9 or 20 of Regulation (EC) No 1907/2006	EUR 1 767
Article 27 or 30 of Regulation (EC) No 1907/2006	EUR 3 534
Article 51 of Regulation (EC) No 1907/2006	EUR 5 301'

ECHA Fees for Appeals Before the BoA (BPR)

- € 2,500
- No reduction for SMEs
- Decisions appealed will have been the subject of the levying of fees

Typical Timeline of BoA Proceedings



Typical Proceedings

- Notice of appeal
- ECHA Defence
- At BoA discretion: Reply submitted by Appellant
- At BoA discretion: Rejoinder submitted by ECHA
- Decision on applications to intervene and submission of observations by interveners
- Submission of observations by Appellant and ECHA on statements in intervention
- Closing of written procedure
- Hearing: Optional, unless requested by Appellant
- BoA Decision (published)

Issues of Confidentiality

- Confidentiality
  - vis-à-vis ECHA
  - vis-à-vis third party interveners
  - vis-à-vis public: announcement, hearing, and final decision of the Board of Appeal
- What can deserve confidential treatment:
  - Personal data
  - Substance
  - Appellant
  - All reference numbers (communication, registration, submission #)
  - Confidential business information

Who Can Lodge an Appeal?

- Who can be an appellant? Individual or joint appeal?
- What are the effects of the appeal? On whom?
- Who can intervene? What are the consequences of intervention?

Who Can Be an Appellant?

- "Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former" (Article 92(1) of REACH)
  - Addressees of a decision
  - Persons who are "*directly and individually concerned* "

Who Can Be an Appellant?

- Addressees of a decision
  - Registration completeness check: concerned registrant
  - Data sharing dispute: concerned data owner / concerned applicant
  - Dossier evaluation: Registrant and co-registrant if on joint submission
  - Substance evaluation: all registrants who received the Agency's draft decision for comments

Who Can Be an Appellant?

- Persons who are "directly and individually concerned"
- Direct concern
  - The Contested Act must directly affect the legal situation of the Appellants; and the addressees of the Contested Act must be left with no discretion in implementing the Contested Act.
- Individual concern
  - "[…] *if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed*". (see for example Case C-583/11 P – *Inuit Tapiriit Kanatami and Others v Parliament and Council*, not yet published, paragraph 72.)

Who Can Intervene? What are the Consequences?

- "Any person establishing an interest in the result of the case submitted to the Board of Appeal" (Article 8(1) of the BoA Rules of Procedure)
- Precedents so far
  - Member States
    - Substance evaluation: evaluating Member States, other Member States
  - Other registrants
    - Dossier evaluation: registrants other than the Lead registrant
  - NGOs
    - Animal rights groups

Analysis of Decisions So Far

Analysis of Decisions So Far

A few principles can be derived from previous experience and BoA decisions (mainly dossier evaluation)

- ECHA's margin of discretion
- ECHA creates legitimate expectations – the Agency's actions cannot frustrate these expectations
- Registrants must present their comments through dossier updates and formal comments

ECHA's Margin of Discretion

- ECHA must assess
  - If the evidence relied on is factually accurate, reliable and consistent,
  - If it contains all the information that must be taken into account in order to assess a complex situation and
  - If the evidence can sustain the conclusions drawn from it
- ECHA is under a duty to examine carefully and impartially all the relevant elements of the individual case
- Different standard than the standard applied by the EU Courts to the European Commission in cases involving scientifically and technically complex cases

ECHA Creates Legitimate Expectations

- Legitimate expectations (that cannot be frustrated) are created through Agency guidelines, fact sheets, guidance documents, or direct communication to registrants
- ECHA's actions must then be consistent with these expectations
  - See ECHA practice of engaging in dialogue with registrants

Registrants' Comments

- The BoA held (Case A-004/2012) that
  - the Appellant "did not clearly put forward adaptation or waiving arguments in the appropriate section of its registration dosser" and the Agency "should not be required to compile adaptation arguments on behalf of registrants from the information set out in other parts of the registration dossier."
  - "The Agency is not required to examine the registration dossier of its own initiative to look for information that may justify an adaptation or waiving."
- The BoA held Case A-004/2012 that
  - "whilst registrants can expect a certain level of expertise within the Agency, it is not the task of the Agency to develop, or improve, read-across adaptations on their behalf."
- Registrants must present their arguments, and should not expect ECHA to develop them

BoA Decisions – Other Conclusions

The BoA decisions so far provide background for dossier evaluation for example on:

- Read across justification
- Waiver justification
- Provision of a second species reprotoxicity study
- Article 41 compliance check do not necessarily cover all end points of a registration
- Communication with the Agency during the dossier evaluation procedure

Focus on Data Sharing

Lessons from the BoA

- **1st decision on a data sharing dispute**, under REACH (Art. 30) issued on December 17, 2014 (Case A-017-2013).
- Key elements giving rise to the dispute:
  - 10% *per annum* increase post-2010 registration deadline (to pre-finance LR's efforts), subject to later reimbursement i.e. deposit (ECHA decision characterized increase as "manifestly discriminatory" but BoA said it did not have sufficient evidence to reach this conclusion, noting the reconciliation)

    No detailed description of what discrimination means in this context.
  - €1,000 handling (one off) (ECHA and BoA held this was not explained with sufficient clarity – did not say it was inappropriate)

Lessons from the BoA (cont'd)

DATA SHARING TERMS

- BoA confirmed that ECHA:
  - Should not assess if the "actual and precise cost of a letter of access is reasonable or justified" (as in Data Sharing Q&A)
  - May make an assessment of whether each of the parties made "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way"
- BoA takes a holistic approach to "every effort" test without separating the three subcomponents:
  - A fact/case driven analysis as to whether every effort is taken based on the "arguments presented during the data sharing negotiations between the parties" (word for word)
  - Only communications between the parties during data sharing negotiations are examined (confirms ECHA practice on DSD, published in August 2014)

Lessons from the BoA (cont'd)

- Reconciliation clauses "may, in certain circumstances, be considered to be an important point in assessing whether every effort has been made" (10% per annum increase was not judged to have been clearly subject to reconciliation)
- Ever-present clarification burden: an effective reversal of burden on data owner to respond to concerns (not fully articulated) and provide unrequested evidence (*e.g. reconciliation mechanism*)?

Lessons from the BoA (cont'd)

ADMISSIBILITY CRITERIA

- BoA held that ECHA must clarify the scope of requests with a data accessor
- BoA held there is a presumption that those requested data are for all V-data in the substance dossier for the tonnage band (if cherry picking then will need to state expressly vis-à-vis the data owner):
  - Willingness to infer "common understanding" (contrast with need for declarative clarity required for cost sharing information)
  - Willingness to deduce scope from absence of questions (so ask questions, include conditional qualifiers to avoid certainty being imputed – or risk being found not to have made every effort)

Lessons from the BoA (cont'd)

NEGOTIATING PRACTICES

- BoA guidance on other aspects:
  - Early circulation of SIEF agreements is "good practice" but analysis really begins at the moment when active negotiations start (what is stored up for 2018?)
  - Repetition of positions is credited if the response is not judged adequate (after the event/by the data accessor?) When are concerns "adequately addressed?"
  - Negotiations close to a registration deadline are not a per se indication of failure to make "every effort." The reason for failure to agree is more important.

The BoA and the BPR

The BoA and the BPR

- **History of EU-level biocides litigation is unhappy**:
  - (i) procedural barriers to justice ('standing' and the *Plaumann* doctrine)
  - (ii) ultimate failure (common with much past chemicals litigation)
    - T-339/00 and C-258/02 P (First Review Regulation cases)
    - Joined Cases T-75/04 and T-77/04 to T-79/04 (Second Review Regulation cases)
    - Joined Cases T-400/04, T-402/04 to T-404/04 (Legislative Amendment cases)
    - Case T-120/08 (Third Review Regulation case)

- **The BoA provide some light at the end of the tunnel.**

ECHA: The BoA and the BPR

BoA remedies apply against ECHA, which has roles which are:

- (1) Advisory
- (2) Decision-Making – BoA remedy
- (3) Coordination

ECHA: The BoA and the BPR

BPR Interlocutor	Potential Action
ECHA	• Legal Advocacy
	• **BoA in specific areas + Ability to rectify**
	• **ECJ (i) on appeal from BoA** and (ii) for ATD and Dissemination
Commission	• Legal Advocacy (even on unchallengeable ECHA action which underlines its own Decisions)
	• General Court
	• ECJ on appeal from General Court
Member States Authorities	• Legal Advocacy
	• National Courts + Preliminary Ruling to ECJ

ECHA Decision-Making and the BoA

Fees∞	Data Sharing	Technical Equivalence
Validation of AS applications - rejection of application for non payment of fees within 30 days (Art 7.(2))	**Mandatory where parties don't agree** (Art 63(3))	**Decision on technical equivalence** (Art 54.(4))
Renewal of AS applications - rejection of application for non payment of fees within 30 days (Art 13.(3))	**Referral to unprotected data when technically equivalent** (Art 64(1))	**Rejection of application where further information requested** for technical equivalence but not provided so rejected (Art 54.(5))▲
Validation of Union Authorisation - rejection of application for non payment of fees within 30 days (Art 43.(2))		
Renewal of Union Authorisation - rejection of application for non payment of fees within 30 days (Art 45.(3))		
Rejection of application for Technical Equivalence for non payment of fees within 30 days (Art 54.(3))		
Rejection of AS applications under Art. 95 Transitional Measures - rejection of application for non payment of fees for submission of a dossier within 30 days (Art 95(1) 4th sub-paragraph. **No explicit BoA Appeal.**		

∞▲*Same remedy for fees non-payments and /or failure to provide requested information under Reg. (EU) 613/2013, Reg. (EU) 564/2013 (also on SME status) and Reg. (EU) 354/2013.*

Steptoe
STEPTOE & JOHNSON LLP

ECHA Decision-Making and the BoA

Although not actionable before the BoA, the ATD regime may support BoA claims.

- Free-standing right to challenge **ECHA decisions** on access to documents (under Regulation (EC) 1049/2001) before General Court. Consider applicability of Article 4 exceptions including commercial interests of a natural or legal person, including intellectual property. **Access to document is useful in itself**, and useful in any later appeal.
- Alternative right to complain to **Ombudsman.**

Take-Home Messages

- Resolving legal issues under the BPR is not all about a 'day in Court' or even before the BoA. Showing you understand the limits on power need not be a hostile gesture. Sound decision-making is not an issue for 'one side'.
- The BPR framework expressly includes a mechanism for ECHA to avoid an appeal before the BoA and reverse a decision. This should set the tone for all interaction under the BPR.
- Failing to address legal issues with all three Interlocutors (ECHA, Commission and Member States) is to store up conflict, generate poor decisions and allow procedures to escalate to conflict when early articulation of messages might have avoided this (before positions harden).

Practical Considerations – Why Introduce an Appeal?

Practical Considerations – Why Introduce an Appeal?

- For a partial or complete annulment of the decision
- Suspensive effect - vis-à-vis the appellant only?
- To be heard:
  - Opens a window of opportunity for a rectification by the Executive Director
  - Opens a further window of opportunity for settlement
- For establishment of best practices?

Expected Forthcoming Issues in the Near Future

Types of Cases

- 2010 – 2013:
  - A large number of fees/SME-related cases
  - A few precedent-setting decisions on dossier evaluation (compliance check and testing proposals)
- 2014:
  - Continuing cases introduced against dossier evaluation decisions
  - First cases against substance evaluation decisions
- 2015:
  - Continuation of cases against dossier evaluation decisions
  - More cases against substance evaluation decisions
  - What about ad hoc ECHA decisions?

Types of Issues

- PBT-testing
- Scope/margin of discretion
- Nano-related issues
- New issues related to endocrine disruption?
- Procedure?
- Others?

BoA Appeals

TO BE CONTINUED!

Some Conclusions

- Real substantive issues are pending, or will be addressed in the near future
- Lack of precedents combined with potential lack of clarity in the law means that real changes can be made to current practices
- The appeals procedure must be used

Questions?