Ruxandra Cana

Chambers Europe notes that Ms. Cana's clients are "unanimous in their praise of her for being 'well-connected and very popular' and state that she has 'great judgment' and understands the way in which the […] industry works.'"

Ruxandra Cana rcana@steptoe.com

Ruxandra Cana, a partner in Steptoe's Brussels office, has more than 15 years of experience advising multinational companies and industry associations on EU regulatory compliance and product defense.

Ms. Cana specifically advises clients on matters arising from the application and implementation of the EU REACH rules, including data sharing, consortia formation, only representatives, corporate structuring, and intermediates. She has formed, and continued to act as a legal advisor to more than 20 REACH consortia. Her practice also covers REACH dossiers evaluation, substance evaluation, SVHC listings, inclusion in Annex XIV to REACH, and restrictions.

She acted as counsel in the first direct case related to EU chemicals legislation to succeed before the EU General Court and represented clients in successful appeals before the Board of Appeal of the ECHA.

Ms. Cana also brings significant experience in European Union (EU) rules on biocides and pesticides, cosmetics, medical devices, consumer products such as electronics, food (labeling, nutrition, food additives, and genetically modified food), food contact materials, and nanotechnology.

Indiana de Seze

Ms. De Seze represented a consortium of companies in a data sharing dispute and an Only representative in a challenge of a decision ordering additional testing, both before ECHA's Board of Appeal.

Indiana de Seze ideseze@steptoe.com

Indiana de Seze is a leading legal practitioner in EU chemicals regulation and competition. Ms. de Seze's practice focuses predominantly on REACH, biocides, plant protection products and other applications of chemicals requiring regulatory clearance or pre-market authorizations. Thanks to her rigorous training as a competition and commercial lawyer, Ms. de Seze delivers cutting-edge analyses and pragmatic solutions to tackle antitrust issues in the context of consortia and data sharing.

Chemicals Regulation: Ms. De Seze regularly advises clients on their registration duties and the legal consequences of substance and dossier evaluation procedures under REACH. She has formed and continues to provide legal support to consortia of companies for the purpose of joint submissions. She counsels on data protection and data sharing negotiations, having assisted in the formation of task forces and in their dealings with the competent authorities and companies. In the biocides area, Ms. de Seze helps companies in the biocidal product market to transition to the Biocidal Product Regulation and roll out successful active substance and product registration strategies across the EU.

Her litigation work in the area involves representing clients before the EU and national courts, and the Board of Appeal of the European Chemicals Agency

Michel Michaux

Michel Michaux mmichaux@steptoe.com

Michel Michaux is a senior adviser in Steptoe's Brussels office, where he is a member of the Regulatory & Industry Affairs Department. His work focuses on EU regulatory affairs, including the management of consortia set up for pesticide, biocide, and REACH registrations that cover in excess of 150 substances.

Mr. Michaux is a chemical engineer who, following a career in academic research on food technology, joined the European Chemical Industry Council (Cefic). His roles at Cefic included serving as counselor in the Internal Market Affairs department, responsible for renewable resources, mineral oil taxation and energy policies. He also oversaw product safety issues in the Technical Affairs department, along with managing several sector groups.

Between 2000 and 2006 he set up and managed the Cefic Biocides Forum and consortia of companies jointly registering biocidal active substances. In 2006 he was assigned to launch the consortium management activities of ReachCentrum, a service unit established as a subsidiary of Cefic.

Mr. Michaux is co-author of RIP 3-4 on data sharing, which served as a basis for the European Chemicals Agency's (ECHA) Guidance on Data Sharing.

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REACH - Substance and Dossier Evaluation

Ruxandra Cana

Indiana de Seze

Michel Michaux

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

Steptoe

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Content

1. Introduction – why evaluation, and why now?
2. Procedural considerations
3. Substantive considerations (previous cases and BoA decisions)
4. BoA decisions: conclusions on specific technical issues
5. Potential flaws, possible corrections
6. “Take-home” messages

Why evaluation, and why now?

Evaluation = review of the information available through the registration dossier so that new information is requested if necessary

Dossier evaluation

- Testing proposals for 2010 substances reviewed or review pending / Testing proposals for 2013 substances to be reviewed by 1 June 2016
- Completeness checks abound

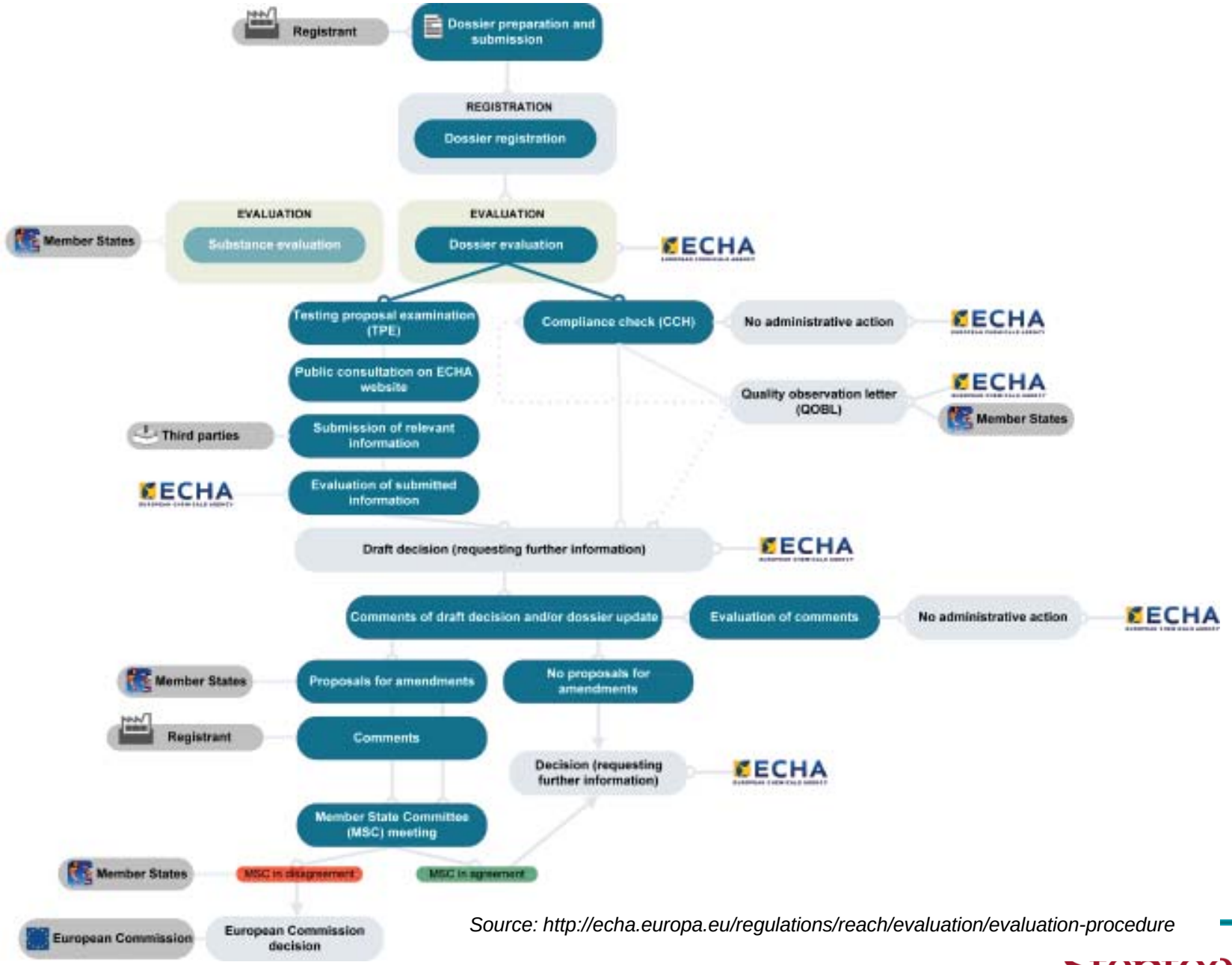
Substance evaluation

- 2012 Corap substances finalized or pending
- 2013 Corap substances – draft decisions imminent

Procedural considerations

Contents

- 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
- Opportunities
  - For registrants
  - For third parties



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

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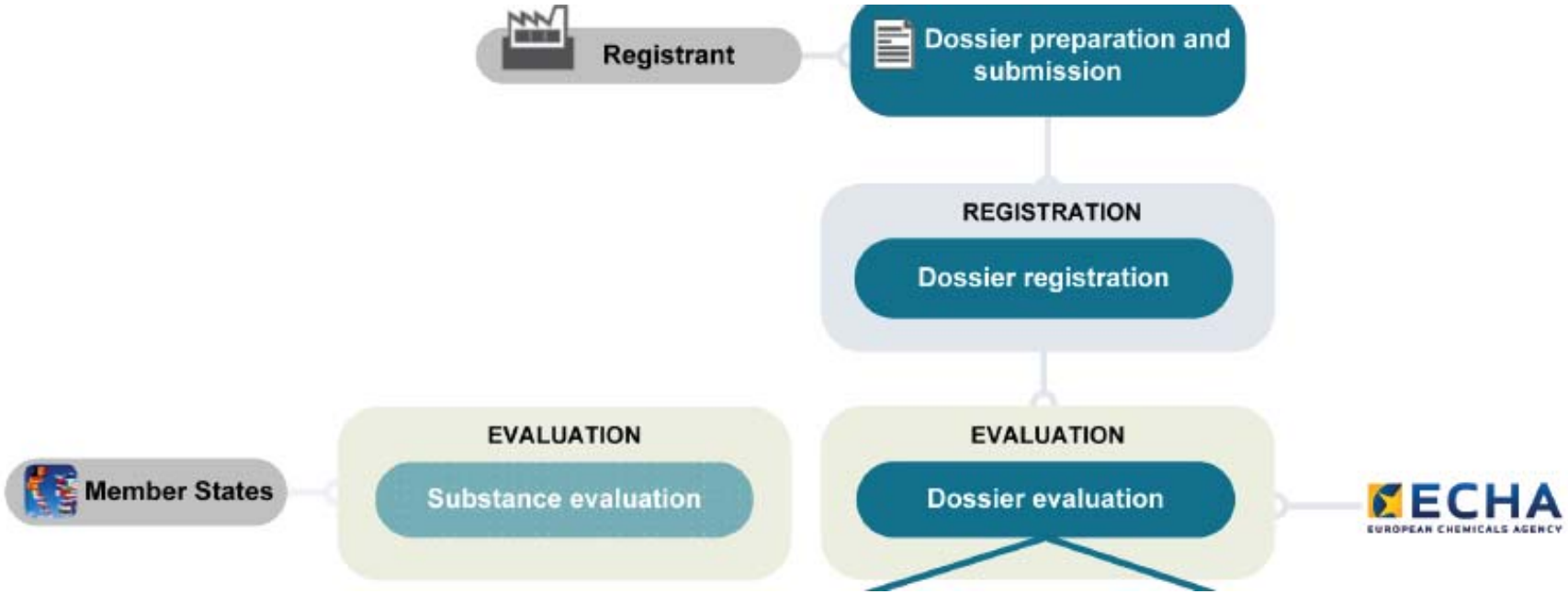
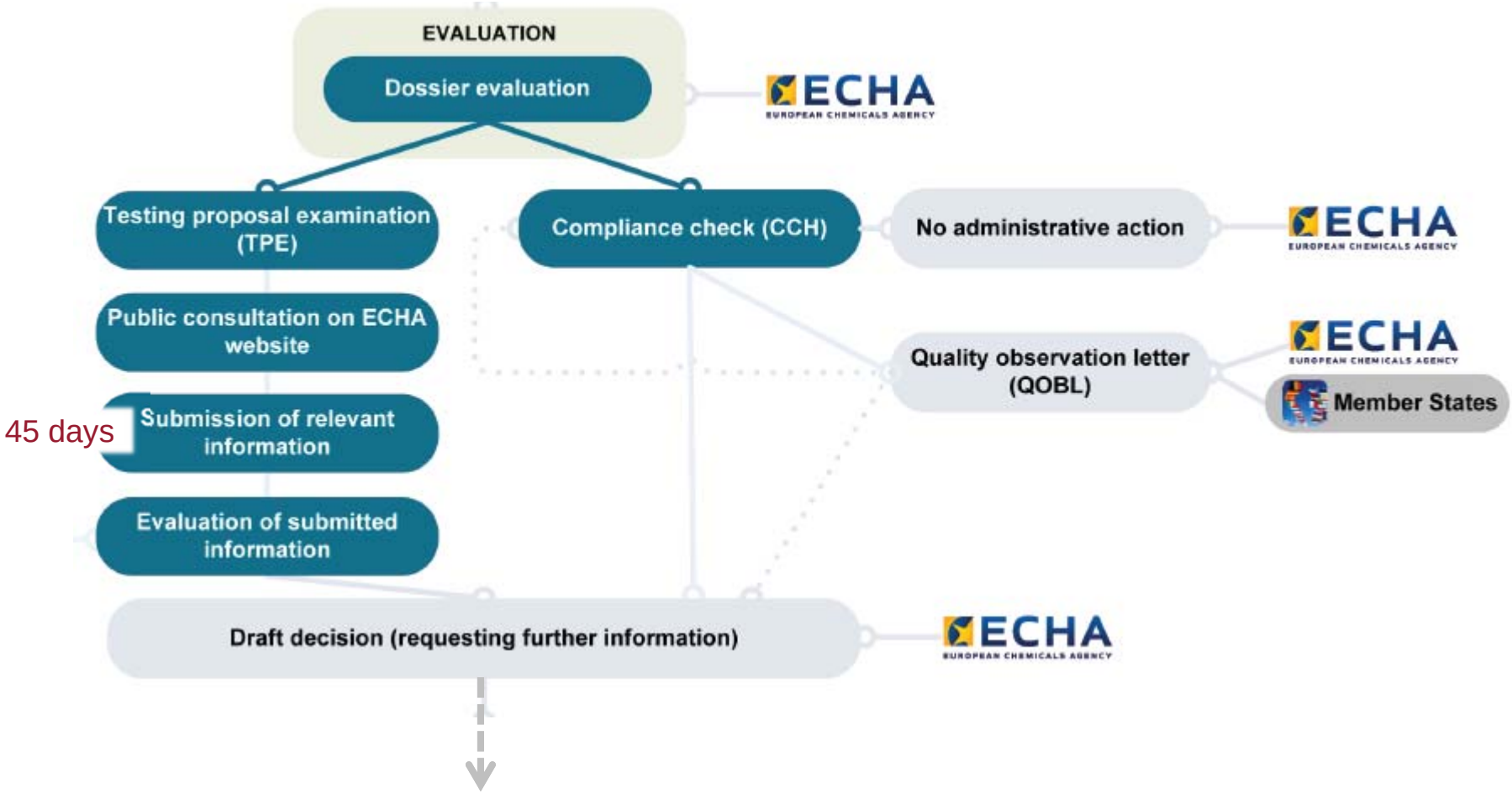
Dossier evaluation / substance evaluation: actors involved



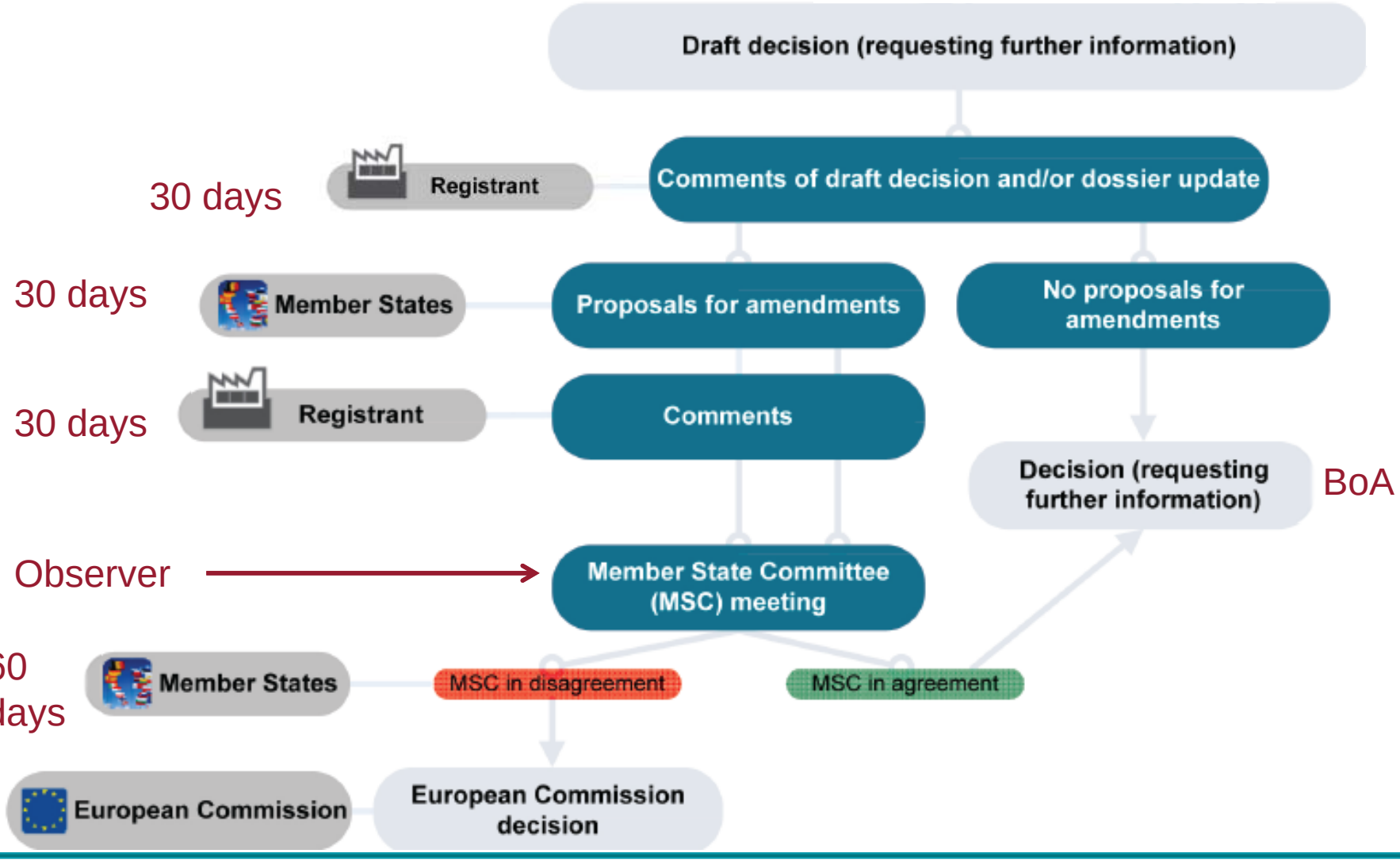
Source: http://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure

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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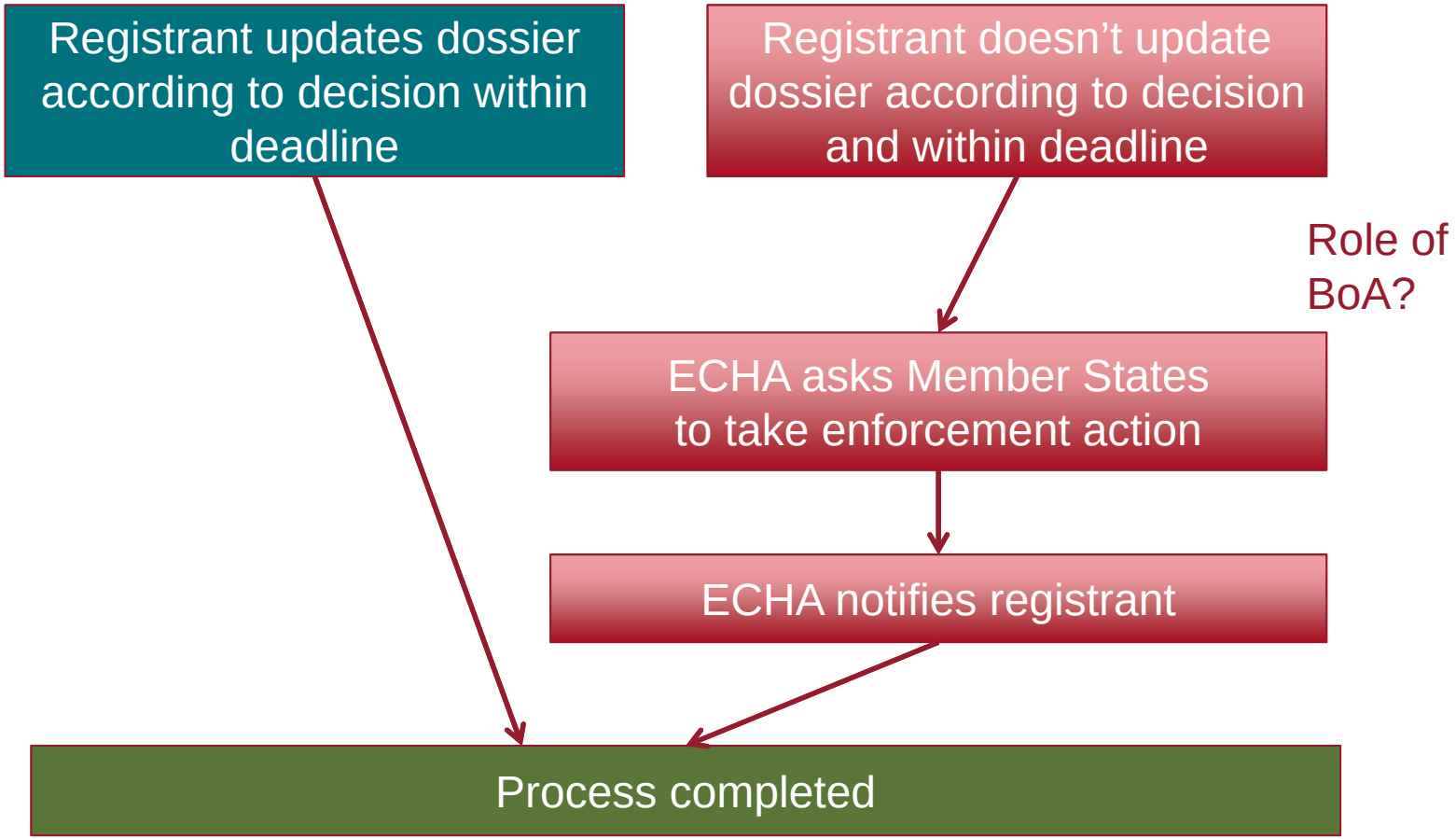
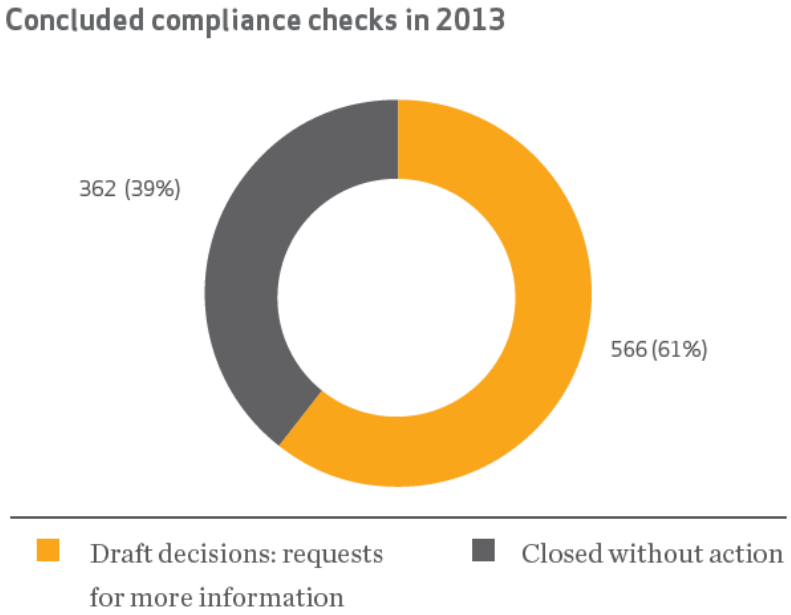
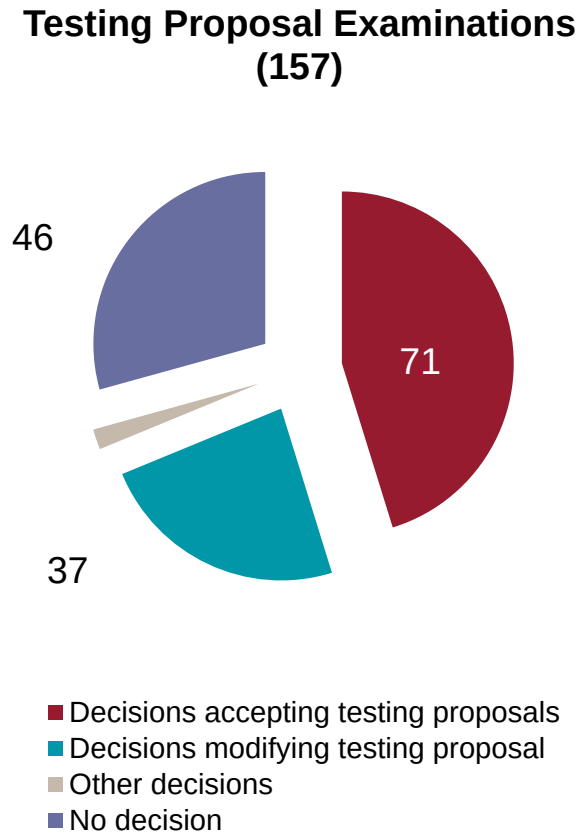
Outcome of dossier evaluation



Outcome of dossier evaluation





Source: ECHA's Evaluation report 2013: knowing more, getting safer

Source: ECHA and Steptoe & Johnson LLP

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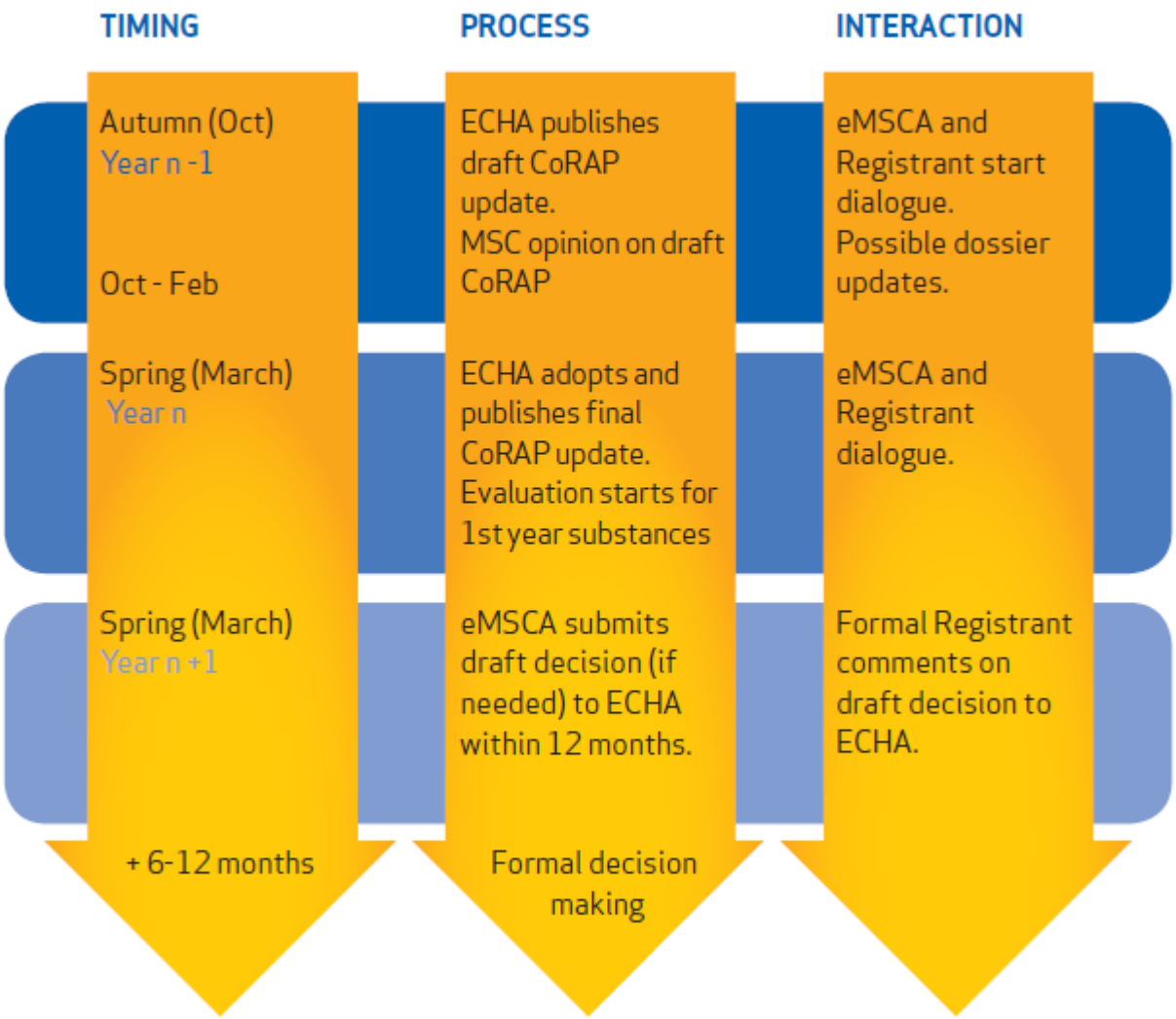
Substance Evaluation

- 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: 26 March 2014 for 2014-2016
  - 51 substances are being evaluated in 2014 by 20 Member States
- May result in a decision ordering additional testing beyond standard REACH information requirements
- 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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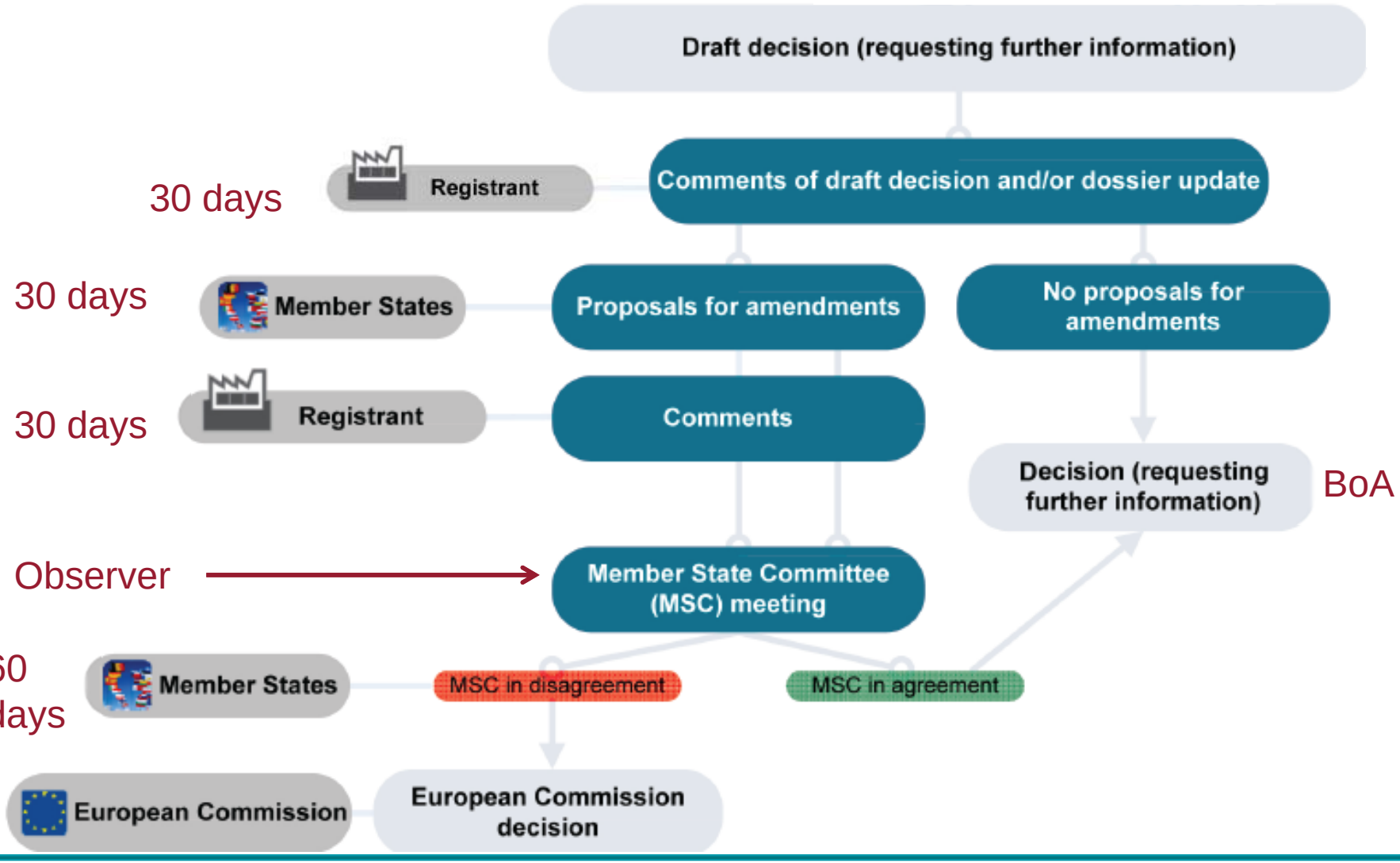
Process leading to final decision



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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.
- 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.

Substantive considerations (previous cases and BoA decisions)

REACH evaluation (previous cases and BoA decisions)

A few principles can be derived from previous experience and BoA decisions

- ECHA's margin of discretion applies to the assessment of the need for further information and to the determination of what further studies are appropriate to address the concerns identified
- 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

- A-005/2012
  - 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. Consistently with case law of the European Courts applicable to the administrative duties of EU institutions, the Board of Appeal also held that ECHA is under a duty to examine carefully and impartially all the relevant elements of the individual case.
  - In this specific case, the Board of Appeal found that ECHA exceeded its margin of discretion by, among others, failing to assess all the information that must be taken into account in order to assess a complex situation.
- Different standard than the standard applied by the EU Court's to the European Commission in cases involving scientifically and technically complex cases

ECHA creates legitimate expectations – the Agency's actions cannot frustrate these expectations

- Legitimate expectations 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 case A-003/2012
  - See ECHA practice of engaging in dialogue with registrants

Registrants must present their comments through dossier updates and formal comments

- Case A-004/2012
  - The BoA held 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."

- Case A-006/2012
  - The BoA held 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

Board of Appeal Decisions: conclusions on specific technical aspects

BoA Decisions – A useful source of technical information for dossier compliance (1)

- BoA composed of legal experts and scientific experts. Case are carefully analysed also for its scientific merits
- Decisions are a unique source of information providing guidance to other registrants
- Out of about 20 decisions (8 were withdrawn) half a dozen deal with issues of scientific matters
- Most of them relate to ECHA's Decisions under Article 51 (dossier evaluation)

BoA Decisions – A useful source of technical information for dossier compliance (2)

- Disputes cover testing requested by ECHA in case the Registrant had considered a waiver or read across
- Tests under scrutiny are studies involving vertebrate animals
- As a general rule, the mere fact that tests involve vertebrate animals is not in itself sufficient to remove the need for testing

BoA Decisions – A useful source of technical information for dossier compliance (3)

These decisions provide background for dossier evaluation principally on the following aspects:

- 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

Testing strategy design

- Principle of stepwise approach to toxicity testing confirmed by BoA
- 90-d subchronic study dismissed and replaced by 28-d sub-chronic study,
- Although it is recognised that 90-d study carries more statistical power to detect an effect, BoA rejected the argument according which the uncertain results of a 28-day study justify undertaking directly a 90-d study

  (Honeywell)

Non-validated study protocols

- The right of ECHA to request further studies to the standard requirements ("column 2 studies") is not contested by the BoA, subject to the scientific objectives being clearly defined by ECHA.
- Deviations from standard protocols are not *per se* beyond ECHA's discretion, but proportionality and animal welfare imposes that ECHA demonstrates that it is the least onerous option (annulment of a 90-d inhalation sub-chronic study on rabbit)

  (Honeywell)

Read across justification

- Must be substantiated and documented following Annex XI-1.5 requirements
- BoA recognises a broad margin of discretion to ECHA in assessing read across justifications (Dow)
- Clarification of the meaning of structural similarity [allowing the concept of a group of substances]
  - Criterion 1: structural similarity must be demonstrated,
  - Criterion 2: properties are likely to be similar, and
  - Criterion 3: the similarity of properties is shown to be “as a result” of structural similarity.

  (Momentive)

Read across justification

- Clear characterisation of the source substance is required
- Read across between a mono-constituent substance and an UVCB not rejected in principle
- Target and source substances must have same toxicological profile
- Burden of proof on the registrant
  - It is the task of the registrant to demonstrate that the substances are structurally similar and for the Agency to judge inter alia whether the facts and evidence are convincing in this regards (Momentive)
- Larger families of chemicals
  - Matrix of hard data must be sufficiently rich and strong
  - Data can be interpolated in a series but extrapolation of data unlikely to be acceptable

(from an Art 41 Decision)

Read across with degradation products

- DPMA (dipropylene glycol methyl ether acetate) and DPM (dipropylene glycol methyl ether)

  (Dow)

- Required that toxicokinetic data is provided
  - Identify degradation products
  - Show that degradation rate is sufficiently rapid

Dossier compliance checks do not necessarily cover all end points of the dossier

- There is no obligation for ECHA to review a registration in its entirety.
- Reciprocally, it cannot be argued that the absence of comment from ECHA on read across for an end point means that it should be accepted for another end point.

Consideration of ongoing testing outside REACH

- A study scheduled outside REACH and similar to the information requested by the Agency is not considered sufficient in itself to dismiss the need for a test required by ECHA (Lanxess – NTP 90-day inhalation study on same substance)
- Because:
  - Uncertainty over the timing
  - Uncertainty over the study design
  - Uncertainty on the availability of the details of information

Prenatal developmental toxicity – testing on a second species

- Clarification on Specific Rules from Annex IX 8.7.2 and Annex X 8.7.2 given by BoA (second column) (Lanxess)
- For 100-1000 tpa registrants: the obligation to test a second species is dependent on the results of the first reprotox study (or other relevant information) in Annex IX, hence not a default requirement,

whereas,

- 1000 tpa + registrants are required to perform a developmental toxicity study on a second species unless that adaptation set out in Column 2 of section 8.7 of Annex X, or the provision of Annex XI demonstrate that it can be waived.

Communicating with ECHA during the dossier compliance procedure

- New information brought in time (rules of procedure to be found in Guidance Nr 12), especially timely updates
- Achieve maximum before submitted to and agreed by MSCA
- Participate in all opportunities provided to discuss scientific issues
- Keep REACH IT mailbox operational

Potential flaws / inconsistencies

Potential flaws/inconsistencies

- Following an ECHA decision on evaluation, updates to the registration dossier are not taken into account before the expiry of the deadline provided to the registrant for submission of the requested information

- 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

- The contribution by co-registrants to costs of requested studies may differ for dossier *v* substance evaluation

- Following an ECHA decision on evaluation, updates to the registration dossier are not taken into account before the expiry of the deadline provided to the registrant for submission of the requested information

  – ECHA does not conduct compliance checks before the expiry of the deadline for the submission of the requested information – despite the REACH Regulation allowing ECHA to do so

  – Registrants expose themselves to risks of enforcement actions

- 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

  – If co-registrants refuse payment, the Lead registrant may file legal actions in national courts

  – Meanwhile, co-registrants may continue to benefit from the submission of the data and from the updated dossier

- The contribution by co-registrants to costs of requested studies may differ for dossier *v* substance evaluation

  – Studies requested as a result of dossier evaluation may be attributed to sections of the REACH Annexes – hence, coregistrants may compensate the studies if they are in the relevant tonnage band

  – Studies requested as a result of dossier evaluation, however, may not correspond to sections of the REACH Annexes, or may not be resulting from the substances reaching certain quantities.

    - REACH does not contain an obligatory mechanism establishing cost compensation after a study has been conducted and its results submitted as part of a dossier update

“Take-home” messages

“Take home” messages

- Formal opportunities for commenting must be taken into account and used, and the comments must be comprehensive – one must not assume that arguments are going to be made or added by ECHA if not expressly presented by the registrants.

- When commenting, registrants should be aware of and take into account the findings of the Board of Appeal so far, both substantively and procedurally.

- Registrants should not forget that ECHA decisions produce direct legal effects; their comments must have a technical dimension but the legal and procedural aspects should not be cast aside.

“Take-home” messages

- Deadlines prescribed by the Agency must be respected strictly, and the Agency’s guidance or indications must be followed or at least taken into consideration as relevant.
- Any opportunities for dialogue and discussions with ECHA must be pursued, in particular when ECHA invites registrants to such dialogue or discussions.
- Registrants must understand their rights to discussion with the national Competent Authorities during the substance evaluation phase, and act accordingly.
- The Lead registrant and co-registrants must agree on the actions and corresponding cost settlements. There is little in terms of “default solutions” that can be applied in case of disagreements.

And more generally, **being surprised is no excuse**!

Questions?

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Ying Huang

Ms. Huang's sophisticated understanding of the political and regulatory systems in China helps navigate clients through barriers to the Chinese market and is an integral part of Steptoe's approach and successful track record in assisting clients to achieve their commercial goals.

Ying Huang yhuang@steptoe.com

Ying Huang is a China counsel and International Government Affairs Senior Director in Steptoe's Washington office, where she is a member of the International Department. Ms. Huang has been working at Steptoe for ten years on US-China regulatory and government affairs matters after having practiced law in China for six years. Ms. Huang's practice focuses primarily on international trade remedies, government affairs, and regulatory compliance.

Ms. Huang's experience provides Steptoe clients with advice and insight that bridge US-China cultural and legal differences. She has a wide network of high-level regulatory contacts within a number of key Chinese government agencies and ministries.

Chinese Chemical Regulatory Update
中国化学品规制体系新发展

Ying Huang

Of Counsel

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Introduction to Steptoe & Johnson LLP

- Steptoe is a Washington, DC-based, international law firm with strong chemical regulatory experience. With offices in Brussels, Washington and Beijing our expertise extends across regulatory regimes.
- We offer combined services including strong technical, regulatory and government affairs capabilities to achieve our clients' objectives.
- Steptoe has rich experience assisting clients to successfully navigate complex regulatory challenges in China.

Introduction to Steptoe & Johnson LLP (cont.)

Ying Huang, Of Counsel

- Deep knowledge of Chinese chemical regulatory system and legal framework.
- Record of success in securing competitive advantages for multi-national companies working in China, including: legislative advocacy, overall compliance, and creative solutions to chemical regulatory challenges.

Content 目录

- Chapter 1: 第一章

  China REACH Regulatory Regime

  中国新化学物质规制体系

- Chapter 2:

  China Hazardous Chemicals Regulatory Regime

  中国危险化学品规制体系

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Chapter 1

China REACH Regulatory Regime

中国新化学物质规制体系

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China REACH Regulatory Regime
中国新化学物质规制体系

- **Provisions on Environmental Administration of New Chemical Substances (MEP Order No. 7)**

《新化学物质环境管理办法》（环保部7号令）

  - *Issued:* *Jan 19, 2010*
  - *Implemented:* *Oct 15, 2010*

- **Guidance for New Chemical Substance Notification**

《新化学物质申报登记指南》

  - *Issued:* *Sep. 2010（by MEP）*

- Supportive document of Order 7; the most important guideline for new chemical notification 7号令的配套文件；指导新化学物质申报的最重要的实施细则；
- Mainline: application procedure and notification categories; main contents: applicable scope, notification type and form, application procedure, required documents, special requirements for polymer, supervision after notification 主线：申报程序和申报类别；主要内容：适用范围、申报类型及形式、申报登记程序、申报材料要求、聚合物特别规定、申报登记后监督管理。

China REACH Regulatory Regime
中国新化学物质规制体系

- What chemicals are subject to notification requirements?

哪些化学物质应进**行申**报**登**记？

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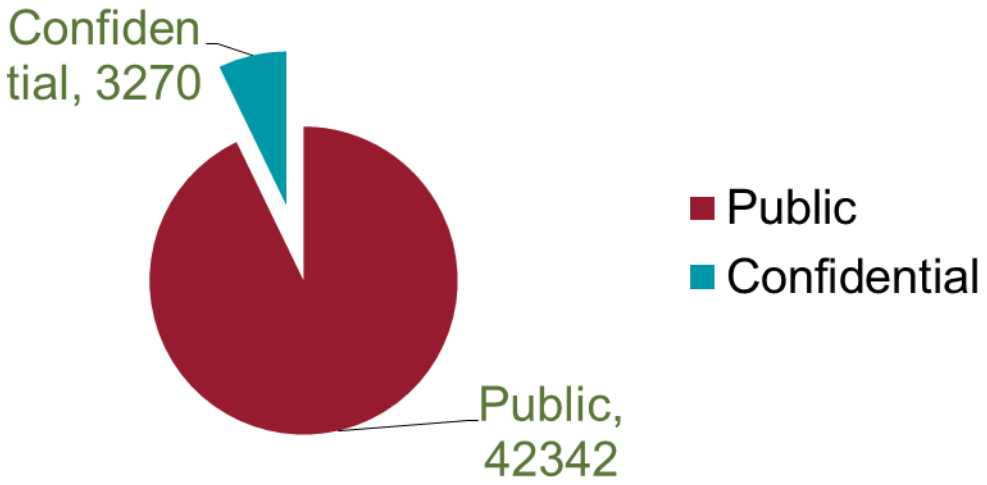
IECSC 2013

- 45612 substances

  42342 in the public portion; 3270 in the confidential section



- Confidential substances: no CAS number or molecular structure is given
  不公开物质:不公布CAS号或分子结构
- Companies have to submit a formal enquiry to CRC to check whether a substance is new or not 企业要查看某种物质是否是新物质，须向化学品登记中心提交正式的问询

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China REACH Regulatory Regime
中国新化学物质规制体系

- Who are entitled / obligated to registration?

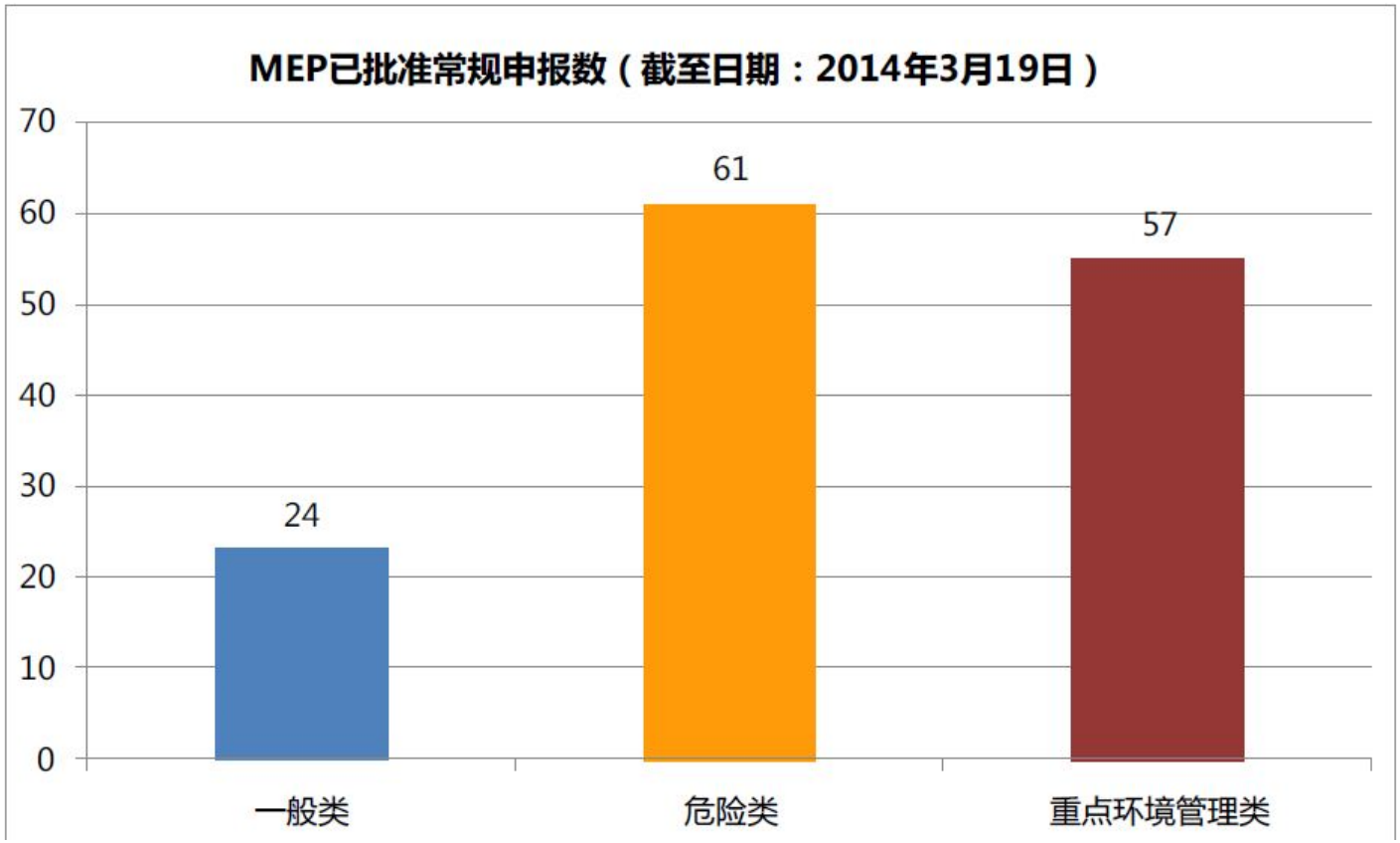
谁有权/有义务进行申报登记？

– 4 kinds of institutions　4类机构

	Domestic 境内申报人	Overseas 境外申报人
Manufacture 生产活动	**Domestic producer** 国内生产商	/
Import 进口活动	**Domestic importer** 国内进口商	**Overseas exporter (including Hong Kong, Macau & Taiwan)** 境外出口商（包括港、澳、台）
+: Domestic institution that are to change the registered use of key hazardous new chemical substances for environmental administration 拟改变已列入《名录》重点环境管理危险类新化学物质的登记用途的国内法人		

MEP's Order No. 7 – Enforcement Summary

Number of typical notifications approved by MEP (updated: 2014.03.19)



General

Hazardous

Priority Hazardous for environmental management

Total: 142

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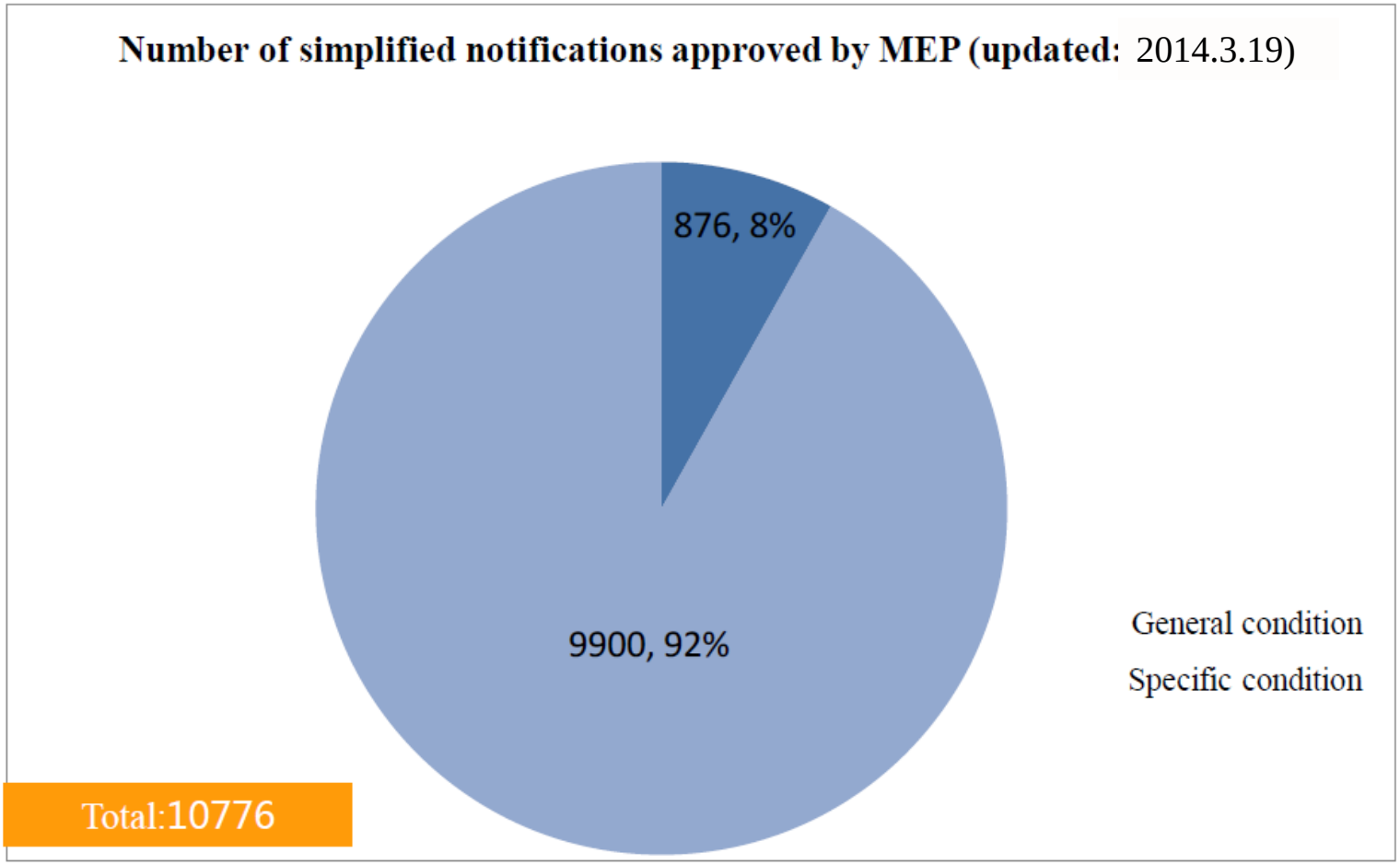
MEP's Order No. 7 – Enforcement Summary



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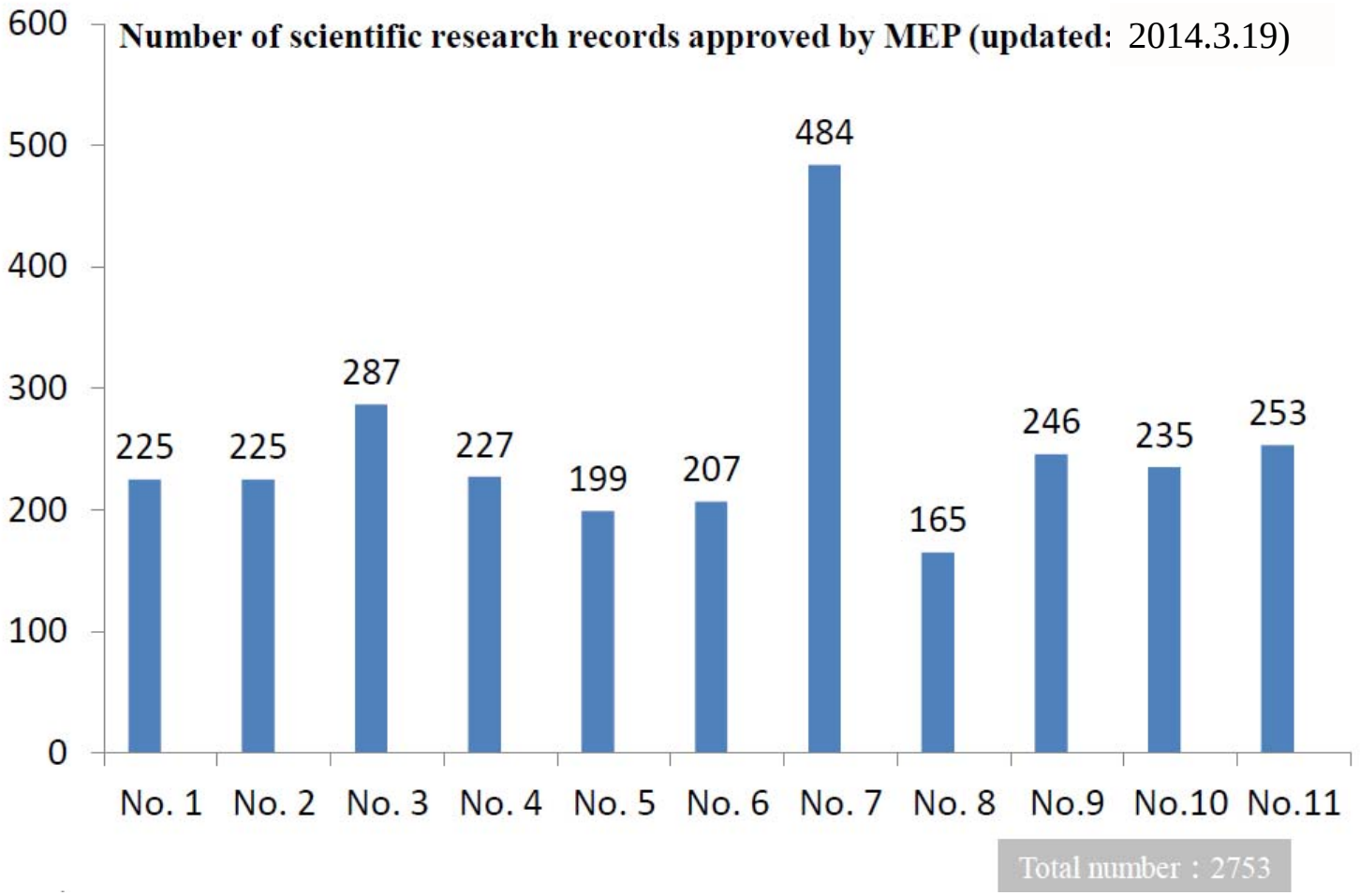
MEP's Order No. 7 – Enforcement Summary



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China REACH Regulatory Regime
中国新化学物质规制体系

- Key points in the notification procedure 申报过程中需要注意的要点

What's New?

- **Guidance for New Chemical Substance Notification under revision《新化学物质申报登记指南》正在修订中**
  - The draft for public comments is expected to publish in around 2014 June or July. 预计约2014年6月或7月会发布征求意见稿
  - Possible changes: 可能会变化的内容:
    - OR qualifications
    - ...
- **The list of high priority chemicals is on the draft 现存化学物质**

Chapter 2

China Hazardous Chemicals Regulatory Regime

中国危险化学品规制体系

China Hazardous Chemicals Regulatory Regime
中国危险化学品规制体系

Regulations on Safety Management of Hazardous Chemicals (Decree 591)
危险化学品安全管理条例（591号令）

- Lead by SAWS, involving MEP, MOT (Ministry of Transport), MPS (Ministry of Public Security), AQSIQ, NHFPC (health department), SAIC (State Administration for Industry and Commerce), SPB (State Post Bureau)etc. 由安监总局牵头，环保部、交通部、公安部、质检总局、卫生部门、工商总局、邮政局等单位参与
- Effective生效日期: Dec. 2011

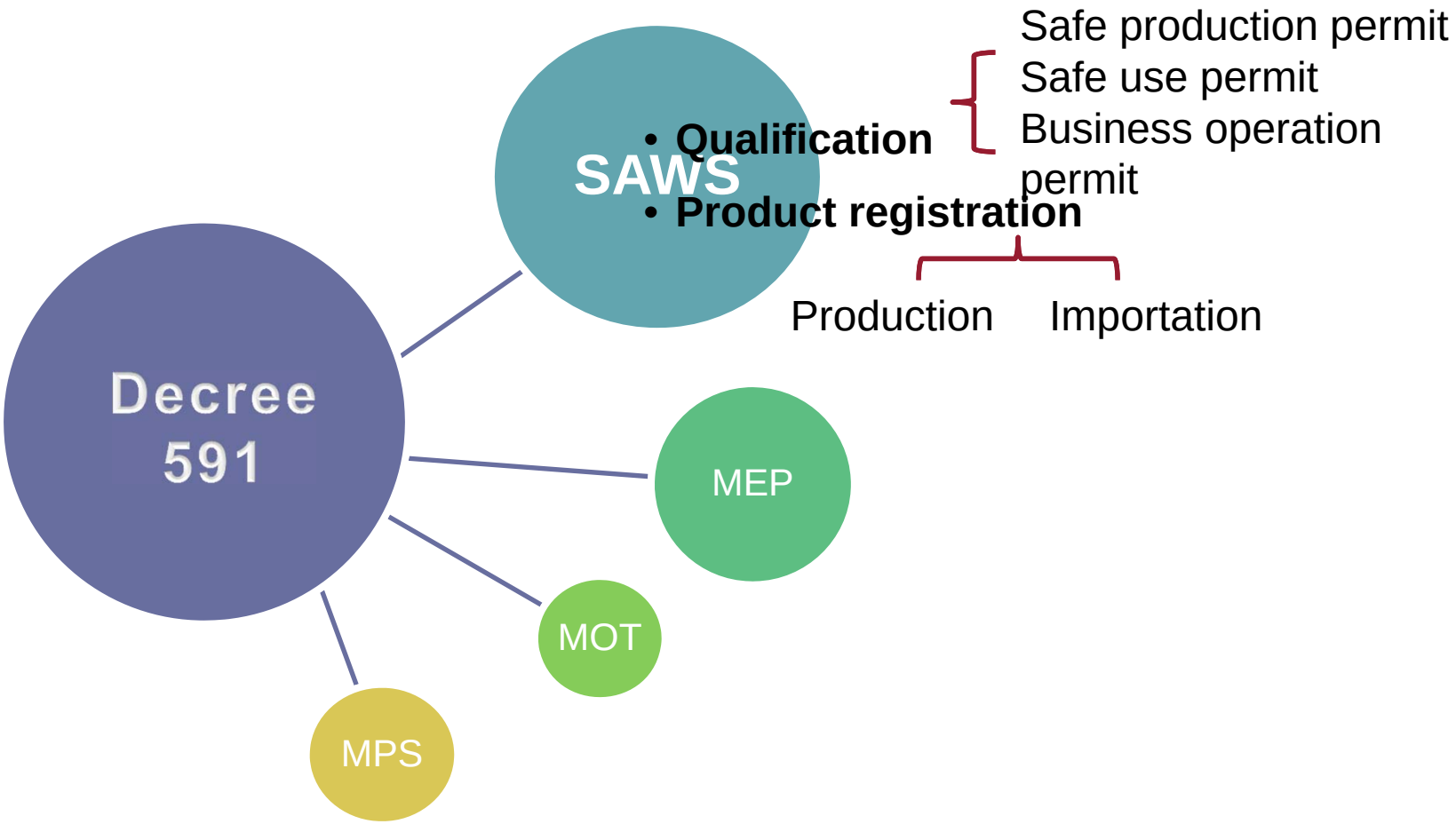
Registration for environmental administration 环境管理登记

- Issued发布日期: 2012.10.10; implemented实施日期: 2013.03.01
- Authority: MEP 监管主体：环保部
- The list hasn't been completed. 清单未完成

Toxic chemicals severely restricted on the import and export
严格限制进出口的有毒化学品

- Latest version – 2014 Catalog: issued: 2013.12.30; implemented: 2014.01.01
  ：2013年12月30日发布，2013年12月30日发布，2014年1月1日实施
- Authorities: MEP & General Administration of Customs (GAC) 监管主体：环保部和海关总署
- Currently 162 chemicals in 2014 version 现行版本中共用162种物质

China Hazardous Chemicals Regulatory Regime
中国危险化学品规制体系



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The Scope of Decree 591 – Hazardous Chemicals
591号令的范围对象——危险化学品

- ***Hazardous chemicals*** are defined as highly toxic chemicals and other chemicals which are toxic, corrosive, explosive, flammable or do harm to the human body, facilities or environment.

危险化学品,是指具有毒害、腐蚀、爆炸、燃烧、助燃等性质,对人体、设施、环境具有危害的剧毒化学品和其他化学品。

- Chemicals meeting GHS classification criteria shall be regarded as hazardous chemicals under Decree 591. 符合GHS分类标准的化学品应被视为591号令下的危险化学品。

- Out of scope: 不在此范围内的
  - Explosives for civil use;
  - Fire crackers, fireworks;
  - Radioactive substances;
  - Dangerous chemicals for national defense.

民用爆炸物品、烟花爆竹、放射性物品、核能物质以及用于国防科研生产的危险化学品

What's New?

SAWS: Catalog of Hazardous Chemicals (open for public comments)《危险化学品目录》(征求意见稿)

Sep 26, 2013
State Administration of Work Safety (SAWS) 安监总局

- The solicitation of public comments has completed 意见征求已经完成
- 2936 kinds of chemicals , including 149 highly toxic chemicals 总共2936种化学物质, 包括149种剧毒化学品
- Old version: 2002 Catalog of Hazardous Chemicals, including more than 3200 substances 旧版:2002年《危险化学品名录》, 3200多种物质

Health Hazards

Physical Hazards

Environmental Hazard

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Obligations under Decree 591
591号令下各相关方的责任

Manufacturer 生产者

- Work safety license 安全生产许可证
- Hazardous chemical registration license 危险化学品登记证
- Environmental management registration license for production and use 生产使用环境管理登记证

User 使用者

- Use safety license 安全使用许可证
- Environmental management registration license for production and use 生产使用环境管理登记证

Operator 经营者

- Operation license 经营许可证

Importer 进口商

- Hazardous chemical registration license 危险化学品登记证
- Environmental management registration license for importation of toxic chemical 有毒化学品进口环境管理登记证
- Notification for clearance of import / export environmental management of toxic chemical 有毒化学品进/出口环境管理放行通知单

Obligations under Decree 591
591号令下各相关方的责任

- Submissions 具体提交资料要求

Work safety license
安全生产许可证

- Application form/letter 申请书
- Personnel qualification certificates 从业人员资质证书
- Safety assessment report 安全评价报告
- Hazardous chemical registration license (copy) 危险化学品登记证（复印件）
- …

受理之日起45天

Use safety license
安全使用许可证

- Application form/letter 申请书
- Personnel qualification certificates 从业人员资质证书
- Safety assessment report 安全评价报告
- MSDS and safety label 安全技术说明书和安全标签
- …

受理之日起30天

Operation license
经营许可证

- Application form/letter 申请书
- Personnel qualification certificates 从业人员资质证书
- Safety assessment report (*for operation with storage facilities only*) 安全评价报告（仅针对带有储存设施的经营申请人）
- Document of property or lease for the operating site (copy) 经营场所产权/租赁证明文件（复印件）
- …

受理之日起30天

Obligations under Decree 591
591号令下各相关方的责任

- Submissions 具体提交资料要求

Hazardous chemical registration license
危险化学品登记证

- Application form/letter 申请书
- Enterprise qualification certificates – import/export or foreign investment 企业资质证书——进出口或外资
- MSDS and safety label 安全技术说明书和安全标签
- Emergency consulting service hotlines letter of authorization for emergency consulting services 应急咨询服务电话号码或应急咨询服务委托书
- Product standards of the hazardous chemicals registered 产品标准
- …

估计40天

Environmental management registration license for production and use
生产使用环境管理登记证

- Application form (MSDS included) 申请表（其中包括化学品安全技术说明书）
- Reply of environmental impact assessment 环境影响评价文件批复
- Emergency preparedness plan 突发事件应急预案
- environmental monitoring report (for self-monitoring enterprise only) 环境监测报告（仅针对自行监测的企业）
- …

30天

Questions?

yhuang@steptoe.com

Lydia Belknap Duff, Assistant General Counsel–EHS,
W. R. Grace & Co.

As lead lawyer for environmental, health and safety matters for W. R. Grace & Co., Lydia Duff advises the company on regulatory compliance in all environmental media and product stewardship areas, response to legacy contamination, defense of enforcement actions, environmental liabilities in bankruptcy, and due diligence in transactional matters. Grace is a publicly traded specialty chemical manufacturer headquartered in the United States with 6,000 employees and diverse operations in over forty countries, including Europe, Asia, and Latin America. Ms. Duff earned her J.D. from Boston University, and an A.B. in Classics from Princeton University.

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W. R. Grace & Co.

Global Chemical Inventories – Challenges and Opportunities for Substance Evaluations

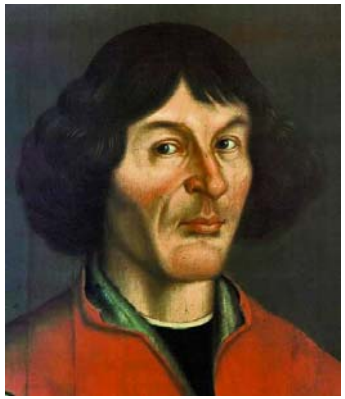
Lydia Duff

April 2014

We live in pre-Copernican times. Legally speaking, the world is still flat. Economically, it's round.

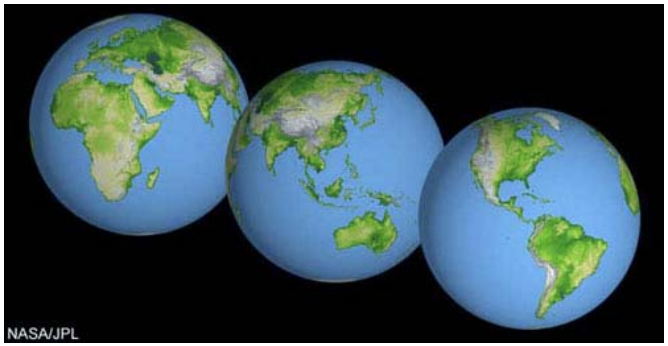
- The next century will involve much effort to bridge pragmatically between the realities of unified commerce and the multiplicity of varied legal systems.

- The efforts to establish inventories of chemicals in commerce, with associated toxicological, and ecological risk information, are in the forefront.



Globalization of Chemical Inventory Programs is Happening

Chemical Inventory Programs	
Currently In Effect	**Coming Soon**
Australia European Union Canada China Korea Japan New Zealand Philippines Taiwan Turkey United States	Cambodia India Malaysia Mexico Russia Serbia



Complexity creates responsibility for business and government

To minimize risks -

To optimize business results -

To achieve regulatory compliance –

Make chemical inventory responsibilities clear

-- in contracts

-- in regulations

-- in labels and safety data sheets

-- in web-sites and guidances

From the World to the EU

REACH – After Registrations Comes Evaluation

Registration & Dossier Evaluation

- Completeness-check on dossier - for each substance registered by each legal entity

- Fixed list of studies required

- Dossier Evaluation check for completeness of individual registration dossier

- ECHA does review

Substance Evaluation – Community Rolling Action Plan (CoRAP)

- Risk-based analysis triggers review (e.g. SVHC)

- Requests for more information can be huge

- Review covers all info in all dossiers and other info

- Member State does review

Discussion

Dr. Anna Gergely

Legal 500 EMEA has noted she “has the rare ability to give clients not only legal advice, but also a scientific interpretation of complex REACH matters,” noting that her “**excellent scientific background**” is a “**great asset**.”

Dr. Anna Gergely agergely@steptoe.com

Dr. Gergely is director EHS regulatory in Steptoe's Brussels office, where she is a member of the Regulatory & Industry Affairs Department. In a role equivalent to partner, with a PhD in analytical chemistry and quantum chemistry, Dr. Gergely is a registered European patent attorney.

Dr. Gergely is particularly experienced in providing comprehensive capabilities for companies seeking compliance strategies that cover the full range of their technical and legal needs in the following areas:
Chemicals (biocides, agro-biotechnology, cosmetics), REACH and Classification, Labeling and Packaging Food and feed and food contact materials (packaging and marketing claims and hygiene rules)
Regulation of medical devices and a range of consumer and industrial products.

In addition to the above areas, Dr. Gergely specializes in nanotechnologies as related to a broad spectrum of industrial sectors.

Food Contact Materials Under the BPR

Dr. Anna Gergely

Director, EHS Regulatory

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

Steptoe

STEPTOE & JOHNSON LLP

Content

1. General regulatory considerations for food contact materials (FCM) and articles
2. The impact of the extension of the scope of the BPR Biocidal Product Regulation
3. Specific requirements for biocides in FCM
4. Recommended follow-up

The EU Food Contact Legislation

- **Objectives of EU food contact legislation (Framework regulation):**
  - Effective functioning of internal market
    - free circulation of goods
  - The protection of consumer health
    - principle of inertness – no migration (unless exempt)
  - The protection of consumer interests
    - do not mislead consumers
- **Other objectives ensured by other EU laws:**
  - Product safety: EU Product Safety and Liability Directives
  - Food safety: EU Food Law
  - Workers' safety: EU legislation for safety of workers
  - Protection of public health and the environment: EU Chemicals Legislation: REACH; Biocidal Products Regulation

Framework Regulation (EC) No. 1935/2004

Definition of FCM

- "food contact materials" = materials and articles, including active and intelligent food contact materials, which in their finished state
  - are intended to be brought into contact with food – OR
  - are already in contact with food and were intended for that purpose – OR
  - can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use

Framework Regulation

Groups of materials and articles which may be covered by specific measures (Annex I)

- 1. Active and intelligent materials and articles
- 2. Adhesives
- 3. Ceramics
- 4. Cork
- 5. Rubbers
- 6. Glass
- 7. Ion-exchange resins
- 8. Metals and alloys
- 9. Paper and board
- 10. Plastics
- 11. Printing inks
- 12. Regenerated cellulose
- 13. Silicones
- 14. Textiles
- 15. Varnishes and coatings
- 16. Waxes
- 17. Wood

Framework Regulation

General requirements

- **Article 3: General requirements**:
  - Manufacture in compliance with good manufacturing practice so that under normal or foreseeable conditions of use, they do not transfer constituents to food in quantities which could:
    - endanger human health – OR –
    - bring about unacceptable change in composition of food – OR –
    - bring about deterioration in the organoleptic characteristics
- The labeling, advertising or presentation of a material or article shall not mislead the consumers.

Framework Regulation

Specific measures

- For the groups of materials and articles in Annex I specific measures may be adopted
  - Positive list with specific restrictions
  - Specific provisions protecting human health
  - Basic rules for checking compliance
  - Rules for sampling and methods of analysis
  - Specific provisions for traceability; publicly available Community Registers
  - Individual authorisation, if necessary
- National measures
  - In the absence of specific measures, Member States may maintain or adopt national provisions (subject of the Principle of Mutual Recognition)

Plastics Regulation (EU) No 10/2011

Definitions

- **Plastic:** polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles.
- **Additive**: a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article which is intended to be present in the final material or article.
- **Plastic materials and articles:**
  - (a) materials and articles and parts thereof consisting exclusively of plastics;
  - (b) plastic multi-layer materials and articles held together by adhesives or by other means;
  - (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
  - (d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
  - (e) plastic layers in multi-material multi-layer materials and articles

Plastics Regulation

Union list of authorized substances

Article 5: Union list

- Only substances included in Union list may by intentionally used in manufacture of plastic layers in plastic materials and articles
- Includes:
  - Monomers and starting substances
  - Additives excluding colorants
  - Polymer production aids excluding solvents
  - Macromolecules obtained from microbial fermentation
- List may be amended

Plastics Regulation

Substances not on Union List

Article 6: Derogations for substances not included in Union List

- Colorants, solvents and polymer production aids;
  - Comply with Article 3 requirements of Framework Regulation and national law
- Salts (Aluminum, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorized acids, phenols or alcohols), mixtures of authorized substances;
- Polymeric additives and Polymeric starting substance
  - Mw > 1000 Da; if capable of functioning as main structural component of final materials/articles
  - Covered by authorisation of monomer - restrictions and specifications of the Union list
- Non-intentionally added substances (NIAS)
- Aids to polymerisation
- Substances in the Provisional List (remaining **only surface biocides**)

Extension of the scope of the BPR

	BPD	BPR
Food Contact materials and articles	**Article 1(j)** The Directive shall **exclude products** that are defined or within the scope of Council Directive 89/109/EEC (now Regulation 1935/2004) on materials and articles intended to come into contact with foodstuffs	**Article 2(2) ..**this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments: **No exemption for FCM under Regulation 1935/2004**
Biocidal product	Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, **intended to** destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or **generating** one or more active substances**, with the intention of** destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action. **A treated article that has a primary biocidal function shall be considered a biocidal product.**
Treated article	None	Any substance, mixture or article which has been treated with, or **intentionally** incorporates, one or more **biocidal products**.

Food contact materials and articles and Biocides

- Products within the scope of Regulation 1935/2004 on Materials and articles intended to come into contact with food (the Framework Regulation) are no longer excluded from the scope of the BPR
- Scope of the Framework Regulation:
  - Materials and articles, including active and intelligent food contact materials and articles, which in their finished state:
    - are intended to be brought into contact with food; or
    - are already in contact with food and were intended for that purpose; or
    - can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.
- Annex I of Regulation 1935/2004 lists 17 groups of materials covered by its scope; including Plastics, Paper, Rubber, Glass, Ceramics, Silicones, Textiles, Wood; but also Printing inks, Adhesives, and Coatings

Food contact materials and articles and Biocides

- Potential Biocide Product Types (PT) in food contact applications in any material category:
  - Surface biocides (PT4) – intended technical effect in the food contact article;
  - Process biocides (PT 6, 7, 9, 11, 12) – not intended to have an effect and to be present in the final food contact material or article;
  - Food preservatives (in active packaging applications) – intended to be released from the packaging into food, for a technological effect in food;
- All these were previously exempt from the scope of the BPD; now they are covered by the BPR; either as Biocidal Product (BP) or Treated Article (TA)

Relevant Product Types

- Product-type 4: Food and feed area disinfectants
  - Products used for the disinfection of equipment, containers, consumption and utensils, surfaces or pipe-work associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals
- Product-type 6: Preservatives for products during storage
  - Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life
- Product-type 7: Film preservatives
  - Products used for the preservation or films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works

Relevant Product Types (cont.)

- Product-type 9: Fibre, leather, rubber and polymerised materials preservatives
  - Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textiles products by the control of microbiological deterioration
- Product-type 11: Preservatives for liquid-cooling and processing systems
  - Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels
- Product-type 12: Slimicides
  - Products used for the prevention or control of slime growth on martials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction

Regulatory considerations for food contact plastics materials and articles

- Plastics Regulation 10/2011 has a positive list for all authorised additives (with some important derogations) – the Union list
  - 'additives' means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;
  - 'polymer production aid' means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;
- Surface biocides are considered additives, so for plastics applications they should be listed on the Union list
- Process biocides may still be used as Polymer Production Aids (PPAs) are under derogation from the Union list
- (Food preservatives still excluded from the scope of the BPR, as covered by Regulation (EC) No 1333/2008 on food additives)

Regulatory considerations for food contact plastics materials and articles (cont.)

Multiple regulatory overlap:

- Dual authorisation is the proposed approach in Discussion document from the Commission: Draft February 2013:
  - ECHA for authorising the active substance
  - EFSA for establishing use restrictions
- Dual regulation:
  - Under the Food contact legislation:
    - Some surface biocides as additives are under derogation from the Union list: listed in the so called Provisional list, permitted in food contact plastics, their use is subject to national law and FR
    - Process biocides as PPAs are also under derogation from Union list, only subject to national law and FR
  - Under the BPR most of these applications are **considered treated articles**, subject to Article 58 requirements under the BPR, harmonised at EU level

Treated articles

- **Treated articles** were not explicitly covered by BPD unless they were biocidal products themselves
- Guidance to address individual examples in the Manual of Decisions (MoD); focusing on the **biocidal effect** of treated articles, contrasting:
  - Internal effect: intended to preserve the article itself, the treated article is **not** a biocidal product (e.g. treated plastics or paper)
  - External effect: treated article is intended to act as a biocidal product
- BPD did **not cover** imported articles for an internal effect. No requirement to use EU approved actives
- **BPR introduced changes that explicitly addressed treated articles; including food contact materials and articles**
- Specific chapter for treated articles which are not biocidal products
- Compliance with the BPR requires a well structured transition period

Treated Articles under the BPR (Regulation 528/2012)

- BPR devotes a specific chapter (Chapter XIII) to treated articles which are not biocidal products (no primary biocidal function):
- Article 58(2): A treated article shall not be placed on the EEA market unless all active **substances contained in the biocidal product** that **it** was treated with or incorporates are EU approved for the relevant PT and use; and the restrictions are met (exception: fumigation and disinfection of premises)
  - placed on the market means: first making available as the treated article itself
  - contained in the biocidal product means: its presence in the treated article is not the requirement
  - it was treated with or incorporates means: the treated article itself and not of its component parts (see *infra* relevance for Complex articles)
  - biocidal product that it was treated with or incorporates means, that
    - First, the intention to use the active substance in the biocidal product is required
    - Second, the intention to use this biocidal product to treat with or incorporate into an article is required

Recommended follow-up

- Most of the food contact applications falling under the Framework Regulation would be Treated articles under the BPR – with a binding positive list for plastics materials and articles
- To avoid legal uncertainty in a dual approval process - beyond the existing uncertainties related to complex articles - it would be necessary:
  - Exclude surface biocides for use in food contact plastics materials and articles from the scope of the Union List under the Plastics Regulation and refer their authorisation to their authorisation under the BPR
  - Review derogation under Article 6 of the Plastics Regulation for Provisional list
  - Coordinate ECHA and EFSA for the active substance authorisation and restrictions in food contact use (SMLs)
- Transition regulated by the BPR rules – Article 93 applies
- Specific legislative changes in national legislation for incorporating the new biocides measure under the BPR – replacing binding national rules for biocides

Questions?

Please share your ideas during our brainstorming panel discussions with the Commission

agergely@steptoe.com

Ying Huang

Ms. Huang's sophisticated understanding of the political and regulatory systems in China helps navigate clients through barriers to the Chinese market and is an integral part of Steptoe's approach and successful track record in assisting clients to achieve their commercial goals.

Ying Huang yhuang@steptoe.com

Ying Huang is a China counsel and International Government Affairs Senior Director in Steptoe's Washington office, where she is a member of the International Department. Ms. Huang has been working at Steptoe for ten years on US-China regulatory and government affairs matters after having practiced law in China for six years. Ms. Huang's practice focuses primarily on international trade remedies, government affairs, and regulatory compliance.

Ms. Huang's experience provides Steptoe clients with advice and insight that bridge US-China cultural and legal differences. She has a wide network of high-level regulatory contacts within a number of key Chinese government agencies and ministries.

Reform of China's Disinfectant Regulatory System: Are You Ready?
中国消毒剂规制体系改革:你准备好了吗?

Ying Huang

Of Counsel

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

Steptoe

STEPTOE & JOHNSON LLP

Introduction to Steptoe & Johnson LLP
世强律师事务所简介

- Steptoe is a Washington, DC-based, international law firm with strong chemical regulatory experience. With offices in Brussels, Washington and Beijing our expertise extends across regulatory regimes.

  世强律师事务所总部位于美国华盛顿，在化学品规制领域拥有丰富经验。世强在布鲁塞尔、北京和华盛顿均设有办公室，我们的专业知识覆盖到各国相关监管体系。

- We offer comprehensive services including strong technical, regulatory and government affairs capabilities to achieve our clients' objectives.

  我们为客户提供综合服务，包括强大的技术、法规监管和政府事务的业务能力，以帮助我们的客户实现目标。

- Steptoe has extensive experience assisting clients in successfully navigating the complex regulatory challenges in China.

  世强曾多次帮助客户成功克服中国复杂的法律监管挑战。

Introduction to Steptoe & Johnson LLP (cont.)

Ying Huang, Of Counsel

- Expert knowledge of Chinese chemical regulatory system and legal framework.
- Record of success in securing competitive advantages for multi-national companies working in China, including: legislative advocacy, overall compliance, and creative solutions to chemical regulatory challenges.

Content 目录

Steptoe
STEPTOE & JOHNSON LLP

Chapter 1: 第一章

Background of the reform of China's disinfectant regulatory system

中国消毒剂规制体系改革的背景

Reform of China's disinfectant regulatory system 中国消毒剂规制体系改革?

- **Background 背景**
- **New regulations 新法规**
  - Bases for Determining New Materials, New Processes and Technologies and New Sterilization Principles for the Production of Disinfectants and Disinfecting Apparatuses 利用新材料、新工艺和新杀菌原理生产消毒剂和消毒器械判定依据

  （2013.12.20）
  - The Regulation of the Health Administrative Approval of New Disinfectant and New Water-related Products 新消毒产品和新涉水产品卫生行政许可管理规定
  - Provisions on Applications for New Disinfectant Products and Acceptance of Applications 新消毒产品申报受理规定

  （2014.02.11）
- **Old system – pre-market approval 旧体系——上市前审批**
- **New system – post-market supervision 新体系——上市后监管**

Chapter 2: 第二章

“Three new” disinfectant vs. “non-three-new” disinfectant

“三新”消毒剂 vs “非三新”消毒剂

What is “Three New” Disinfectant
什么是“三新消毒剂”

Definition of “disinfection” “消毒”的定义

- **China**: *Technical Standard For Disinfection*, 2002, Article 1.3.1《消毒技术规范》

  Treatments that kill or eliminate pathogenic microorganisms on the transmitting vector, making it harmless 杀灭或清除传播媒介上病原微生物，使其达到无害化的处理

- **EU BPR** (No 528/2012, Biocidal Products Regulations) “Main Group 1: Disinfectants”

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How to Apply 申报程序

- **Step 1: production capability check - by provincial health inspection authority** 第一步：省级卫生监督机构进行生产能力审核

Submissions 需要提交的材料：

- Application form 生产能力审核申请表;
- Opinion form 生产能力审核意见表;
- Product formula, structural diagram and function mechanism 产品配方、结构图和作用原理;
- Brief description and diagram of production techniques 生产工艺简述和简图;
- Inventory list of manufacturing equipment and inspection equipment 生产设备及检验设备清单;
- Design draft of product instruction, label or nameplate 说明书、标签或铭牌设计样稿;
- A color photo of the product (for disinfecting apparatus only) 产品彩色照片（消毒器械）;
- For commissioning manufacture: the contract of commissioning manufacture that both parties signed on 委托生产的还应当提供双方签订的委托生产协议书;
- Other materials required 省级卫生监督机构要求提供的其他材料。

焦点:样品

How to Apply 申报程序

- **Step 2: materials submission – NHFPC 第二步：向国家卫生计生委提交书面申请材料及样品**
  - Hygiene administrative license application form for new disinfectant products新消毒产品卫生行政许可申请表;
  - Examination and verification opinion for production capacity by provincial hygienic supervision authority 省级卫生监督机构出具的生产能力审核意见;
  - Research and production report 研制报告;
  - Quality standard 质量标准;
  - Inspection methods 检验方法;
  - Certifications reflecting permission from the producing countries (regions) to allow the production and sales of the product 产品生产国(地区)允许在当地生产销售的证明文件(进口新消毒产品);
  - Letter of authorization of the responsible organization in China (for imported new disinfectant products)在华责任单位授权书(进口新消毒产品);
  - Letter of commission for application (needed for commission application)申报委托书(委托代理申报时需要提供);
  - Other materials that may contribute to the assessment 可能有助于审查的其他材料 。

另附送审样品1件。A sample shall be attached for review.

焦点:检验报告

“Three New” Approval Procedure “三新”审批程序

- **Application and acceptance** 申报和受理
  - 5 days
- **Expert review** 专家技术评审
  - National Center for Health Inspection and Supervision - *organize* expert review: within 60 days 卫生监督中心60个工作日内组织专家进行技术评审
  - Expert review period: unsettled 专家评审时长：不确定
- **NHFPC issues approval decision** 国家卫生计生委作出许可决定
  - 20 + 10 days
    - 20 days since receiving the expert review result; 自收到技术评审结论之日起20个工作日内作出
    - Additional 10 days can be granted if NHFPC cannot make a decision within 20 days. 20个工作日内不能作出卫生行政许可决定的，可以延长10个工作日

Imported "Three-New" Product Approval Procedure
进口"三新"产品审批程序

- **Additional application materials:** 所需提交的材料
  - Certifications reflecting permission from the producing countries (regions) to allow the production and sales of the product 产品生产国（地区）允许在当地生产销售的证明文件（进口新消毒产品）；
  - Letter of authorization of the responsible organization in China (for imported new disinfectant products) 在华责任单位授权书（进口新消毒产品）；

- Note: 注意
  - the *provincial production capability check opinion* is still needed; 对于进口产品，*省级卫生监督机构生产能力审核意见*仍是必须的
- Under very special circumstances, during expert review, if experts deem necessary, the authority will send inspection staff for on-site inspection 在特殊情况下，若专家评审时认为必要，则会派专人赴生产地进行现场审查或核查

“Non-Three-New” Procedure - Disinfectants Hygiene Assessment “非三新”产品——卫生安全评价程序

Steps:

- Conduct designated tests for inspection 完成指定项目的测试
- File record with local authorities 向地方部门备注/备案

Submissions 提交材料:

- Inspection report, enterprise standards applied, product labels and introduction, certificate for production and sales as well as customs report form (for imported products), and hygiene license (for domestic products)

  检验报告、企业标准、标签说明书、进口产品销售证明及报关单、国产产品生产企业卫生许可证

- New regulation: Provisions for Hygienic Safety Evaluation of Disinfection Products (in the processing of finalizing) 新法规正在酝酿:《消毒产品卫生安全评价规定》

Chapter 3: 第三章

Disinfectant for food contact application

食品用消毒剂

Disinfectant for Food Contact Application
食品用消毒剂

- **Step 1**: Check against the List –
  - Inventory of Food Disinfectant Ingredients (2009)

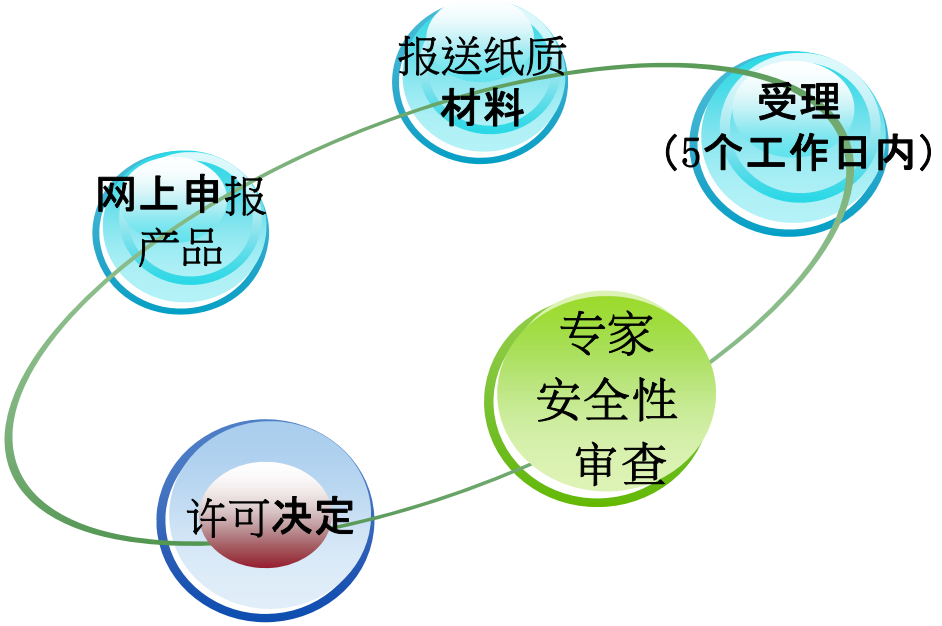
    食品用消毒剂原料(成份)名单(2009版)

    -- 68 items

- **Step 2:**
  - Not on the list ⟶ move to be included in the list
  - On the list ⟶ for the end product:
    - New product? ⟶ see page 9;
    - Existed product? ⟶ see page 13.

Procedure to be on the List of Food Disinfectant
食品用消毒剂新品种的许可程序

- User registration
- Obtain user name and password from the center
- Apply for the product online
- Provide written materials
- Receive notice of acceptance or notice of rejection within 5 days
- Organize the safety review by experts within 60 days
- Grant licensing and announce to the public; deny licensing and give written reasons



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Procedure to be on the List of Food Disinfectant
食品用消毒剂新品种的许可程序

- Application form申请表
- Physical and chemical properties理化特性
- Technical necessity, purpose and conditions of use技术必要性、用途及使用条件
- Production process生产工艺
- Quality specifications, inspection methods and inspection reports质量规格要求、检验方法及检验报告
- Toxicology safety assessment data毒理学安全性评估资料
- Migration and/or residue, estimated dietary exposure and the method of assessment迁移量和/或残留量、估计膳食暴露量及其评估方法
- Materials or supporting documents on permitted use domestically and in other countries; and 国内外允许使用情况的资料或证明文件
- Any other materials that help the assessment 其他有助于评估的资料

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Procedure to be on the List of Food Disinfectant
食品用消毒剂新品种的许可程序

- Documentary evidence for production and sales: issued by the relevant department or institution of the exporting country;生产销售证明：由出口国相关部门或者机构出具；
- Documentary evidence proving that the qualification of the manufacturer has been reviewed or certified: issued by the relevant institution or organization in the country (region) where the manufacturer is located. e.g. manufacturer's GMP certificate; 生产企业审查或者认证证明：由生产企业所在国有关机构或者组织出具，例如生产企业GMP认证材料等；
- Chinese translation notarized by the Chinese notary organ.翻译为中文，译文应当由中国公证机关的公证。

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Procedure to be on the List of Food Disinfectant
食品用消毒剂新品种的许可程序

Safety Review Requirements 安全性审查要求

- Organize medicine, food, chemical, materials and other experts to conduct technical review of the safety of the new food-related product variety within 60 days after accepting an application; 受理后60日内组织医学、食品、化工、材料等方面的专家召开评审会议，对申报材料进行技术审查
- The applicant shall be present on-site to introduce the product and answer experts' questions.申请人到评审会现场介绍产品情况并回答专家提问
- Experts make a technical review conclusion based on the review opinions of the application materials and the replies.专家根据申请材料的审查意见以及答辩情况作出技术审查结论
- There are 3 kinds of conclusions of the technical review: supplement materials and defer review; recommend approval; recommend unapproved. 技术审查结论分三种：补充资料延期再审、建议批准、建议不批准。

Questions?

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Dr. Mitchell Cheeseman

Dr. Mitchell Cheeseman, Ph.D. mcheeseman@steptoe.com

Managing Director in Steptoe's Washington office.

Prior to Steptoe, worked for 20 years as an official in FDA's Foods Program, including leadership roles as the Deputy Director and Acting Director of the Office of Food Additive Safety.

Internationally recognized for his leadership in safety assessment of food ingredients, food packaging, and food contaminants.

Two decades of experience working within FDA's food contact materials regulatory program Including 13 years leading that program.

Led establishment of FDA's food contact notification program.

Assists food retailers, manufacturers, and food packaging manufacturers in all aspects of regulatory compliance.

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Regulating Antibacterials in Food Contact Applications in the US

Dr. Mitchell Cheeseman, Ph.D.

Managing Director, Environmental & Life Sciences

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Content

1. Relevant Statutes
2. Definitions
3. Regulatory Options
4. Food Contact Notifications
5. Food Contact Substances
6. Pesticides

Relevant Statutes

- Federal Food Drug and Cosmetic Act
  - Section 409 Food Additives (FDA)
  - Section 408 Pesticide Chemicals (EPA)

- Federal Insecticide Fungicide and Rodenticide Act (EPA)
  - Pesticide Labeling
  - Pesticide Definition Does Not Exclude Food Additives

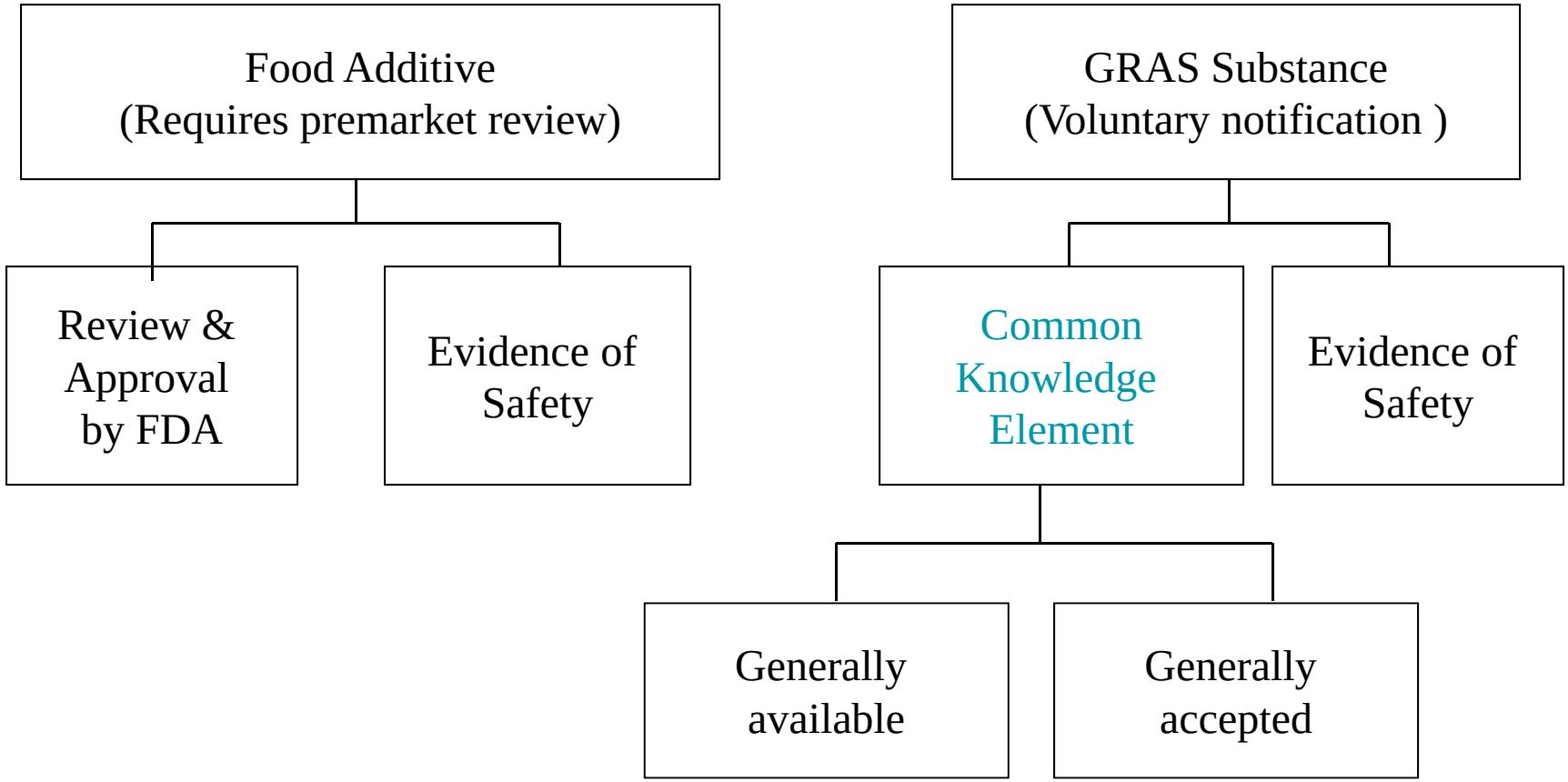
Definitions

- Food Additive
  - Any substance the intended use of which results in or may reasonably be expected to result … in its becoming a component of food … if such substance is not generally recognized as safe … except such term does not include – any substance used in accordance with a sanction or approval granted prior to [1958]

- Food Contact Substance
  - Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food, if such use in not intended to have a technical effect in food

- Pesticide Chemical (FFDCA)
  - …any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest,… (with certain exceptions)

GRAS Criteria: Comparing a GRAS Substance and a Food Additive



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Regulatory Options

- Food Contact Notification
  - 120-day Hammer Deadline
  - Web Site Listing
  - Manufacturer Specific

- Food Additive Petition
  - Ongoing Technical Effect
  - Requires a Regulation to be Published (CFR)

- Independent GRAS Determination
  - GRAS Notice (~180 days)
  - Web Site Listing

Food Contact Notifications

- 120-Day Review Period
- Data Necessary
  - Manufacturing and Use
  - Toxicological Data (More Data)
  - Environmental Assessment
- Two Phases
  - Phase 1
    - 45-60 days
    - May Request Additional Information (10 days)
    - Results in Acknowledgement Letter
  - Phase 2
    - Problems Usually Require Withdrawal

Food Contact Substances

- Biocides Used in Manufacturing Food Contact Materials
  - Slimicides in papermaking
  - Material preservatives (water-based polymers)
  - Material preservatives in the finished material (no surface antimicrobial effect)
- Biocides used on aseptic packaging

- Other Food Contact Substances?
  - Boiler chemicals
  - Biocides in process water
  - Biocides used as processing aids on food

- May Require USDA Review as Well

Pesticides

- Food Contact Surface Sanitizers
- Food Contact Substances Intended to Sanitize the Surface of an Article
- Antimicrobials Applied to Raw Agricultural Commodities

- FIFRA Pesticides
  - Labeling And Pesticide Claims
  - Will Apply to Some Food Contact Substances
  - Will Require a Second Review by EPA
  - Potential for Labeling Issues

Questions?

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Indiana de Seze

Ms. De Seze represented a consortium of companies in a data sharing dispute and an Only representative in a challenge of a decision ordering additional testing, both before ECHA's Board of Appeal.

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Indiana de Seze is a leading legal practitioner in EU chemicals regulation and competition. Ms. de Seze's practice focuses predominantly on REACH, biocides, plant protection products and other applications of chemicals requiring regulatory clearance or pre-market authorizations. Thanks to her rigorous training as a competition and commercial lawyer, Ms. de Seze delivers cutting-edge analyses and pragmatic solutions to tackle antitrust issues in the context of consortia and data sharing.

Chemicals Regulation: Ms. De Seze regularly advises clients on their registration duties and the legal consequences of substance and dossier evaluation procedures under REACH. She has formed and continues to provide legal support to consortia of companies for the purpose of joint submissions. She counsels on data protection and data sharing negotiations, having assisted in the formation of task forces and in their dealings with the competent authorities and companies. In the biocides area, Ms. de Seze helps companies in the biocidal product market to transition to the Biocidal Product Regulation and roll out successful active substance and product registration strategies across the EU.

Her litigation work in the area involves representing clients before the EU and national courts, and the Board of Appeal of the European Chemicals Agency

Craig Simpson

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Craig Simpson is a UK qualified solicitor and Senior European Legal Advisor in Steptoe's Brussels office, where he is a member of the Regulatory & Industry Affairs Department. His practice focuses on EU regulatory requirements and related commercial issues in the life sciences field and EC competition law.

Mr. Simpson's regular clients are leading multinational companies and trade associations operating at both European and international levels. His experience includes advising clients on the procedures and remedies available before the European courts.

Before joining Steptoe, Mr. Simpson was an EU regulatory lawyer in the Brussels office of a well-known London-based firm and trained with the European Commission's Directorate-General Internal Market, dealing with actions against EU Member States for infringement of EC Treaty rules on free movement of goods.

Mr. Simpson regularly lectures and publishes on matters affecting the Life Sciences industries and competition law. He is consistently recommended as a leading practitioner in the Global Counsel Which Lawyer? Yearbook for EU Life Sciences, an independent survey of leading multinational companies' approved counsel.

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Regulatory Overview of the Biocides Regime

Indiana de Seze, Senior Associate

Craig Simpson, Senior European Legal Advisor

Annual Chemicals Regulation Seminar

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Overview

1. Harmonised biocides regulation in EU
2. Basic features of biocides regulation
3. Biocidal product types
4. New features under BPR
5. New actors: the role of ECHA
6. Timing issues

Harmonised Biocides Regulation in EU: Helicopter View

- 'Biocidal products':
  - chemicals used to suppress organisms (for example, moulds, bacteria) that harm human or animal health or damage natural or manufactured materials
  - examples, bleach, antifouling paint, wood preservatives, anti-mould paint
  - categorised into 22 'product types' under 4 main groups: disinfectants, preservatives, pest control, other (antifoulants, embalming fluids)
  - new legislation expands scope of biocidal products (subject to authorisation) to expressly include:
    - biocidal products generated 'in-situ' from non-biocidal substances/mixtures
    - certain products treated with/incorporating biocidal products ('treated articles' with a 'primary biocidal function')
  - approval of actives in imported treated articles (without primary biocidal effect)
- Current legislation is Biocidal Products Regulation 528/2012
  - repealed Biocidal Products Directive 1998/8 from 1 September 2013 (continuing transitional relevance: incomplete BPD active approvals and product authorisations)

Harmonised Biocides Regulation in EU: Helicopter View

- Purpose of legislation:
  - single market in biocidal products (harmonised regulation of sale and use in EU)
  - human, animal and environmental safety
- What it covers:
  - approval (and renewal) of 'active substances' (substance/microorganism in the product with controlling effect on target organism)
  - authorisation (and renewal) of biocidal products (containing active substance)
  - data sharing and data protection re substance and product dossiers, at approval and authorisation stages
  - labelling requirements
  - new role of ECHA (Biocidal Products Committee)
  - appeal from relevant ECHA decisions (on data sharing, non-acceptance of applications, etc.)
  - central biocide registry: R4BP
  - enforcement

Biocidal Product Types

ANNEX V

BIOCIDAL PRODUCT-TYPES AND THEIR DESCRIPTIONS AS REFERRED TO IN ARTICLE 2(1)

MAIN GROUP 1: Disinfectants

These product-types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product-type 1: Human hygiene

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.

Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

Basic features of biocides regulation

- Core structures continue under BPR:
  - pre-market authorisation regime, with two levels:
    - approval for active substance (EU level), authorisation of biocidal product (national or EU)
  - positive 'Union' list of active substances
    - specific active substance/product type combinations with RMM/use conditions
  - distinction between 'existing active substances' (on market in biocidal products other than for R&D on 14.5.2000) and 'new active substances' (not on14.5.2000)
- Commission programme for review of existing active substances
  - industry previously notified substances for review by deadline
  - 'participants' (data holders) submitted application/joint dossier supporting inclusion
  - letter of access to dossier required by non-participants for BPR product authorisation
  - …and now also for inclusion on approved source list from September 2015 (Art 95)
    - addresses non-participant 'free rider' issue pending Commission inclusion decision

New features under BPR: active substances

- More streamlined review process
  - chosen CA within 365 days of validation (or longer where further info required)
  - sends assessment report and conclusions to ECHA, taking account written comments from applicant during 30 day consultation period
  - ECHA prepare and submit approval opinion to Commission within 270 days of receiving evaluation conclusions from CA
  - will apply to AS for which draft CA assessment report has been issued after 01.09.2013
- Mandatory data sharing with all active substance suppliers (Article 95)
- Nanomaterials
- Exclusion:
  - active substances that meet the criteria for CMR (1A or 1B), PBT or ED (REACH criteria)
  - unless negligible risk under realistic worst case conditions of use; or, essential; or, disproportionate negative impact on society (socio-economic analysis) → substitution
- Substitution
  - e.g. sensitiser, 2 of PBT criteria, significant proportion of impurities or non-active isomers
  - public consultation 60 days
  - approval not exceeding 7 years

New features under BPR: products

- New (more efficient) product authorisation procedures…
  - Commission estimates EUR 2.7 billion cost savings over 10 years
- Union authorisation phased in by PT until January 1, 2020
  - single procedure for Union wide market access
  - not available for certain product types or products containing excluded actives
- Simplified product authorisation (low risk, Annex I, not nano)
- Mutual recognition of product authorisation:
  - ‘in parallel’ with first authorisation (time efficient)
  - dedicated procedures for Commission to resolve MS deadlock
  - not required for Union and simplified authorisation (but notification, similar conditions of use across Union)

New features under BPR

- Market Access without authorisation: parallel trade permit
  - product sold in other MS and identical to that already sold on relevant MS market
- Mandatory data sharing between market players
  - reduction of animal testing
  - ability for ECHA to force sharing of data by data holder
  - data protection periods
- Expanded substitution powers
  - Comparative assessment during approval/renewal of product containing active which is 'candidate for substitution' (excluded, respiratory, sensitiser, etc.):
    - prohibit or restrict marketing or use if lower risk effective substitutes, no significant economic/practical disadvantages and low target resistance risk
    - if no appropriate substitute, maximum 5 years product authorisation/renewal
- Excluded actives (CMR, PBT, vPvB, endocrine disruptors)
  - approved only exceptionally for 5 years if negligible risk and disproportionate negative societal impact of non-approval

New actors: the role of ECHA

- In addition to MS CAs and Commission in product/active evaluation
- Role phased in to permit capacity/experience development
- Approval of active substance:
  - European Biocidal Products Committee Opinion on CA evaluation – basis for inclusion decision
  - existing active applications under BPR since 1 January 2014 (replaces DG JRC)
- Product authorisation:
  - Union authorisation: Commission decision taken on ECHA Opinion
  - Simplified authorisation: initial receipt and acceptance of application
  - Mutual Recognition: provide Commission with technical/scientific opinion where MR disagreements not resolved in Coordination Group
- Technical Equivalence assessment
  - is your active the same as Union listed 'reference' active?
    - where active source other than applicant for Union List inclusion
    - where same source but change in manufacturing process or location
  - application to ECHA with fee

New actors: the role of ECHA

- Active Data Access (Article 95):
  - receives active dossier on LoA
  - publishes approved sources list
- Data sharing compensation:
  - permits data sharing in absence of parties' agreement (Article 63(3))
- Maintains Register for Biocidal Products:
  - exchange of information between CAs, ECHA, Commission for applications

Timing issues

- EU biocides harmonised legislation since 1998, yet still in practice …
  - non-harmonised national product authorisation procedures for products containing unapproved existing actives
  - provisional harmonised authorisation (up to 3 years) for products containing unapproved 'new' actives (where evaluating CA recommends)
- Programme for review of existing active substances significantly delayed from 2010 to 2024
  - ambitious Commission working programme (50 actives a year…)
- Inclusion decision on active = trigger for BPR product authorisation
- Inclusion decision provides 'date of approval' deadline for lodging BPR product authorisation to remain on market

Timing issues: Transitional periods where product under BPD authorisation

- Evaluation of BPD biocidal product authorisation applications subject to:
  - more expansive BPR authorisation conditions apply if excluded active (for example, vulnerable groups such as pregnant women and children)
  - BPR comparative assessment procedure applies if product contains candidate active
- Biocidal products already BPD authorised/registered which remain on market subject to BPR:
  - BPR labelling?
- Significant transitional periods for biocidal products newly in scope (in situ products, treated articles with a primary biocidal function)

Questions?

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Darren Abrahams

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Mr. Abrahams is an English Barrister and a partner in Steptoe's Brussels office. His practice is focused on EU regulatory requirements and related commercial issues in the chemical regulatory and life sciences area. His clients are leading companies and associations in sectors including chemicals (REACH, biocides, cosmetics and pesticides), agricultural biotechnology, electronics, food and feed, metals and mining. An important part of his practice is helping clients to shape their legislative and policy environments, representing them before EU institutions, EU Member States and in the European Court of Justice.

The *PLC Which Lawyer? Yearbook* consistently recommends Mr. Abrahams in EU Life Sciences and *Legal 500 EMEA* has recognized his '**comprehensive understanding**' and 'detailed expert knowledge' of EU environmental regulation.

Who's Who Legal Environment identifies him as one of the leading individuals in EU environmental regulation, as does *Chambers & Partners Europe*, which reports the market's assessment that he is 'exceptionally hard-working and diligent.'

BPR
Data Protection, Sharing and Compensation

Darren Abrahams

Partner

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Content

DAY 1

1. BPD: From where did we come?
2. BPR Timing And Objectives
3. Protection
4. Mandatory Sharing
5. List of Active Substances (Art. 95)

DAY 2

1. Data Negotiation Process
2. Data Compensation
3. Dispute Procedure
4. Adapting Consortia

BPD or
From where did we come?

BPD: Encouraging - Not Forcing

- **2nd BPD encouraged (Art.13):**
  - **Formation of consortia/task forces to generate joint vertebrate data**
  - **Data sharing of vertebrate data (with MS option to compel)**

'The holder or holders of former authorisations and the applicant shall take all reasonable steps to reach agreement on the sharing of information, so as to avoid, if possible, the duplication of testing on vertebrate animals.

The competent authorities … shall encourage data-holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.

If it is still not possible for the applicant and holders of former authorisations of the same product to reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of former authorisations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals …'

BPD: Encouraging - Not Forcing

- **2nd Review Regulation (Art. 8) echoed this:**
  - **Requiring explanation of why a collective dossier was not submitted:**

'(1) In the preparation of the complete dossier, all reasonable efforts shall be made, inter alia, to avoid duplication of testing on vertebrate animals and, where appropriate, to establish a collective complete dossier…

5) …Where, in those circumstances, a collective dossier is not submitted, each individual dossier shall detail the efforts made to secure cooperation and the reasons for non-participation.

(6) Details shall be given in the complete dossier and in the summary dossier of the efforts made to avoid duplication of testing on vertebrate animals.'

BPR
Timing And Objectives

BPR: Timing And Objectives

- **Open season for competitors' accessing data since 1 Sept, 2013.** New data sharing and compensation rules for all data submitted under BPD and BPR applied immediately.

- **Stated objectives:**
  - create a *'level playing field....as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of* ***avoiding the establishment of monopolies****, of* ***sustaining free competition*** *between economic operators and of a fair compensation of the costs borne by data owners' (Recital 58)*

  - *'****minimise the number of tests on animals*** *and for testing with biocidal products, or active substances contained in biocidal products' (Recital 57)*

BPR: Timing And Objectives

- **Data owners lose exclusive use but should now be able to exclude 'free-riders'.** During the BPD transitional period, Member States may apply their national rules for placing biocidal products on the market. Free-riders may continue to place existing active substances on the market until the inclusion of the existing active substance into Annex I/IA to the BPD. So companies who had invested € millions in the review programme had the same market access as those who had spent nothing ('1st free rider problem').

- **Art. 89(2) BPR provides for ongoing product transitional periods**: MS may continue to apply current system on biocidal products 'for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product'.

BPR
Protection

What Can Be Protected?

- Data protection is distinct from Confidentiality:
  - Public information can be subject to data protection
  - Secret information may not be subject to data protection

  No necessary link between data protection and confidentiality.

- No definition of 'data protection' in the BPR (as under the BPD and REACH). However, clear intention to ensure nothing slips between the gaps:

  'With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.' (Recital 55)

What Can Be Protected?

- Data requirements are those for:
  - existing and new AS data (Annex II and Article 6)
  - existing and new BP data (Annex III and Article 20)

  All protected data submitted for BPD/BPR purposes. What is submitted is not limited to studies alone.

- A far more complex situation than the '12 year' rule under REACH (see Art. 25(3), REACH).

- Open Source Public Data may be subject to national copyright law. Minimum harmonisation at EU level.

Protection Periods

- All data protection periods start from when data under BPD or BPR is submitted for the first time. No cumulative protection periods once they have expired. (Arts. 60 and 95)

ACTIVE SUBSTANCE (AS)	BIOCIDAL PRODUCT (BP)
Approval of a NEW AS **15 years** from the first day of the month following the date of adoption of AS approval decision (i.e. adoption of Implementing Regulation) of each AS/product-type combination	**BP with a NEW AS** **15 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
Approval of an EXISTING AS **10 years** from the first day of the month following the date of adoption of AS approval of each AS/product-type combination If AS (product-type combination) is not already approved before Sept. 1, 2013, all data protection periods for AS (product-type combination) still under review remain until a (longstop of) **December 31, 2025.**	**BP with ONLY EXISTING AS** **10 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
RENEWAL/REVIEW of an AS approval **5 years** from the first day of the month following the decision on renewal/review of a the approval of an AS	**RENEWAL/AMENDEMENT OF BP AUTHORIZATION** **5 years** from the first day of the month following the decision on the renewal/amendment of a BP authorization

BPR
Mandatory Sharing

BPR Mandatory Sharing

- **Sharing of what? Art. 62(2):**

  – '*Where the data acquired under those tests or studies are still protected… the prospective applicant:*

  (a) shall, in the case of data involving tests on vertebrates; and

  (b) may, in the case of data not involving tests on vertebrates,

  request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.'

Ambiguity will be used to argue that hard copies are required.

BPR Mandatory Sharing

- Mandatory data sharing more extensive than REACH and PPPR.

- For **existing AS data** mandatory data sharing **not limited to vertebrate animals** but also under Art. 95(3):

  – '*to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates*'.

  – The amended BPR text also provides that the expanded mandatory data sharing rules for AS under Article 95(3) apply retroactively 'from 1 September 2013'.

- No mandatory data sharing for non-vertebrate data on:
  – **new AS**
  – **BP**

BPR Mandatory Sharing

- As an exception to the rules on **existing AS data**, mandatory data sharing **not applicable to AS 'listed in Annex I in categories 1 to 5 and 7** or to biocidal products containing only such substances'):
  - Substances authorised as food additives according to Regulation (EC) No 1333/2008
  - Weak acids
  - Traditionally used substances of natural origin
  - Substances included in Annex IV to REACH Regulation
  - Pheromones
  - Others

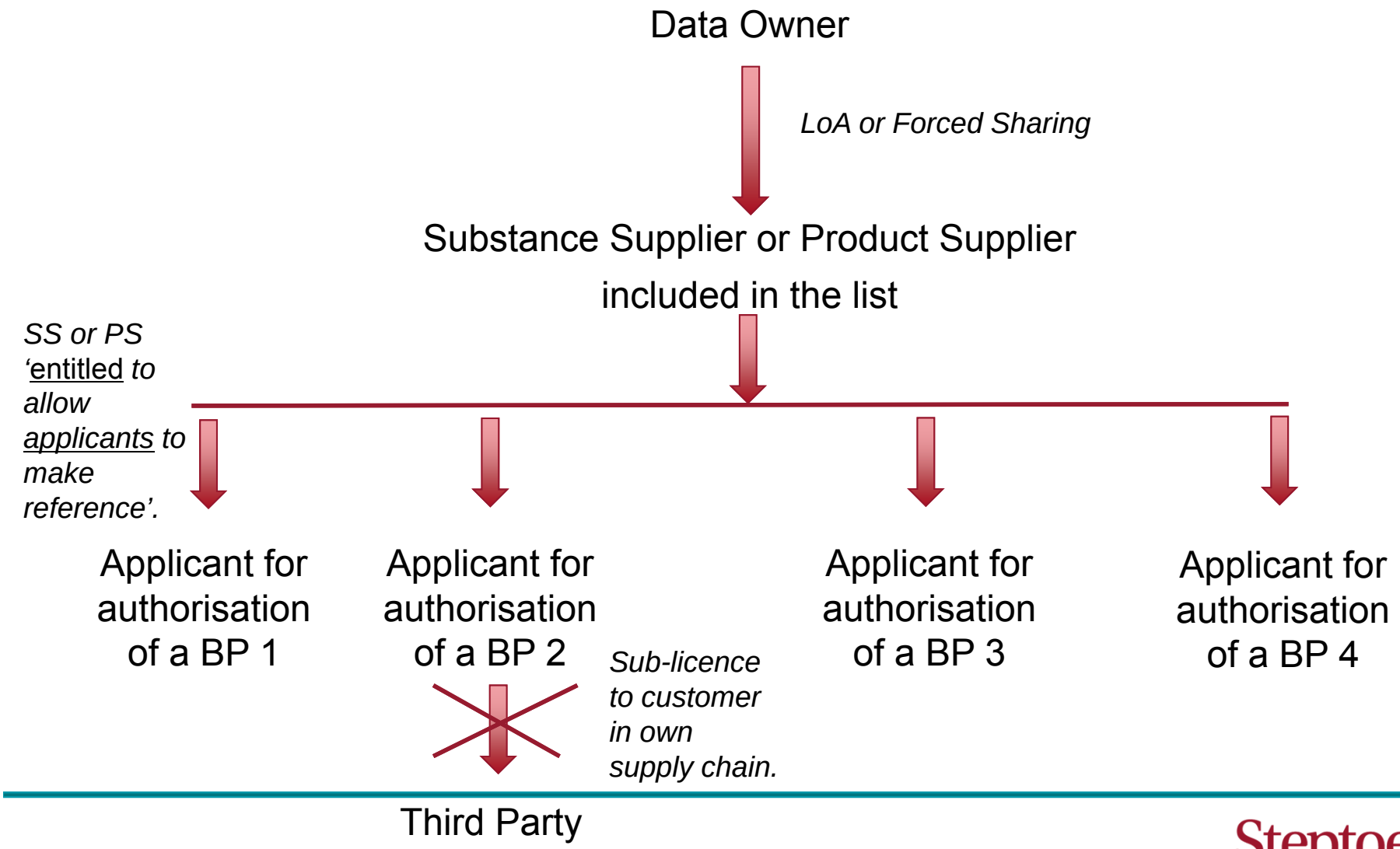
(NB: Commission Implementing Regulation (EU) No 88/2014 on procedure for amending Annex I)

BPR
List Of Active Substances

List Of Active Substances

- **As of 1 Sept. 2015 those who** (i) do not have access to a 'complete substance dossier' and (ii) therefore have not been included on the list of **approved sources** drawn up by **ECHA by will be excluded from the market**:
  - **Biocidal products** 'consisting of, containing or generating a relevant substance…shall not be made available [i.e. 'any supply'] on the market or used unless either the substance supplier or the product supplier is included in the list…for the product-type(s) to which the product belongs'.
    - '**Substance supplier' :** 'who manufactures [in EU] or imports a relevant **substance**, on its own or in biocidal products' *(No 'Only Representative' role to displace EU importer)*
    - '**Product supplier**' : 'who manufactures [in EU] or makes available on the market a **biocidal product** consisting of, containing or generating that relevant substance'
    - **Data Submitters**: under the Review Regulation or for New AS, will also be included in list

List Of Active Substances



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List Of Active Substances

- Provisional list established by ECHA (last updated 28 Feb 2014).

- Underlines that any one company may fulfill multiple roles (e.g. Data Submitter, Participant and Substance Supplier)

- Used as a marketing/commercial tool albeit that this is not a definitive list. Substance suppliers on the list will offer data access linked to supply contracts. Every 'Alterative Supplier' must calculate whether it is better to:
  - 'cherry pick' from the dossier (using own data where already owned)
  - "buy in" completely (Fees Regulation encourages a complete buy in)

- No clear legal framework. Corrections and comments dealt with by ECHA helpdesk. No legal rights granted and no legal remedies offered.

Questions?

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BPR
Data Negotiation Process

DAY 2

BPR: Data Negotiation Process

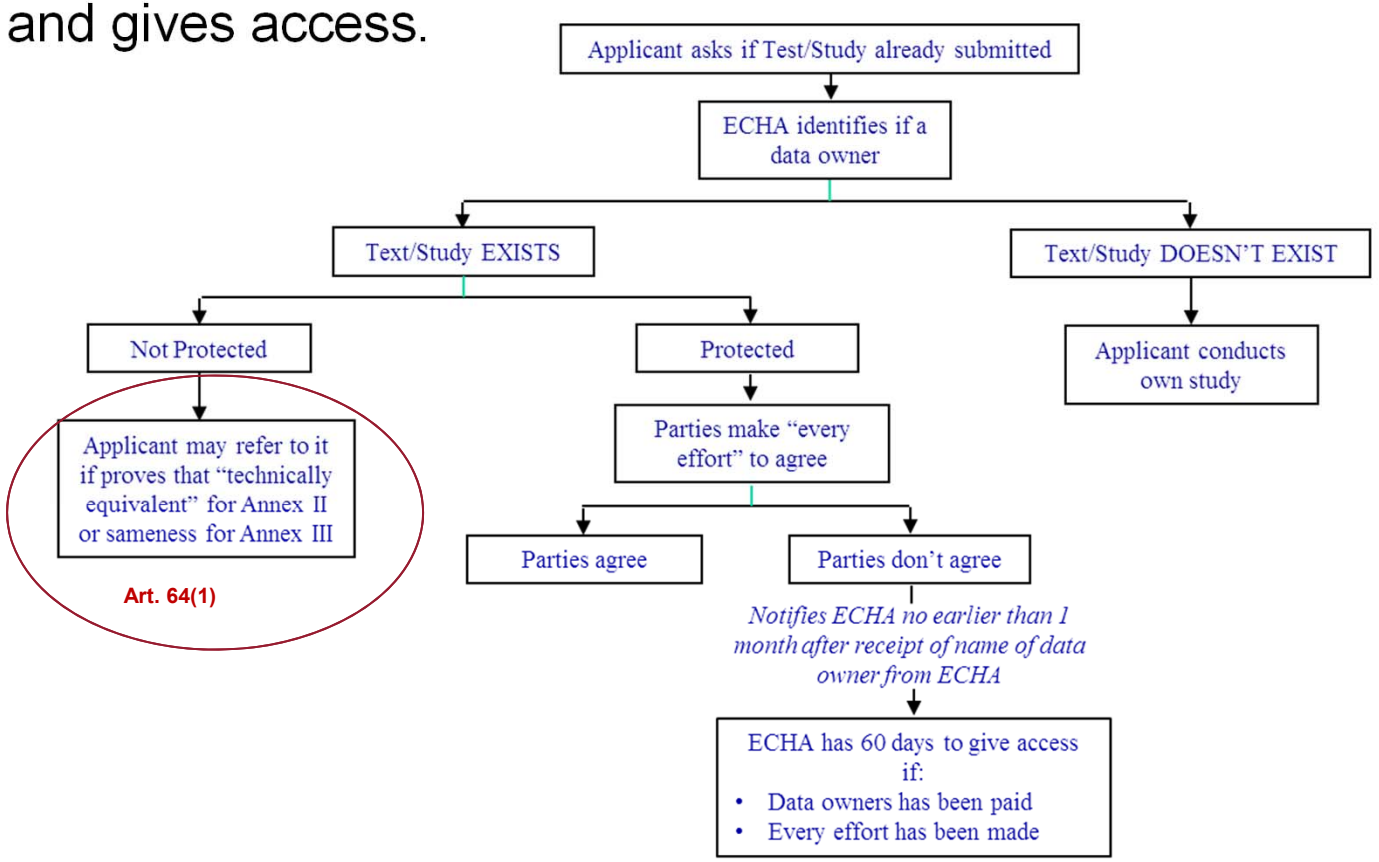
	Prospective Applicant		Data Owner	
Data	Inquire to ECHA before testing whether already submitted by previous applicant?	Request Access from Data Owner (if data is protected)	Provide access	What data must be provided
Vertebrate	**Must** *ECHA will determine whether such tests or studies have already been submitted to ECHA or Competent Authorities*	**Must** *Request all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications*	**May submit agreement on sharing to an arbitrator. If not, even if no agreement reached, from as early as 1 month after applicant receives name/address of data submitter it can trigger mandatory sharing procedure:** *Within 60 days of ECHA being notified by Prospective Applicant it will give permission to refer to tests or studies on vertebrate animals provided that prospective applicant demonstrates:* *•every effort has been made to reach agreement, AND* *•prospective applicant has paid the data owner a share of costs incurred.* *'Proportionate share" may be determined by national courts if parties cannot agree .*	**Permission to refer (LoA) to the data owner's tests or studies**
Non Vertebrate	**May** *ECHA will determine whether such tests or studies have already been submitted to ECHA or Competent Authorities*	**May** *Request all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications*	**Must make an effort** *'Shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by the submission of the matter to an arbitration body and a commitment to accept the arbitration order'* **No compulsion if no agreement reached (unless – see next column).**	*Art. 95 for existing AS, mandatory data sharing applies also to studies not involving tests on vertebrates'.*

REACH Comparison: Process for Phase-In Substances

	PROSPECTIVE REGISTRANT		DATA OWNER	Compensation Terms
Data	**Inquire before testing whether a relevant study is available**	**Request Access from Data Owner (if data is protected)**	**Provide Access**	
Existing Study Involving Vertebrate Animal Tests	Must Art 30(1) para. 1	Must Art 30(1) para. 1	**Must** **ECHA will give access if Data Owner refuses to provide (i) proof of costs or (ii) the study, and block Data Owner's Registration.** **Art. 30(3)**	Calculated 'in a fair, transparent and non-discriminatory way' If agreement cannot be reached on the amount of compensation 'the cost shall be shared equally' Art 30(1) para. 1
Existing Study does <u>not</u> involve testing on vertebrate animals (wider than just animal i.e. non-animal as well)	Must Art 30(1) para. 1	May Art 30(1) para. 1	May ECHA has no power to oblige access but if a study is requested by a SIEF member, and a data owner refuses to share, the other SIEF participants can proceed as if the study did not exist. Art. 30(4)	
Any new study involving tests which is required for Registration and is not available	*One SIEF participant conducts one new study (for the purpose of fulfilling a Registration information requirement) on behalf of all other SIEF participants. The SIEF participants need to agree on (or ECHA will impose on them) which party should secure the new testing.* *Art 30(2)* *(see Art 29(3) also)* ***More likely to be necessary in 2013 where data paucity* anticipated**.			Costs for 'the elaboration of the study with a share corresponding to the number of participating registrants'. (This does not necessarily mean that equal shares will be borne by each of the SIEF members.) Art 30(2)

BPR Data Negotiation Process

- **Timelines for data negotiation potentially very short:** as little as 1 month. ECHA acts within 60 days *after negotiations fail* and gives access.



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BPR Data Negotiation Process

- Mandatory data sharing resembles REACH but no 'SIEF' to limit their substance-specific focus. BPR has no LR of SFF equivalents.
- BPR requires any person 'who intends to perform tests or studies' to determine if done before with ECHA. Not *expressly* qualified by idea that those tests/studies relate to their specific substance.
- This suggests possibility of mandatory data access for 'read-across' purposes (interpolation to other substances) BUT conflicting indication in Art. 64(1) on non-protected data:
  - '…subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities'.
  - '…so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity…'
- Companies with common interests may want to re-create SIEF-like structures – consortia/task forces for data rights management.

BPR Data Negotiation Process

- As a voluntary (not free) alternative to full technical equivalence, ECHA has developed the chemical similarity check procedure:
  - 'an assessment similar to the technical equivalence assessment described in Article 54 of the BPR. However, it is performed solely on the substance identity and chemical composition of an active substance originating from one source with the aim of establishing its similarity regarding the chemical composition of the same substance originating from a different source'.
  - '…differs from the technical equivalence assessment under Article 54 of the BPR because a decision on the approval of the active substance has not yet been adopted and, therefore, the official reference source of the active substance is not yet established'.
- Envisaged for:
  - **Individual applications**: The comparison of one alternative source of AS with the source(s) described in the dossier submitted for the assessment of this biocidal active substance.
  - **Joint applications**: The comparison of two or more sources of the same active substance in view of a prospective joint application for AS approval.

BPR Data Negotiation Process

- **Essential to set in place standard**:
  - data sharing agreements
  - negotiation protocols
  - cost calculation spreadsheets/baseline data

  to allow for rapid responses.

- **Typical stages in process**:
  - Confidentiality Agreement (vanilla or pre-empting negotiations)
  - Agreement on what is sought (list)
  - Delegation of entire process to binding arbitration
  - Exchanges on principles for compensation
  - Review of numbers
  - Review of draft agreement
  - Face to face negotiation
  - Offer to pay

BPR
Data Compensation

BPR Data Compensation

- General requirement that compensation must be determined in **a fair, transparent and non-discriminatory manner** (as under REACH), 'having regard to' the REACH ECHA guidance on data sharing (April 2012) and ECHA note clarifying which chapters 'are of particular relevance to applicants under BPR').
- ***N.V. Elektriciteits Netherlands*** (10 October 2011) confirms guidance does not constitute a source of law, which would be comparable to legislation but if published, can nevertheless bind the administrative body in question. Where ECHA has decided to publish guidance its conduct can be confined by such guidance. This flows from the creation of a legitimate expectation, legal certainty and equal treatment/non-discrimination.
- **Repeat players are unlikely to want to have compensation decisions to be settled by EU national** courts (who have little/ no experience on these matters).
- ECHA decisions to grant data access within 60 days **could be challenged by data owners before the Board of Appeal**: quick and cost efficient mechanism – with suspensive effect on decision.

BPR Data Compensation

- REACH ECHA guidance on data sharing (April 2012) is a poor guide to the BPR process:

BPR elements not in REACH

- If no agreement reached the prospective applicant should pay a share of the cost which data owner 'shall not refuse to accept'. Without prejudice to claim before national courts for additional compensation.
- Registration not limited to one legal entity, but a right to refer to the AS substance data granted to an alternative substance supplier can be relied on by applicants for authorisation of BP
- Nature of the data subject to mandatory data sharing is quite different (wider).
- Fairness determination could take into account the number of MS for authorisation, PTs, or the automatic right to sub-licence the referral right to one's own "customers".

BPR Data Compensation

- REACH ECHA guidance on data sharing (April 2012) is a poor guide to the BPR process:

REACH elements not in BPR

- No "equal" cost sharing - default formula under Articles 27(6), 30(1) and 30(3) of REACH where no agreement is reached
- No disclosure of 'full study reports' in case of a failure to agree –
- No Lead Registrant submitting a joint registration dossier on behalf of all market players (sharing financial burden of developing it with co-registrants either upfront or at the applicable registration deadline).
- Determination of a fair share of the cost takes account:
  - volumes of substance placed on the whole of the EEA market by one legal entity
  - four tonnage bands and the information requirements corresponding to them
  - size of the suppliers (through the SME status)
  - use of the substance (intermediate or for R&D)

BPR Data Compensation

- **Indicative list of issues to consider in negotiations:**

- **Scope of rights**
  - Citation or ownership?
  - Geographical spread (EU, EEA, EFTA, EU + US etc?)
  - Purpose (BPR only? BPR + PPP, REACH?)

- **Cost**
  - Distinction between costs & commercial data value
  - Dossier costs versus raw data costs
  - Actual cost (+ inflation) or replacement cost?
  - Management costs (actual or fixed/variable percentage)
  - Risk premium (compare REACH and BPR risk)?
  - Loss of opportunity?
  - Early market access premium?

BPR Data Compensation

- **Indicative list of issues to consider in negotiations:**

- **Dynamic cost formula or static?**
  - Reimbursement mechanism for overpaying
  - Claw-back for underpaying and updates
  - EU only considerations or discounts for other jurisdictions?

- **Other**
  - Are you being asked for commercial information not required by BPR (use of black box trustees)?
  - Bundling?
  - Tying data access to supply contracts?
  - Lump sum penalties for change of supplier? Royalty systems to incentivise loyalty to suppliers?

BPR
Disputes Procedure

Disputes Procedure

- Decision to grant permission to refer lies with ECHA (where negotiations fail after 'every effort')
- ECHA's decision is subject to BoA review.
- ECHA will not form judgments on cost calculations.
- Share of costs will be decided by national courts (unless parties have already agreed to another means of resolution).
- No data sharing disputes decided under BPR or REACH yet.

Disputes Before ECHA: Lessons from REACH

- Process for dealing with disputes:
  - Define the subject matter of the dispute (studies)
  - Description of negotiations setting out the full record
  - Each side asked to provide all correspondence ('request for information' and 'documentation') showing efforts
  - Separate communications between ECHA and each party (no automatic sharing of each others' submissions) – right to be heard/defence?
  - Willing ness to adopt 'contingency procedure' to accelerate market access pending decisions on data sharing.
  - Suspensory effect of BoA challenges is in issue (REACH phase-in specific?)
  - Repetition of positions can gain credit.
  - Promptness applied particularly as against data owner.
  - Surface analysis of discrimination.

BOA Appeals

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) **No 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.*

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Adapting Consortia

Adapting Consortia

- What you agreed under the BPD may not necessarily be imposed on data accessors under the BPR.

Questions?

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Practicalities of the Dossier Submission for Active Substances and Products – Part I

Dr. Michael Werner, SCC GmbH, Bad Kreuznach, Germany

SCC
SCIENTIFIC CONSULTING COMPANY

Dossier Preparation and Structure under the BPD (Directive 98/8/EEC)

—

Steptoe & Johnson LLP

Annual Chemicals Regulation Seminar

01/02 April 2014, Brussels

Dr. Michael Werner, SCC GmbH, Bad Kreuznach

SCC
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Content

- **Dossier preparation under Directive 98/8/EEC: Need for expertise in the former BPD system - Rules to be applied in the evaluation process**
- **Overview of dossier structure and of “Doc” levels**
- **Evaluation of BPD dossiers by RMS/MS: Technical and regulatory aspects of the different Doc levels – “RCOM” tables**
- **Review/commenting of Biocide dossiers: Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks**
- **Exposure and risk assessments under the BPD and BPR system: First experiences**

BPD dossier preparation under Directive 98/8/EEC

- Rules of the BPR (Regulation (EC) No 528/2012) apply as 01 September 2013.

- Rules to be applied in the evaluation of BPD dossiers prepared according to Directive 98/8/EC are provided for in Article 90 (2) of the BPR and in the CA document designated “Principles for the Approval of AS”(CA-March14-Doc4.1).

- Is there still a need for expertise in the former BPD system and/or to familiarize with this system?

→ Answer is YES!

BPD dossier preparation under Directive 98/8/EEC

- **Discrimination required for Biocide Dossiers prepared under the BPD:**

  - BPD dossier evaluation by RMS completed and draft CAR(s) available **before** 01 September 2013: BPD rules fully apply in the further evaluation procedure from the technical and regulatory point of view.

  - BPD dossier evaluation ongoing and draft CAR(s) available only **after** 01 September 2013: BPR rules apply in the further evaluation procedure from the regulatory point of view **but** from technical point of view former BPD dossier structure/format will be maintained.

Overview of dossier structure and of “Doc” levels

Dossier structure under the BPD: Guidance available

- Guidance for applicants: “*Technical Notes for Guidance for the Preparation and Presentation of Complete Dossiers for the Inclusion of Active Substances in Annex I, IA or IB of Directive 98/8/EC or for Authorisation or Registration of Biocidal Products (Dossier Preparation – Part I)”.*

- Guidance for CAs: “*Technical Notes for Guidance for the Preparation and Presentation of Reports by Competent Authorities Relating to the Proposed Inclusion of Active Substances in Annex I, IA or IB of Directive 98/8/EC or for Authorisation or Registration of Biocidal Products (CAs' Report Guidance – Part II)”.*

Overview of dossier structure and of “Doc” levels

- **BPD dossiers were structured in different “Doc levels” → Docs I, IIA/IIB/IIC, IIIA/IIIB, IVA/IVB**

Document type	Subdocument
DOCUMENT I OVERALL SUMMARY AND ASSESSMENT	I.1 Application form Appendices, if relevant: - Documentation relating to the joint submission I.2 Overall summary and conclusions Appendices: - Listing of end points - List of terms and abbreviations - Check for completeness - Active substance - Check for completeness - Biocidal product(s) I.3 Proposal for decision regarding Annex I, IA or IB inclusion
DOCUMENT II RISK ASSESSMENT	II-A Effects and exposure assessment - Active substance II-B Effects and exposure assessment - Biocidal product II-C Risk characterisation for the use of the active substance in biocidal product(s) Appendices: - Reference lists
DOCUMENT III STUDY SUMMARIES	III-A Study summaries - Active substance III-B Study summaries - Biocidal product(s) Appendices: - Reference lists - Confidential data and information (if applicable)
DOCUMENT IV ORIGINAL TEST AND STUDY REPORTS	IV-A Original test and study reports - Active substance IV-B Original test and study reports - Biocidal product*) Appendices, if applicable: - Profile and results of literature search

Overview of dossier structure and of “Doc” levels

Doc I:

- Overall Summary and Conclusion („applicant version“) and Evaluation Report (CA version) → contains conclusions on eligibility for the application as a biocide and reasons, proposals/background for the decision.

- Summarizes identity AS and BP, hazard assessments, exposure/risk assessments, C&L etc.

- Contains List of Endpoints (LoEP) → most relevant/critical endpoints are summarized there!

Overview of dossier structure and of “Doc” levels

- **Doc IIA (“Active substance assessment“):**

  - „Hazard assessment level of AS“ and related to data on AS only.

  - Summary on identity, C&L, physical chemistry, efficacy, hazard assessments for tox/ecotox (largely based on summaries provided in more detail on Doc IIIA level) → Details on „subheadings“ can be found in the TNsG on Dossier Preparation, Part I.

  - In later Doc IIA documents, deducion of reference values such as AELs, AECs, PNECs and the reasoning was included (reference value deduction for human health usually also included on the Doc IIC level).

Overview of dossier structure and of “Doc” levels

- **Doc IIB (Biocidal product hazard assessment including exposure):**

  - **Focus of Doc IIB: Use description** („how is biocidal product applied in its intended uses) as well as **exposure assessment for human health and the environment.**
  - **Note:** Exposure assessment was included also for SOCs (Substances of concern) or for precursors of *in situ* generated actives.
  - Hazard effects assessment for the biocidal product including substances of concern related to tox, ecotox/environment and physical-chemistry → Details on „subheadings“ can be found in the TNsG on Dossier Preparation, Part I.
  - Doc IIB includes also information on identity, C&L, efficacy of the biocidal product.

Overview of dossier structure and of “Doc” levels

- **Doc IIC („Risk assessments“):**
  - **Focus:** Risk characterization for human health and the environment as well as for physico-chemical properties.
  - **Note:** Risk characterization was included also for SOCs (Substances of concern) or for precursors of in situ generated actives!
  - Doc IIC includes „Measures to Protect Man, Animals and the Environment“ → mostly based on information of the MSDS!

Overview of dossier structure and of “Doc” levels

- **Doc IIIA/Doc IIIB: Robust Study Summaries (RSS) on Active Substance and Biocidal Product Level**

  - Summary of the active substance/biocidal product properties based on study reports or publications → endpoints comprise identity, PC, analytics, efficacy, human health, ecotox/environement, safety (MSDS) information and C&L.

  - Summaries were prepared using standard formats for study summaries (i.e. word templates) as provided for in the Parts III-1 to III-6 of the „TNsG on Dossier Preparation and Study Evaluation“ → Data entry fields were predefined for each endpoint and had „only“ to be populated with data by the applicant.

  - **Note:** For endpoints such as in vitro skin irritation/corrosion or in vitro dermal absorption, no templates were available and had to be created by the applicant.

Overview of dossier structure and of “Doc” levels

- **Doc IIIA/Doc IIIB: Robust Study Summaries (RSS) on Active Substance and Biocidal Product Level (cont‘d)**

  - Only **key studies** were **described on Doc IIIA/Doc IIIB6 level** → **non-key studies** were briefly **summarized in IUCLID only**!

  - Example for Doc IIIB6 („Toxicology Biocidal Product“): For many biocidal products, no studies are usually available for tox/ecotox endpoints → endpoints were very often addressed by justifications for non-submission („waivers“).

  - Details on the „subheadings“ to be addressed on Doc IIIA/IIIB level can be found in the TNsG on Dossier Preparation, Part I.

Overview of dossier structure and of “Doc” levels

- **Doc IIIA + IIIB: Reliability indicators for studies/publications summarized**

  - **Important:** Only studies with reliability 1 + 2 (= fully reliable or reliable with restrictions) were usually accepted by the RMS for evaluation.

  - Studies/publications with reliability 3 considered as supporting information only → such information was included in the assessment when e.g. a WoE („Weight of the Evidence“) approach was applied by the applicant.

Overview of dossier structure and of “Doc” levels

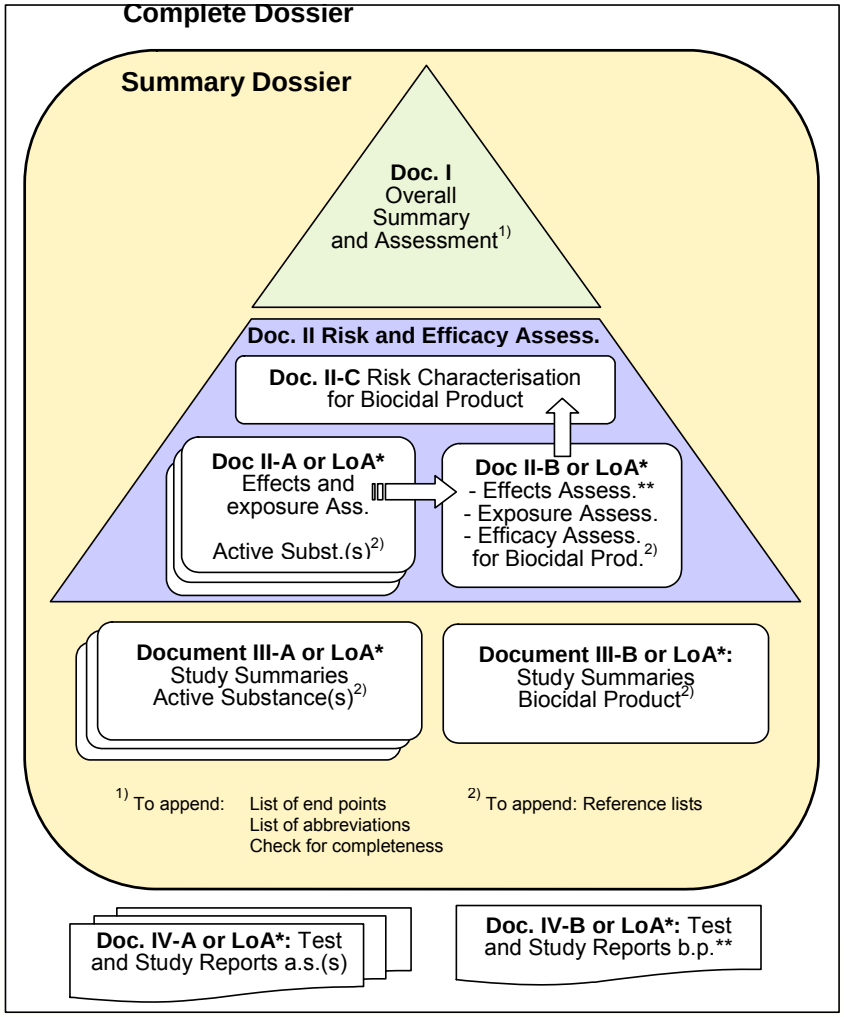
Doc IVA + IVB: Study reports/publications

- The original study reports on the active substance and biocidal product (where performed and available) are included on a Doc IVA / IVB level.

- Study reports were used by the RMS in case of discrepancies between study summary and study results and when a closer look at the studies was deemed necessary.

Overview of dossier structure and of “Doc” levels

- **Overview of detailed “98/8/EEC” BPD dossier structure:**



* LoA = Letter of access

** In the case of applications for registration of low-risk products, the effects assessment is confined to data on the active substance(s) only. In general, the data to be provided in Doc. IV-B and III-B are limited.

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Dossier preparation/evaluation under the BPD:**

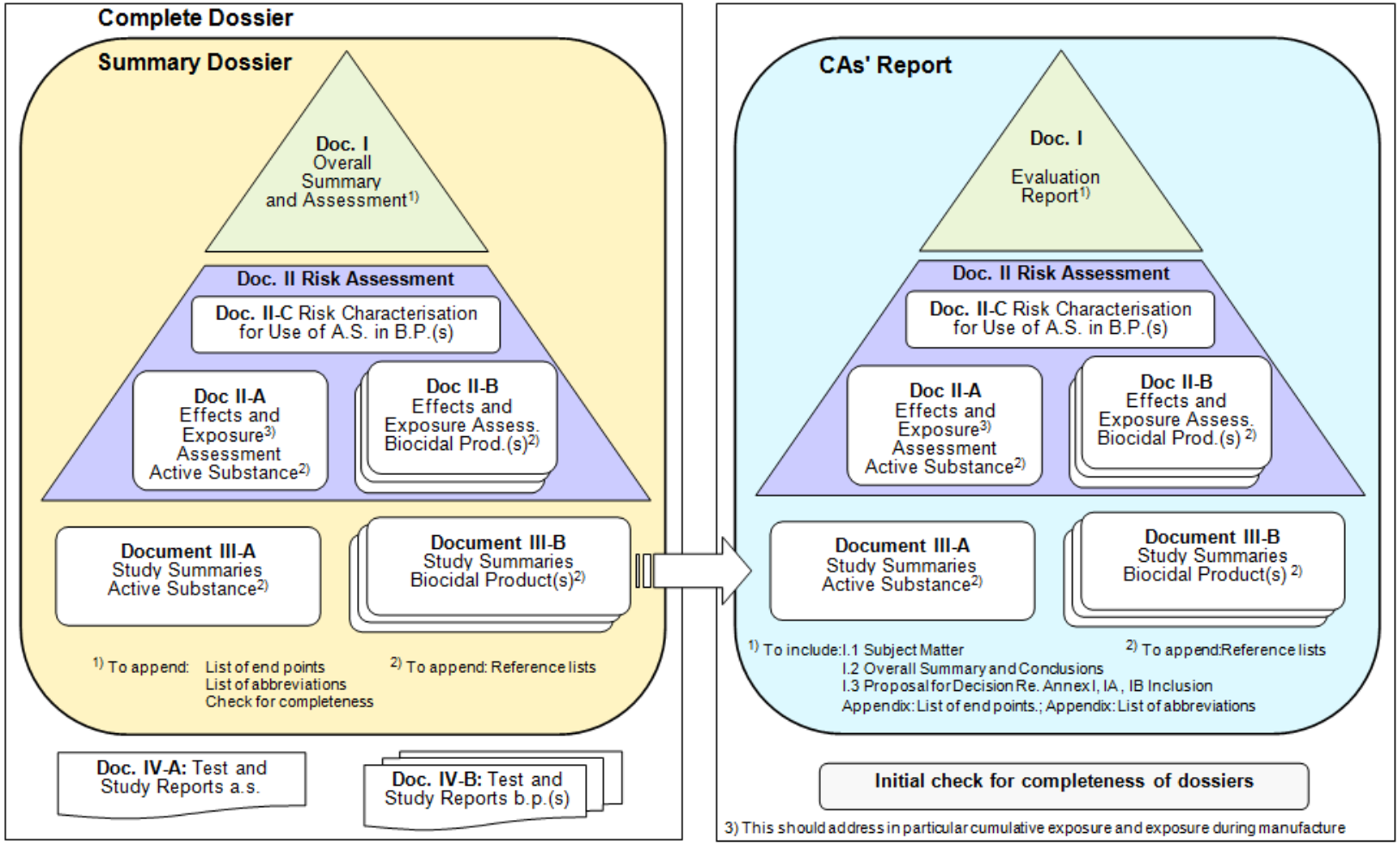
  - **BPD:** All „Doc levels“ were prepared in the form of word documents following largely the guidance provided for in the TNsG on Dossier Evaluation.

  - Dossiers submitted by the applicant were/are evaluated by the RMS and OMS following review of different Doc levels.

  - **Note:** The BPR requires dossier preparation in the form of a IUCLID file!

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Structure of (a) applicant's dossier and (b) CAs' report:**



Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Practical aspects (1):**

  - **Task of applicants once dossier has been evaluated (e.g. draft CAR level):**

    - Review of all Doc levels in order to identify discrepancies:.

      →Where is agreement / disagreement between the applicant and CA version of the dossier?

    - Identify minor / major differences between applicant version and RMS version of BPD dossier.

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Practical aspects (2):**

  - Doc IIIA / IIIB level: Study summaries contain an **„Evaluation by Competent Authorities“** field where the outcome of the evaluation and the comments of the RMS on the respective study summary are included → Discrepancies and the evaluation by RMS could easily be identified.

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Example of CA/RMS remarks on applicant's study summary:**

	3 MATERIALS AND METHODS	
3.1.2 Specification	Deviating from specification given in section 2 as follows:	**X**
3.1.2.1 Description		
3.1.2.2 Purity	93,6%	**X**

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	14 Feb. 2000
Materials and Methods	In accordance with method OECD 408, groups of 10 male and 10 female Wistar rats were administered XXXX (purity 93.6 %) at levels of 0, 11, 111 or 611 ppm in their diet over a period of 90 days. Additional recovery groups ……. **Comments:** The purity of the test substance (**see 3.1.2.2**) is much lower than that given in section 2. No further specification is given in **3.1.2**. However, a check of the original study report revealed that the impurities are not substances of concern.
Results and discussion	Reversible findings in the high-dose group include a depressed general condition and an ungroomed coat, retarded body weight gains (not fully reversible), transiently lower thrombocyte counts (THRO), elevated …….
Conclusion	NO(A)EL: 11 ppm, equivalent to: 1.1 mg/kg bw/day (males), 1.1 mg/kg bw/day (females), based on histopathological findings in the liver at 111 ppm
Reliability	1

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Practical aspects (3):**

  - **Comparison of other Doc levels other than Doc IIIA / IIIB:**

    - Experience shows that there are large differences as regards the preparation of the Doc II level in particular → some RMS took the applicant dossier as a basis and continued from there, some other RMS prepared completely new documents.

    - Identification of discrepancies and identification of major points was/is only be possible by a detailed review of the respective Doc levels.

    - **Advantage of Word documents:** Use the **„compare documents mode“** in Word to identify differences between applicant and RMS version of BPD dossier.

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

- **Practical aspects (4):**

  - **Recommendations for review and annotations:**

    - Document/introduce comments/justifications either in the respective „Docs“ (done in general during the bilateral part of the evaluation work, i.e. between applicant and RMS before discussions on TM/BPC-WG level take place).

    or

    - **Documentation** of comments/discrepancies/justifications **in the RCOM** („commenting tables“ which are based on PPP format).

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

Practical aspects (5):

➢ Recommendations for review and annotations (cont'd):

- RCOM tables for biocides differentiate between „General comments" and „Specifc comments" on the different Doc levels.

IMPORTANT:

The system and use of „RCOM Tables" continues to be the commenting tool for dCARs under the BPR!

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

Extract of commenting table („RCOM“): General comments

General Comments to Docs I, II and III

Doc.I

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Doc.II-A

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Doc.II-B

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

Extract of commenting table („RCOM“): General comments

Doc.III-A

5. Effectiveness and intended uses

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

8. Measures necessary to protect man, animals and the environment

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

9. Classification and labeling

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

Extract of commenting table („RCOM“): Specific comments

Toxicological Comments to Docs I, II and III

Doc.I

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Doc.II-A

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Doc.II-B

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks

Evaluation of BPD dossiers: Technical and regulatory aspects of the different Doc levels

Extract of commenting table („RCOM“): Specific comments

Toxicological Comments to Docs I, II and III

Doc.II-C

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

Doc.III-A

6. Mammalian toxicology

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks
(1)	Vol. #, <<data point>>, <<description>>	<<MS>>: <<comment>>	<<comment>>	<<conclusion / recommendation>>

9. Classification and labeling

No.	Column A Reference to CA report *	Column B Comment * (restricted to 500 characters, ca.10 lines) – if not practicable, attach separate document with copy from report and comments in ‘track changes’	Column C Rapporteur Member States comments on MS/applicants/third parties comments	Column D Conclusions of the TM and/or, where relevant, opinion of the Scientific Committee on Health and Environmental Risks

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Dossier evaluation of 98/8/EEC BPD dossiers under the BPR:**

  .

  - The RMS evaluation of the BPD dossier submitted by applicants under the BPD was initiated under the BPD but has not been completed by 1 September 2013 → **No dCAR available before 1 September 2013! How to go from there?**

  - The structure of the original „Doc I, II, III level-based“ BPD dossier is being maintained in the evaluation process under the BPR for these dossiers:

→ „Doc I, II, III levels“ form the basis for evaluation of „former“ BPD dossiers still under evaluation.

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Dossier preparation/evaluation under the BPR (cont'd):**

  - **BPR: No word templates are used anymore, IUCLID files are required** for preparation of active substance and biocdial product dossiers.

  - **Consequence:** Annotations in word templates (like in the former Doc IIIA / IIIB documents for instance) are not possible anymore!

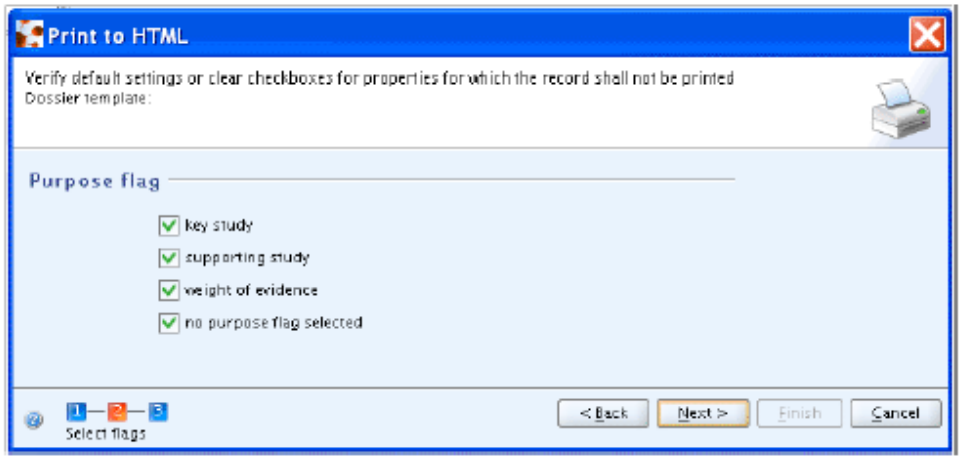
  - IUCLID format is somewhat inconvenient and „error-prone" for review and commenting → Incorporation of annotations and comments into the IUCLID file is not practical.

  - **Alternatives:** Create HTML or PDF-File from IUCLID data set(s).

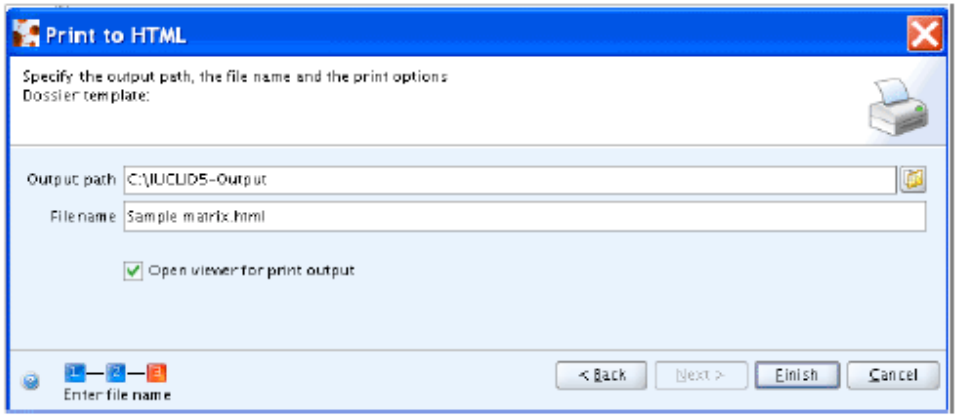
  → „Conversion" of IUCLID file to a more readable („handy") form for review and commenting.

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

Review and commenting of IUCLID files – HTML file option:

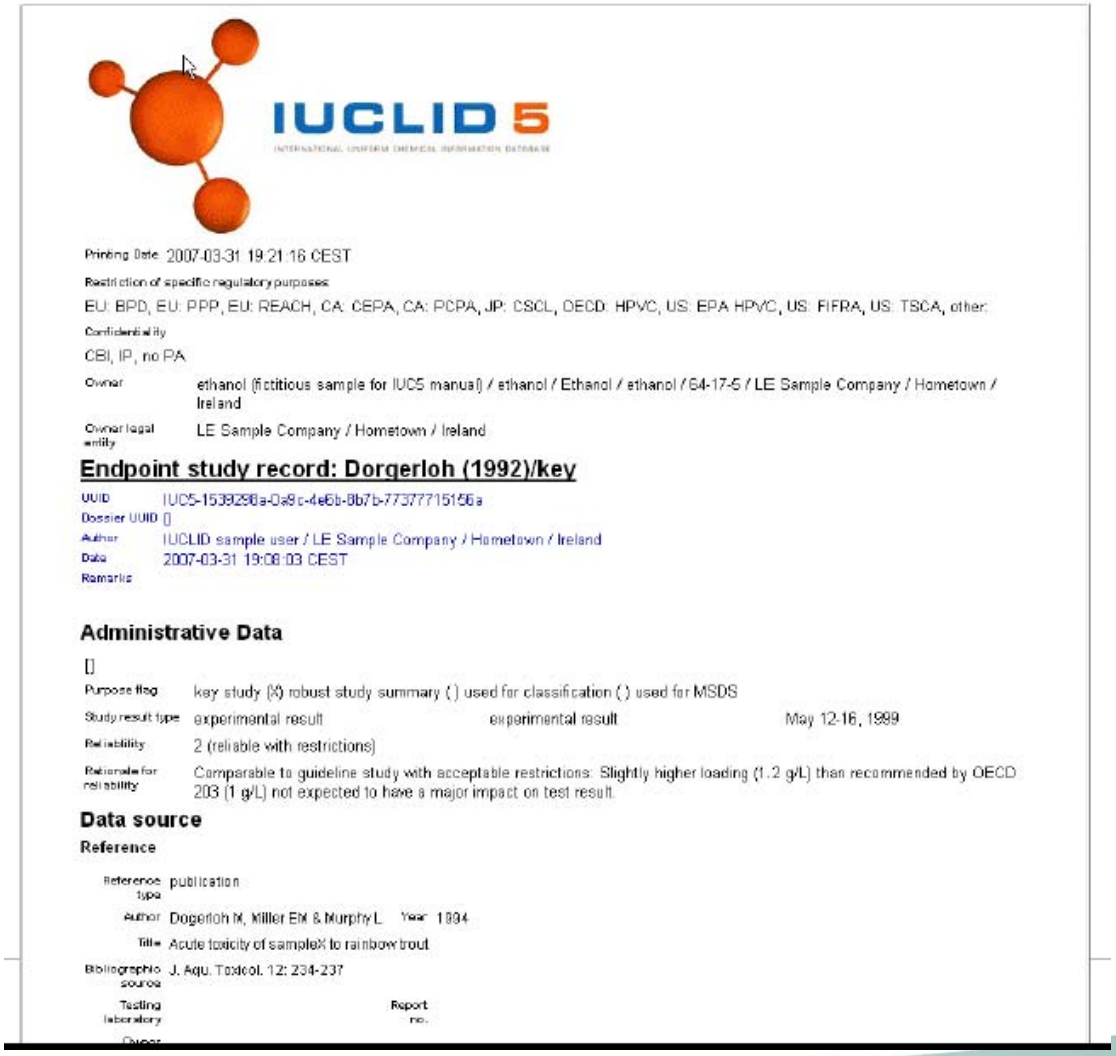


- Step 3: Specify the output path, file name and print option (i.e. whether print-out shall be opened by the viewer, i.e. browser) and click the **Finish** button.



Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **HTML file output – Example from IUCLID 5.5 User Manual:**



IUCLID 5

Printing Date: 2007-03-31 19:21:16 CEST

Restriction of specific regulatory purposes:

EU: BPD, EU: PPP, EU: REACH, CA: CEPA, CA: PCPA, JP: CSCL, OECD: HPVC, US: EPA HPVC, US: FIFRA, US: TSCA, other:

Confidentiality:

CBI, IP, no PA

Owner: ethanol (fictitious sample for IUC5 manual) / ethanol / Ethanol / ethanol / 64-17-5 / LE Sample Company / Hometown / Ireland

Owner legal entity: LE Sample Company / Hometown / Ireland

Endpoint study record: Dorgerloh (1992)/key

UUID: IUC5-1539298a-0a9c-4e6b-8b7b-77377715156a

Dossier UUID: []

Author: IUCLID sample user / LE Sample Company / Hometown / Ireland

Date: 2007-03-31 19:08:03 CEST

Remarks:

Administrative Data

[]

Purpose flag: key study (X) robust study summary ( ) used for classification ( ) used for MSDS

Study result type: experimental result — experimental result — May 12-16, 1999

Reliability: 2 (reliable with restrictions)

Rationale for reliability: Comparable to guideline study with acceptable restrictions: Slightly higher loading (1.2 g/L) than recommended by OECD 203 (1 g/L) not expected to have a major impact on test result.

Data source

Reference

Reference type: publication

Author: Dogerloh K, Miller EM & Murphy L. Year: 1994

Title: Acute toxicity of sampleX to rainbow trout

Bibliographic source: J. Aqu. Toxicol. 12: 234-237

Testing laboratory: Report no.:

Owner:

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **HTML file output – Example from IUCLID 5.5 User Manual:**

Details on test conditions

TEST SYSTEM
- Test vessel: 10 L all-glass aquaria (30x22x24 cm)
- Type (delete if not applicable): open
- Aeration: slightly aerated
- No. of organisms per vessel: 10
- No. of vessels per concentration (replicates): 2
- No. of vessels per control (replicates): 2
- Biomass loading rate: 3.9 g fish per L test water

TEST MEDIUM / WATER PARAMETERS
- Source/preparation of dilution water: synthetic, prepared as described in test guideline
- Alkalinity: 0.8 mmol/L
- Conductivity: max. 10 micro mho

OTHER TEST CONDITIONS
- Adjustment of pH: no
- Photoperiod: 12:12 h light-dark regime

EFFECT PARAMETERS MEASURED (with observation intervals if applicable) : mortality, behaviour, respiratory function, other observable morphological criteria (at least at 24 / 48 h)

TEST CONCENTRATIONS
- Range finding study: conducted with same species

Any other information on materials and methods incl. tables

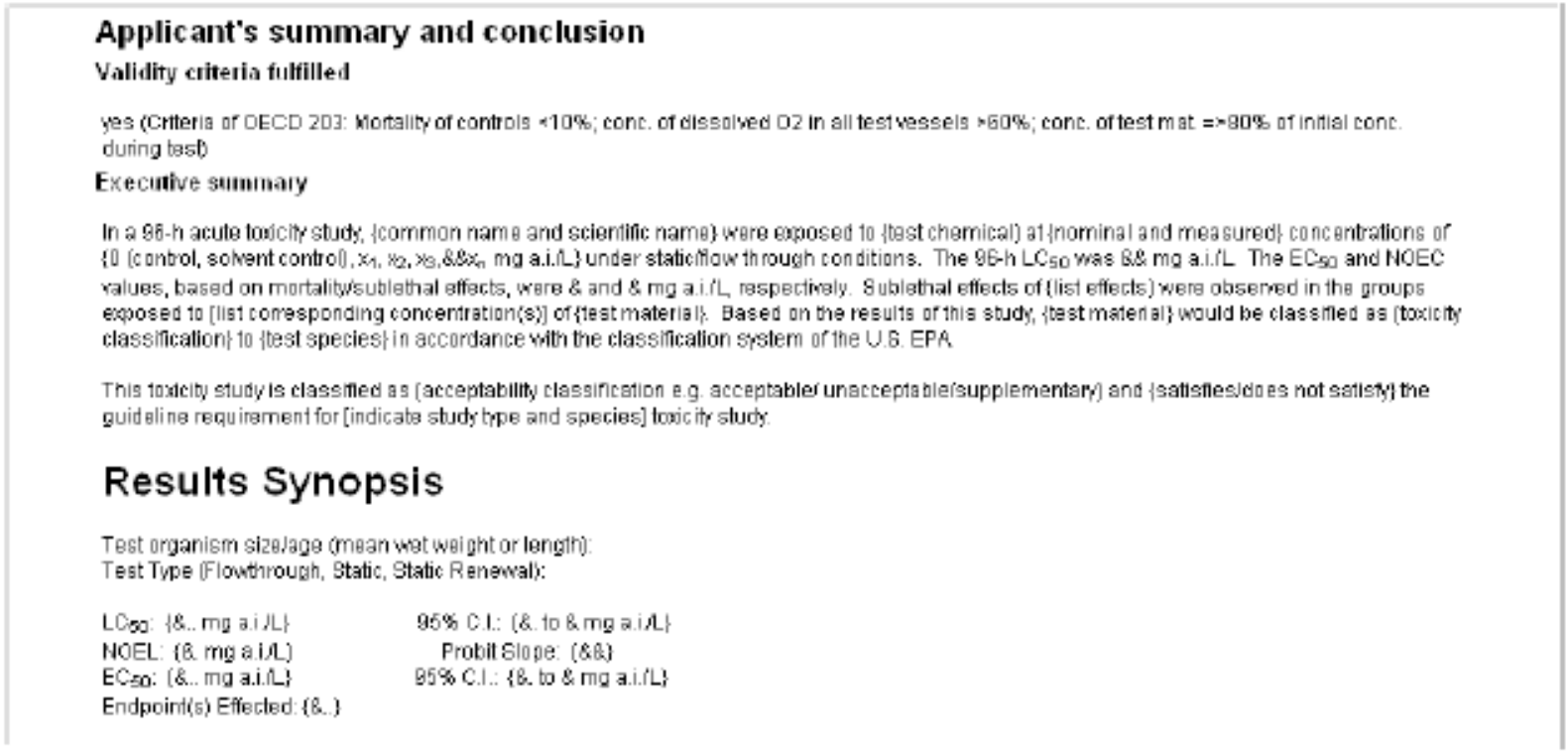
Table 1: Nominal and measured concentrations at 0 and 96 h

	Measured concentration (mg/L) results					
Nominal concentr.	0 (control)	500	1000	1800	3200	5800
Range (min.-max.)		492 - 507.5	987 - 1006	1787 - 1812	n.a.	5712 - 5874
Median						
Mean* ± st. dev.		499.7	996.5	1799.5		5793
% of nominal (ref. to mean)		100	99.7	100		99.8

*Basis: mean of 0 and 96 h measurements

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **HTML file output – Example from IUCLID 5.5 User Manual:**



Applicant's summary and conclusion

Validity criteria fulfilled

yes (Criteria of OECD 203: Mortality of controls <10%; conc. of dissolved O2 in all test vessels >60%; conc. of test mat. =>80% of initial conc. during test)

Executive summary

In a 96-h acute toxicity study, {common name and scientific name} were exposed to {test chemical} at {nominal and measured} concentrations of {0 (control, solvent control), x_1, x_2, x_3,&&x_n mg a.i./L} under static/flow through conditions. The 96-h LC_{50} was && mg a.i./L. The EC_{50} and NOEC values, based on mortality/sublethal effects, were & and & mg a.i./L, respectively. Sublethal effects of {list effects} were observed in the groups exposed to {list corresponding concentration(s)} of {test material}. Based on the results of this study, {test material} would be classified as {toxicity classification} to {test species} in accordance with the classification system of the U.S. EPA.

This toxicity study is classified as {acceptability classification e.g. acceptable/ unacceptable/supplementary} and {satisfies/does not satisfy} the guideline requirement for {indicate study type and species} toxicity study.

Results Synopsis

Test organism size/age (mean wet weight or length):
Test Type (Flowthrough, Static, Static Renewal):

LC_{50}: {&.. mg a.i./L} 95% C.I.: {&. to & mg a.i./L}
NOEL: {& mg a.i./L} Probit Slope: {&&}
EC_{50}: {&.. mg a.i./L} 95% C.I.: {&. to & mg a.i./L}
Endpoint(s) Effected: {&..}

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Dossier terminologies under the BPD and BPR – brief comparison:**

  .

  - **BPD:**
    - Doc IIIA / IIIB = „Robust Study summaries“ (RSS) were prepared in the form of Word table with endpoint-specific pre-defined data entry fields. → RSS were prepared only for key studies, non-key studies were described in a IUCLID file.

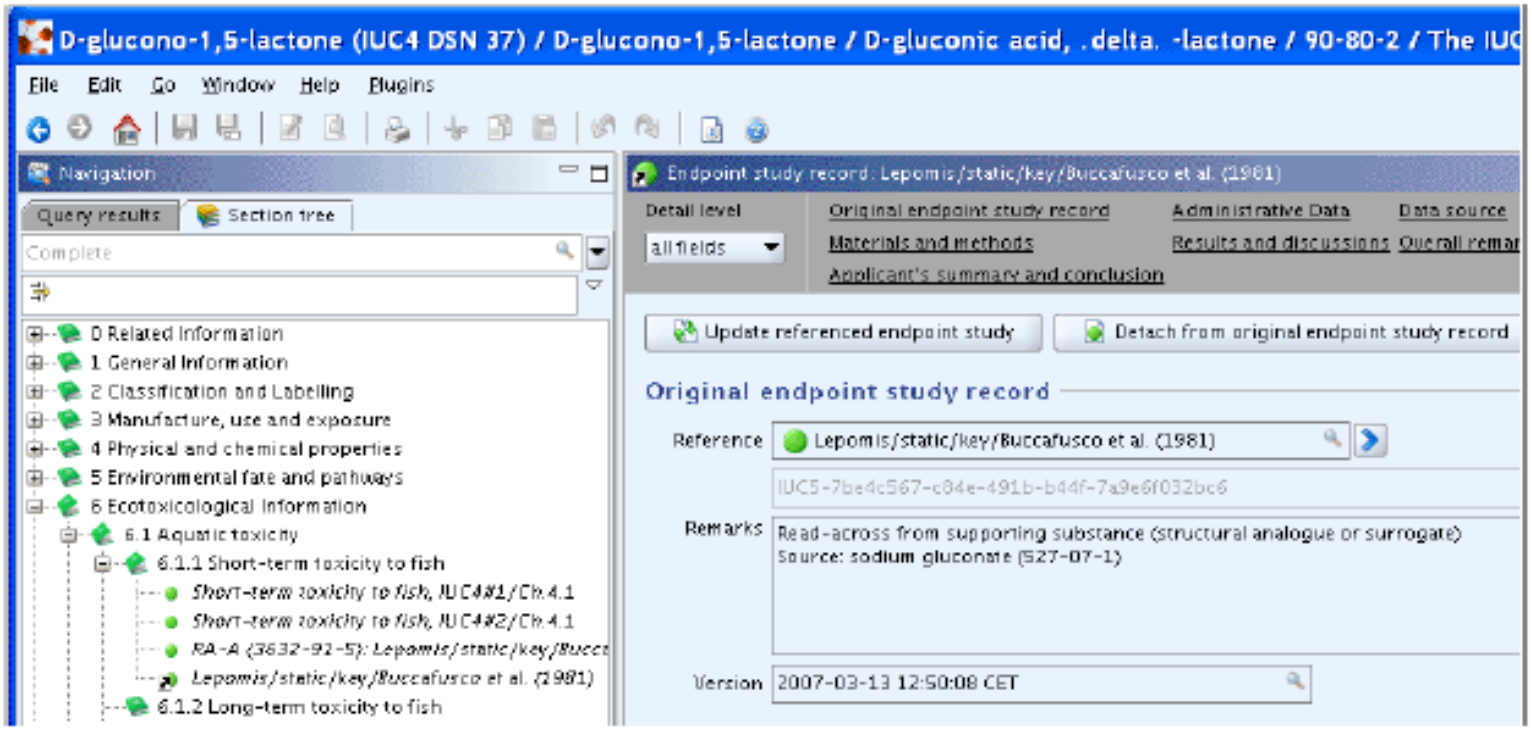
  - **BPR:**
    - **„Endpoint study records“** represent the equivalent to RSS on Doc III level under the BPD.

    → For each endpoint several studies can be described and thus several endpoint study records are prepared in IUCLID.

    → Endpoints study records are „flagged“ as key studies, supporting studies or as a waiver.

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Endpoint study record – Example from IUCLID 5.5 User Manual:**



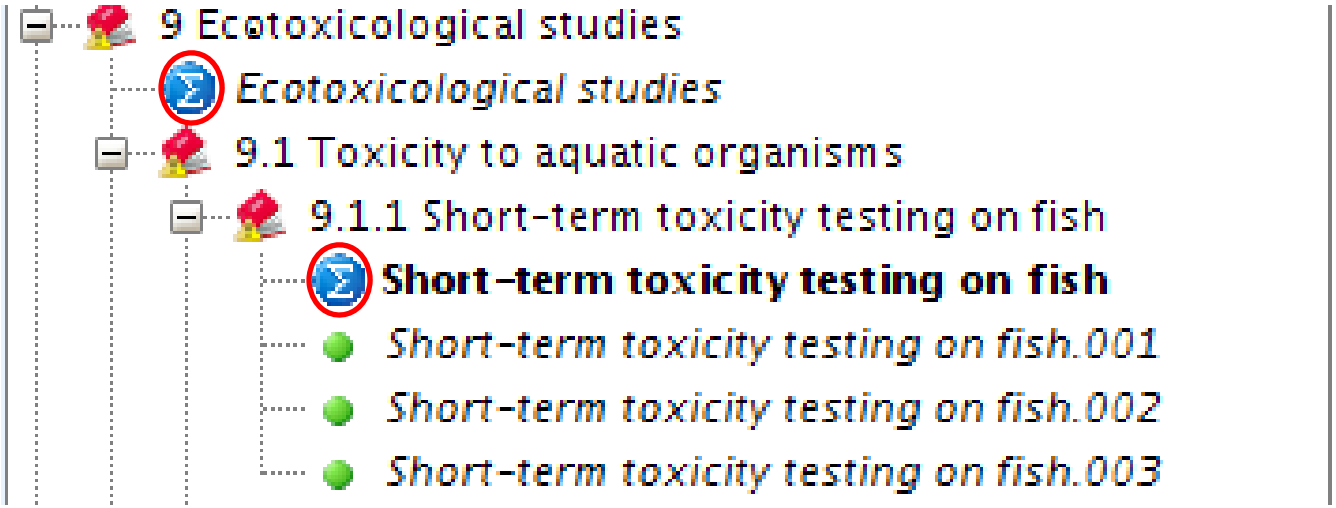
= equivalent to Doc IIIA 7.4.1.1

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Dossier terminologies under the BPD and BPR – brief comparison (cont'd):**
  - **BPD:**
    - **Doc IIA + IIB** = Hazard assessment on each endpoint for active substance/biocidal product including reference value deduction on Doc IIA level and exposure assessment on Doc IIB level.
    - **Doc IIC** = Critical endpoints, reference value deduction and risk characterization.
  - **BPR:**
    - **„Endpoint summary"** (Σ sign) to be prepared on each endpoint (e.g. acute toxicity or primary irritation) represents the equivalent to Doc IIA / IIB regarding the summary on each tox/ecotox endpoint for instance.
    - Endpoint summary on the superior IUCLID section point (e.g. (eco)toxicological information) represents the equivalent for reference value deduction on Doc IIA /II C level.
    - **Exposure/risk assessments:** No equivalent in IUCLID (attached as Word/PDF file to IUCLID section point 13).

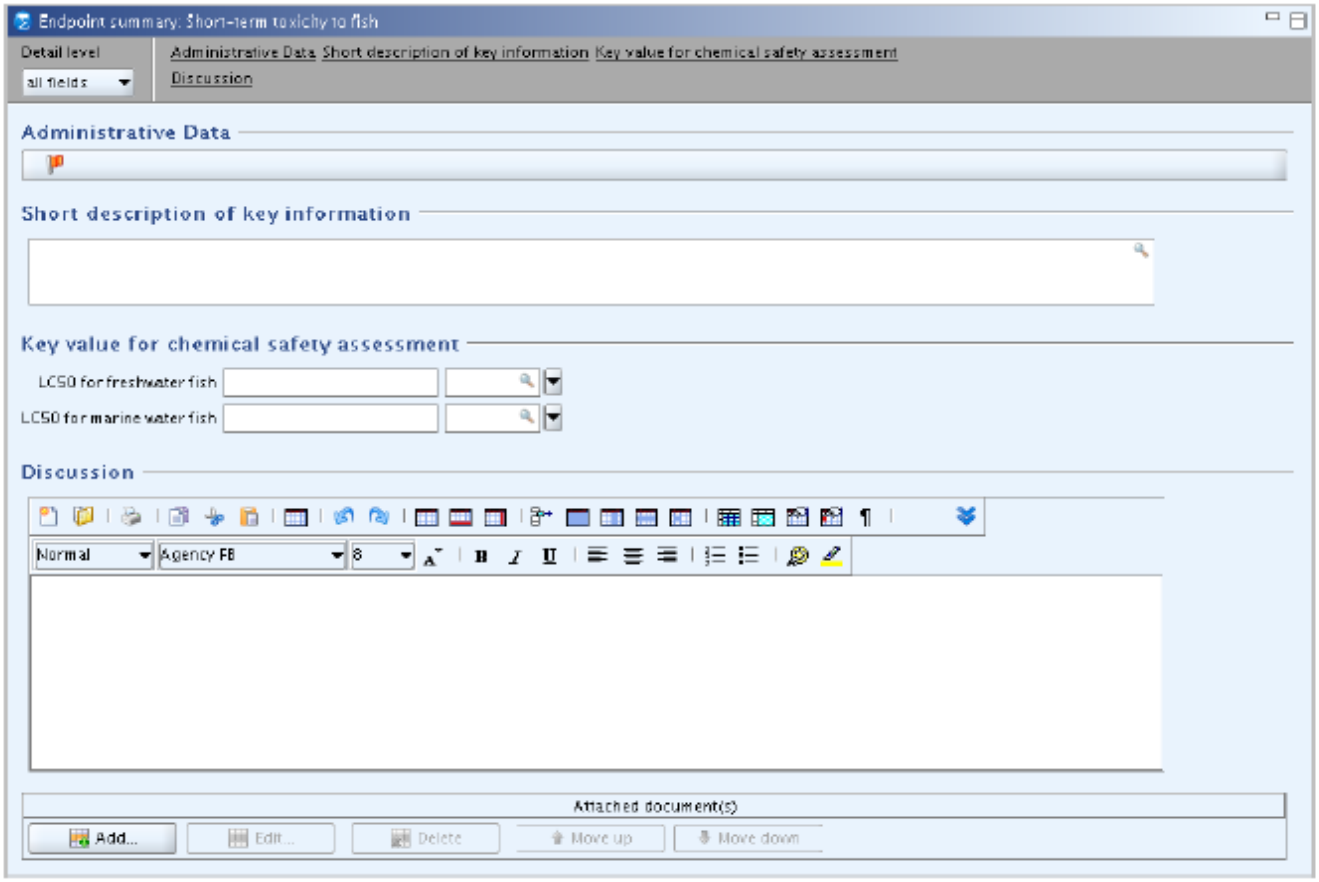
Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Endpoint summary – Example from IUCLID 5.5.1 for a biocidal active substance on the endpoint „Ecotoxicological studies“:**



Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

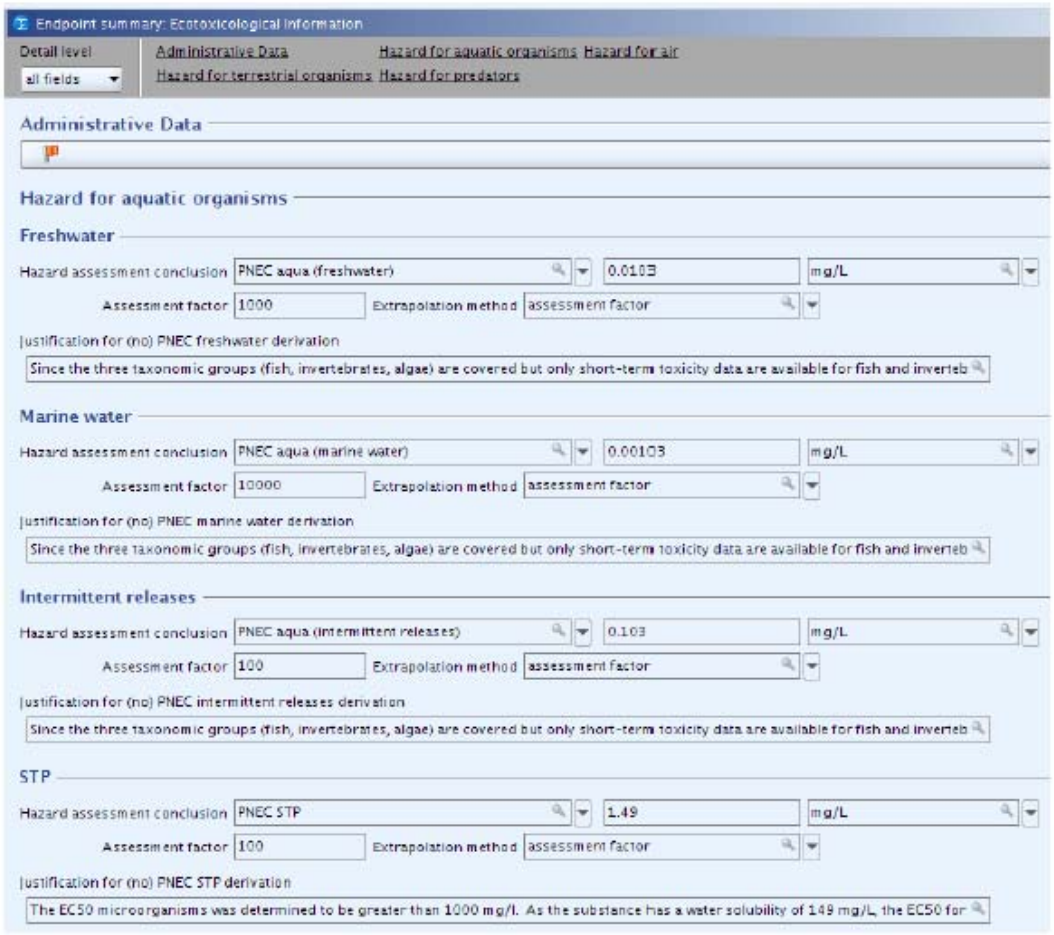
- **Endpoint summary – Example from IUCLID 5.5.1 for a biocidal active substance on the endpoint „Ecotoxicological studies“(cont‘d):**



= equivalent to Doc IIA 4

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **Endpoint summary – Example from IUCLID 5.5.1 for a biocidal active substance on the endpoint „Ecotoxicological studies“(cont‘d):**



= equivalent to Doc IIA4

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

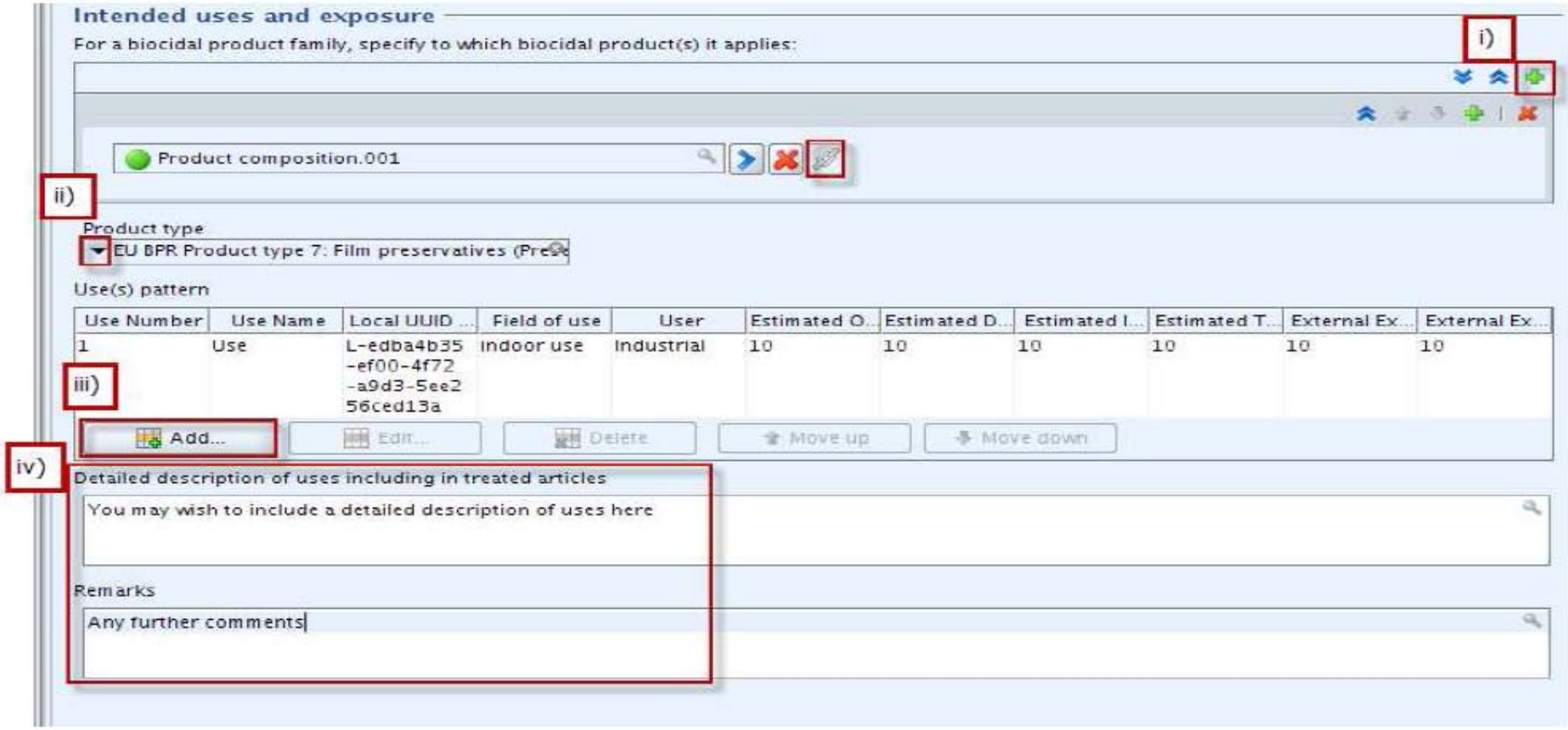
- **Human and environmental exposure and risk assessments under the BPR: .**

  - **IUCLID section point 7 „Intended uses and exposure“** is intended to

    - map intended uses (= use description of Doc IIB8.1 in former BPD dossiers) and provide information on application methods.

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

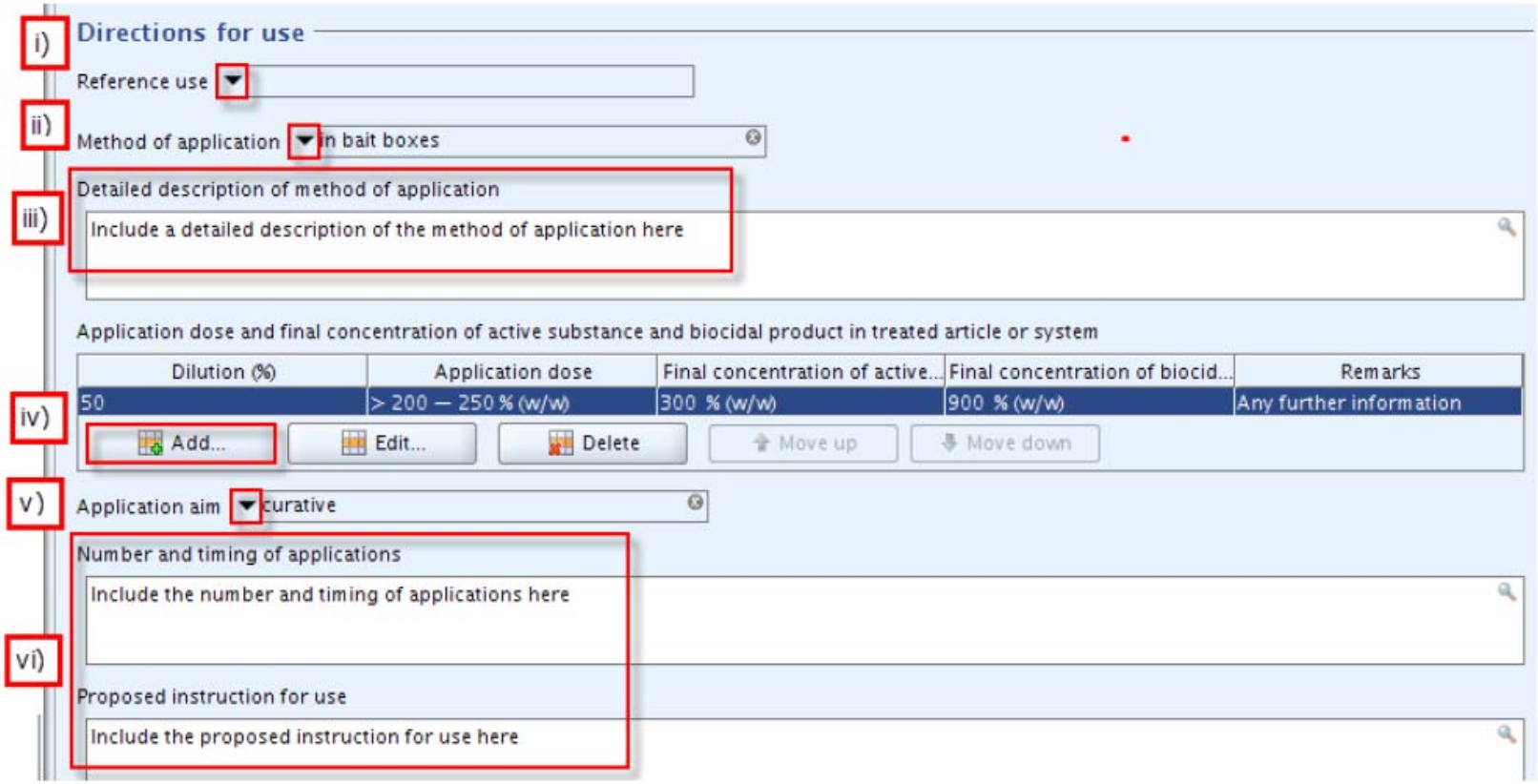
- **IUCLID section point 7 „Intended uses and exposure“: IUCLID section 7.1 „Fields of use“**



= equivalent to Doc IIB8.1

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **IUCLID section point 7 „Intended uses and exposure“: IUCLID section 7.6 „Method of Application“**



= equivalent to Doc IIB8.1

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

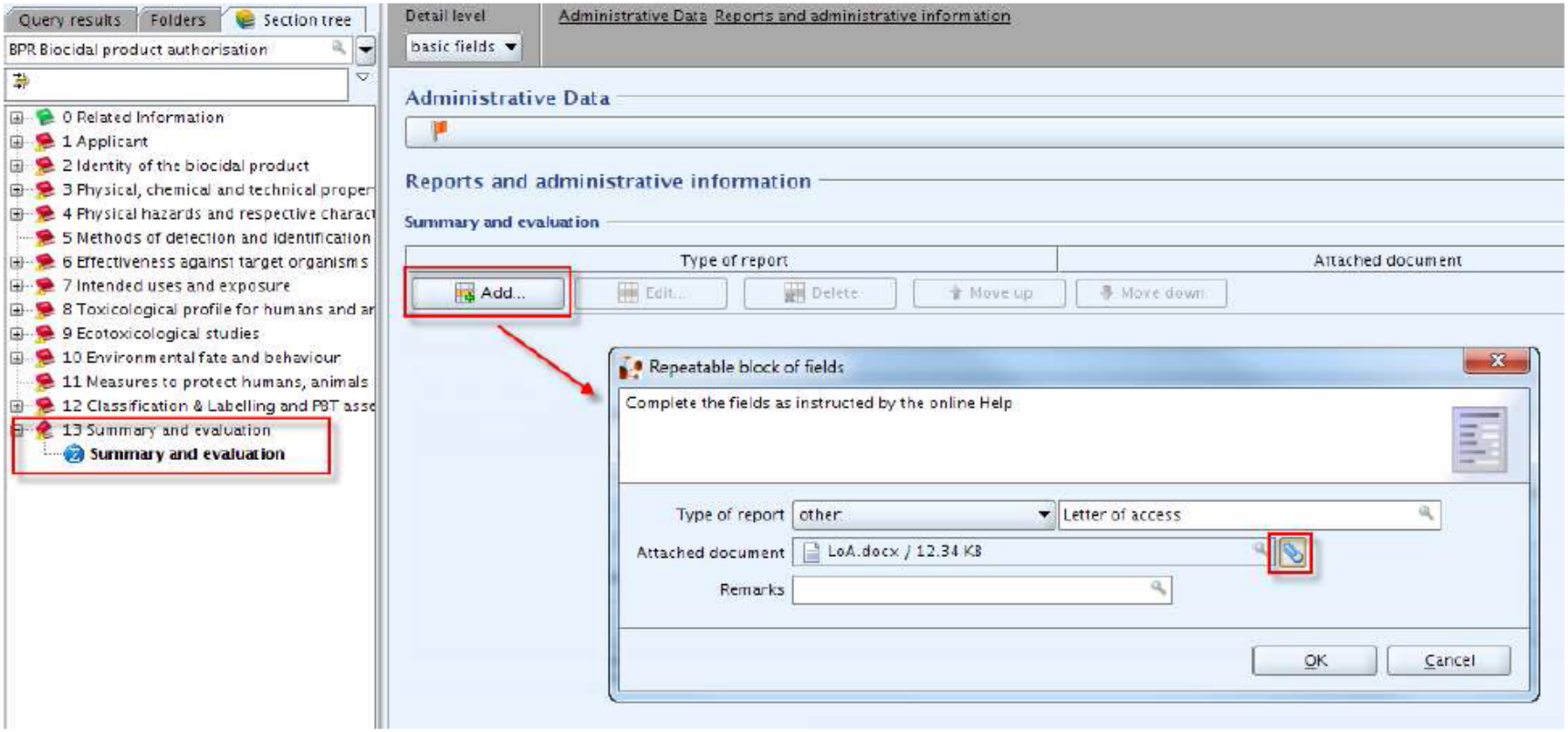
- **Human and environmental exposure and risk assessments under the BPR: .**

  - **IUCLID section point 13 „Summary and Evaluation“** can be used to

    - provide exposure and risk assessments on intended uses of the biocidal product (equivalent to Doc IIB8.2/IIB8.3 and DocIIC12/IIC13 for human health and environmental exposure assessments in former BPD dossiers).

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **IUCLID section point 13 „Summary and Evaluation“:**



= equivalent to Doc IIB8.2/IIB8.3 and Doc IIC12/IIC13

Comparison of the former BPD and the new BPR systems – Practical aspects, tips and tricks

- **First experiences for mapping exposure and risk in IUCLID 5.5. for biocidal product application:**

  - Description of uses and methods of application fields of IUCLID section point 7 „Intended uses and exposure“ were not really used yet; instead, the use description as provided for on the former Doc IIB8.1 level was provided in an attachment.

  - Exposure assessments and risk characterization for human health and the environment were included as attachments in IUCLID section point 13 „Summary and Evaluation“.

  - The exposure and risk assessments were delivered in accordance with the format used at the Doc IIB8.2/IIB8.3 and Doc IIC12/IIC13 levels of the former BPD dossiers.

REFERENCES:

- TNsG on Dossier Preparation, Parts I + II.
- Technical Guidance Document in Support of the Directive 98/8/EC Concerning the Placing of Biocidal Products on the Market – Guidance on Data Requirements for Active Substances and Biocidal Products ("TNsG on Data Requirements.").
- TNsG on Annex I inclusion.
- TNsG on Human Exposure (2002 + 2007).
- All TNsGs can be found on the ECHA webpage under the following link:

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation

and then click on "Biocidal Products Directive"

Thank you very much for your attention!

Web: www.scc-gmbh.de

Email: scc@scc-gmbh.de

Fon: + 49 (0) 671-298 46-0

Practicalities of the Dossier Submission for Active Substances and Products – Part II

Dr. Stefan Nave, SCC GmbH, Bad Kreuznach, Germany

SCC
SCIENTIFIC CONSULTING COMPANY

IUCLID 5 and R4BP3

-

IT tools for biocides applications

Steptoe & Johnson LLP

Annual Chemicals Regulation Seminar,

01/02 April 2014, Brussels

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Legal software requirements according to BPR

- **Article 71, para. 1-3:**

"1. The Agency shall establish and maintain an information system which shall be referred to as the **Register for Biocidal Products**.

2. The Register for Biocidal Products shall be used for the **exchange of information** between […] applicants and competent authorities, the Agency and the Commission.

3. Applicants shall use the Register for Biocidal Products to **submit applications and data** for all procedures covered by this Regulation."

- **Article 79:**

"The Agency shall specify formats and software packages and make them available free of charge on its website for submissions to the Agency. The competent authorities and applicants shall use these formats and packages in their submissions pursuant to this Regulation.

The **technical dossier** referred to in Article 6(1) and Article 20 shall be submitted using the **IUCLID** software package."

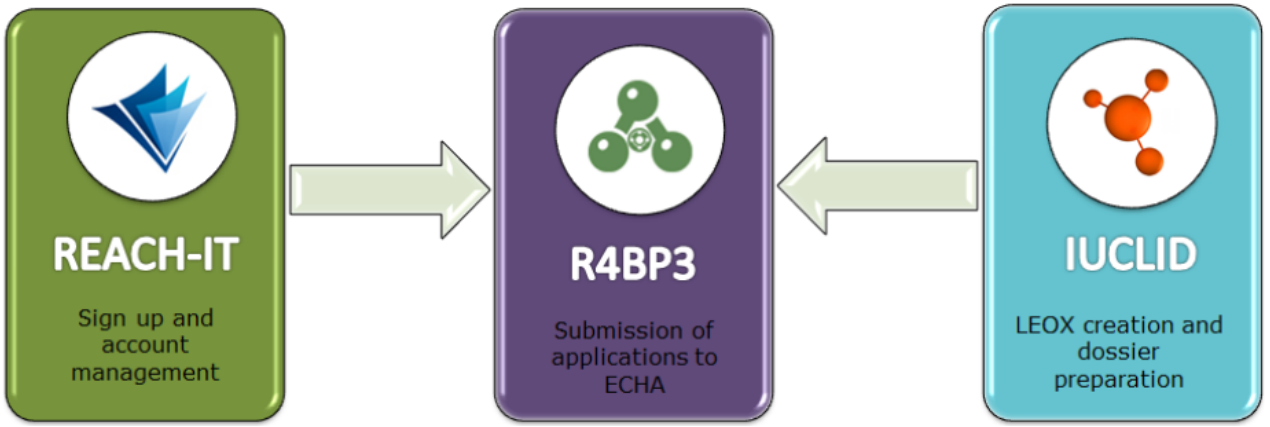
Aims of this presentation

- **Familiarize** you with
  - The **IT tools** currently in place for the handling of biocides applications
  - The most important **terms and concepts**, related to dossier preparation under the BPR
- **Provide hands-on experience** with submissions under the regime of the BPR
- **Review and discuss** the processes related to dossier preparation and submission

Content

- Introduction: Interaction of the IT systems
- A short version history of IUCLID
- The user interface of IUCLID 5.5.1
- Dossier creation in IUCLID
- Submission of dossiers via R4BP3
- Post-submission phase
- Available guidance

How R4BP3, IUCLID and REACH-IT interact*



- **R4BP3**
  - IT system for **submission of applications and data** and
  - **secure communication** between authorities and industry
- **REACH-IT**
  - IT system for the purposes of REACH (dossier submission…)
  - for R4BP3, user **account management** is handled via REACH-IT
- **IUCLID**
  - Local software used to **organise and exchange data** on substances, mixtures and microorganisms

* Image source: Biocides submission manual 2, p. 11, European Chemicals Agency, http://echa.europa.eu/

A short version history of IUCLID

- International Uniform ChemicaL Information Database

- First introduced in **1993** for the European Existing Substances Regulation (793/93/EEC)

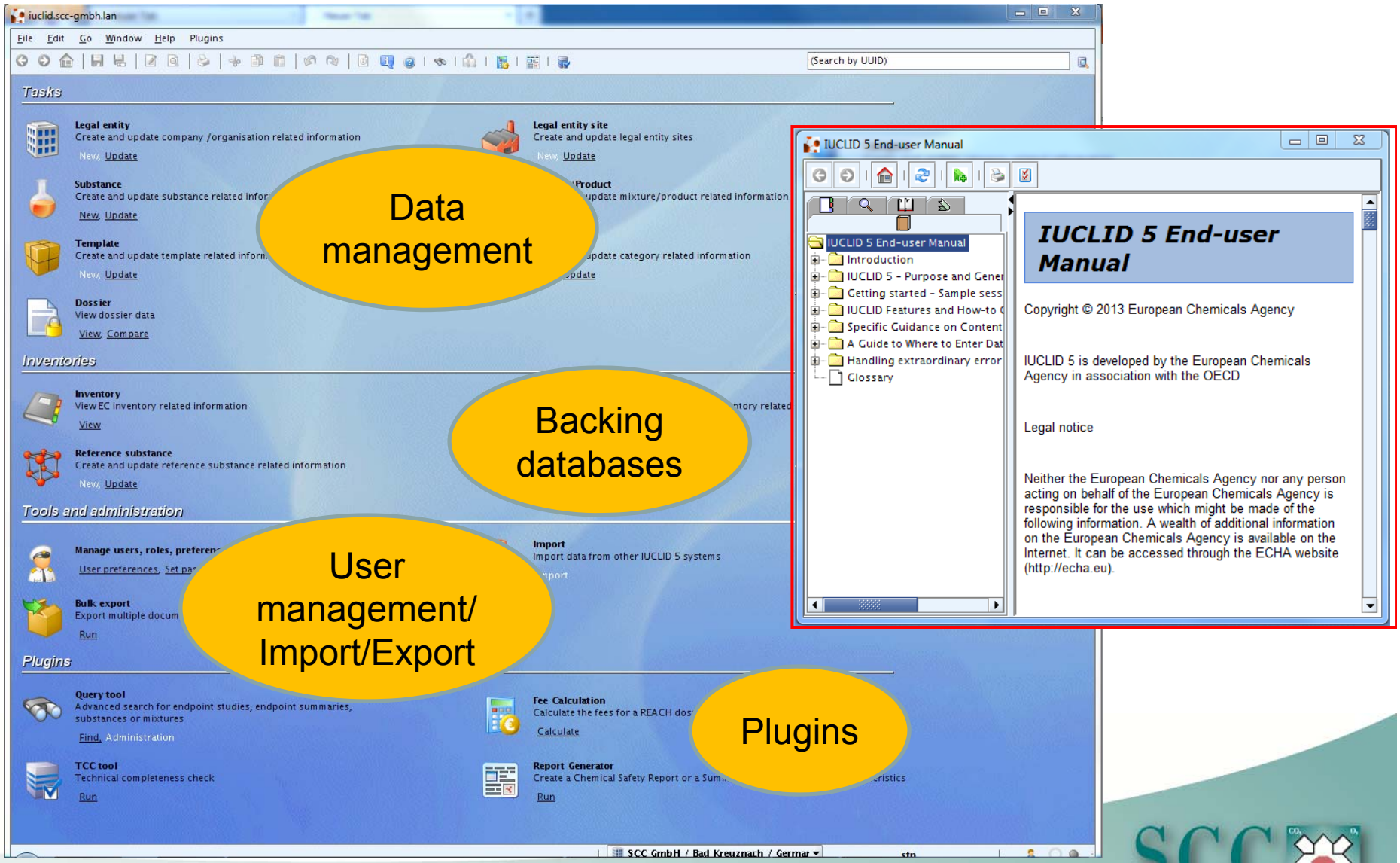
- Biocides: prescribed software for notification of existing active substances in Reg. (EC) No 1896/**2000**

- IUCLID is the REACH format to be used for data collection, preparation of technical dossiers and submission

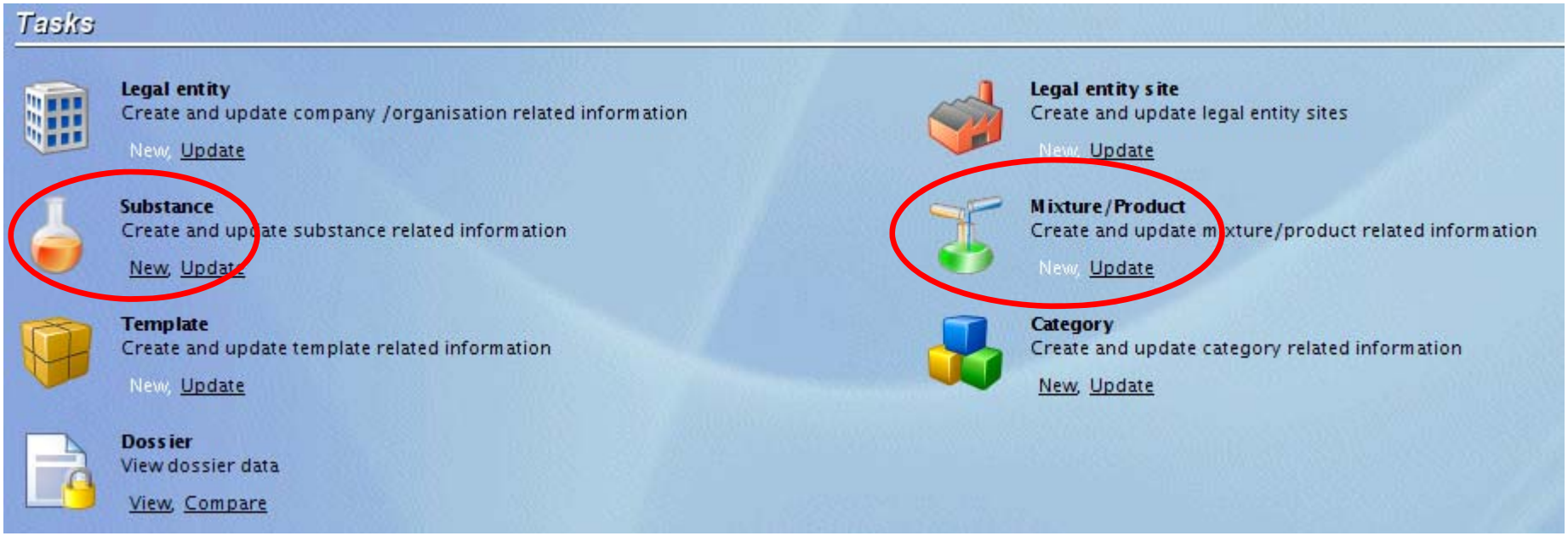
  → **2007**: Introduction of IUCLID 5 (**file format *.i5z**)

- Current version: IUCLID 5.5.1 (since 11 September **2013**)

IUCLID 5.5.1 start page



IUCLID 5.5.1 task menu



- Creation and handling of
  - Legal entities
  - (Active) substance and
  - (Biocidal) product datasets
  - Dossiers

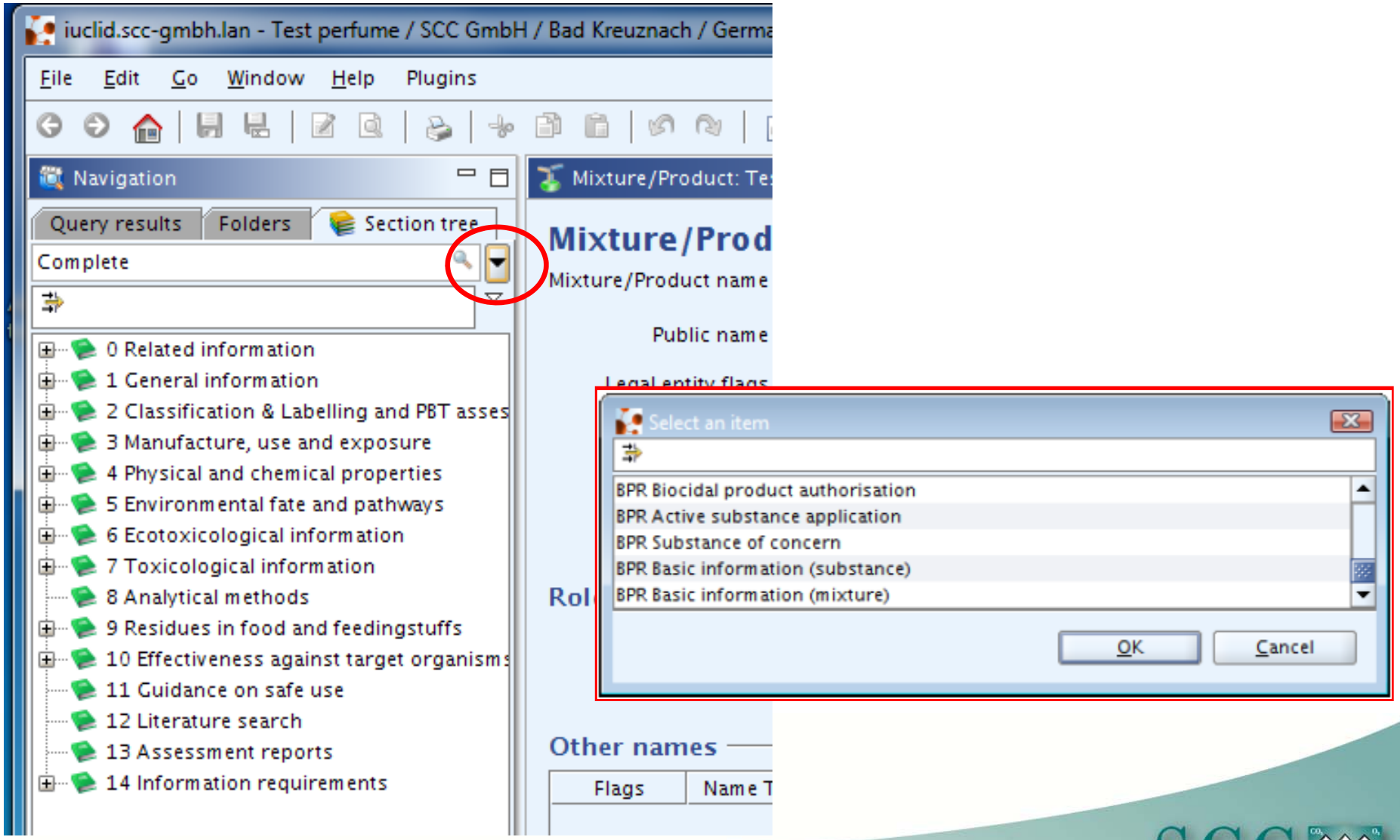
Definitions: Legal entities in the context of IUCLID 5

- **L**egal **E**ntities (**LE**)
  - LE information can be stored in a Legal Entity Object (**LEO**)
  - The same LEO should be used in IUCLID 5 and REACH-IT, identified by the same UUID
  - LEO can be exported as an Xml file (= **LEOX**)

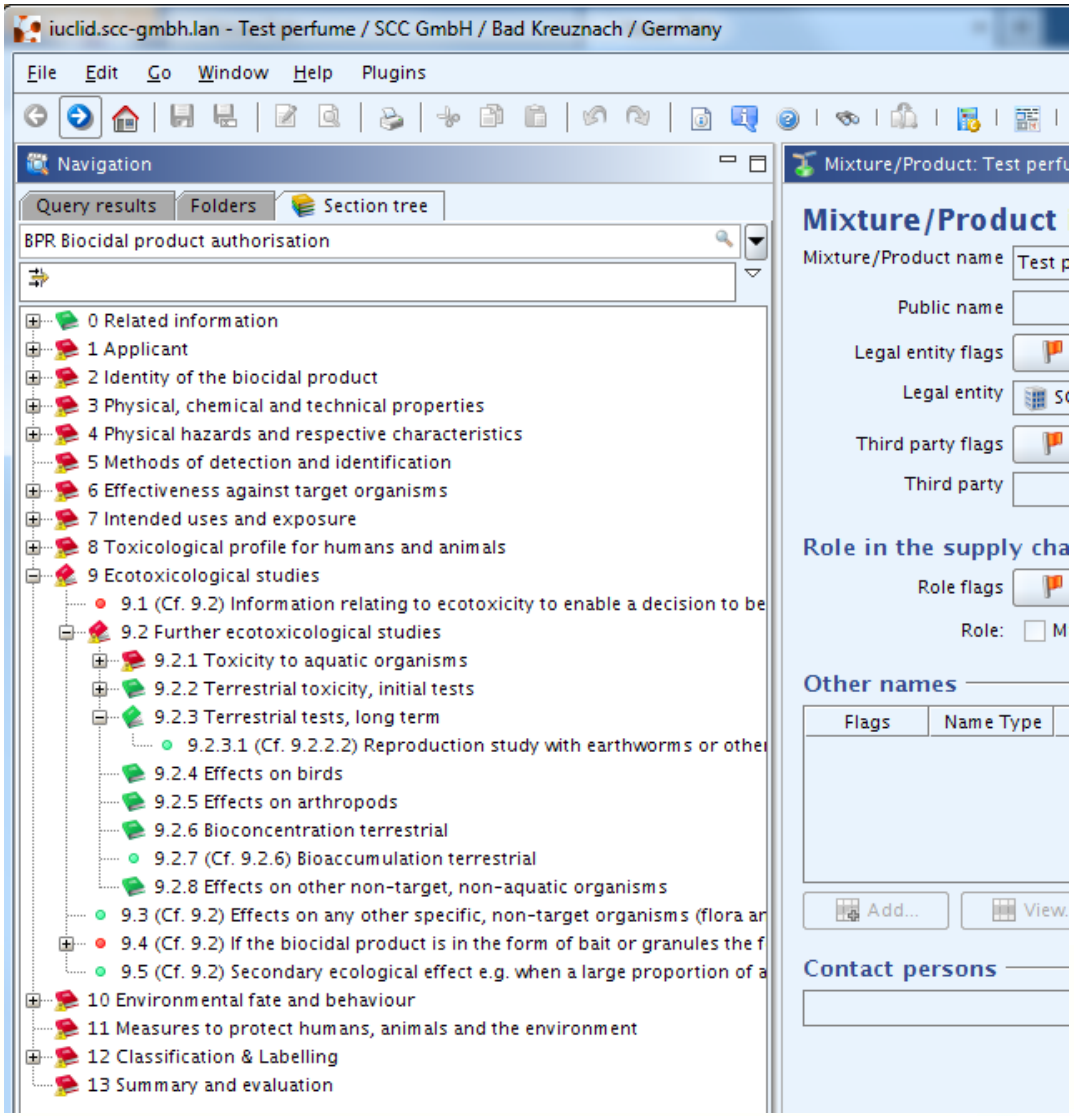
- **U**niversal **U**nique **ID**entifier (**UUID**)
  - "Fingerprint" code for every item (e.g. LEO, but also e.g. dossiers, datasets, endpoint study records…) in IUCLID and REACH-IT
  - Format: Random string of letters and numbers,

    e.g. IUC5-bfa610ea-fe3c-36b3-8fa2-6faf50bbe66c

IUCLID 5.5.1 user interface - templates



Section tree of a biocidal product template



- Section numbering according to Annex II/III BPR
- **Red** section symbols: **core** data

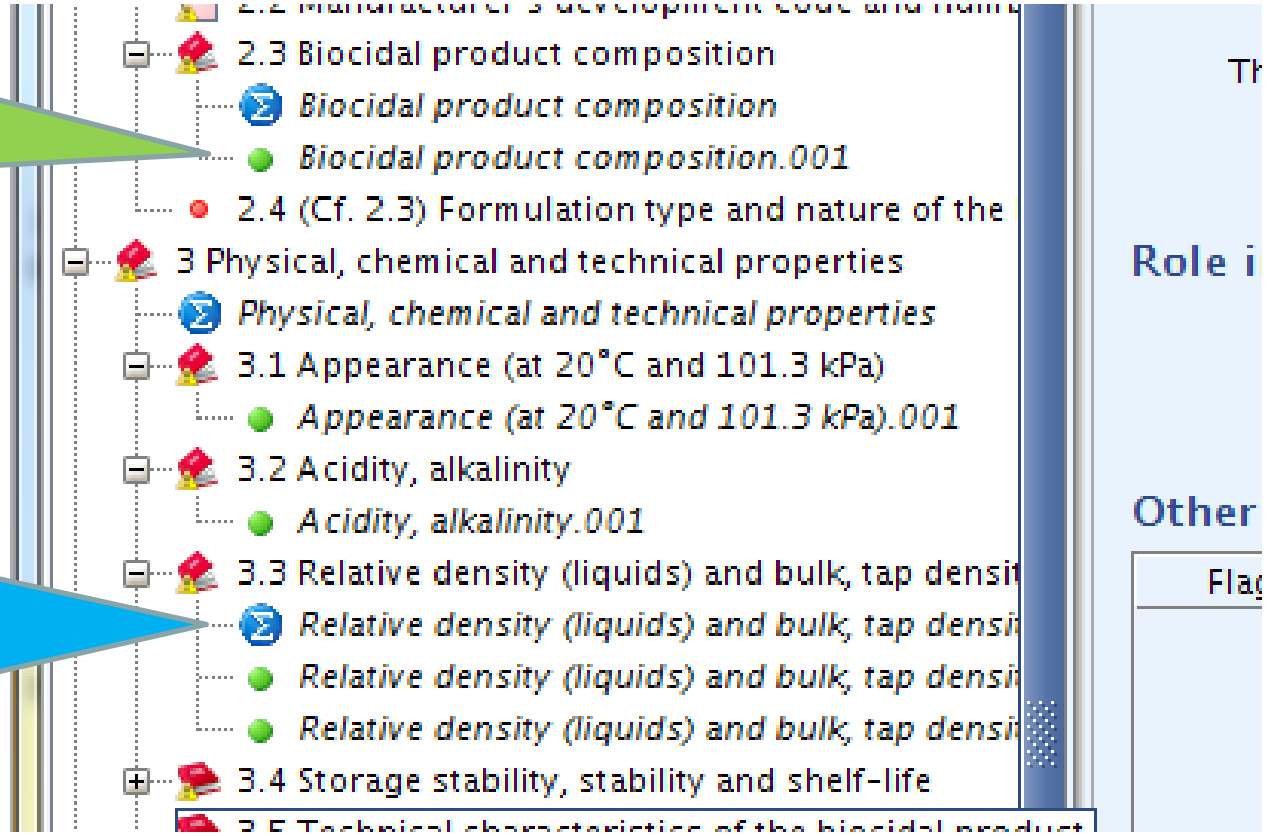
- **Green** section symbols: **additional** data

- Not yet included: templates for **microorganisms**

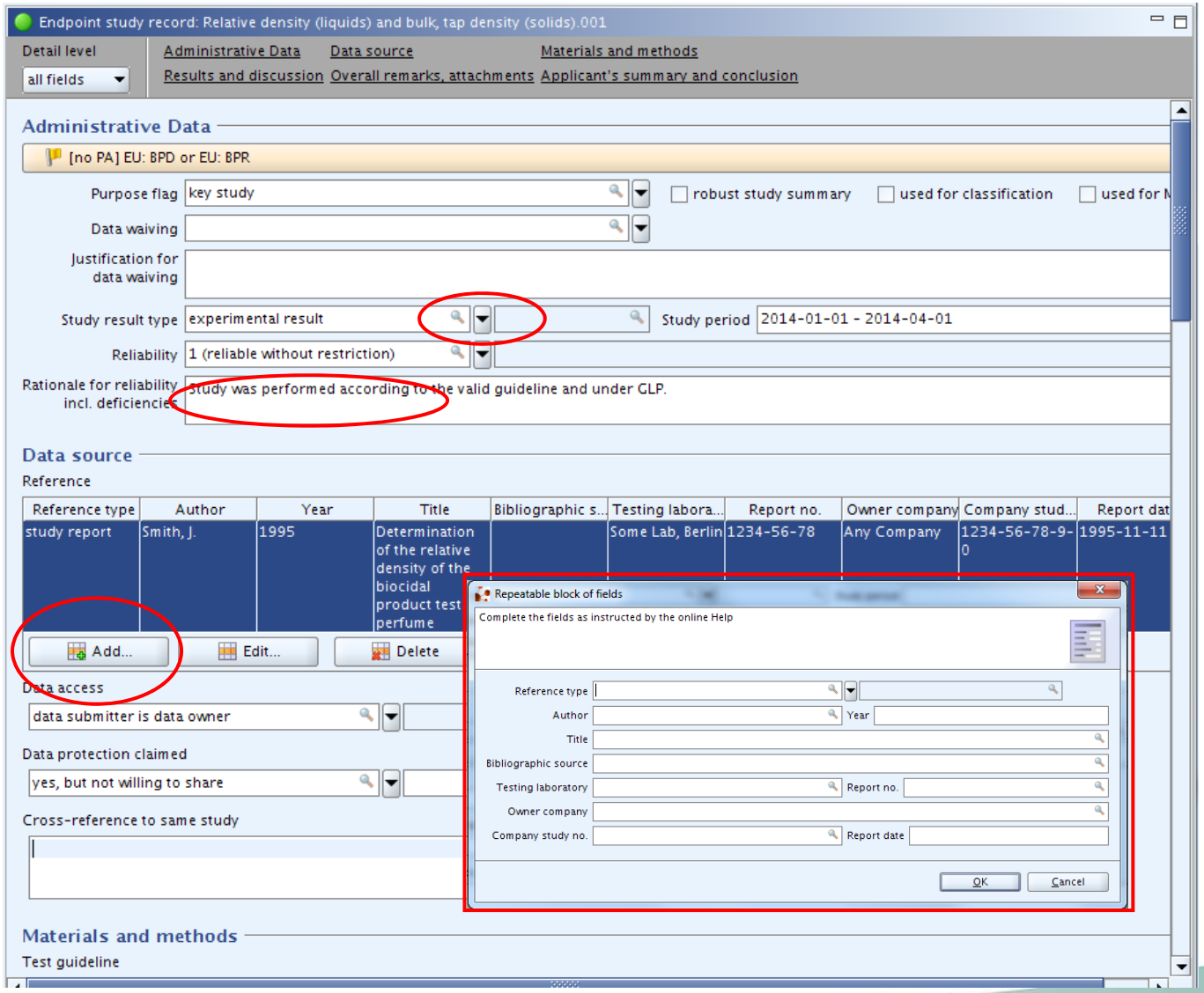
Endpoint study records vs. Endpoint summaries

Endpoint study record ≈ Former Doc III level → Study summary

Endpoint summary ≈ Former Doc II chapters → Summary of different studies

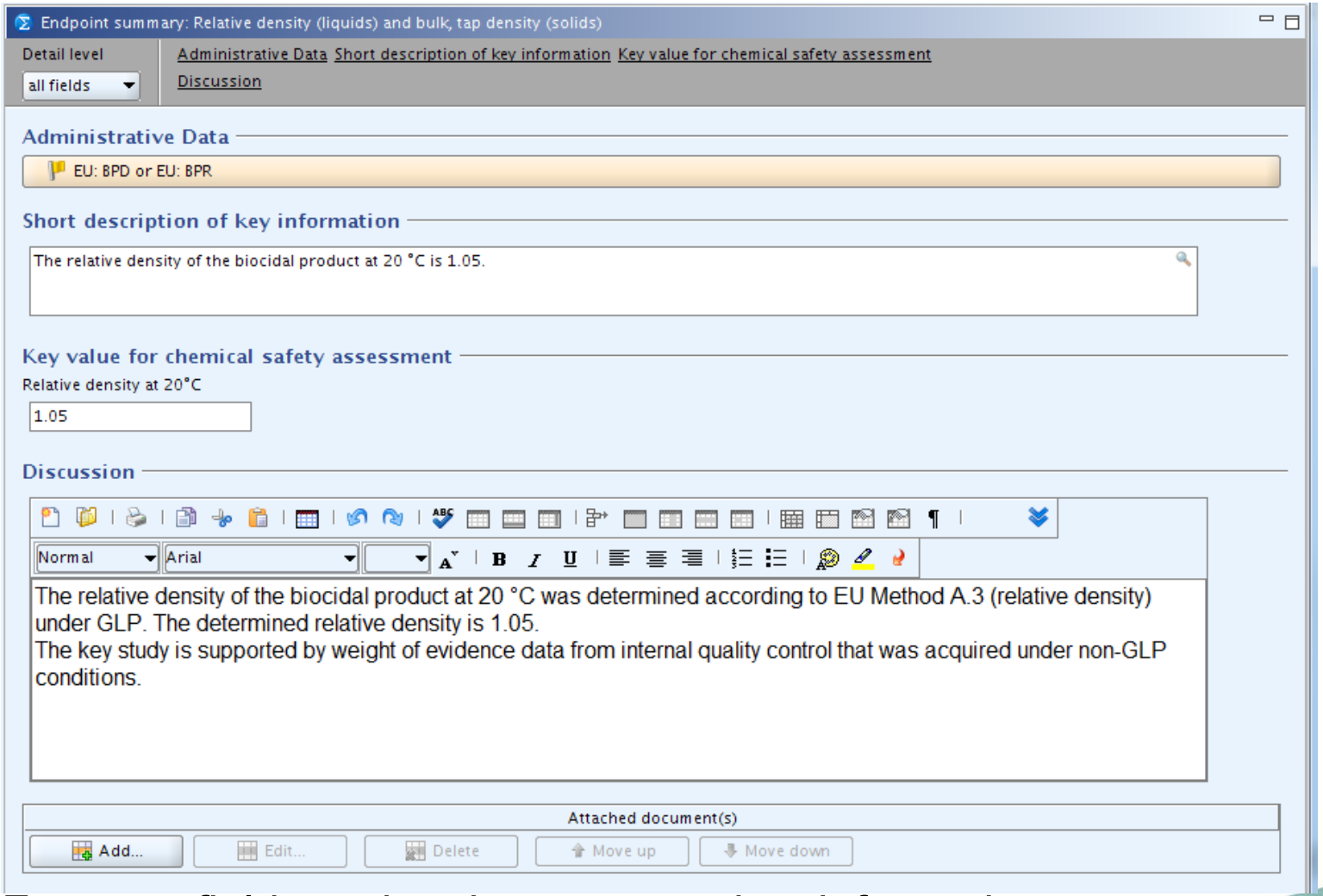


Example for an Endpoint study record



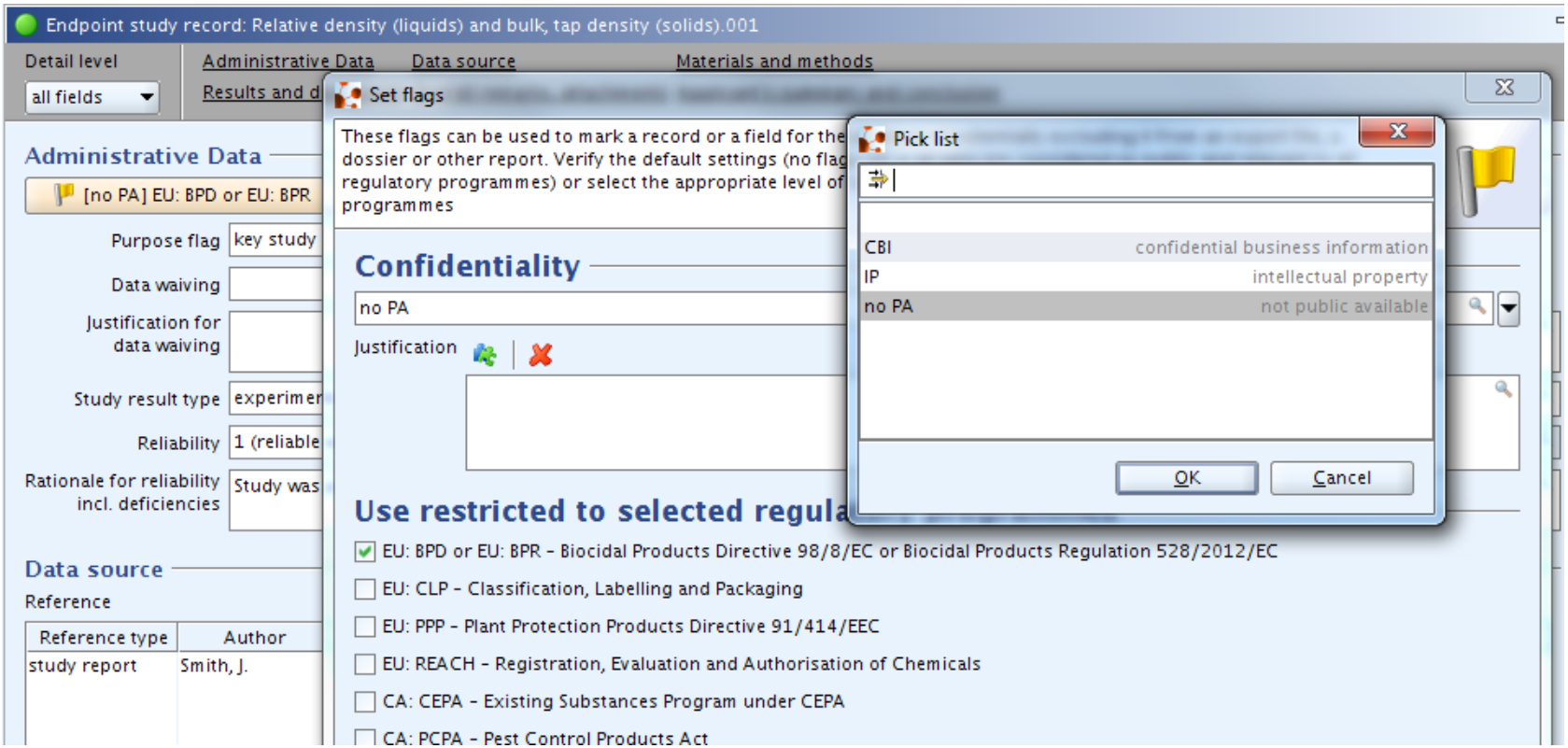
- Relevant data has to be filled in for a
  - Study
  - Literature reference
  - Waiver
- Different types of fields:
  - Free text
  - Drop-down
  - Repeatable blocks

Example for an Endpoint summary



- Free text fields and options to enter key information

Flags



- Endpoint study records (and summaries) in a IUCLID 5 dataset can be flagged as
  - Belonging to a certain regulatory programme and/or
  - Confidential in accordance with Article 66(4) of the BPR

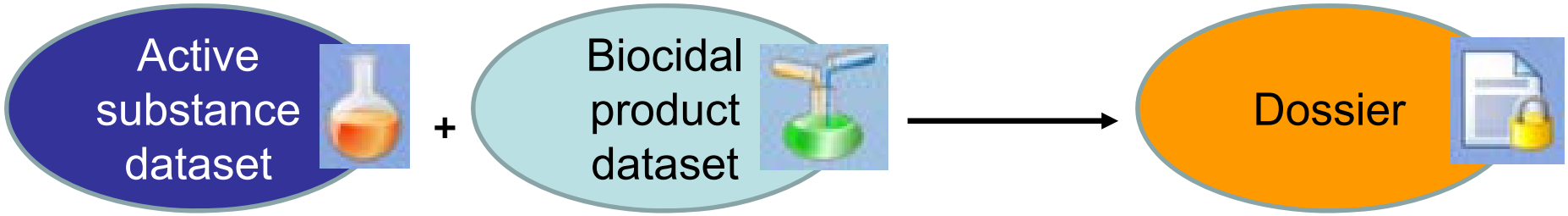
Confidentiality claims

- Dissemination:
  - ECHA is required to publish certain information on active substances and biocidal products free of charge on the internet (Art. 67).
  - Amongst other information, this includes the (robust) study summaries of studies submitted to support the approval or authorisation.

- Options to keep details of study summaries confidential:
  - Confidentiality claim according to Article 66(4) BPR - fees according to regulation (EU) No. 564/2013
  - Confidential text fields: If the information is only partially confidential, IUCLID offers the following free text fields:
    - 'Confidential details on test material'
    - 'Any other information on materials and methods including tables', and
    - 'Overall remarks'

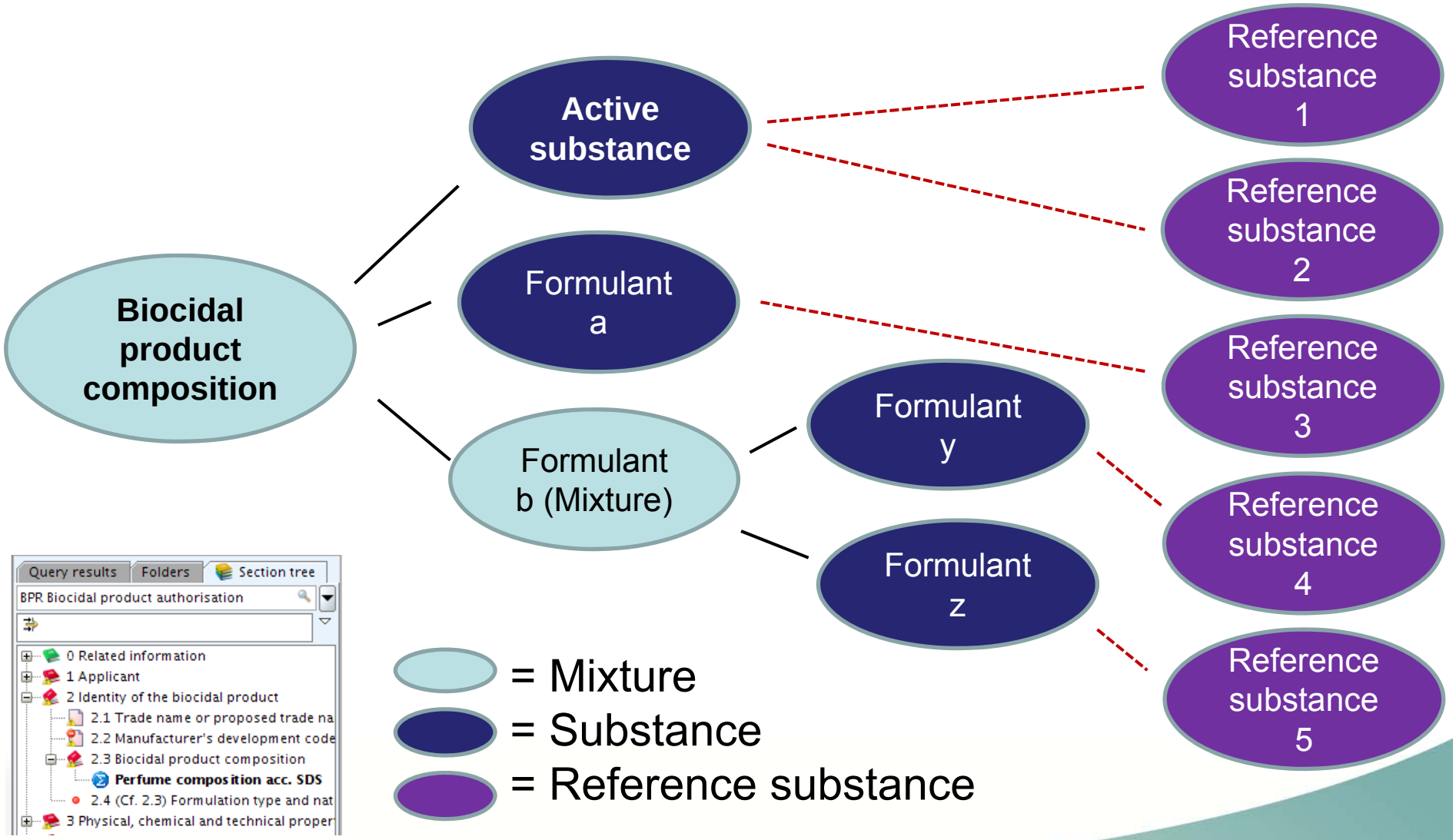
Particulars of preparing an application

- A dossier must **always** be created from a mixture dataset that is linked to an active substance dataset



- Datasets can be created and edited independently but need to be connected before the dossier is created
- Connection is done on the level of the product composition

How different datasets are connected



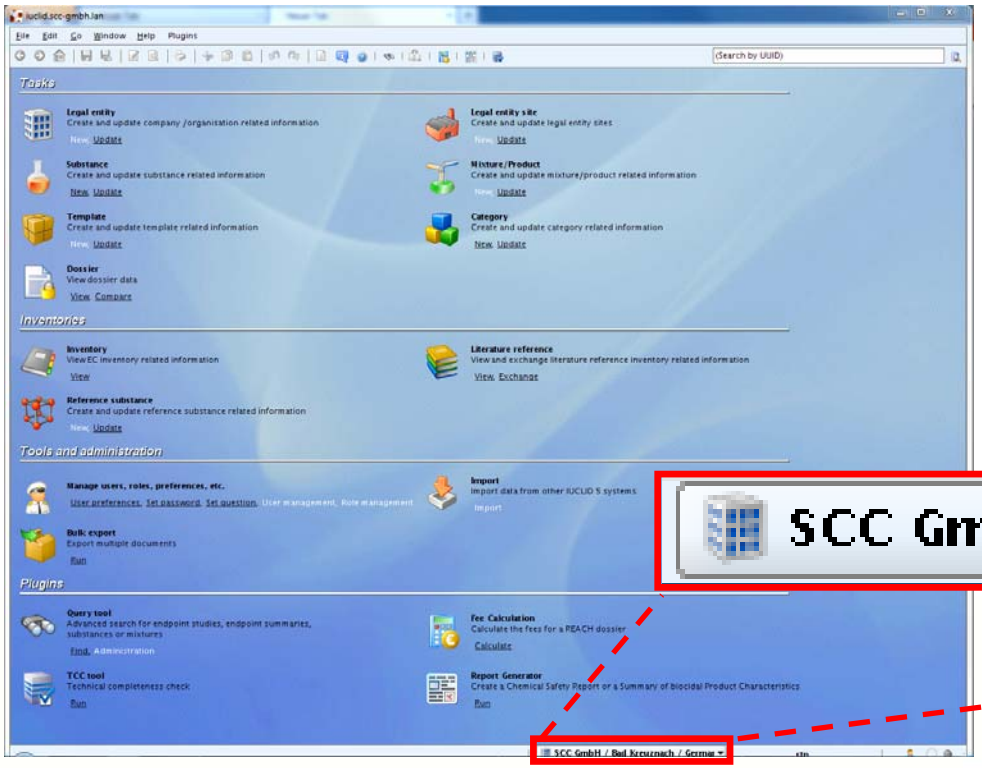
Minimum requirements for datasets – ECHA's technical completeness check

- Minimum requirements for an **active substance** dataset:
  - ✓ **Name** of the active substance and an **identifier** (e.g. CAS-/EC-No.)
  - ✓ Degree of **purity** (incl. Units)
  - ✓ At least one **constituent** linked to the correct reference substance
  - ✓ Correct **product type** selected in ‚Use' section
  - ✓ Information requirements, national forms, supporting documents etc.

- Minimum requirements for a **biocidal product** dataset:
  - ✓ **Name** of the biocidal product
  - ✓ **One Composition block** incl. function, concentration percentage and a link to an AS
  - ✓ The **same product type** selected as for the AS
  - ✓ Draft Risk Assessment attached
  - ✓ Information requirements, national forms, supporting documents etc.

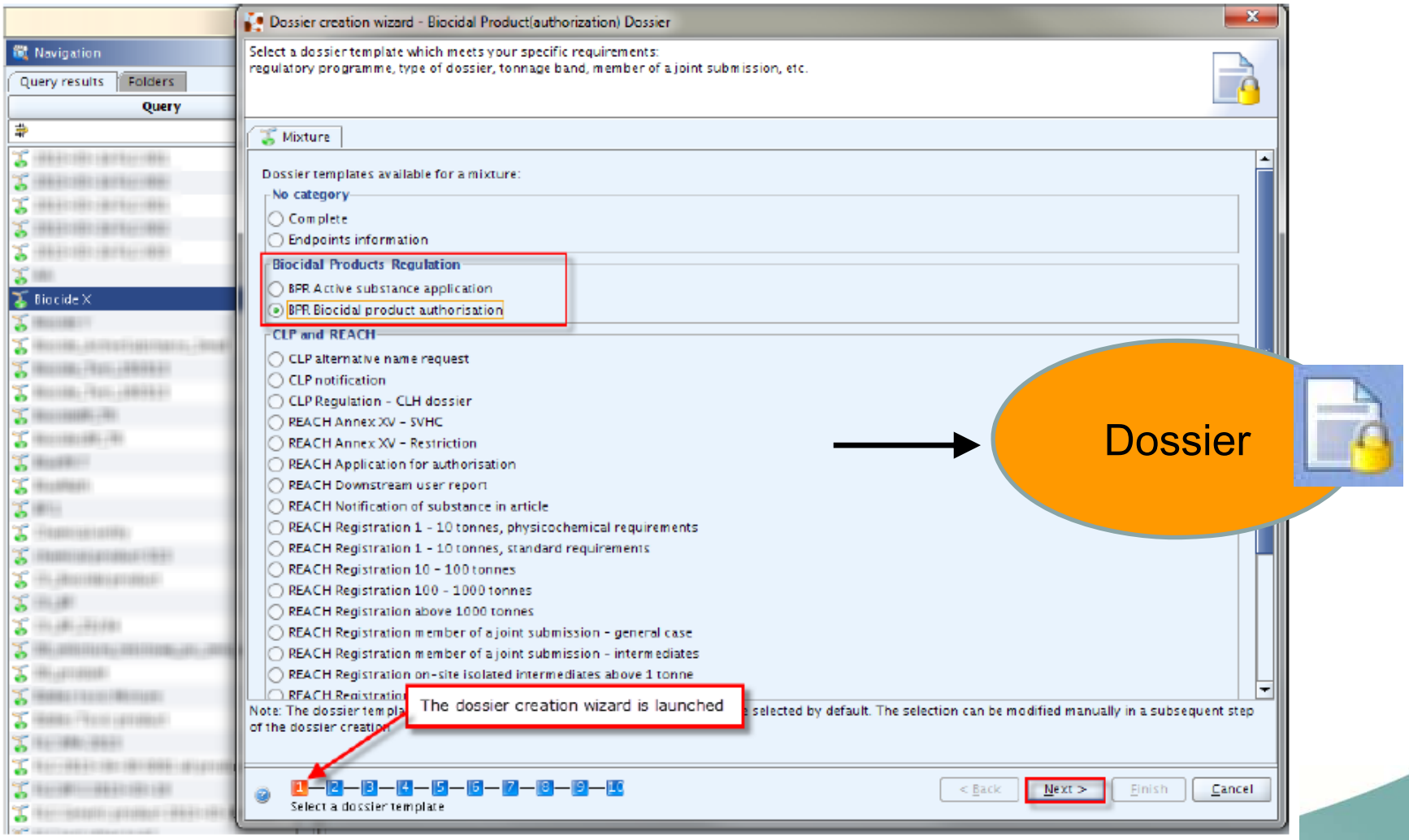
Create a dossier

- **Checklist for the dossier**
  - ✓ Dossier created from the biocidal product dataset
  - ✓ Make sure the correct LE is selected at the bottom of the IUCLID screen



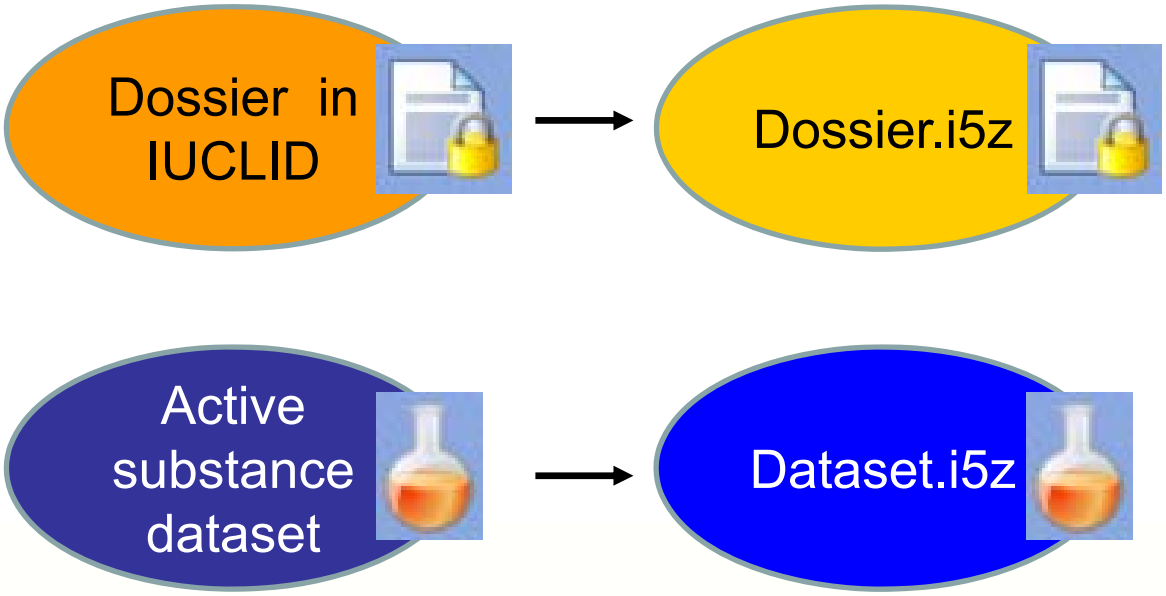
- **This LE will be saved in the dossier header**
- Exactly the same LE will need to appear in R4BP3 (same UUID!)

Start the dossier creation wizard



The export functionality

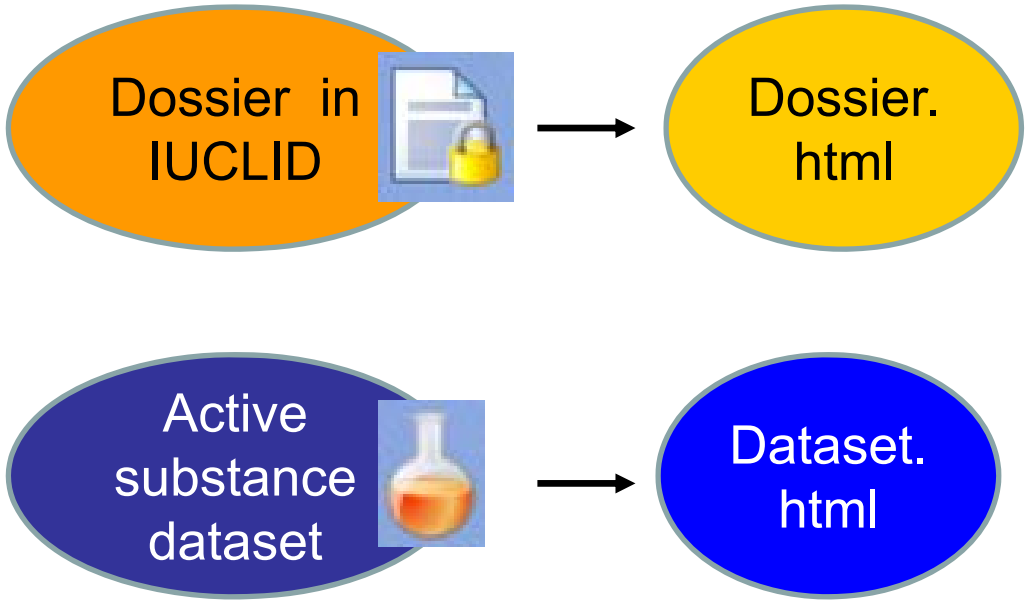
- The dossier needs to be exported before it can be uploaded to R4BP3
- Export functionality creates .i5z files



- Communication with authorities; submission file
- Handy for generating external backup files

The printout functionality

- Printout functionality creates html files:



Dossier

1. General
2. C&L
3. Manu-facture

...

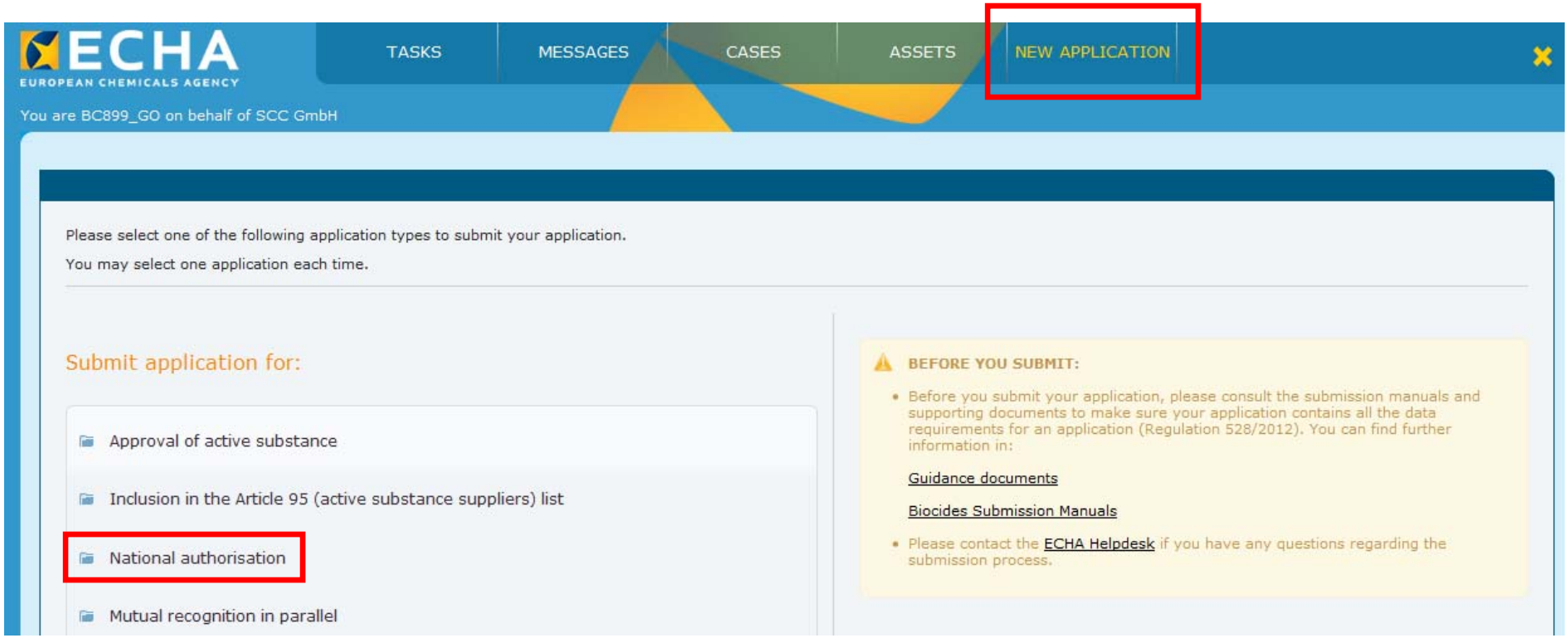
Dataset

1. Applicant
2. Identity
3. PhysChem

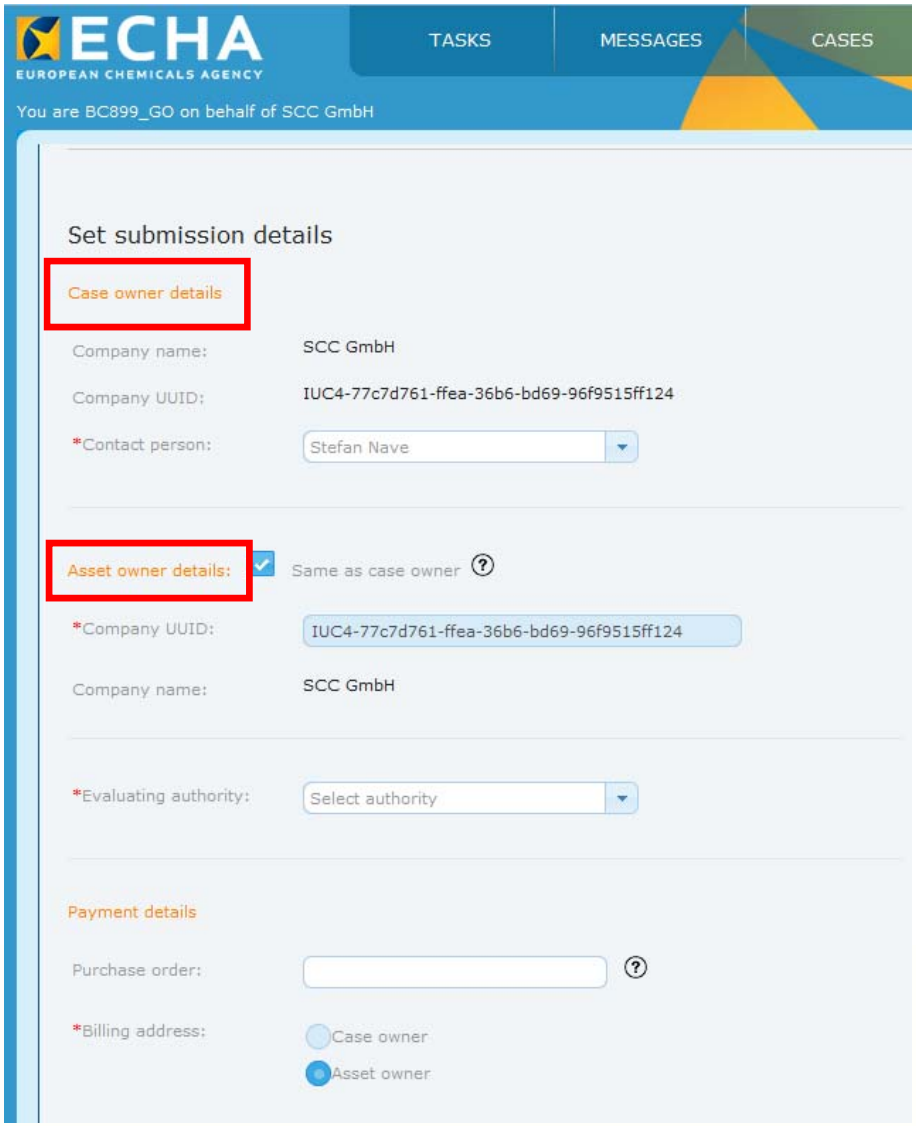
...

- **BUT:**
  - Dossier printout with IUCLID section numbering only
  - Attached documents are not printed → V 5.6.0

Submission of Dossiers in R4BP3



Cases and Assets in the context of R4BP3



- **Definitions**
  - Case = An accepted application in progress
  - Asset = A regulatory decision on an application

→ **2 different roles** for LEs in R4BP3
  - Case owner = Submitter of an application
  - Asset owner = Applicant

- **May be identical**, but not necessarily (e.g. if case owner is a consultant)

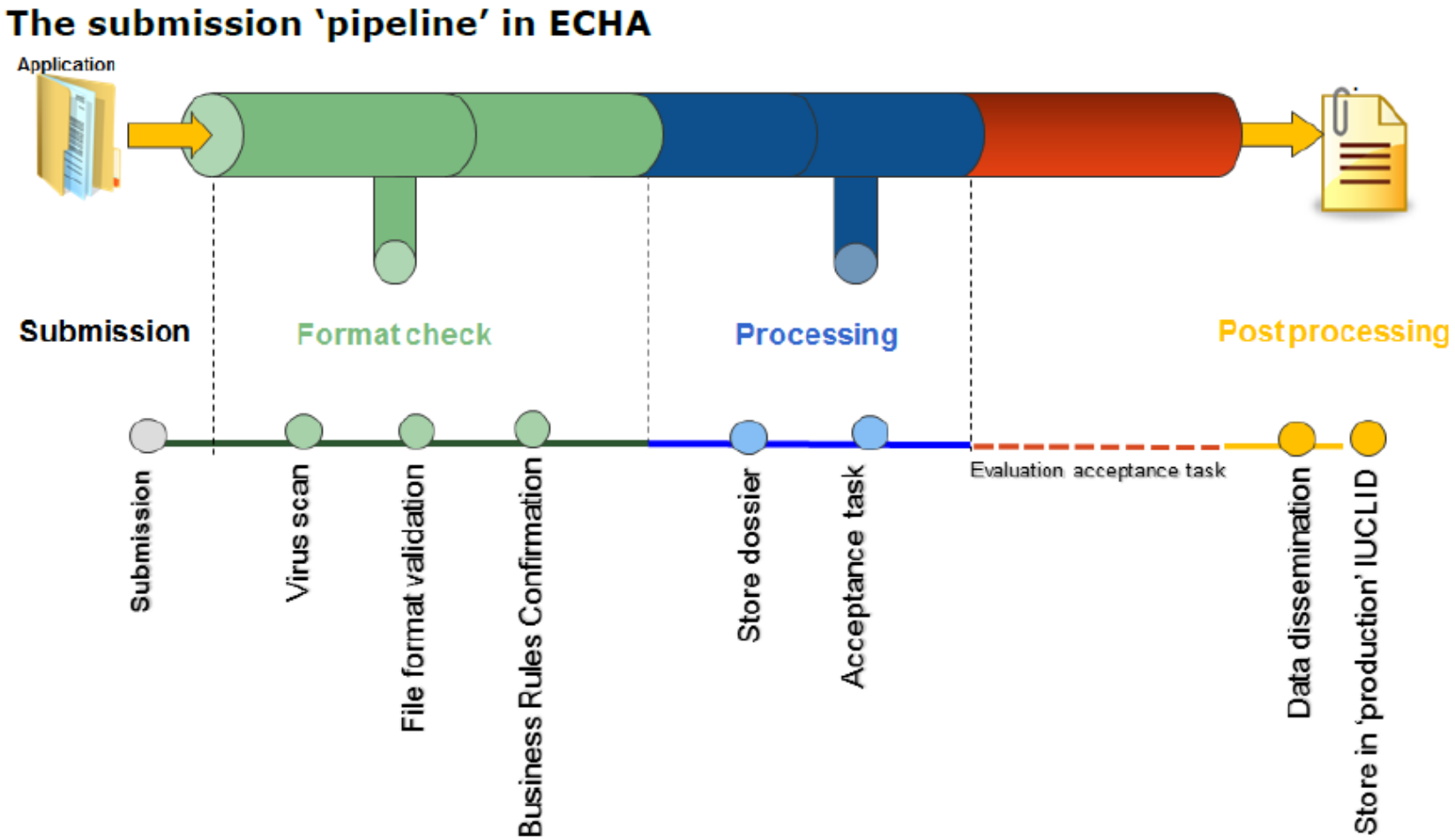
- Case owner‘s and/or asset owner‘s UUID has to match the UUID in the dossier header

Access for case owner and asset owner in R4BP3

	Case owner	Asset owner
View case details	Y	Y
View asset details	Y	Y
Receive and complete task items	Y	**N**
Receive messages	Y	**N***
Receive negative decisions	Y	**N**
Receive positive decisions	Y	Y* (= Asset)

- During the processing of a case, the case owner can receive messages from the authorities, while the asset owner cannot.

What happens after submission?



* Image source: Biocides submission manual 4a, p. 47, European Chemicals Agency, http://echa.europa.eu/

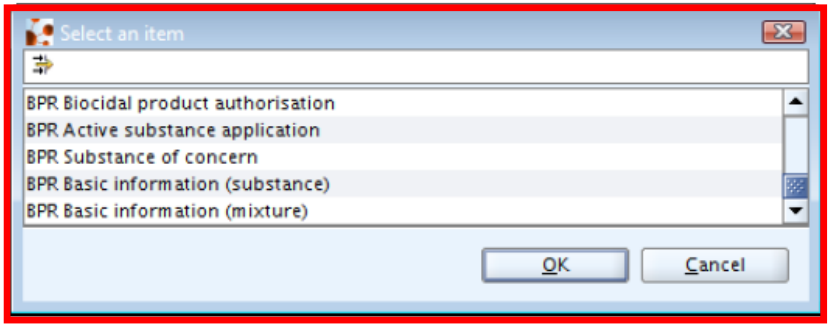
Post-submission tasks

- After submission, the application cannot be updated by a case owner at any time.
- Only if the evaluating authority decides on certain actions to be taken (e.g. request for additional information), they will assign a task in R4BP3.
- The case owner will have to claim and fulfill the task in time.
- Deadlines are usually brief.

→ Utmost importance to check the R4BP3 regularly to avoid missing any deadlines.

Outlook: Upcoming versions of IUCLID

- IUCLID 5.6.0: release planned for **mid-April 2014**
  - Inclusion of full study reports in dossier printout
  - Transfer of annotations
  - Several minor improvements
    - *Memorizing of templates*



- IUCLID 6.0: working phase scheduled until **January 2015**
  - Security and data access
    - *Defined access rights per user/item*
  - Legislations
    - *Templates can be updated independently*
  - Attachments
    - *Versioning of attached documents*

Guidance

- **Biocides Submission Manuals**
  - 1 Using IUCLID for biocide applications
  - 2 Using R4BP3 for biocide applications
  - 3 Active substances
  - 4 Biocidal products
  - 5 Invoicing in R4BP3
  - 6 Confidentiality requests for biocide application

- **Guidance on**
  - ➢ Active substance Suppliers
  - ➢ Information requirements

    (No guidance yet how to proceed with substances of concern)
  - ➢ Applications for Technical Equivalence
  - ➢ Data sharing

    (Published for reach purposes, adaptation for biocidal purposes by an explanatory note)

Thank you very much for your attention!

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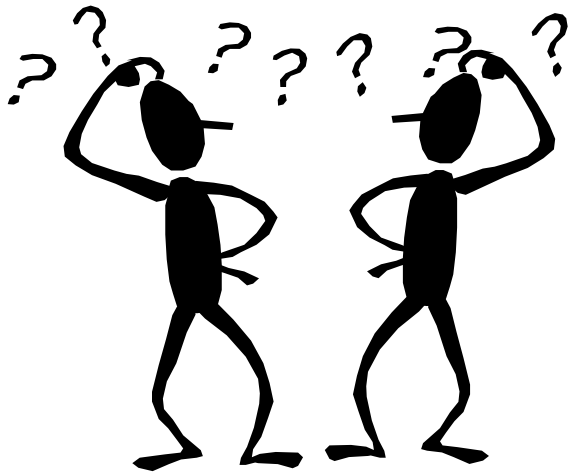
Questions?



BPR: Key Commission Issues and Next Steps

Steptoe Annual Chemicals Regulation Seminar
2 April 2014
Brussels

Pierre Choraine
European Commission
DG Environment, Unit A.3

Introduction

- Main principles
- Approval of active substances
- Authorisation of biocidal products
- Costs and data sharing
- Implementing legislation and guidance documents
- Treated articles

Main principles

- Authorisation required prior to placing on the market
- Approval of biocidal active substances at EU level
- National product authorisation with mutual recognition
- Industry responsible for submitting data allowing evaluation
- National rules apply during the programme for review of existing active substances

The European Chemicals Agency (ECHA)

- Provide scientific and technical support
- Coordinate substance approval, Union authorisation
- Secretariat for BPC and the Coordination group
- IT platform (R4BP)
  - Electronic submissions
  - Data dissemination
- Data sharing
- Technical equivalence
- List of (alternative) suppliers of active substances
- Helpdesk

Approval of active substances

Approval of active substances

- Hazard based exclusion criteria (Article 5)
  - Objective : exclude active substances of very high concern
  - CMR category 1A or 1B, PBT, vPvB, endocrine disruptors
  - The principle: cannot be approved
  - The derogation: approval possible
    - if exposure negligible, substance essential or non-approval has disproportionate negative impact
    - subject to risk mitigation measures
    - only for Member States where needed
    - for maximum 5 years
    - as candidate for substitution

Approval of active substances

- Substitution criteria (Article 10)
  - Objective: Substitution of substances of high concern
  - Criteria: Exclusion criteria, other properties of high concern (Art 10)
  - Approved for a maximum of 7 years
  - Comparative assessment at product authorisation
  - Alternatives must present significantly lower risk, be sufficiently effective, present no significant disadvantage, and provide sufficient chemical diversity
  - Possible derogation for a maximum of 4 years in order to gain experience

Review programme for existing active substances

Product-type		Number of substance approvals																			
		2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	
Wood preservatives	8	1	1	8	6	1	4	5	6	3	3	3	1								10
Rodenticides	14		2	1	6	3	0	1	1	0	0										0
Molluscicides	16																				0
Insecticides	18				2	4	6	3	10	6	6	8	5	5	5	2	2	1			40
Repellents	19					1	2	2	3	3	3	3									9
Antifoulings	21						0	0	2	4	4	1									9
Disinfectants	1							0	1	4	4	4	4	3	3	3	3	1	1		30
	2							2	1	4	4	4	5	8	8	8	10	10	10	9	80
	3							0	2	7	5	5	4	4	4	5	3	3	2	2	44
	4							0	5	2	4	4	5	5	5	5	4	4	6	5	49
	5							0	0	1	2	2	3	1	2	2	2	1	1	1	18
Preservatives (in-can & metalworking-fluid)	6							0	1	4	4	4	6	4	4	4	4	3	3	3	43
	13							0	0	3	3	3	3	3	2	2	2	1	1		23
Preservatives (film, fiber, masonry, liquid cooling & processing systems)	7							0	1	2	2	2	2	3	3	3	3	3			23
	9							0	1	1	1	2	3	3	3	3	3	5	4	1	29
	10							0	1	1	1	1	3	3	3	3	3	3	1	1	23
	11							0	0	2	2	2	3	5	5	6	6	6	6	6	49
	12							0	0	3	1	2	3	3	3	4	4	6	6	4	39
Avicides	15							0	0												0
Piscicides	17							0	0									1			1
Embalming fluids	22							0	1								1	1	1	3	6
Control of other vertebrates	20							0	1												0
Total		1	3	9	14	9	12	13	37	50	49	50	50	50	50	50	50	49	42	35	525

Approval process

- Application submitted to a Member State
- Dossier evaluated by this Member State
- Peer-review in the Biocidal Products Committee
- ECHA opinion
- COM decision approving the substance

Substances of no concern

- Substances eligible for simplified authorisation
- List of criteria to be met (Article 28.2)
  - No CMR, no PBT
  - No skin or respiratory sensitizer
- If substance does not give rise to concern
- Annex I inclusion
- Draft Regulation on Annex I inclusion

Authorisation of biocidal products

Authorisation of biocidal products

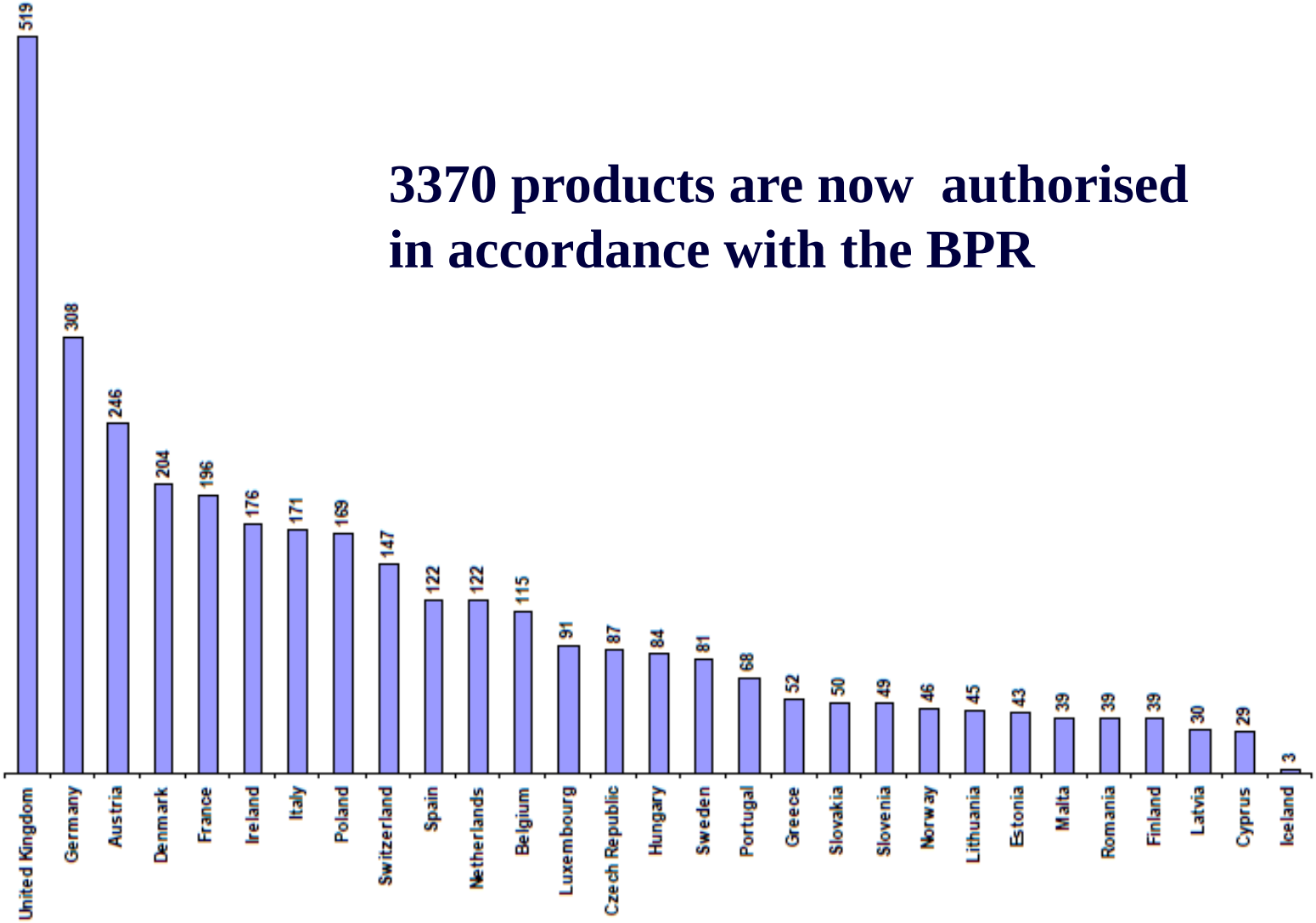
- National authorisation
- Mutual recognition
- Union authorisation
- Simplified authorisation
- Changes, same products, renewals Regulations
- Product families

Mutual recognition procedures

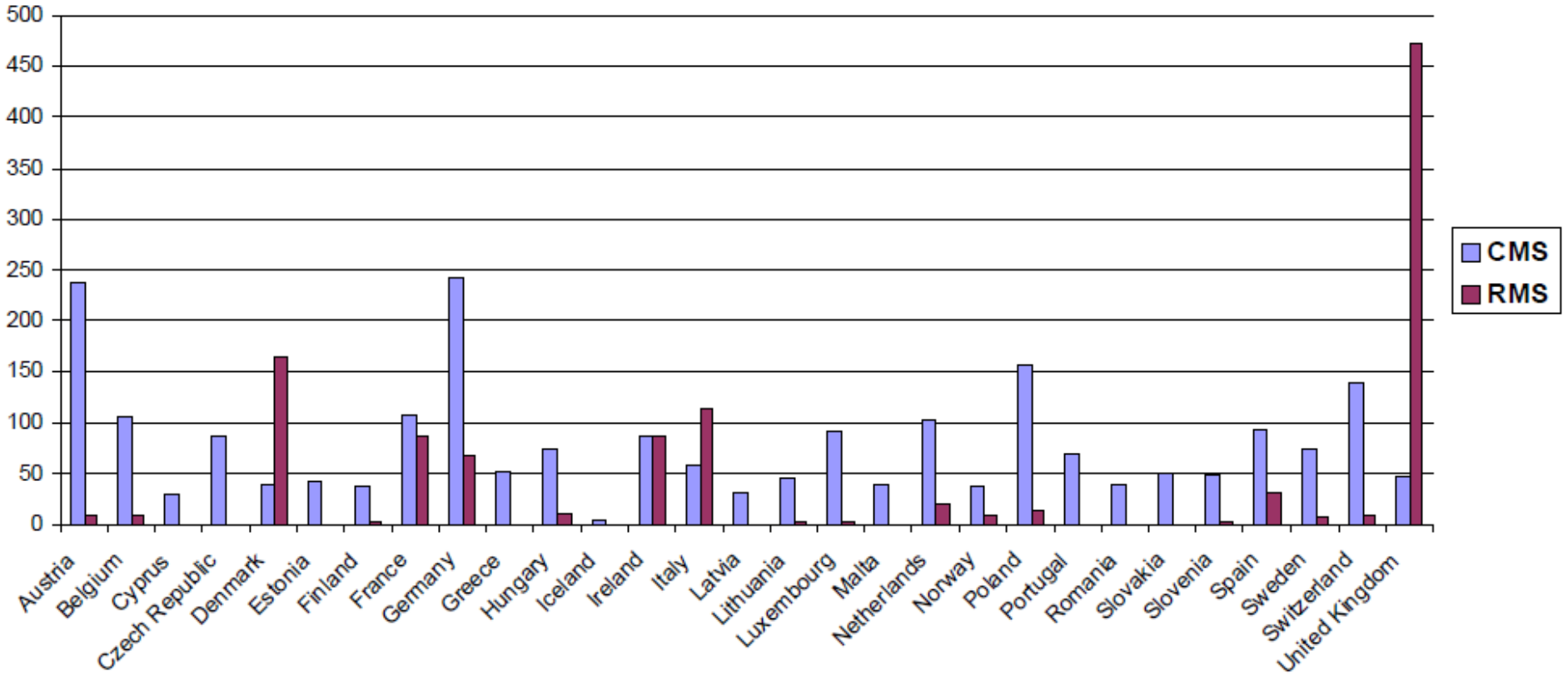
- In sequence or in parallel
- 90 days for Member States to agree between them
- Unresolved disagreements referred to co-ordination group
- Commission to settle un-resolved disagreements
- Refusal or adjustment possible on grounds of
  - **protection of, e.g., environment or health, or**
  - **absence of target organism**
- Refusal or adjustment subject to agreement with applicant or Commission decision

European Commission

3370 products are now authorised in accordance with the BPR



Authorisations granted per MS



Union authorisation

- Objective: Facilitate access to the entire EU market
- Authorisation valid across EU unless explicitly restricted
- Products with similar conditions of use
- Not open to substances fulfilling the exclusion criteria, rodenticides or antifouling products (Article 42(1))
- Progressive phase-in period for workability until 1 January 2020

Union authorisation

- Phase-in period for reasons of workability for ECHA and COM
  - **From 1/9/2013**, products containing **new active substances** and PTs 1,3, 4, 5,18 and 19;
  - **From 1/1/2017**, PTs 2, 6 and 13;
  - **From 1/1/2020**, the remaining PTs.

Union authorisation

- Pre-submission meeting
- Application submitted to ECHA
- Dossier evaluated by evaluating competent authority chosen by applicant
- Evaluation (12 months)
- Peer-review by Biocidal Products Committee (6 months)
- ECHA opinion
- COM decision allowing the placing on the market of the product on the entire Union market

Simplified authorisation

- Objective: promote products with lower concern for health and environment
- For certain products containing only active substances listed in Annex I
- Additional criteria (Article 25)
  - No nanomaterial or substance of concern contained in product
  - No personal protective equipment required
- Faster procedure: evaluation in 90 days instead of 365
- Once an authorisation is granted, other Member States' markets accessible subject only to notification

Costs and Data Sharing

Mandatory cost sharing

- As of 1 Sept. 2013, all active substance manufacturers or importers to submit a dossier or a letter of access to ECHA.
- ECHA to publish list of manufacturers.
- Provisional list available at: http://echa.europa.eu/information-on-chemicals/active-substance-suppliers
- Mandatory data and fair costs sharing to apply to all tox. and eco-tox. studies, including environmental fate and behaviour.
- Data protection until 31 Dec. 2025.
- Biocidal products containing existing active substances of manufacturers not listed by ECHA shall not be placed on the market after 1 Sept. 2015.
- Storage and use of existing stocks allowed until 1 Sept. 2016.
- Competent authorities to carry out official controls.

Mandatory data sharing

- Objectives: Limit vertebrate testing, prevent competition distortions
- Data from tests on vertebrate animals
- All tox- and eco-tox studies for existing active substances for alternative suppliers and their clients
- Prospective applicant and data owner must seek agreement
- If negotiation fails, ECHA gives prospective applicant right to refer
- Fair compensation

Technical equivalence

- Similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out.
- Agency responsible for establishing technical equivalence (Article 54).

Implementing legislation and guidance documents

Implementing legislation

- ✓ **Regulation on changes to product authorisation :** Reg. (EU) No 354/2013 of 18th April 2013
- ✓ **Regulation authorisation of same biocidal products :** Reg. (EU) No 414/2013 of 6th May 2013
- ✓ **Regulation on fees to ECHA :** Reg. (EU) No 564/2013 of 18th June 2013
- ✓ **Regulation on the extension of duration of review programme to 2024 :** Reg. (EU) No 736/2013 of 17th May 2013
- ✓ **Regulation on the modification on data requirements (proof of technical equivalence in BP applications) :** Reg. (EU) No 837/2013 of 25th June 2013
- ✓ **Regulation on the procedures for the inclusion of active substances into Annex I of the BPR :** Reg. (EU) No 88/2014 of 31st January 2014
- ✓ **Regulation on the procedures for the renewal of authorisations by mutual recognition :** under formal process of adoption, publication around April/May 2014
- ✓ **Regulation on the organisation of the review programme of active substances (to replace Reg. (EU) 1451/2007) :** under discussion, for adoption by 2nd semester of 2014

Commission guidance

- **Work on guidance documents or proposals on various topics :**
  - ***Management of nanomaterials:***
    https://circabc.europa.eu/w/browse/f2d79b34-2f5a-4bb4-97e8-b982c9def765
  - ***Guidance on fees payable to Member States*:**
    https://circabc.europa.eu/w/browse/b5c900a2-ef66-4a46-996d-00d5a29aee9a
  - ***Guidance on similar conditions of use, for the Union authorisation* :**
    https://circabc.europa.eu/w/browse/2ac21f0f-d790-4667-9358-1bcd0db0b35e
  - ***Guidance on treated articles:***
    https://circabc.europa.eu/w/browse/e1adf8de-0ad6-4484-84ec-80704391a038
  - ***Document on comparative assessment :***
    https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e
  - ***Other Guidance under discussion :***
    - Borderline between biocidal products and cosmetics :

    https://circabc.europa.eu/w/browse/6283ad7a-7416-4b83-a201-92ba58224222

    etc.

Treated Articles

Control of articles treated with biocidal products

- Objective: Protection of health and environment, level playing field between production within vs outside of the EU
- Allowed on the market only if all the active substances are approved (or under evaluation under the review programme) for the relevant use
- Labelling requirement for certain articles, when
  - **Claim is made regarding biocidal properties of the article, or**
  - **Conditions of substance approval so require**
- Obligation to provide consumer information within 45 days

Challenges

- New objectives
- New criteria
- New procedures
- Ambitious timelines

- Comparative assessment
- MRLs
- SMEs
- Innovation
- Sustainable use

Thank you for your attention!

For further information:

Commission website on biocides:

http://ec.europa.eu/environment/biocides/

CIRCABC public space on biocides:

https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942

ECHA website & Helpdesk on Biocides:

http://echa.europa.eu/regulations/biocidal-products-regulation

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Mr. Abrahams is an English Barrister and a partner in Steptoe's Brussels office. His practice is focused on EU regulatory requirements and related commercial issues in the chemical regulatory and life sciences area. His clients are leading companies and associations in sectors including chemicals (REACH, biocides, cosmetics and pesticides), agricultural biotechnology, electronics, food and feed, metals and mining. An important part of his practice is helping clients to shape their legislative and policy environments, representing them before EU institutions, EU Member States and in the European Court of Justice.

The *PLC Which Lawyer? Yearbook* consistently recommends Mr. Abrahams in EU Life Sciences and *Legal 500 EMEA* has recognized his '**comprehensive understanding**' and 'detailed expert knowledge' of EU environmental regulation.

Who's Who Legal Environment identifies him as one of the leading individuals in EU environmental regulation, as does *Chambers & Partners Europe*, which reports the market's assessment that he is 'exceptionally hard-working and diligent.'

BPR
Data Protection, Sharing and Compensation

Darren Abrahams

Partner

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

Steptoe

STEPTOE & JOHNSON LLP

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6. Take to Dinner Messages

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BPD or
From where did we come?

BPD: Encouraging - Not Forcing

- **2nd BPD encouraged (Art.13):**
  - **Formation of consortia/task forces to generate joint vertebrate data**
  - **Data sharing of vertebrate data (with MS option to compel)**

'The holder or holders of former authorisations and the applicant shall take all reasonable steps to reach agreement on the sharing of information, so as to avoid, if possible, the duplication of testing on vertebrate animals.

The competent authorities … shall encourage data-holders to cooperate in the provision of the requested data, with a view to limiting the duplication of testing on vertebrate animals.

If it is still not possible for the applicant and holders of former authorisations of the same product to reach an agreement on the sharing of data, Member States may introduce national measures obliging the applicant and holders of former authorisations located within their territory to share the data with a view to avoiding duplicative testing on vertebrate animals …'

BPD: Encouraging - Not Forcing

- **2nd Review Regulation (Art. 8) echoed this:**
  - **Requiring explanation of why a collective dossier was not submitted:**

'(1) In the preparation of the complete dossier, all reasonable efforts shall be made, inter alia, to avoid duplication of testing on vertebrate animals and, where appropriate, to establish a collective complete dossier…

5) …Where, in those circumstances, a collective dossier is not submitted, each individual dossier shall detail the efforts made to secure cooperation and the reasons for non-participation.

(6) Details shall be given in the complete dossier and in the summary dossier of the efforts made to avoid duplication of testing on vertebrate animals.'

BPR
Timing And Objectives

BPR: Timing And Objectives

- **Open season for competitors' accessing data since 1 Sept, 2013.** New data sharing and compensation rules for all data submitted under BPD and BPR applied immediately.

- **Stated objectives:**
  - create a *'level playing field....as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of* ***avoiding the establishment of monopolies****, of* ***sustaining free competition*** *between economic operators and of a fair compensation of the costs borne by data owners' (Recital 58)*

  - *'****minimise the number of tests on animals*** *and for testing with biocidal products, or active substances contained in biocidal products' (Recital 57)*

BPR: Timing And Objectives

- **Data owners lose exclusive use but should now be able to exclude 'free-riders'.** During the BPD transitional period, Member States may apply their national rules for placing biocidal products on the market. Free-riders may continue to place existing active substances on the market until the inclusion of the existing active substance into Annex I/IA to the BPD. So companies who had invested € millions in the review programme had the same market access as those who had spent nothing ('1st free rider problem').

- **Art. 89(2) BPR provides for ongoing product transitional periods**: MS may continue to apply current system on biocidal products 'for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product'.

BPR
Protection

What Can Be Protected?

- Data protection is distinct from Confidentiality:
  - Public information can be subject to data protection
  - Secret information may not be subject to data protection

  No necessary link between data protection and confidentiality.

- No definition of 'data protection' in the BPR (as under the BPD and REACH). However, clear intention to ensure nothing slips between the gaps:

  'With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.' (Recital 55)

What Can Be Protected?

- Data requirements are those for:
  - existing and new AS data (Annex II and Article 6)
  - existing and new BP data (Annex III and Article 20)

  All protected data submitted for BPD/BPR purposes. What is submitted is not limited to studies alone.

- A far more complex situation than the '12 year' rule under REACH (see Art. 25(3), REACH).

- Open Source Public Data may be subject to national copyright law. Minimum harmonisation at EU level.

Protection Periods

- All data protection periods start from when data under BPD or BPR is submitted for the first time. No cumulative protection periods once they have expired. (Arts. 60 and 95)

ACTIVE SUBSTANCE (AS)	BIOCIDAL PRODUCT (BP)
Approval of a NEW AS **15 years** from the first day of the month following the date of adoption of AS approval decision (i.e. adoption of Implementing Regulation) of each AS/product-type combination	**BP with a NEW AS** **15 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
Approval of an EXISTING AS **10 years** from the first day of the month following the date of adoption of AS approval of each AS/product-type combination If AS (product-type combination) is not already approved before Sept. 1, 2013, all data protection periods for AS (product-type combination) still under review remain until a (longstop of) **December 31, 2025.**	**BP with ONLY EXISTING AS** **10 years** from the first day of the month following the first decision taken to authorize a BP (either by a MS authority or by the Commission, Union authorization)
RENEWAL/REVIEW of an AS approval **5 years** from the first day of the month following the decision on renewal/review of a the approval of an AS	**RENEWAL/AMENDEMENT OF BP AUTHORIZATION** **5 years** from the first day of the month following the decision on the renewal/amendment of a BP authorization

BPR
Mandatory Sharing

BPR Mandatory Sharing

- **Sharing of what? Art. 62(2):**

  – '*Where the data acquired under those tests or studies are still protected… the prospective applicant:*

  (a) shall, in the case of data involving tests on vertebrates; and

  (b) may, in the case of data not involving tests on vertebrates,

  request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.'

Ambiguity will be used to argue that hard copies are required.

BPR Mandatory Sharing

- Mandatory data sharing more extensive than REACH and PPPR.

- For **existing AS data** mandatory data sharing **not limited to vertebrate animals** but also under Art. 95(3):

  – '*to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates*'.

  – The amended BPR text also provides that the expanded mandatory data sharing rules for AS under Article 95(3) apply retroactively 'from 1 September 2013'.

- No mandatory data sharing for non-vertebrate data on:
  – **new AS**
  – **BP**

BPR Mandatory Sharing

- As an exception to the rules on **existing AS data**, mandatory data sharing **not applicable to AS 'listed in Annex I in categories 1 to 5 and 7** or to biocidal products containing only such substances'):
  - Substances authorised as food additives according to Regulation (EC) No 1333/2008
  - Weak acids
  - Traditionally used substances of natural origin
  - Substances included in Annex IV to REACH Regulation
  - Pheromones
  - Others

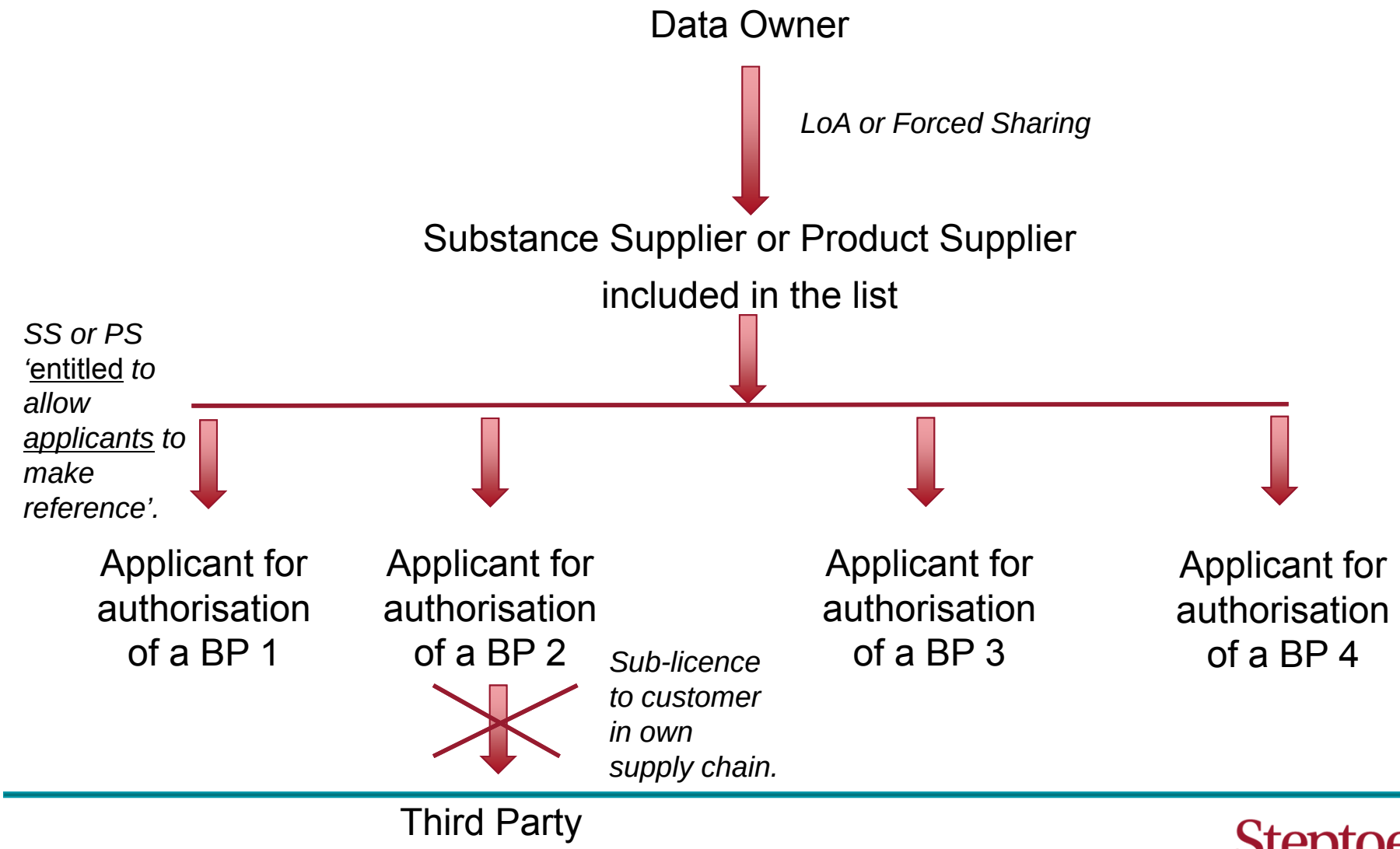
(NB: Commission Implementing Regulation (EU) No 88/2014 on procedure for amending Annex I)

BPR
List Of Active Substances

List Of Active Substances

- **As of 1 Sept. 2015 those who** (i) do not have access to a 'complete substance dossier' and (ii) therefore have not been included on the list of **approved sources** drawn up by **ECHA by will be excluded from the market**:
  - **Biocidal products** 'consisting of, containing or generating a relevant substance…shall not be made available [i.e. 'any supply'] on the market or used unless either the substance supplier or the product supplier is included in the list…for the product-type(s) to which the product belongs'.
    - '**Substance supplier' :** 'who manufactures [in EU] or imports a relevant **substance**, on its own or in biocidal products' *(No 'Only Representative' role to displace EU importer)*
    - '**Product supplier**' : 'who manufactures [in EU] or makes available on the market a **biocidal product** consisting of, containing or generating that relevant substance'
    - **Data Submitters**: under the Review Regulation or for New AS, will also be included in list

List Of Active Substances



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List Of Active Substances

- Provisional list established by ECHA (last updated 28 Feb 2014).

- Underlines that any one company may fulfill multiple roles (e.g. Data Submitter, Participant and Substance Supplier)

- Used as a marketing/commercial tool albeit that this is not a definitive list. Substance suppliers on the list will offer data access linked to supply contracts. Every 'Alterative Supplier' must calculate whether it is better to:
  - 'cherry pick' from the dossier (using own data where already owned)
  - 'buy in' completely (Fees Regulation encourages a complete buy in)

- No clear legal framework. Corrections and comments dealt with by ECHA helpdesk. No legal rights granted and no legal remedies offered.

Take To Dinner Messages

- BPD carrots replaced by BPR sticks.
- Open season in data access.
- Protection periods are longer to encourage new chemistry
- Protection is not the same as confidentiality – do not confuse them and let out your secrets.
- Publically available data is not the same as lawfully cited data.
- Mandatory sharing is a right of referral but expect to be under pressure to provide hard copies.
- Free-riding should end but the price is no more exclusive use.
- Art. 95 LoAs have legs but should not run away.
- Time is ripe to decide what you want to access and to prepare for requests.

Questions?

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BPR
Data Negotiation Process

DAY 2

BPR: Data Negotiation Process

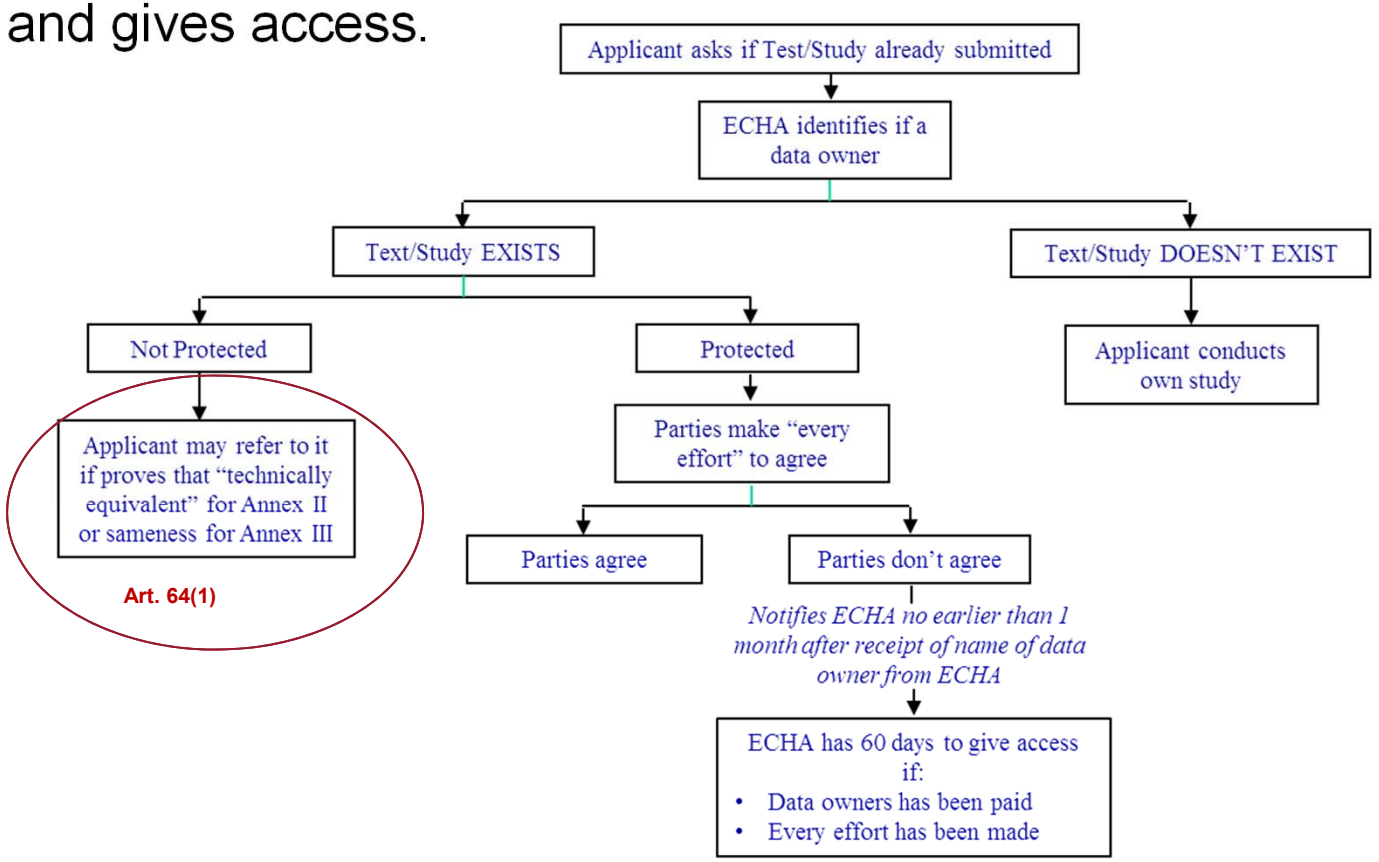
	Prospective Applicant		Data Owner	
Data	Inquire to ECHA before testing whether already submitted by previous applicant?	Request Access from Data Owner (if data is protected)	Provide access	What data must be provided
Vertebrate	**Must** *ECHA will determine whether such tests or studies have already been submitted to ECHA or Competent Authorities*	**Must** *Request all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications*	**May submit agreement on sharing to an arbitrator. If not, even if no agreement reached, from as early as 1 month after applicant receives name/address of data submitter it can trigger mandatory sharing procedure:** *Within 60 days of ECHA being notified by Prospective Applicant it will give permission to refer to tests or studies on vertebrate animals provided that prospective applicant demonstrates:* *•every effort has been made to reach agreement, AND* *•prospective applicant has paid the data owner a share of costs incurred.* *'Proportionate share" may be determined by national courts if parties cannot agree .*	**Permission to refer (LoA) to the data owner's tests or studies**
Non Vertebrate	**May** *ECHA will determine whether such tests or studies have already been submitted to ECHA or Competent Authorities*	**May** *Request all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications*	**Must make an effort** *'Shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by the submission of the matter to an arbitration body and a commitment to accept the arbitration order'* **No compulsion if no agreement reached (unless – see next column).**	*Art. 95 for existing AS, mandatory data sharing applies also to studies not involving tests on vertebrates'.*

REACH Comparison: Process for Phase-In Substances

	PROSPECTIVE REGISTRANT		DATA OWNER	Compensation Terms
Data	**Inquire before testing whether a relevant study is available**	**Request Access from Data Owner (if data is protected)**	**Provide Access**	
Existing Study Involving Vertebrate Animal Tests	Must Art 30(1) para. 1	Must Art 30(1) para. 1	**Must** **ECHA will give access if Data Owner refuses to provide (i) proof of costs or (ii) the study, and block Data Owner's Registration.** **Art. 30(3)**	Calculated 'in a fair, transparent and non-discriminatory way' If agreement cannot be reached on the amount of compensation 'the cost shall be shared equally' Art 30(1) para. 1
Existing Study does <u>not</u> involve testing on vertebrate animals (wider than just animal i.e. non-animal as well)	Must Art 30(1) para. 1	May Art 30(1) para. 1	May ECHA has no power to oblige access but if a study is requested by a SIEF member, and a data owner refuses to share, the other SIEF participants can proceed as if the study did not exist. Art. 30(4)	
Any new study involving tests which is required for Registration and is not available	*One SIEF participant conducts one new study (for the purpose of fulfilling a Registration information requirement) on behalf of all other SIEF participants. The SIEF participants need to agree on (or ECHA will impose on them) which party should secure the new testing.* *Art 30(2)* *(see Art 29(3) also)* ***More likely to be necessary in 2013 where data paucity* anticipated**.			Costs for 'the elaboration of the study with a share corresponding to the number of participating registrants'. (This does not necessarily mean that equal shares will be borne by each of the SIEF members.) Art 30(2)

BPR Data Negotiation Process

- **Timelines for data negotiation potentially very short:** as little as 1 month. ECHA acts within 60 days *after negotiations fail* and gives access.



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BPR Data Negotiation Process

- Mandatory data sharing resembles REACH but no 'SIEF' to limit their substance-specific focus. BPR has no LR of SFF equivalents.
- BPR requires any person 'who intends to perform tests or studies' to determine if done before with ECHA. Not *expressly* qualified by idea that those tests/studies relate to their specific substance.
- This suggests possibility of mandatory data access for 'read-across' purposes (interpolation to other substances) BUT conflicting indication in Art. 64(1) on non-protected data:
  - '…subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities'.
  - '…so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity…'
- Companies with common interests may want to re-create SIEF-like structures – consortia/task forces for data rights management.

BPR Data Negotiation Process

- As a voluntary (not free) alternative to full technical equivalence, ECHA has developed the chemical similarity check procedure:
  - 'an assessment similar to the technical equivalence assessment described in Article 54 of the BPR. However, it is performed solely on the substance identity and chemical composition of an active substance originating from one source with the aim of establishing its similarity regarding the chemical composition of the same substance originating from a different source'.
  - '…differs from the technical equivalence assessment under Article 54 of the BPR because a decision on the approval of the active substance has not yet been adopted and, therefore, the official reference source of the active substance is not yet established'.
- Envisaged for:
  - **Individual applications**: The comparison of one alternative source of AS with the source(s) described in the dossier submitted for the assessment of this biocidal active substance.
  - **Joint applications**: The comparison of two or more sources of the same active substance in view of a prospective joint application for AS approval.

BPR Data Negotiation Process

- **Essential to set in place standard**:
  - data sharing agreements
  - negotiation protocols
  - cost calculation spreadsheets/baseline data

  to allow for rapid responses.

- **Typical stages in process**:
  - Confidentiality Agreement (vanilla or pre-empting negotiations)
  - Agreement on what is sought (list)
  - Delegation of entire process to binding arbitration
  - Exchanges on principles for compensation
  - Review of numbers
  - Review of draft agreement
  - Face to face negotiation
  - Offer to pay

BPR
Data Compensation

BPR Data Compensation

- General requirement that compensation must be determined in **a fair, transparent and non-discriminatory manner** (as under REACH), 'having regard to' the REACH ECHA guidance on data sharing (April 2012) and ECHA note clarifying which chapters 'are of particular relevance to applicants under BPR').
- ***N.V. Elektriciteits Netherlands*** (10 October 2011) confirms guidance does not constitute a source of law, which would be comparable to legislation but if published, can nevertheless bind the administrative body in question. Where ECHA has decided to publish guidance its conduct can be confined by such guidance. This flows from the creation of a legitimate expectation, legal certainty and equal treatment/non-discrimination.
- **Repeat players are unlikely to want to have compensation decisions to be settled by EU national** courts (who have little/ no experience on these matters).
- ECHA decisions to grant data access within 60 days **could be challenged by data owners before the Board of Appeal**: quick and cost efficient mechanism – with suspensive effect on decision.

BPR Data Compensation

- REACH ECHA guidance on data sharing (April 2012) is a poor guide to the BPR process:

BPR elements not in REACH

- If no agreement reached, the prospective applicant should pay a share of the cost which data owner 'shall not refuse to accept'. Without prejudice to claim before national courts for additional compensation.
- Registration not limited to one legal entity. A right to refer to the AS substance data granted to an alternative substance supplier can be relied on by subsequent applicants for authorisation of BP (LoAs with legs).
- Nature of the data subject to mandatory data sharing is quite different (wider).
- Fairness determination could take into account the number of MS for authorisation, PTs, or the automatic right to sub-licence the referral right to one's own 'customers'.

BPR Data Compensation

REACH elements not in BPR

- No 'equal' cost sharing - default formula under Articles 27(6), 30(1) and 30(3) of REACH where no agreement is reached.
- No disclosure of ‘full study reports’ in case of a failure to agree – under REACH - Articles 27(6), 30(3) - that is a condition for having a claim on the potential registrant for an equal share of the cost incurred by him (enforceable in national courts).
- No Lead Registrant submitting a joint registration dossier on behalf of all market players (sharing financial burden of developing it with co-registrants either upfront or at the applicable registration deadline).
- Determination of a fair share of the cost takes account:
  - volumes of substance placed on the whole of the EEA market by one legal entity
  - four tonnage bands and the information requirements corresponding to them
  - size of the suppliers (through the SME status)
  - use of the substance (intermediate or for R&D)

BPR Data Compensation

- **Indicative list of issues to consider in negotiations:**

- **Scope of rights**
  - Citation or ownership?
  - Geographical spread (EU, EEA, EFTA, EU + US etc?)
  - Purpose (BPR only? BPR + PPP, REACH?)

- **Cost**
  - Distinction between costs & commercial data value
  - Dossier costs versus raw data costs
  - Actual cost (+ inflation) or replacement cost?
  - Management costs (actual or fixed/variable percentage)
  - Risk premium (compare REACH and BPR risk, and nature of study)?
  - Loss of opportunity?
  - Early market access premium?

BPR Data Compensation

- **Indicative list of issues to consider in negotiations:**

- **Dynamic cost formula or static?**
  - Reimbursement mechanism for overpaying?
  - Claw-back for underpaying and updates?
  - EU only considerations or discounts for other jurisdictions?

- **Other**
  - Are you being asked for commercial information not required by BPR (use of black box trustees)?
  - Bundling?
  - Tying data access to supply contracts?
  - Lump sum penalties for change of supplier? Royalty systems to incentivise loyalty to suppliers?

BPR
Disputes Procedure

Disputes Procedure

- Decision to grant permission to refer lies with ECHA (where negotiations fail after 'every effort')
- ECHA's decision is subject to BoA review.
- ECHA will not/ should not form judgments on cost calculations.
- Share of costs will be decided by national courts (unless parties have already agreed to another means of resolution).
- No data sharing disputes decided under BPR or REACH yet.

BOA Appeals

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) **No 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.*

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Disputes Procedure: Lessons from REACH

- **ECHA' Process for dealing with disputes**:
  - Define the subject matter of the dispute (which studies)
  - Description of negotiations setting out the full record.
  - Each side asked to provide all correspondence ('request for information' and 'documentation') showing 'every effort' made.
  - Separate communications between ECHA and each party (no automatic sharing of each others' submissions) – right to be heard/defence?
  - Willingness to adopt 'contingency procedure' to accelerate market access pending decisions on data sharing (but BPR has 60 day rule).
  - Suspensory effect of BoA challenges is in issue.
  - Repetition of positions can gain credit.
  - Promptness applied particularly as against data owner.
  - Surface analysis of discrimination: in EU competition law this means that the behavior of a dominant market player (i) is discriminatory and (ii) tends to cause downstream competitive disadvantage. Also should be opportunity to show objective necessity.

Adapting Consortia

Adapting Consortia

- What you agreed under the BPD may not necessarily be imposed on data accessors under the BPR.
- The rules in Arts. 62 and 95 apply to non-consortium members irrespective of what consortium members agreed among themselves.
- New data access and compensation rules will require consortium modifications to account for the realities of forced data sharing. You will need a commonly agreed way to process these negotiations (principally for common data generated by group).
- New rules will also force inward looking discussions about how to deal with compensation for existing data (brought to the table by individual members).

Take Home Messages

- Negotiation process is potentially short before mandatory access granted.
- Technical equivalence is not required by ECHA (currently) and chemical similarity is a voluntary tool not in the BPR.
- Protocols need to be in place to deal with negotiations. Better prepared parties do well in these procedures.
- Compensation principles are not just “REACH for Biocides”.
- Dispute procedure appears slanted towards accessors but process is not about cost formulae. Only national courts will resolve compensation questions.
- BoA appeals will suspend data access decisions, so there is reason for accessors to remain at the negotiating table.
- Consortia and task forces face the same data comp. issues which you will face in the bilateral context.

Questions?

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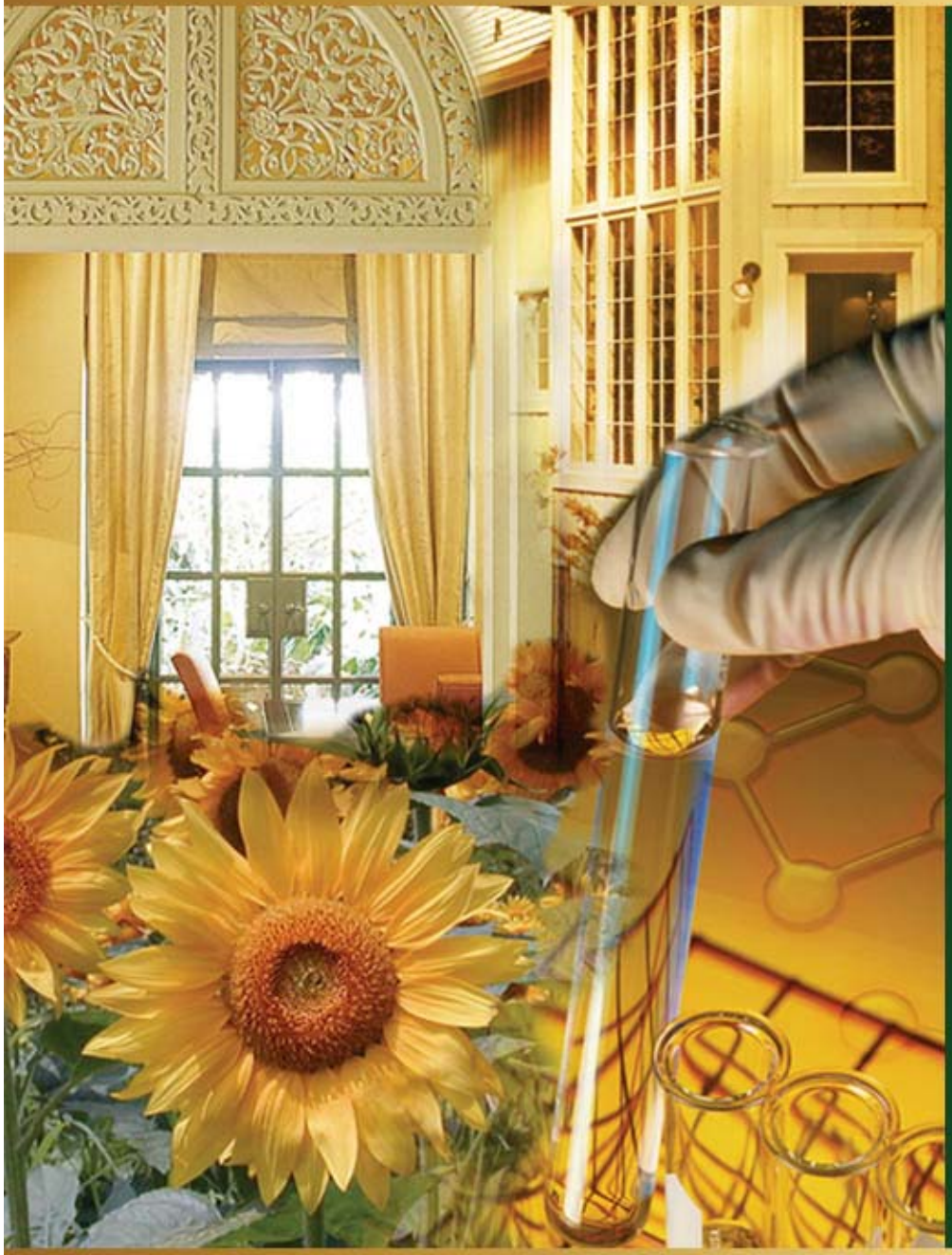

Business Impacts of the BPR:

An Industry Perspective

Nathalie Hanon
Regulatory Affairs Manager Europe

April 2nd , 2014

Annual Chemicals Regulation Seminar – Steptoe & Johnson LLP

Information about Troy

- US Company represented worldwide in more than 100 countries
- Offices in Europe
- Supplier of Biocide Active Substances
- Supplier Biocide Products
- Mainly active in the Biocide “preservative” business

Content

1. How the BPR impacts our Biocide Business?
2. And what about the other EU legislations ?
3. How the Biocide market is going to end-up?

How the BPR impacts our Biocide Business?

- Before the BPD (1998), Biocides were poorly regulated in Europe
- Entry into force of the BPD has substantially changed the rules – Huge new barrier to overcome (cost and complexity)
- A limited number of actives/PTs has been supported by Industry (business decision as huge investment)

How the BPR impacts our Biocide Business?

- Cost:
  - Active substance: a few millions of euros
  - Biocide product: ¼ million of euros
- Biocide field: a lot of different applications and uses → different dossiers or more complex dossiers
- Data requirements are not tonnage related as for REACH
- Return on investment?

How the BPR impacts our Biocide Business?

- Legal uncertainty: high risk of rejection with evolving guidance
- BPD (Risk based) >< BPR (Hazard based)
- Evolving guidance in terms of :
  - Env Risk Assessments: additionnal worst-case scenarios or aggregated exposure
  - Endocrine Disrupting properties – Criteria still under development
  - ...

How the BPR impacts our Biocide Business?

- Review program and inclusion of an active in the Annex I/Union list often leads to:
  - Restriction of uses
  - Worse classification
- Market will mainly be impacted at product authorization stage
- BPD/BPR review program: huge investment but uncertainty about the results

How the BPR impacts our Biocide Business?

- BPR has introduced new provisions:
  - Exclusion criteria
  - Force data sharing
  - Article 95 – Stop of free-riding
  - Union Authorisation
  - Treated Articles
  - Biocide Product Families
- BUT still a lack of clarity with regard to their implementation

How the BPR impacts our Biocide Business?

- SMEs?
- Fee regulation allows reduction for SMEs
- But still huge cost related to data requirements and complexity of the dossier
- Ban of SMEs in the Biocide business?
- Unless supported by main actors (through “same product” application)

How the BPR impacts our Biocide Business?

- Down-Stream users / DUs?
- BPD/BPR is a Black Box for DUs
- Uncertainty that their need will be properly covered by Biocide active substances and products suppliers
- Unlike REACH, DUs do not have the opportunity to make their own Chemical Safety Assessment
- DUs are also impacted by the new provisions with regard to treated articles under the BPR

How the BPR impacts our Biocide Business?

- Some conclusions on the BPR impact:
  - Data requirement and high cost
  - Still a high number of uncertainties
  - Biocide sector is in transition:
    - Reduction of actives and products
    - Fewer variability in terms of products
  - All the actors of the supply chain will be impacted (at EU but also Global levels)

Content

1. How the BPR impacts our Biocide Business?
2. And what about the other EU legislations ?
3. How the Biocide market is going to end-up?

And what about the other EU legislations ?

- Several other legislations do impact the Biocide sector (preservative business): BPD/BPR, REACH, CLP, WFD, Ecolabel, VOC, Food contact, CO2 footprint, Indoor air quality….
- Focus on some aspects:
  - REACH
  - The Skin sentitization Elicitation sentence (2^{nd} ATP CLP)
  - The leaching issue (BPD/BPR and WFD)

REACH

- Biocide products:
  - Biocide active substances considered as registered under REACH (Article 15(2))
  - Co-formulants have to comply with REACH
- Follow-up on REACH legislations and assessment (Registered substances, SVHC, CORAP, ...)
- Additional hurdles and cost for global players manufacturing their product outside of EU and importing them in EU

CLP & Elicitation Sentence

EU Hazard statement – EUH208

Contains “name of sensitizing substance”.
May produce an allergic reaction.

CLP & Elicitation Sentence

- Today: this sentence has to be indicated on the label at 0.1% of a sensitizing substance contained in the product

- June 2015 (2nd ATP of the CLP): add the 1/10 treshold value for sensitizing substance having a specific limit

CLP & Elicitation Sentence

- Impact drastically the Isothiazolinones – few others alternatives (FA releasers?)
- Huge pressure mainly from customers of the Paint & Coating business as request for a label free of any classification statement
- >< BPR provisions with regard to labelling of Treated Articles

The leaching issue

- BPD/BPR:

  → need of leaching data to demonstrate a safe use for ENV RA

- Water Framework Directive (WFD): EU Directive aiming at the protection of waters (surface, ground, coastal)

  → As a rule, MSs must meet environmental quality standards for priority substances

The leaching issue

- What about connecting legislations?
- Hence if unacceptable presence in waters, this might affect the BPR status as well
- Restriction of uses at national level or ban of substances

Content

1. How the BPR impacts our Biocide Business?
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How the Biocide market is going to end-up?

Availability

- Reduction of number of biocide active substances – very few new active substances
- Reduction of number of Biocide products (market has started recently to be impacted with the Product Authorization stage)
- Huge cost : Companies will try to use the Biocide Product Family (BPF) Concept or will get “Same product” authorization from big players
- → Fewer variability in terms of products

How the Biocide market is going to end-up?

Classification & Labelling

- Biocide active substances will go through the harmonized classification process
- Harmonized classifications are always worse
- Classification rules become more and more stringent (2nd ATP with the Elicitation sentence and Chronic tox for environment)
- At some point, it will lead to have all Biocide actives/products/end-products classified

How the Biocide market is going to end-up?

Options:

- Industry is aware that quantities of Biocides have to be reduced

  → But need to consider benefit-risk

- Need for the Biocide Industry to develop new formulations to reduce exposure to Human and Environment

Conclusions

- High regulatory pressure on Biocide Business (high requirements and/or high costs)
- Reduction of the chemical diversity / actives
- Reduction of the number of products
- Fewer variability in terms of Biocide products
- All the actors of the supply chain will be impacted
- Future:
  - Biocide Industry will not defend new actives
  - Development of new formulations with existing actives

Thank you

The Gold Standard for Performance

Indiana de Seze

Ms. De Seze represented a consortium of companies in a data sharing dispute and an Only representative in a challenge of a decision ordering additional testing, both before ECHA's Board of Appeal.

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Indiana de Seze is a leading legal practitioner in EU chemicals regulation and competition. Ms. de Seze's practice focuses predominantly on REACH, biocides, plant protection products and other applications of chemicals requiring regulatory clearance or pre-market authorizations. Thanks to her rigorous training as a competition and commercial lawyer, Ms. de Seze delivers cutting-edge analyses and pragmatic solutions to tackle antitrust issues in the context of consortia and data sharing.

Chemicals Regulation: Ms. De Seze regularly advises clients on their registration duties and the legal consequences of substance and dossier evaluation procedures under REACH. She has formed and continues to provide legal support to consortia of companies for the purpose of joint submissions. She counsels on data protection and data sharing negotiations, having assisted in the formation of task forces and in their dealings with the competent authorities and companies. In the biocides area, Ms. de Seze helps companies in the biocidal product market to transition to the Biocidal Product Regulation and roll out successful active substance and product registration strategies across the EU.

Her litigation work in the area involves representing clients before the EU and national courts, and the Board of Appeal of the European Chemicals Agency

Craig Simpson

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Craig Simpson is a UK qualified solicitor and Senior European Legal Advisor in Steptoe's Brussels office, where he is a member of the Regulatory & Industry Affairs Department. His practice focuses on EU regulatory requirements and related commercial issues in the life sciences field and EC competition law.

Mr. Simpson's regular clients are leading multinational companies and trade associations operating at both European and international levels. His experience includes advising clients on the procedures and remedies available before the European courts.

Before joining Steptoe, Mr. Simpson was an EU regulatory lawyer in the Brussels office of a well-known London-based firm and trained with the European Commission's Directorate-General Internal Market, dealing with actions against EU Member States for infringement of EC Treaty rules on free movement of goods.

Mr. Simpson regularly lectures and publishes on matters affecting the Life Sciences industries and competition law. He is consistently recommended as a leading practitioner in the Global Counsel Which Lawyer? Yearbook for EU Life Sciences, an independent survey of leading multinational companies' approved counsel.

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Successful Dossier Strategies for Actives and Products

Indiana de Seze, Senior Associate

Craig Simpson, Senior European Legal Advisor

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Active Substances

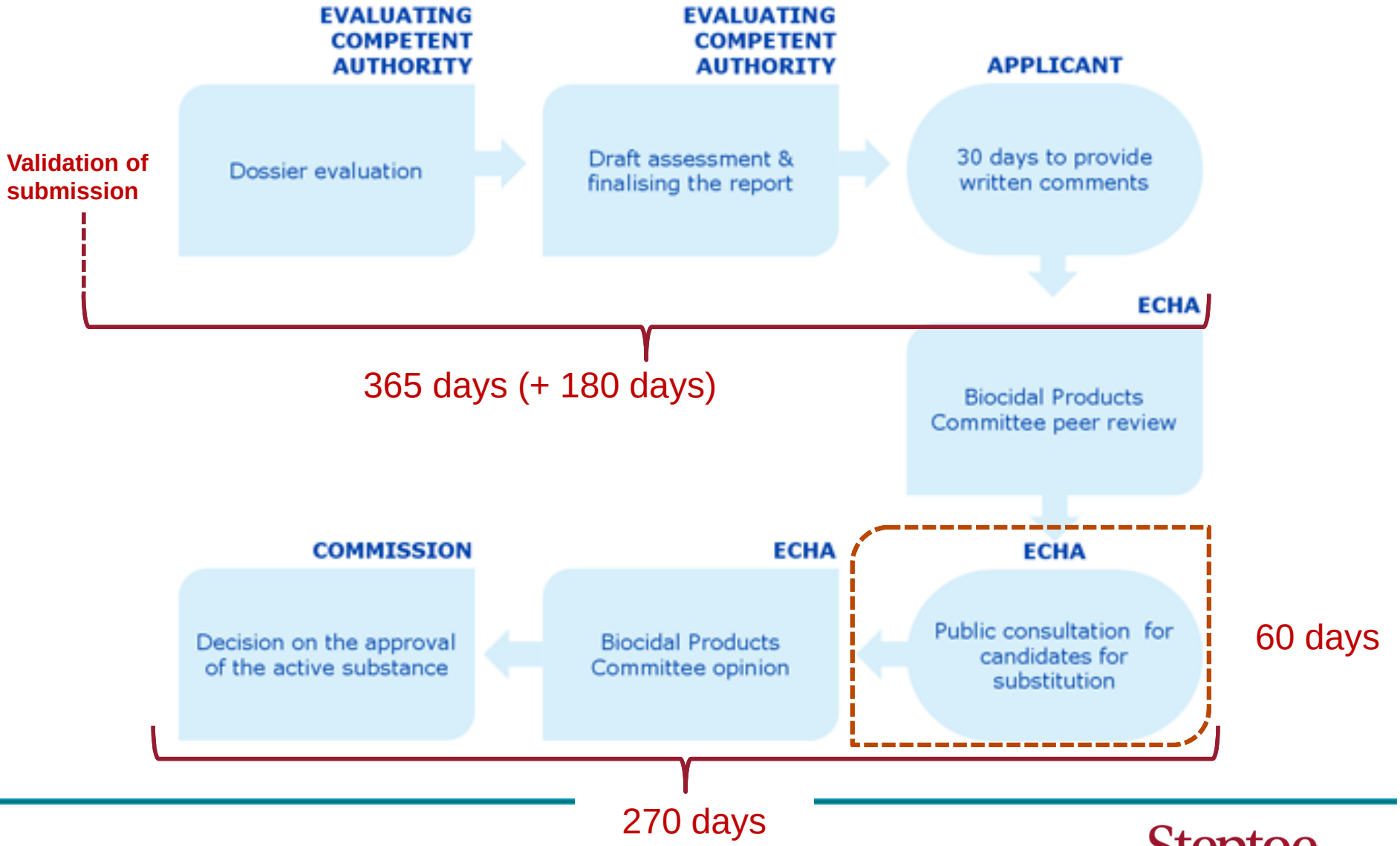
Content

1. Transitioning from BPD to BPR: advantages and shortcomings
2. Streamlined review process
3. Review programme
4. Exclusion and substitution: opportunities

Transitioning from BPD to BPR

- Active review process not completed by 1 September 2013: review will be done under BPR based on dossier submitted according to BPD
  - « Completed » means distribution of draft Competent Authority Report
  - Where the evaluation identifies concerns arising from the application of provisions of the BPR which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information → review possibly extended
- ECHA becomes active and "responsible for coordinating the process of evaluation of dossiers submitted after 1 September **2012** and shall facilitate the evaluation by providing organisational and technical support to the Member States and the Commission" as well as, since 1 January 2014, for dossiers whose evaluation has not been completed by 1 September 2013.

Streamlined review process



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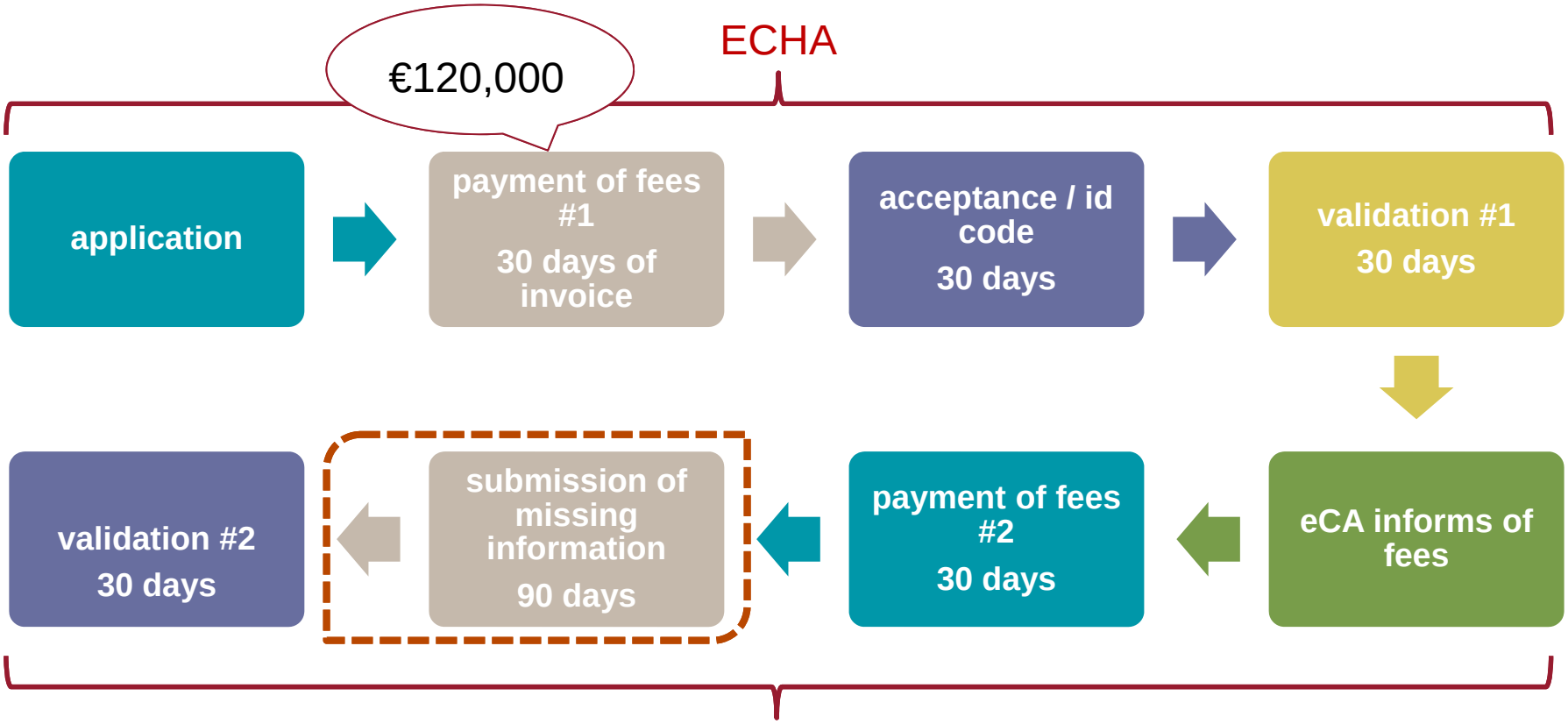
Streamlined review process (validation)



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Review programme (1)

- Extension of the review programme until 31 December 2024: extension of the transitional regime
- Commission delegated regulation adopted in May 2013
- Ambitious plan of circa 50 active substance/product type combinations approved or not approved per year

Priority	Existing active substances for product types	All draft CARs have to be submitted to ECHA by	The BPC have to submit all its opinions by
1st priority list	8, 14, 16, 18, 19, 21	31/12/2015	31/12/2016
2nd priority list	3, 4, 5	31/12/2016	31/12/2017
3rd priority list	1, 2	31/12/2018	31/12/2019
4th priority list	6, 13	31/12/2019	31/12/2020
5th priority list	7, 9, 10	31/12/2020	31/12/2021
6th priority list	11, 12,15,17, 22, 23 (new PT20 under BPR)	31/12/2022	31/06/2024

Review programme (2)

- New active substances/PT combinations:
  - Regulation 613/2013 amends Reg. 1451/2007 as regards additional active substances in the review programme
  - Submission of dossier and inclusion in the review programme
  - Eligibility:

    Persons relying on guidance notes published, or written advice given, by the Commission or by a competent authority designated in accordance with Article 26 of Directive 98/8/EC may therefore have failed to notify the existing active substance/product-type combination in a product placed on the market, or to take over the role of participant, in the objectively justified belief that the product is excluded from the scope of Directive 98/8/EC or that it falls under a different product-type (Recital 4)

    No decision not to include based on an assessment report reviewed by the Standing Committee on Biocidal Products
  - Submission process is similar to that of the situation where a person wishes to take over the role of participant

Exclusion and substitution: opportunities (1)

- Exclusion is not new under the BPR:

  "An active substance cannot be included in Annex IA if it is classified according to Directive 67/548/EEC as:
  - carcinogenic,
  - mutagenic,
  - toxic for reproduction,
  - sensitising, or
  - is bioaccumulative and does not readily degrade." (Article 10(1) BPD)

- BPR has broadened the scope and refers to either classification or criteria for classification under the CLP Regulation 1272/2008, or REACH:
  - carcinogen category 1A or 1B;
  - mutagen category 1A or 1B
  - toxic for reproduction category 1A or 1B
  - with endocrine-disrupting properties (pending the adoption of legally binding criteria, carcinogen category 2 and toxic for reproduction category 2 / toxic for reproduction category 2 and that have toxic effects on the endocrine organs)
  - PBT

Exclusion and substitution: opportunities (2)

Derogations to exclusion, three alternative conditions, which have to apply in MS:

1. the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible (e.g. closed systems)
2. evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment;
3. not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance

- The availability of suitable and sufficient alternative substances or technologies shall be a key consideration (comparative assessment?)

Exclusion and substitution: opportunities (3)

- Candidates for substitution (Article 10):

a) meets one of the criteria for exclusion but with derogation

b) meets the criteria to be classified, in accordance with CLP Regulation, as a respiratory sensitiser

c) acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario (comparative assessment?)

d) meets two of the criteria for being PBT (REACH Annex XIII)

e) reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures

f) contains a significant proportion of non-active isomers or impurities

Exclusion and substitution: opportunities (4)

- Public consultation process (60 days) prior to ECHA submitting its opinion on the approval or renewal of the approval of an active substance to the Commission
- Interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion
- Approval for a maximum of 7 years (vs 10 years)
- Comparative assessment
- BUT, if reviewed under the BPD criteria, maximum of
  - 10 years for substances that meet the substitution criteria
  - 5 years for substances that meet the exclusion criteria
  - While applying comparative assessment and SEA

(source: CA-March14-Doc.4.1 – Final)

Product Authorisation

Content

1. Looking ahead: preparing for product authorisation under BPR
2. Product authorisation options: which available when?
3. Considerations when choosing between authorisation procedures

Preparing for product authorisation under BPR (I)

- Market access/staying on market for products with existing actives?

- Non-harmonized national authorisation regimes 'only game in town':
  - efficiency of MS authorities varies - 5 months to 12 months from lodging
  - significant prospect of procedural deadline slippage
  - dossier data, EU SDS, label, legal documents (power of attorneys, commercial registry extracts), translations, etc.
  - allow sufficient time before going to market

- When will Commission decide on inclusion of relevant active (condition of BPR product authorisation application)?
  - triggers requirement to lodge BPR authorisation application in order to remain on market until BPR authorisation decision
  - short window for lodging (20 months?) - not long for dossier preparation
  - strategic/budget planning: company resources, external advisors, fees, data costs
  - choice of authorisation procedure resource significant – do you understand the different available options?

Example BPR Union list inclusion decision (adapted 24.10.13)

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Date of approval	Expiry date of approval	Product type
Benzoic acid	IUPAC Name: Benzoic acid EC No: 200-618-2 CAS No: 65-85-0	990 g/kg	1 July 2015	30 June 2025	3

Preparing for product authorisation under BPR (II)

- Submission of active dossier/letter of access for product authorisation (and approved sources list (Article 95 BPR)):
  - obtain LoA (relevant Task Force? fee/conditions of access?)
  - register for Biocidal Products ('R4BP'):
    - user friendly
    - potential for technical issues…past experience of REACH-IT
  - BPR implications for participants supporting active Task Force Agreements?
    - dealing with data requests under mandatory data sharing?
    - balance exploitation of data with FRAND requirements/avoiding forced data sharing

- BPD product authorisation applications do not escape BPR:
  - be prepared to respond where BPD evaluation incomplete re:
    - more expansive BPR authorisation conditions (Article 19) if excluded active (for example, human health of vulnerable groups such as pregnant women and children)
    - BPR comparative assessment procedure if candidate active
  - biocidal products already authorised/registered under BPD which remain on market subject to BPR:
    - comply with supplementary Article 19 conditions when amend existing authorisations?
    - BPR labelling?

Product authorisation options: 'short-cut' procedure available?

- Abbreviated procedures may be only route, or most resource efficient, for specific product characteristics/uses
  - simplified authorisation for low risk products;
  - same authorisation for a product materially identical to another which has already been authorised/is subject to an application;
  - provisional authorisation for products not fulfilling authorisation conditions (including active approval) in limited circumstances; and
  - parallel trade permit for product already authorised in another EU MS and identical to product already authorised in intended sales market
- Otherwise available procedures limited to one or two post active approval:
  - national authorisation in EU member state;
  - mutual recognition ('in sequence') by other MS CAs of national authorisation already granted in 'reference' MS;
  - mutual recognition ('in parallel') by MS CAs when no existing authorisation;
  - Union authorisation (EU wide) granted by European Commission on basis of ECHA opinion post MS CA evaluation.

Comparing authorisation procedures and timing (I)

	1. National Biocidal Product Authorization	2. Product Mutual Recognition in Parallel	3. Product Mutual Recognition in Sequence	4. Union Authorization of Biocidal Products	5. Simplified Biocidal Product Authorization
Maximum approval period (years)	10 (5 if contains candidate for substitution)	10 (5 if contains candidate for substitution)	10 (5 if contains candidate for substitution)	10 (5 if contains candidate for substitution)	10 (5 if contains candidate for substitution)
Contents of application	-Dossier/LoA for product and each active (potential data waiver/adaptation) -Summary of product characteristics in appropriate language(s) -Confirmation that not applied to other CA	<u>To chosen evaluating CA ('reference MS'):</u> -As for national or simplified product authorization, as appropriate -List of other MSs where national authorization sought <u>To other MSs where national authorization sought</u>: -Identity of reference MS and other MSs where national authorization sought -Summary of product characteristics in MS required languages	Translation of national authorization granted in reference MS into relevant official languages	-Dossier/LoA for product and each active (potential data waiver/adaptation) -Summary of product characteristics -Confirmation of similar conditions of use across Union in appropriate language(s)	-Summary of product characteristics -Efficacy data (potential data waiver/adaptation) -Information evidencing eligible for simplified procedure in appropriate language(s)
Application submitted to	Chosen CA where want to market product Application accepted on receipt of fee **within 30 days** of informing applicant	Simultaneously to reference MS and other MSs concerned (see above) Application accepted if fee received **within 30 days** of informing applicant	Each CA of countries (other than reference MS) where want to market Application accepted if receives fee **within 30 days** of informing applicant	ECHA, with confirmation of which CA has agreed to evaluate Application accepted on receipt of fee **within 30 days** of informing applicant	ECHA, with confirmation of evaluating CA Application accepted if fee received **within 30 days** of informing applicant of fee
Validation by	Chosen CA **within 30 days** of acceptance Decline to evaluate if same product/use already subject of authorization application with another authority Applicant to provide missing information **within <u>normally</u> max 90 days**	Evaluating CA ('reference MS') **within 30 days** of its acceptance Applicant to provide missing information **<u>normally</u> within max 90 days**	Each CA **within 30 days** of its acceptance	Chosen CA within **30 days** of ECHA acceptance subject to payment of CA fee Applicant to provide missing information **<u>normally</u> within max 90 days** **30 days** for CA to validate thereafter	No formal validation stage

Comparing authorisation procedures and timing (II)

	1. National Biocidal Product Authorization	2. Product Mutual Recognition in Parallel	3. Product Mutual Recognition in Sequence	4. Union Authorization of Biocidal Products	5. Simplified Biocidal Product Authorization
Evaluation by	Chosen CA **within 365 days of validation** **Applicant to provide missing information within normally max 180 days** (during which 365 timer is suspended)	Evaluating CA ('reference MS') **within 365 days** of validation **Same coordination and resolution procedures as per "In Sequence"** Drafts assessment report, conclusions and reasons for granting or refusing authorization Send assessment report and summary of product characteristics to other MSs and applicant Other MSs CAs to agree summary of biocidal product characteristics **within 90 days** of receipt of report and record agreement in Register for Biocidal Products Reference MS to enter report and summary and any conditions on marketing and use in Register	CAs agree summary of product characteristics **within 90 days** of validation and record agreement in Register for Biocidal Products **Coordination group (including applicant) and Commission resolution procedure** if MS objection that safety authorization conditions not met Commission resolution procedure (including applicant) for mutual recognition derogation (public policy, public security, protection of environment, etc.)	Chosen CA **within 365 days** of validation of application Applicant to provide missing information **within normally max 180 days** Applicant written comments on evaluation conclusions during 30 day period Chosen CA send assessment report and conclusions to ECHA, taking into account applicant comments **ECHA prepare and submit to Commission opinion** on authorization of product **within 180 days** of receipt (including any conditions on marketing or use) ECHA submits draft summary within **30 days** in all languages	Reduced evaluation by chosen CA ("verification of eligibility" for simplified authorization) **within 90 days** of accepting application (or longer where further information required) Applicant to provide missing information **within normally max 90 days**
Approval/Non-approval	Chosen CA: - drafts assessment report with conclusions and reasons for granting or refusing authorization; - send electronic copy to applicant requesting comments within 30 days; - finalizes report taking account of conclusions.	All relevant MSs to authorize biocidal product **within 30 days** of agreement on summary and in conformity with summary If absence of agreement between all CAs, those CAs agreeing to summary may authorize product	Each CA to authorize biocidal product **within 30 days** of agreement on summary and in conformity with summary In absence of agreement between all CAs, CAs agreeing to summary may authorize product	Commission authorization approval Regulation or non-approval decision on receipt of ECHA opinion Commission can require conditions particular to certain MS territory or exclude a certain territory on MS derogation request	Provided eligible, chosen CA must authorize **within 90 days** of acceptance of application or of submission of additional information requested by applicant
Timeline (days)*	**725**	**845** **935 (If Coordination Group Required)**	**905** **(725 + 180)**	**935**	**300**

* *Assumes that (i) each time period is used in full, (ii) periods for additional information are always required, (iii) that the Coordination Group, where applicable, is able to resolve differences without requiring the Examination Procedure in Article 35, and (iv) that each stage follows on immediately from that preceding it.*

Product authorisation options: multi-country sales?

- Intended sales territory?
  - one country only: national authorisation
  - more than one country or EU wide: Union authorisation or MR 'in parallel'/'in sequence' (where existing national authorisation)
- Is Union authorisation an option?
  - not:
    - products containing actives meeting exclusion criteria (Article 5) (cat 1A or 1B CMRs, vPvBs, PBTs or considered as having endocrine disruptor properties);
    - PTs 14, 15,17, 20, 21 (rodenticides, avicides, piscicides, control of other vertebrates, antifouling products) where harmonised conditions of use previously problematic
    - unless product has 'similar conditions of use across the Union' (Commission interpretation: MSs unlikely to refuse authorisation on environmental, health or public policy grounds)
  - available *yet* for other PTs – phased in until 2020?

Phase-in of Union Authorisation

NOT eligible for Union authorization	From 1 September 2013	From 1 January 2017	From 1 January 2020
• *Rodenticides* • *Avicides* • *Piscicides* • *Control of other vertebrates* • *Antifouling products*	• *Biocidal products containing one or more NEW active substances* • *Human hygiene* • *Veterinary hygiene* • *Food and feed area* • *Drinking water* • *Insecticides, acaricides and products to control other arthropods* • *Repellents and attractants*	• *Disinfectants and algaecides not intended for direct application to humans or animals* • *Preservatives for products during storage* • *Working or cutting fluid preservatives*	• *Film preservatives* • *Wood preservatives* • *Fiber, leather, rubber, and polymerized materials preservatives* • *Construction material preservatives* • *Preservatives for liquid-cooling and processing systems* • *Slimicides* • *Molluscicides, vermicides, and products to control other invertebrates* • *Embalming and taxidermist fluids*

Product authorisation options: choice of Union authorisation or MR – timing? costs?

- Which quicker?
  - Union authorisation: alternative to national authorisation and MR
  - procedural timelines for Union authorisation approx. 3 months slower than MR in parallel (ECHA opinion delay)
  - but… increased potential for delay in MR procedures due to many MSs:
    - refusal of authorisation on public policy, health or environmental or animal welfare grounds (Article 37) – lengthy procedure involving applicant and Commission
    - claim that authorisation conditions not met – lengthy referral to cross-member state Coordination Group and, in absence of agreement, to Commission
- Which cheaper? Many variables to be weighed:
  - application and annual fees of ECHA and single evaluating MS (in Union authorisation) *v.* fees of CAs and own resources multiplied by MS (MR), plus ECHA submission fee
  - large ECHA fee range (Regulation 564/2013) dependent on:
    - product identical to that pre-assessed for active approval (50% reduction)?
    - single product or biocidal product family (less)?
    - where comparative assessment required (punitive 50-100% fee increase)
    - SME reduction available (reduce by 10-30%)?
  - check MS fees; decided on individual MS basis

Multiple products: using procedures efficiently

- 'Biocidal product family'
  - reduced authorisation costs and administrative burden for applicants and authorities
  - simultaneous authorisation of group of products:
    - same actives
    - similar uses
    - similar compositions with specified variations
    - 'similar levels of risk and efficacy' (BPR amendment)?
  - entrance fee cheaper? depends on number of products:
    - EUR 150,000 – 210,000 family Union authorisation *v.* single product Union authorisation of EUR 40,000 to 120,000 (without SME reductions)
    - ECHA annual fee for family Union authorisation only 2 x single product (EUR 20,000)
- 'Same product procedure' cheaper alternative to family? ECHA fee for Union authorisation of same biocidal product = EUR 2,000
  - sequential, not simultaneous
  - 'identical' to reference product already authorised/subject to application for national or Union authorisation (only 'administrative differences')

Conclusion

- Still individual non-harmonised procedures for many products
- Anticipate BPR authorisation/obligation:
  - short timelines for dossier post active inclusion
  - resources/budget
  - understand authorisation options
- Factors limiting choice of BPR authorisation procedures:
  - nature of active substance (exclusion criteria, candidate for substitution)
  - product type
  - number of countries where authorisation sought
- Where multi-country authorisation sought:
  - consider relative costs and duration of MR *v.* Union authorisation
  - fees: many variables re ECHA fees, MS fees not harmonised
- Multiple product authorisation:
  - 'biocidal product family' or 'same product' may represent significant cost savings

Questions?

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Darren Abrahams

The *PLC Which Lawyer? Yearbook* consistently recommends Mr. Abrahams in EU Life Sciences and *Legal 500 EMEA* has recognized his '**comprehensive understanding**' and 'detailed expert knowledge' of EU environmental regulation.

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Mr. Abrahams is an English Barrister and a partner in Steptoe's Brussels office. His practice is focused on EU regulatory requirements and related commercial issues in the chemical regulatory and life sciences area. His clients are leading companies and associations in sectors including chemicals (REACH, biocides, cosmetics and pesticides), agricultural biotechnology, electronics, food and feed, metals and mining. An important part of his practice is helping clients to shape their legislative and policy environments, representing them before EU institutions, EU Member States and in the European Court of Justice.

Who's Who Legal Environment identifies him as one of the leading individuals in EU environmental regulation, as does *Chambers & Partners Europe*, which reports the market's assessment that he is 'exceptionally hard-working and diligent.'

BPR
Protecting Business Secrets

Darren Abrahams

Partner

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Content

1. BPR rules on confidentiality – ATD Interface
2. Electronic Public Access
3. Glyphosate case appeal
4. Take Home Messages

BPR Rules On Confidentiality – ATD Interface

BPR – ATD Interface

- BPR confidentiality rules are not freestanding.

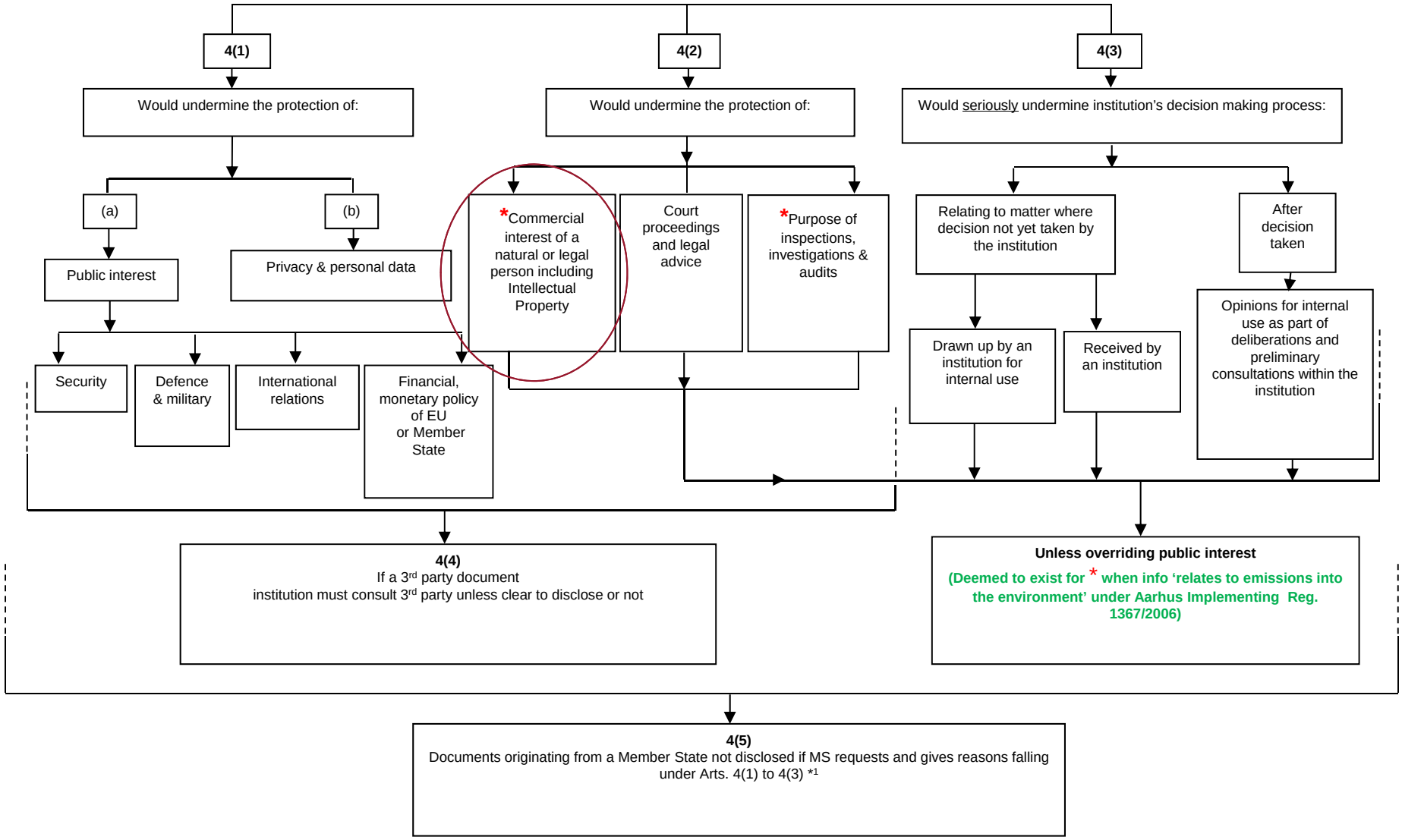
- Horizontal Rules on Sharing and Confidentiality under the EU Access to Documents (ATD) Regulation (EC) 1049/2001 apply to a wide range of documents which ECHA will receive (under REACH and BPR). These intersect the BPR specific provisions.

- In addition, Electronic Public Access (free) will apply to a wide range of information held by ECHA or the Commission. Wider than REACH.

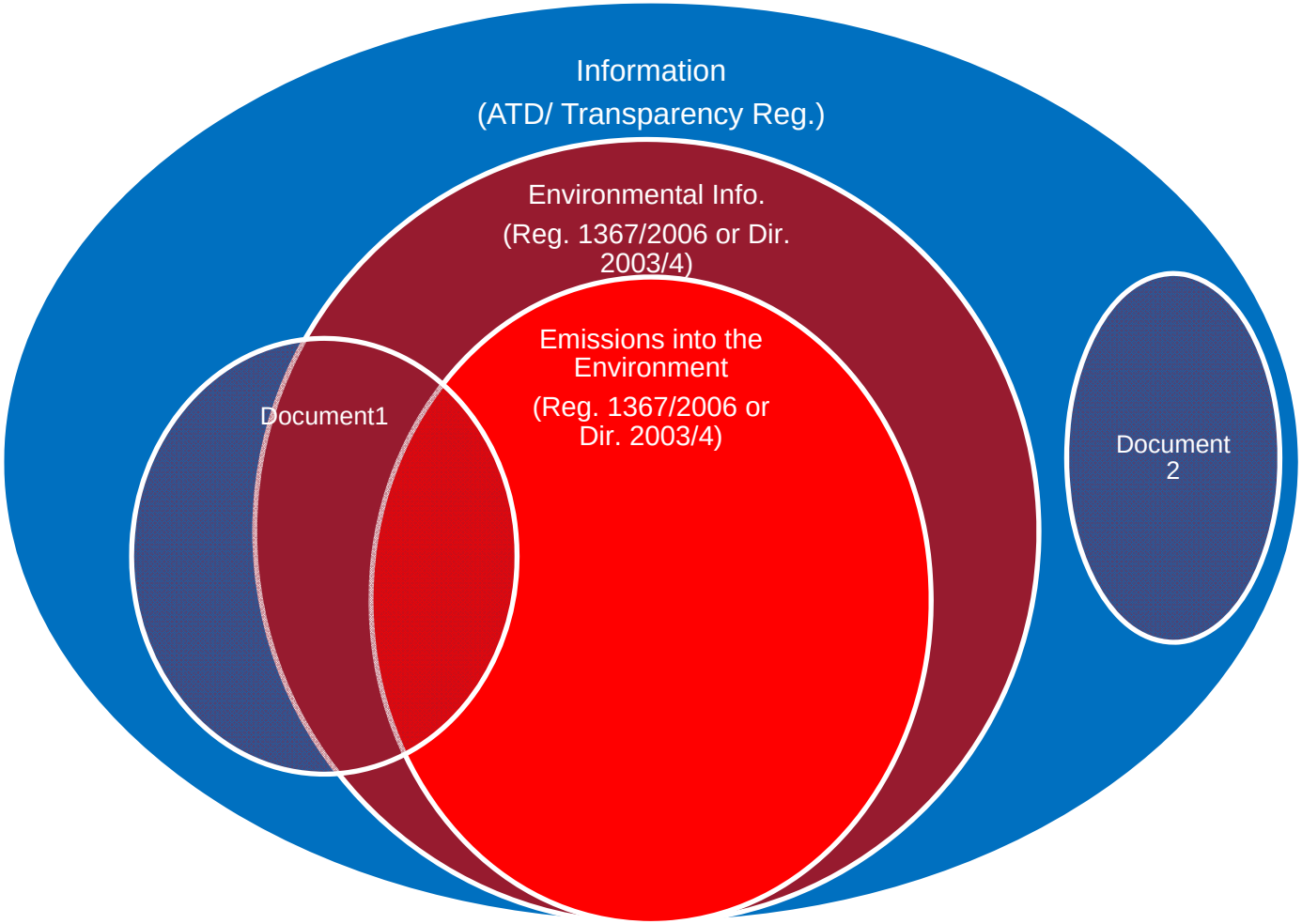
- Under REACH both mechanisms have been aggressively used by Competitors and NGOs. A push-pull relationship.

- Litigation on ATD Regulation and lobbying on ever broader public dissemination (from environmental NGOs) is rife and will continue.

Exceptions to Disclosure ATD Reg. (EC) 1049/2001



Different types of data



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Definition of ‘environmental information’

‘any information in written, visual, aural, electronic or any other material form on:

(i) the **state of the elements of the environment, such as** air and atmosphere, **water, soil, land**, landscape and natural sites including wetlands, coastal and marine areas, **biological diversity** and its components, **including genetically modified organisms**, **and the interaction among these elements**;

(ii) factors, such as **substances**, energy, noise, radiation or waste, including radioactive waste, **emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment referred to in point (i)**;

(iii) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities **affecting or likely to affect the elements and factors referred to in points (i) and (ii)** as well as measures or activities designed to protect those elements;

(iv) reports on the implementation of environmental legislation;

(v) cost-benefit and other economic analyses and assumptions used within the framework of the measures and activities referred to in point (iii);

(vi) the state of human health and safety, including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures in as much as they are or may be **affected by the state of the elements of the environment referred to in point (i) or, through those elements, by any of the matters referred to in points (ii) and (iii)**’.

(Term ‘emissions, discharges and other releases’ is not defined.)

Protection Pre-Authorisation Of Product

- Strong Presumption of **non-disclosure** by ECHA and CAs under Art. 66(2) (save where health, environment or public interest urgency):
  - details of the full **composition** of a biocidal product
  - **precise tonnage** of the active substance or biocidal product manufactured or made available on the market
  - **links between** a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;
  - name and addresses of **persons involved in testing of vertebrate** animals

- Strong legislative presumptions as a basis for non-disclosure under the Article 4 of ATD Reg: Case T-494/08, *Ryanair v Commission*: Commission could '*refuse access to all the documents relating to the procedure for the review of State aid, and may do so without first making a concrete, individual examination of those documents'.*

Disclosure Post-Authorisation Of Product

- Disclosure always under Art. 66 (3) after authorisation granted:
  - name and address of the authorisation holder;
  - name and address of the biocidal product manufacturer;
  - name and address of the active substance manufacturer;
  - content of the active substance or substances in the biocidal product and the name of the biocidal product;
  - physical and chemical data concerning the biocidal product;
  - methods for rendering the active substance or biocidal product harmless;
  - summary of the results of the tests required for Product Authorisation to establish efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;
  - recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;
  - SDS
  - methods of analysis for Product Authorisation
  - methods of disposal of the product and of its packaging;
  - procedures to be followed and measures to be taken in the case of spillage
  - or leakage;
  - first aid and medical advice to be given in the case of injury to persons.

Electronic Public Access

Electronic Public Access: Actives Post Approval

- Disclosure always under Art. 67(1) of 'up to date' info held by ECHA or Commission from date of adoption of Implementing Reg:
  - where available, the ISO name and the name IUPAC nomenclature;if applicable, the name as given in the EINECS
  - classification and labelling, including whether the active substance meets any of the BPR exclusion criteria
  - physicochemical endpoints and data on pathways and environmental fate and behaviour
  - result of each toxicological and ecotoxicological study
  - acceptable exposure level or predicted no-effect concentration
  - guidance on safe use
  - specified analytical methods
- Disclosure always under Art 67(3) of 'up to date' info unless valid justification submitted why disclosure 'could' (not 'would') be harmful to commercial interests:
  - if essential to classification and labelling, the degree of purity and identity of impurities and/or additives known to be hazardous
  - study summaries / robust study summaries
  - other information in SDS
  - trade name(s) of the substance
  - assessment report

Electronic Public Access: Products Post Authorisation

- Disclosure always under Art. 67(2) of 'up to date' info held by ECHA or Commission:
  - terms and conditions of the authorisation
  - summary of the biocidal product characteristics
  - specified analytical methods

- Disclosure always under Art. 67(4) of 'up to date' info unless valid justification submitted why disclosure 'could' (not 'would') be harmful to commercial interests:
  - study summaries, or robust study summaries
  - assessment report.

Glyphosate Case Appeal

T-545/11 Greenpeace Netherlands & PAN Europe v Commission

8 October 2013

Commission **refused access to part of DAR issued by German rapporteur on glyphosate under PPPD** based on protection of commercial interests Art. 4(2), first indent. Court annulled refusal for information on 'emissions to environment':

1. data which concerns **'the identification and the quantity of various impurities present in the active substance** notified by each of the operators which took part in the procedure for the inclusion of glyphosate in Annex I of Directive 91/414';

2. '**the analytical profile of batches tested':** 'information **concerning the quantity of all the impurities present** in the various lots and the minimum, median and maximum quantity of each of those impurities…' set out, for each operator; and

3. '**the composition of plant protection products developed by the operators** which applied for the inclusion of glyphosate in Annex I to Directive 91/414…the exact quantities, per kilogramme or per litre, of the active substance and of adjuvants used in their manufacture [of which were]…indicated…'

T-545/11 Greenpeace Netherlands & PAN Europe v Commission

Two types of information did not concern 'emissions to the environment':

4. the '**structural formulas of impurities**', and

5. '**methods of analysis and validation**' of the data provided to establish the analytical profile of batches.

'Emissions to the environment'

Key term defined through a process of **extrapolation**. For each category it concluded that it related 'in a sufficiently direct manner to emissions into the environment' – a proximity test.

'Since the active substance must be included in a plant protection product, which, it is common ground, will be released into the air, principally by spraying…'

So refused access where request 'did not contain…information allowing the determination, in a sufficiently direct manner, of the level of emission into the environment of the various components of the active substance'.

T-545/11 Greenpeace Netherlands & PAN Europe v Commission

What does 'emissions to environment' trigger/effect?

Took a **plain reading approach** of the legislative texts, the Article 6(1) of the Aarhus Implementing Regulation:

'…requires that if the institution concerned receives an application for access to a document, it must disclose it where the information requested relates to emissions into the environment, even if such disclosure is liable to undermine the protection of the commercial interests of a particular natural or legal person, including that person's intellectual property, within the meaning of Article 4(2), first indent, of Regulation No 1049/2001'. This is described as an 'irrebuttable presumption'.

General Court stated, regarding the confidentiality provisions in Directive 91/414 that it 'suffices to note that the existence of such rules cannot rebut the irrebuttable presumption arising from Article 6(1)'.

Appeal pending !

Take Home Messages

- You are operating in an environment where openness is the rule. Initiate protocols to protect yourself.
- Think about what is necessary for market access/regulatory compliance and what is beyond that.
- The ATD rules and Electronic Dissemination will be used by competitors and those philosophically opposed to your products. Think about how these tools can also serve your objectives.
- Be prepared to respond systematically to ATD inquiries about disclosure.
- Be aware that the scope of access is being defined in the courts more quickly than the legislators can react.

Questions?

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Anna Gergely

Legal 500 EMEA has noted she “has the rare ability to give clients not only legal advice, but also a scientific interpretation of complex REACH matters,” noting that her “**excellent scientific background**” is a “**great asset**.”

Dr. Anna Gergely agergely@steptoe.com

Dr. Gergely is director EHS regulatory in Steptoe's Brussels office, where she is a member of the Regulatory & Industry Affairs Department. In a role equivalent to partner, with a PhD in analytical chemistry and quantum chemistry, Dr. Gergely is a registered European patent attorney.

Dr. Gergely is particularly experienced in providing comprehensive capabilities for companies seeking compliance strategies that cover the full range of their technical and legal needs in the following areas:
Chemicals (biocides, agro-biotechnology, cosmetics), REACH and Classification, Labeling and Packaging Food and feed and food contact materials (packaging and marketing claims and hygiene rules)
Regulation of medical devices and a range of consumer and industrial products.

In addition to the above areas, Dr. Gergely specializes in nanotechnologies as related to a broad spectrum of industrial sectors.

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Controversy Around Treated Articles and In-situ Generated Active Substances

Dr. Anna Gergely

Director, EHS Regulatory

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Content

- The impact of the extension of the scope of the BPR
- In-situ generated active substances
- Treated articles

Extension of the scope of the BPR

	BPD	BPR
Active substance	A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.	A substance or a microorganism that has an action on or against harmful organisms.
Biocidal product	Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, **intended to** destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.	Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or **generating** one or more active substances**, with the intention of** destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action. **A treated article that has a primary biocidal function shall be considered a biocidal product.**
Treated article	None	Any substance, mixture or article which has been treated with, or **intentionally** incorporates, one or more **biocidal products**.

In-Situ Generated Active Substances

In-situ formed active substances: Definitions

- Biocidal product definition is expanded: also covers substances or mixtures **generating** active substances. But the emphasis on **intention** to destroy etc. remains unchanged.

Article 2(1)(a) of the BPD: Biocidal products are:

- Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

Article 3 (1)(a) of the BPR: Biocidal product means:

- — any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
- — any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

In-situ formed active substances: Definitions

- On the basis of the BPD definition precursors were not considered biocidal products.
- MoD interpretations – confusing situation. As a result, applicants have submitted dossiers for the authorisation of
  - Precursors
  - Generated active substances
  - Both
  - Neither
- The extended BPR definition clarified this situation – however, no clarity whether some of the precursors were already covered by the BPD – issue of "biocidal intention"
- Impact of the interpretation – needs clarity that the transitional measures under Article 93 of the BPR apply

In-situ formed active substances: New requirements

- Under the BPR it is foreseen that BOTH the precursor and the *in-situ* generated active substance would go through authorization
- Commission's Call for information on *in-situ* generated active substances (published 31 January 2014) has requested feedback from companies on:
  - active substances (AS) /PTs supported under the review program
  - new authorisation requests for other precursor/AS pairs – whether or not the company is participant already in the review program
  - other precursors for the same AS
- Commission will decide on the basis of the input received how *in-situ* generated active substances will be managed. Examples:
  - Active substances generated by deliberate reaction of multiple substances
  - Active substances generated by devices (from basic chemicals or ambient sources)

In-situ formed active substances: New requirements?

- Difficulties of applying the new BPR definition
- Questions of “overregulation” – is there need for separate authorization for all precursor(s)/AS combinations?
- Possibility to review non-active precursors during product authorisation? - Family approach?
- Precursors: intermediate registration under REACH. Reduced requirement under the BPR as well?
- Need clarity whether the REACH derogation from registration of the active substances should be then extended to cover the precursors as well

Treated Articles

Treated articles

- **Treated articles** were not explicitly covered by BPD - but extensive guidance on how to address individual examples in the Manual of Decisions (MoD)
- **MoD focuses on the biocidal effect of treated articles, contrasting:**
  - Internal effect: intended to preserve the article itself, the treated article is not a biocidal product (e.g. treated paper or wood)
  - External effect: treated article is intended to act as a biocidal product
- BPD did **not cover** imported articles treated with an active substance outside the EEA for an internal effect. No requirement to use EU approved actives.
- **BPR introduced changes that explicitly addressed treated articles**
- Specific chapter for treated articles which are not biocidal products
- Compliance with the BPR requires a well structured transition period

Treated Articles under the BPR

- BPR devotes the entire Article 58 to treated articles which are not biocidal products (no primary biocidal function)
- Article 58(2): A treated article shall not be placed on the EEA market unless all active substances contained in the biocidal product that it was treated with or incorporates are EU approved for the relevant PT and use; and the restrictions are met (exception: fumigation and disinfection of premises)
  - placed on the market means: first making available as the treated article itself
  - contained in the biocidal product means: its presence in the treated article is not the requirement
  - it was treated with or incorporates means: the treated article itself and not of its component parts (see *infra* relevance for Complex articles)
  - EU approved for the relevant PT and use means: 0% threshold on all active substances which are not permitted pursuant to Article 58(2).

Interpretation of Legal Terminology

- Treated article: "..*treated with, or intentionally incorporates..*"
  - *intentionally incorporates:* it is intended to become part of the treated article and it is present
  - *treated with:* it is not intended to become part, but is applied with intention. This means that the product (and hence the active substance) must have been applied with the intention of exerting a biocidal effect in the treated article itself.
    - First, the intention to use the active substance in the biocidal product is required
    - Second, the intention to use this biocidal product to treat with or incorporate into an article is required
- In agreement with Article 58(2) on treated articles, which applies for active substances contained in the biocidal product it was treated with or incorporates. Based on this interpretation, even active substances which do not remain in the treated article do require authorization (exemption: residues of fumigation or disinfection of premises or containers).
  - Biocidal product which consists of, contains or generate an active substance
  - Treated article which is treated with or incorporates a biocidal product

Conflict of interpretation: Legal text vs. Note for Guidance

Note for Guidance:

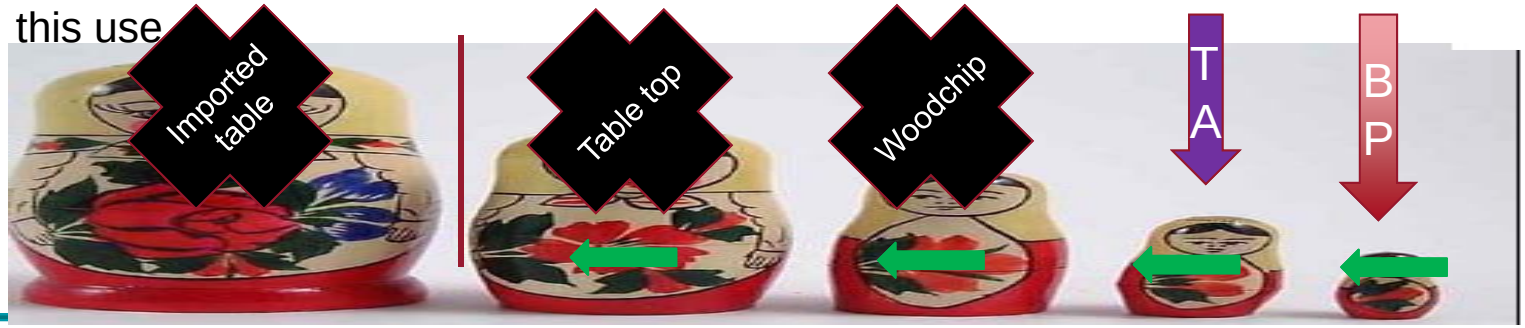
- Question 24: *Do the requirements for treated articles cover treatments only of the finished article, or treatments of components that were treated further back in the supply chain? If so, how far back in the supply chain do possible treatments have to be identified?*
  - *For example, a table is manufactured outside the EU from composite wood, and the wood is bound with glue containing a preservative (also manufactured outside the EU) – does the preservative have to be approved if the table is then placed on the EU market?*
  - *Or, electrical components within a television were treated with a biocidal product to give them fungicidal properties (and no other part of the TV was treated). Does the active substance in the fungicide have to be approved?*
- Answer: *The BPR defines a treated article as 'any substance, mixture or article which has been treated with, or intentionally incorporates one or more biocidal products'. This is* ***to be understood as covering both treatment of the article itself as well as the treatment of any of its components further back in the supply chain.*** *Thus complex articles such as cars, ships, planes are subject to the provisions of Article 58. It is however recognised that such earlier treatments of components might be difficult to identify, especially for complex articles. Practical enforcement is therefore likely to concentrate on articles where man or the environment can be exposed to the treated components.*

"Complex" Treated Articles

- The BPR does not define "complex" articles and Article 58(2) does not distinguish between a treated article and/or its components. The only element of the definition is that treated article **which** has been treated with…
- The Note for Guidance introduces the notion of "a component" of a treated article and "complex articles" (made up of a series of components and subassemblies). In its Answer to Question 2 it states that "treating with" indicates that a biocidal product has been applied to a mixture or an article or to a component thereof.
- The Commission claims that the Note for Guidance, while not legally binding as it is, represents the Commission's position. Hence, in case of conflict of interpretation the Commission – using its power based on Article 3(3) of the BPR – will support this reading in specific cases with implementing acts.
- This discrepancy has led to several conflicting interpretations and lots of activities at industry level and at the authorities.

Our position on “Complex” treated articles

- Question 24: Does the preservative in a glue which is used to bound the woodchips to make a table top which is then imported into the EU need authorization?
- Proposed answer by the now finalised Note for Guidance:
  - In theory - Yes
  - In practice - No (it is difficult to identify the treatment)
- Our interpretation:
  - In theory and in practice - No - No
  - Based on the legal text of the BPR, the definition of treated article refers to intentionally incorporating or being treated with a biocidal product. The bound woodchip (which contains the glue which incorporates a biocidal product) is not a biocidal product, hence the glue preservative is not an active substance in this use



CA-March14-Doc.6.1

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green economy
ENV.A.3 - Chemicals

NOTE FOR DISCUSSION WITH COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

Subject: Comments received from stakeholders on treated articles

1.- Background and purpose of the document

During the past months, the Commission received a number of written and oral comments from various stakeholders (Trade and industry associations, third country governments – see annex) on the BPR provisions on treated articles, and the current detailed interpretation of these provisions as laid down in the Note for Guidance: Frequently asked questions on treated articles, endorsed by the CA meeting in September 2013.

One point of particular concern that was raised in all of these comments concerned the use of biocidal products during upstream steps in production, on components or pre-finished forms of an article, from which no or only very low levels of residues remain in the final article. Such treatments are currently considered to be covered by Article 58 of BPR, with the consequence that after the transitional period only biocidal active substances that are approved in the EU or under evaluation in the review programme can be used.

Apart from frequently stated doubts whether such interpretations are in line with the legal text of the BPR, they are considered to create serious practical problems for business operators. It is expected that, in particular due to the wide-spread use of preservatives, the majority of all finished goods would fall under the provisions for treated articles. Examples for cases where this was considered excessive and not relevant to prevent a consumer risk include e.g. in-can preservatives in glues used to assemble complex articles, preservative in printing ink, or preservatives in paper pulp as discussed in the CA meeting in December 2013.

For products which are entirely produced in the EU, compliance with the requirement to use only approved active substances is ensured as only biocidal products containing such AS are available for treatments. However for goods which are imported, or contain imported components, it was considered that it will be virtually impossible to ensure compliance. While importers and manufacturers of the finished goods should be aware of the BPR provisions, third-country operators further up in the production chain would not usually have this knowledge, and not pass on the relevant information to the person responsible for placing the product on the EU market.

Way Forward

- **What is the problem?**
  - If the Note for Guidance interpretation is not changed, all treated articles – complex or not, imported or EU manufactured – will need to comply with:
    - Article 58(2) on authorization of active substances contained in any of the biocidal products any component of the article was treated with or has incorporated at any stage in the supply chain
    - Article 58(3) on labelling – as only required when a claim is made; there is no concern
    - Article 58(5) on information requirement for consumers – notwithstanding labelling rules – within 45 days on the biocidal treatment of the article; this is of great concern

Way Forward

- **The DMF controversy**
  - DMF treated leather, imported into Europe in sofas and shoes, caused allergic reactions and serious customer complaints
  - However, DMF is already banned as a biocide by Commission Decision of 17 March 2009
    - product containing DMF means any product or any part of a product where the concentration of DMF is greater than 0,1 mg/kg of the product

COMMISSION DECISION

of 17 March 2009

requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

(notified under document number C(2009) 1723)

(Text with EEA relevance)

Way Forward

- **What is the reason for concern? – Our view**
  - Why target DMF (and potentially other active substances) with another legal ban? – rather enforce existing measures and create similar ones for targeted hazardous substances
  - Why target articles produced from non-EU supplied raw materials in any of their components? – discrimination against non-EU manufacturers
  - Why target articles where the active substances may not even be present any more? – no public health concerns
  - Why target "silent active substances" which were not used for biocidal effect? – not possible to demonstrate intention
  - Why only target biocidal active substances with potential health hazards? – what about hazardous substances for other uses?

Way Forward

- **What is the reason for concern? – Authority's view**
  - The approach of the Note for Guidance is meant to protect EU customers from active substances present in treated articles which are not authorised in Europe for these applications
  - See latest discussions at the 55th CA meeting (12-13 March 2014) Discussion point 6
    - The provisions for treated articles were brought to ensure safety and should be maintained; as compliance seems feasible
    - As some companies (major players) seem to be able to comply; the approach should be upheld
    - Some Member States suggested to revisit the approach to facilitate international trade
    - Concerns that the approach would jeopardise the success of BPR

Way Forward

- **What is the recommended solution? - To define an approach which is legally sound, proportionate and non-discriminative**
  - Revise Note for Guidance interpretation so that it respects the legal text of the BPR
  - For "true" treated articles apply the requirements of the BPR, as foreseen
  - For "complex articles" do not create specific rules under the BPR – apply the "carry-over principle", such as for food additives
  - For targeted hazardous substances rely on other measures, such as REACH and/or targeted Commission Decisions under the General Product Safety Directive 2001/95/EC

Questions?

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Ruxandra Cana

Chambers Europe notes that Ms. Cana's clients are "unanimous in their praise of her for being 'well-connected and very popular' and state that she has 'great judgment' and understands the way in which the chemicals industry works.'"

Ruxandra Cana rcana@steptoe.com

Ruxandra Cana, a partner in Steptoe's Brussels office, has more than 15 years of experience advising multinational companies and industry associations on EU regulatory compliance and product defense.

Ms. Cana advises clients on matters arising from the application and implementation of the EU REACH rules, including data sharing, consortia formation, only representatives, corporate structuring, and intermediates. She has formed, and continued to act as a legal advisor to more than 20 REACH consortia. Her practice also covers REACH dossiers evaluation, substance evaluation, SVHC listings, inclusion in Annex XIV to REACH, and restrictions.

She acted as counsel in the first direct case related to EU chemicals legislation to succeed before the EU General Court and represented clients in successful appeals before the Board of Appeal of the ECHA.

Ms. Cana also brings significant experience in European Union (EU) rules on biocides and pesticides, cosmetics, medical devices, consumer products such as electronics, food (labeling, nutrition, food additives, and genetically modified food), food contact materials, and nanotechnology.

Barry Podd

Dr. Barry Podd
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Dr. Barry Podd is a technical & regulatory advisor in Steptoe's Brussels office. Prior to joining the firm, Dr. Podd spent 26 years within the chemical industry in various positions, including research and development, marketing, sales, and regulatory affairs. He also served as associate director of global regulatory affairs for a major multinational consumer goods company.

Dr. Podd has been heavily involved in numerous trade associations, including EDANA, where he chaired the Industrial Wipes Group and the REACH Core Group. He also participated in the European Tissue Symposium (ETS), serving as a member of its Food Contact Working Group and representing the European Tissue Industry on a number of cross-industry working groups.

Borderline Issues (Chemical Legislation, Biocides, Cosmetics, Medicinal Products and Packaging)

Ruxandra Cana, Partner

Dr. Barry Podd, Technical & Regulatory Advisor

Annual Chemicals Regulation Seminar

Overcoming New Hurdles: Biocides, REACH, and Food Contact Materials

1 – 2 April 2014, Brussels

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Content

1. Products excluded from the scope of the BPR

2. Rules applicable at the same time as the BPR

Scope of the BPR – products excluded

The BPR does not apply to biocidal products or treated articles that are within the scope of

- Directive 90/167 on medicated feedingstuffs
- Directives 90/385, 93/42 and 98/79 (medical devices)
- Directives 2001/82 and 2001/83 on veterinary and human medicinal products
- Regulation 1831/2003 on feed additives
- Regulation 852/2004 on food hygiene
- Regulation 1333/2008 on food additives

Scope of the BPR – products excluded

The BPR does not apply to biocidal products or treated articles that are within the scope of

- Regulation 1334/2008 on food flavourings
- Regulation 767/2009 on feed
- Regulation 1107/2009 on plant protection products
- Regulation 1223/2009 on cosmetics
- Directive 2009/48 on toys

Scope of the BPR – products excluded

But

- « when a biocidal product falls within the scope of the [above laws] and is intended to be used for purposes not covered by those instruments, this Regulation [the BPR] shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments »

(Article 2.2, last paragraph)

Scope of the BPR – products excluded

- The BPR does not apply to
  - Food or feed used as repellents or attractants
  - Biocidal products when used as processing aids

  (Article 2.5)

Rules applicable at the same time as the BPR

Rules applicable at the same time as the BPR

The following EU rules apply in parallel to the BPR

- REACH and CLP Regulations
- Workers protection legislation
- Water quality and water framework legislation
- The POPs Regulation
- Laws on misleading and comparative advertising
- PIC rules
- Laws on ozone depleting substances
- Industrial emissions directive

Rules applicable at the same time as the BPR

- Member States may restrict or ban the use of biocidal products in the public supply of drinking water

(Article 2.7)

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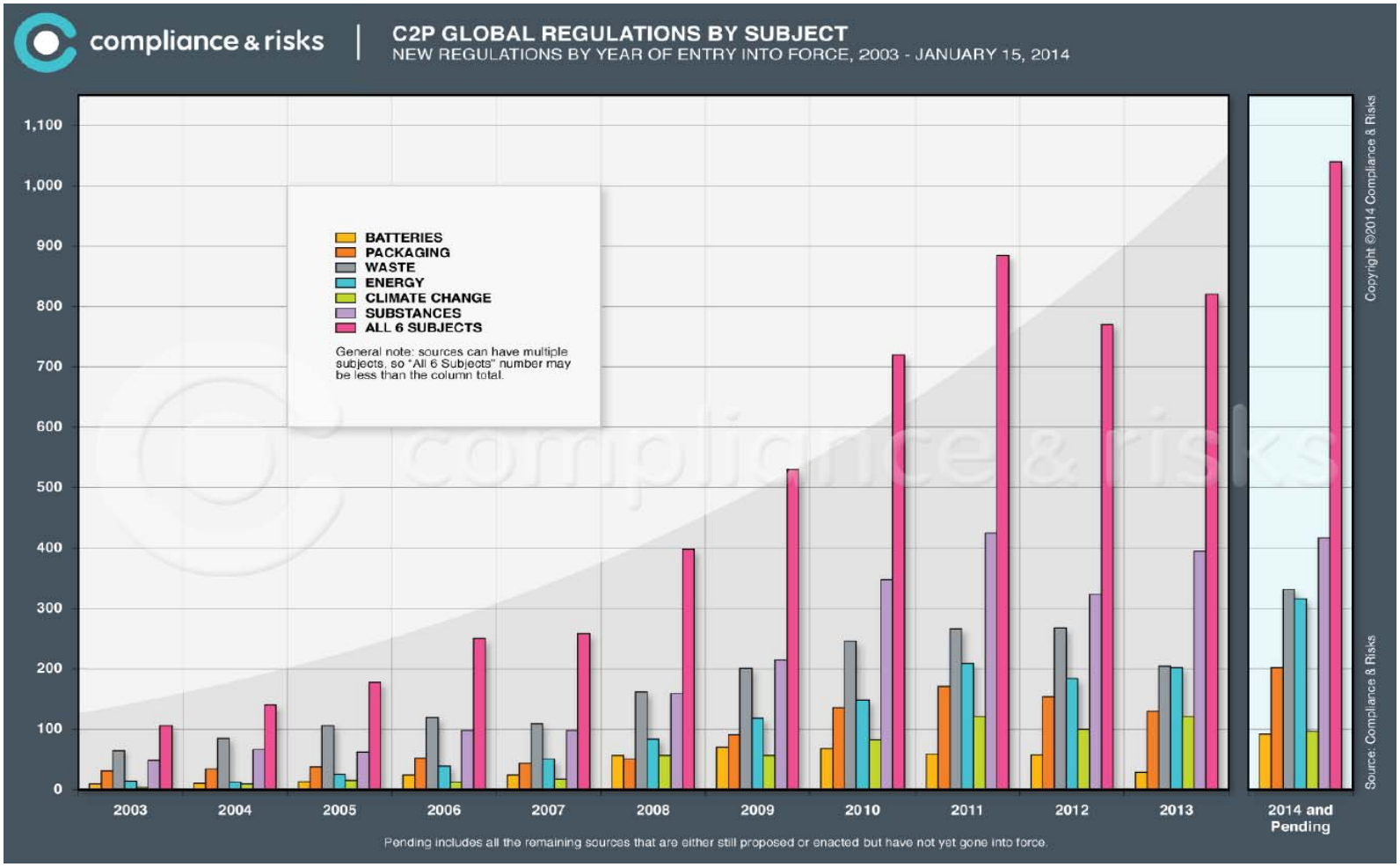
Legislation - Keeping Up With Developments



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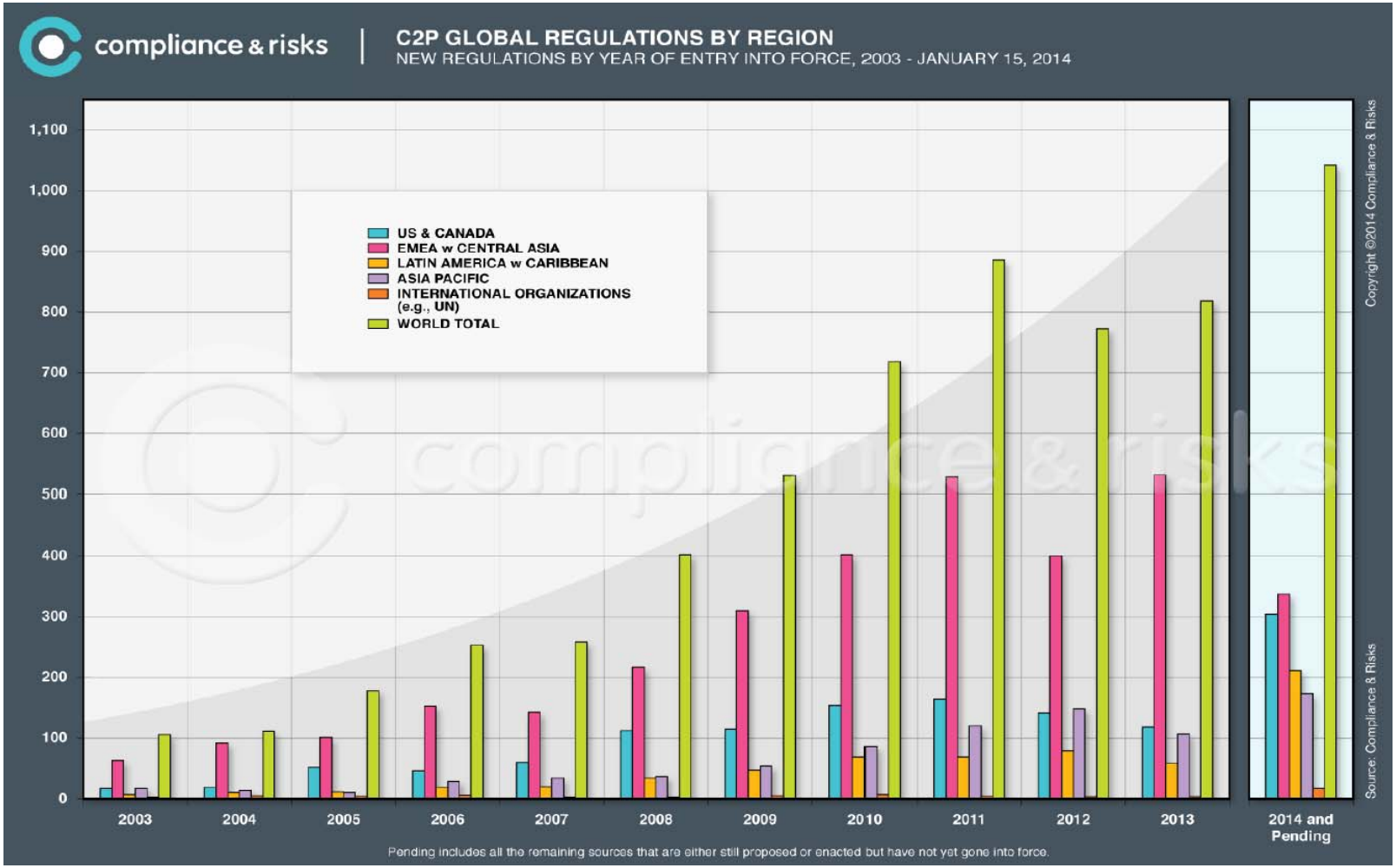
Legislation - Keeping Up With Developments



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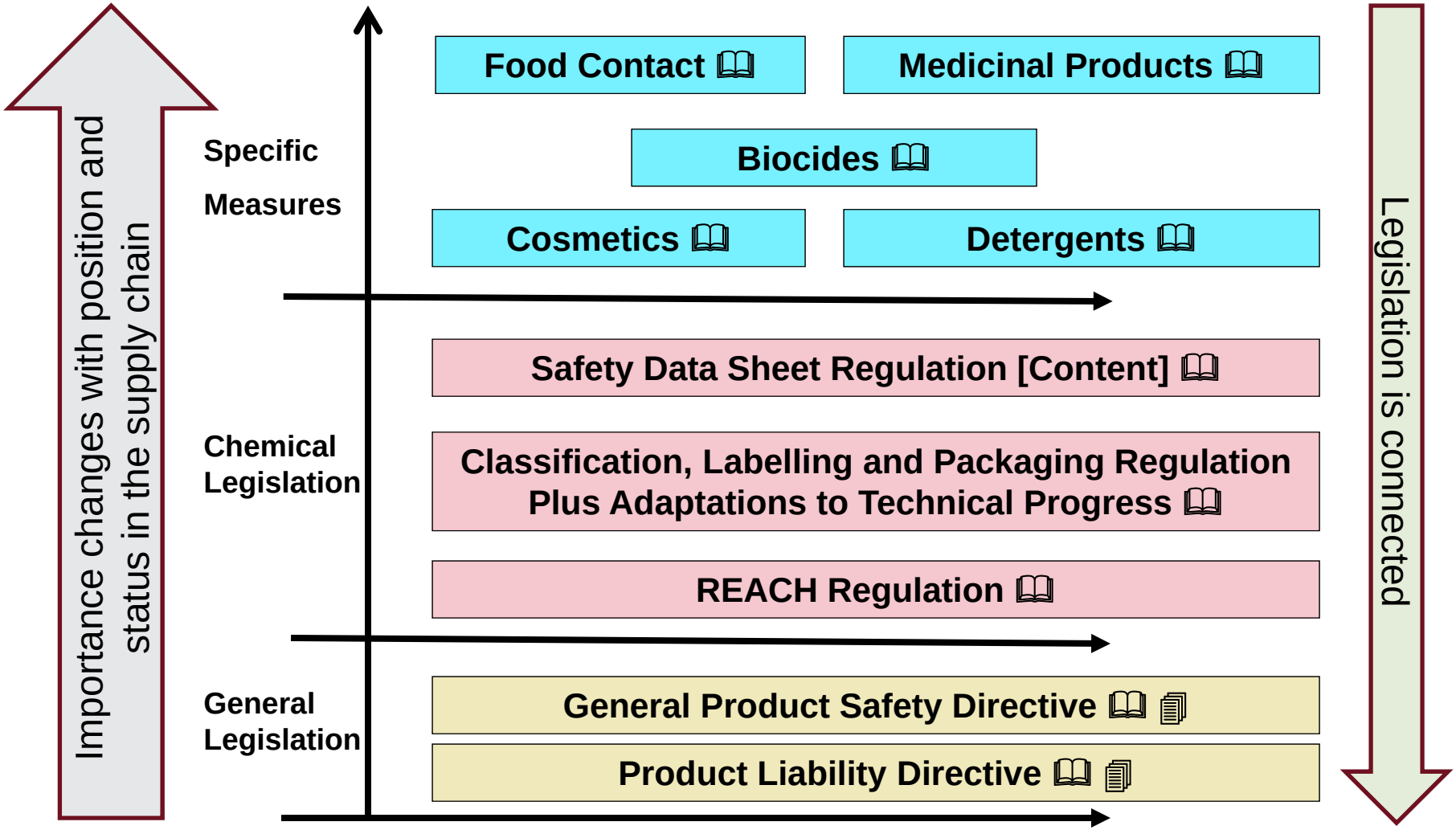
Harmonised Legislation in Europe



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Chemical Legislation, Biocides, Cosmetics, Medicinal Products and Packaging

- The composition of a product could essentially be the same but, depending on the claims made, it could be classified differently, e.g.,
  - Washing liquids and powders
    - Detergent
  - Hand cleanser with a cosmetic claim
    - Cosmetic
  - Hand sanitiser with a primary biocidal claim
    - Biocide
  - Hand cleanser claiming a therapeutic benefit
    - Medicinal product
- Chemical substances and mixtures are used in the manufacture of all the above products but the requirements for placing the products on the EU market are different

Where the Legislation Overlaps

- Chemical legislation referenced in the biocides and detergents legislation but not that for cosmetics (except CMR substances and those for public information) and medicinal products
  - Safety data sheet (SDS) requirements fall under the REACH Regulation and the label falls under the CLP Regulation
  - Cosmetics and medicinal products in the finished state rely on the label while biocides and detergents use a combination of the SDS and the label unless intended for the general public
  - For biocides classification is by CLP, SDS by REACH and the suitability of the non-active substances by the Cosmetics Regulation
- Understanding the interactions between the various legislative instruments and following all the changes is key to ensuring compliance

3.3 Information to be provided to the general public

When hazardous substances or dangerous mixtures are also offered or sold to the general public, an SDS does not need to be supplied. To rely on this exemption however, the supplier must provide "*sufficient information to enable the user to take all necessary measures as regards the protection of human health, safety and the environment*". REACH does not specify how this safety information should be provided, hence the supplier can choose the most suitable means according to the case and the recipient (e.g. by labelling or with product inserts).

3.4 Products for which an SDS is not required

For some mixtures REACH provides a general exemption from the need to supply information covered by Title IV "Information in the supply chain", including the provision of SDSs. The mixtures which benefit from such an exemption are such that are in the finished state, intended for the final user, and that belong to specific categories for which other pieces of legislation exist and an ovelap with REACH requirements should be avoided (e.g. medicinal products, cosmetic products and food and feedingstuffs).

Responsibilities when products no longer sold

- Responsibilities do not end when a product is removed from the EU Market and timing and data requirements are not harmonised
  - Under the REACH Regulation manufacturers, importers, downstream users and distributors are required to keep all necessary information available for a period of 10 years after he last used the substance or preparation and to make it available to a Member State competent authority upon request (Article 36)
  - For biocides, the period is at least 10 years (Article 68-1) and the data required will be defined in an implementing act (Article 68-3)
  - For cosmetics, the product information file shall be kept for a period of 10 years after the last batch of the cosmetic product was placed on the market
  - For detergents, there is no requirement to store information and for medicinal products the stricter approval regime includes adverse reaction reporting
- Understanding the interactions between the various legislative instruments and following all the changes is key to ensuring compliance

Packaging - Ensuring compliance

- For products sold in small quantities and directly to the general public, how is packaging covered by the legislation
  - REACH describes packaging as an article and must fulfil any requirements including restrictions in Annex XVII and presence of SVHCs
  - CLP assigns provisions for child-resistant fastenings and tactile warnings
    - Flammable, skin corrosion and skin sensitisation materials impacted
  - For biocides, CLP requirements plus directions for the safe disposal of the biocidal product and (or reuse) its packaging and status as a treated article
  - For cosmetics, the non-intended, technically unavoidable, presence of a small quantity of a prohibited substance is permitted
  - For detergents, there are no new requirements and for medicinal products the stricter approval regime includes treating the packaging as an excipient where it is part of the registration process
- Packaging is often forgotten but it falls within the scope of the legislation in Europe

2.3. Packaging

Substances, mixtures and articles can be contained inside of packaging, such as a carton, a plastic wrapping or a tin can. **The packaging does not belong to the substance, mixture or article being packaged and is therefore to be considered as a separate article under REACH**. Producers, importers and suppliers of packaging or of packaged substances, mixtures or articles have to fulfil the same requirements for that packaging as for any other article. Packaging with different functions needs to be considered separately (e.g. if an article is directly wrapped in plastic and then packed in a cardboard box, the plastic and the cardboard box should be considered separate articles).

2.5. Documentation

From Article 36(1)[11] of the REACH Regulation it follows that downstream users (article producers are considered also as downstream users under REACH, if they use a substance or mixture in the production of their articles) have to keep available all the information they require to carry out their REACH obligations. But even if it has been identified that no obligations under REACH apply, these companies should consider documenting the results of their compliance checking. This includes documenting the decision-making on whether certain products are articles, substances or mixtures as well as the checking if specific requirements apply for these. **Documenting this is recommended to producers and importers of articles in general, as it facilitates demonstrating REACH compliance towards customers and (inspecting/enforcing) authorities.**

Summary

- Keeping up with developments in chemical legislation is challenging because of the number of new regulations and amendments to existing legislation.
- Understanding the interactions between the pieces of legislation on your products and packaging is key to ensuring compliance and then following the amendments to ensure that compliance is maintained.

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Restrictions for Packaging in REACH

Number	Contaminant	Wording in Annex XVII
19	Arsenic	Treated wood shall not be used in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption.
22	Pentachlorophenol	Treated wood shall not be used in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption or other materials that may contaminate them.
23	Cadmium	Shall not be used to stabilise the finished articles listed below manufactured from polymers or copolymers of vinyl chloride - packaging materials (bags, containers, bottles, lids)
31	Coal Tar Distillates	Treated wood shall not be used in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption or other materials that may contaminate them.