EU Biocides

Changes after 2012

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Biocides – historical context

Resolution of 1 February 1993 on a Community programme of policy and action in relation to the environment and sustainable development

→ approved the general approach and strategy of the programme presented by the Commission, in which the need for risk management of non-agricultural pesticides is emphasised

Amendment (5) to Council Directive 76/769/EEC and discussion in the Council on Directive 91/414/EEC

→ the Council expressed concern at the lack of harmonised Community provisions for biocides

→ the Council invited the Commission to examine the situation in Member States and the possibility for action at Community level

DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market

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DIRECTIVE 98/8/EC

- **This Directive concerns:**

  a) the authorisation and the placing on the market for use of **biocidal products** within the Member States;

  b) the mutual recognition of authorisations within the Community;

  c) the establishment at Community level of a positive list of active substances which **may be used** in biocidal products.

- This Directive shall apply to biocidal products **but shall exclude** medicinal products, veterinary medicinal products, in vitro diagnostic medical devices, cosmetic products, foodstuffs and their additives, colours and sweeteners, food additives other than colours and sweeteners, materials and articles intended to come into contact with foodstuffs and plant protection products, covered by current effectual legislative acts

- Lots of imperfections appeared within the years

  → **Time for change**

Biocides – Preamble

Biocidal Products

necessary for the control of organisms that are harmful to human or animal health and for the control of organisms that cause damage to natural or manufactured materials

can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patterns

Biocidal products should neither be made available on the market nor used unless authorised in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation.

Regulation 528/2012/EU (BPR)

- This Regulation **lays down rules for**:

  a) the establishment of a list of active substances at Union level which **may be used** in biocidal products;

  b) the authorisation of biocidal products;

  c) the mutual recognition of authorisations within the Union;

  d) **the making available** on the market and **the use** of biocidal products within one or more Member States or the Union;

  e) the placing on the market of **treated articles**.

- This Regulation **shall not apply** to biocidal products and treated articles that are within the scope of medicated feedingstuffs , veterinary medicinal products, medicinal products for human use, flavourings and certain food ingredients with flavouring properties for use in and on foods, feed , plant protection products, toys, covered by current effectual legislative acts (1831/2003; 1333/2008, 1223/2009)

What's going on in BPR? (Understanding BPR*)

- The text was adopted on 22 May 2012 and is applicable from 1 September 2013, with a transitional period for certain provisions
- Aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.
- Certain exceptions to authorisation principle - Provisional product authorisations for new active substances that are still under assessment are also allowed on the market. *(for example:* Active substances under Review Programme)
- The BPR aims to harmonise the market at Union level; simplify the approval of active substances and authorisation of biocidal products; and introduce timelines for Member State evaluations, opinion-forming and decision-making. It also promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods.
- The approval of active substances takes place at Union level and the subsequent authorisation of the biocidal products at Member State level. This authorisation can be extended to other Member States by mutual recognition. However, the new regulation also provides applicants with the possibility of a new type of authorisation at Union level (Union authorisation).
- A dedicated IT platform, the Register for Biocidal Products (R4BP 3), will be used for submitting applications, exchanging data and information between the applicant, ECHA, Member State competent authorities and the European Commission.

*Source: http://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Current EU Biocidal Legislation

- REGULATION (EU) NO 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

- DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market

Information managment and National authorities for biocides legislation

- *European Environment Agency (EEA)*
  - ➢ agency of the European Union – major information source for professionals from environmental area and also the general public (33 member countries)
    - Czech Environmental Information Agency (CENIA)
    - Slovak Environmental Agency (SEA)

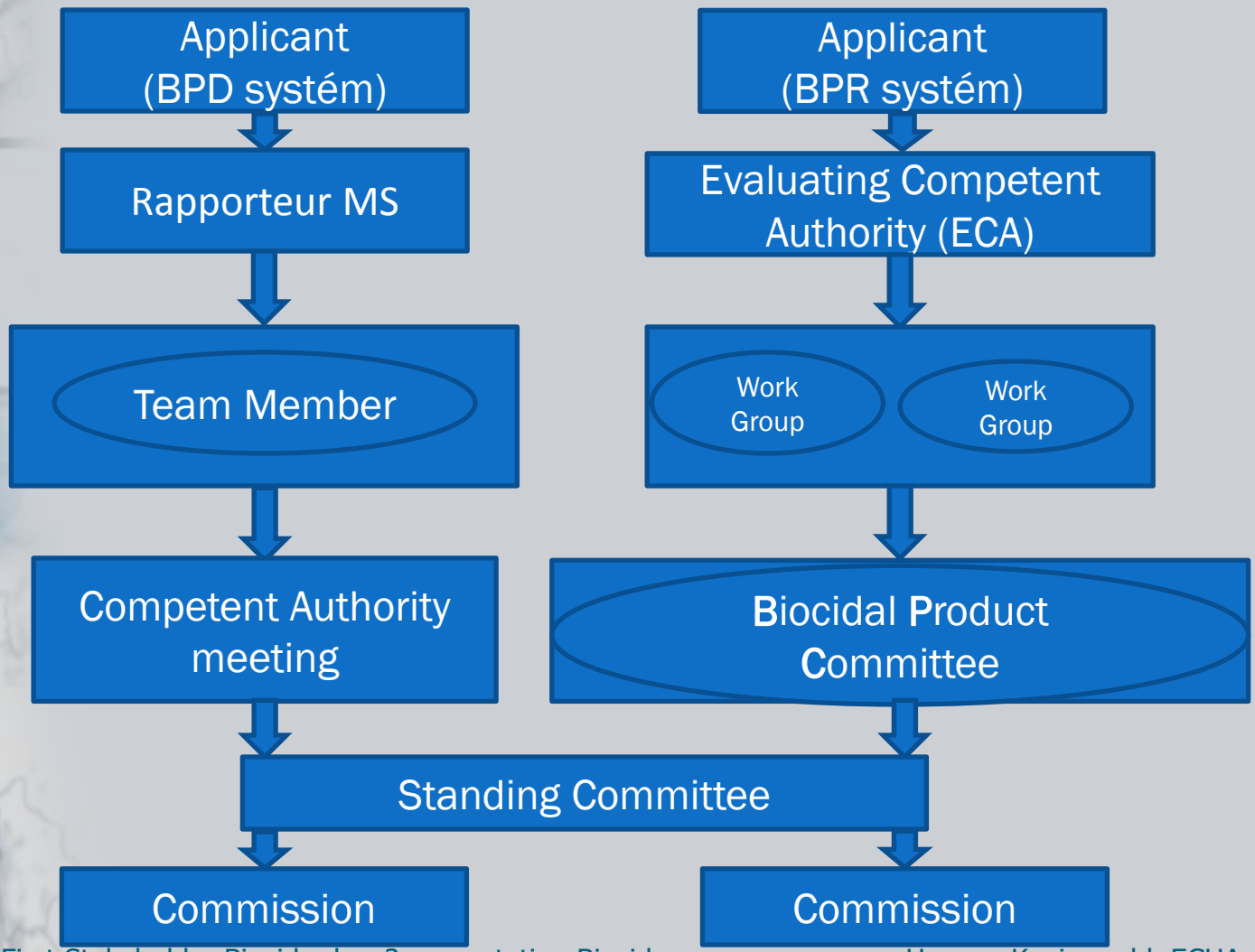
- *Czech Republic:*
  - ➢ *Ministry of Health*

  Slovak Republic:
  - ➢ *Centre for Chemical Substances and Preparations (also: REACH, Detergents, CLP)*

**National competent authority of the Slovak Republic responsible for the preparation and implementation of chemicals legislation concerning the placing of substances, mixtures, detergents and biocides on the market

*http://www.eea.europa.eu/cs/about-us/who
**Sources: http://www.cchlp.sk/
http://echa.europa.eu/sk/regulations/biocidal-products-regulation/understanding-bpr
http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/biocides-1#

Old versus new system - mapping



*First Stakeholder Biocide day, 2.presentation Biocides new processes - Hugues Kenigswald, ECHA

Problems a barriers - Regulation 528/2012/EU

- Main problem identified - the transitional rules of the Biocidal Products Regulation will introduce an **un-intended market freeze of up to eleven years** for articles treated with biocidal substances which are legal on the EU market, but which have not yet been evaluated at EU level.
- Other **un-intended market barriers** for certain companies have also been identified.
- The Biocidal Products Regulation fails to define a **protection period for data relating** to those products with the most favorable risk profile.
- It should be clarified in the first subparagraph of Article 96 of Regulation (EU) No 528/2012 that Directive 98/8/EC **is repealed without prejudice** to all provisions of Regulation (EU) No 528/2012 referring to Directive 98/8/EC..
- **Phase-out periods, dates, periods of time** – their definitions are in mny cases unsufficiently determined in the system e.g.: The phase-out period for use of biocidal products provided for by the second subparagraph of Article 95(3) of Regulation (EU) No 528/2012 should depend on the time when the substance is included in the list.
- From the date on which the Commission adopts a Regulation, the following up-to-date information held by the Agency or the Commission on that **active substance** shall be made publicly and **easily available** free of charge:
- Annex I Regulation 528/2012/EU **Category 6** – Active substances listed in Annex I or IA of 98/8/EC

  Problem:

  Those substances have been included in Annex I based on submissions of complete dossiers, the owners of which should be entitled to benefit from the cost compensation mechanism installed by that Article. In the future, other substances may be included in Annex I to that Regulation should therefore be regulating **all such substances**.

Problems a barriers - Regulation 528/2012/EU

- Article 86 of Regulation 528/2012 refers to **active substances included** in Annex I to Directive 98/8/EC of the European Parliament concerning the placing of biocidal products on the market

  Not clarified, that:

  - the provision applies to all active substances for which the Commission has adopted a Directive including them in that Annex.
  - the conditions for an inclusion is applicable to an approval
  - the approval date is considered to be the date of inclusion

- The Article 89(2) of Regulation 528/2012 allows Member States to **apply** their **current system** until two years after the date of approval of an active substance. The first subparagraph of Article 89(3) requires Member States to ensure that product authorisations are granted, modified or cancelled within two years of approval of an active substance.

  Necessary to postpone the deadline:

  - However, taking into account the time required for the various steps of the authorisation process, in particular where a disagreement on mutual recognition persists between Member States and therefore has to be submitted to the Commission for a decision, it is appropriate to extend those deadlines to three years, and to reflect that extension in the second subparagraph of Article 37(3).

- A biocidal product may contain a combination of new active substances which have been approved and existing active substances which have not yet been approved..

  Solution of market barriers:

  - For the purpose of rewarding innovation by granting such products access to the market, Member States should be allowed to apply their current systems to such products until the existing active substance has been approved, and the products are hence eligible for authorisation in accordance with Regulation 528/2012.

- The Article 95(1) of Regulation 528/2012 prescribes the submission of a complete substance dossier.

  Not clarified:

  - such a complete dossier may include data referred to in Annex IIIA or IVA to Directive 98/8/EC..

Published Law Changes related to Regulation 528/2012/EU

To ensure the correct application of the law

- COMMISSION DELEGATED REGULATION 736/2013/EU
  of 17 May 2013
  amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances

- COMMISSION IMPLEMENTING REGULATION 564/2013/EU
  of 18 June 2013
  on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

- COMMISSION DELEGATED REGULATION 837/2013/EU
  of 25 June 2013
  amending Annex III to Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the information requirements for authorisation of biocidal products

Other Important Documents related to BPR

- ECHA is publishes, actualizes and maintain information about BPR on its websites
  - http://echa.europa.eu/regulations/biocidal-products-regulation;jsessionid=7FE26051E3B525F6A8533D87B15D1435.live2
- ECHA publishes two new Guidance documents concerning biocides
  - http://www.echa.europa.eu/guidance-documents/guidance-on-biocides-legislation
  - http://www.echa.europa.eu/view-article/-/journal_content/title/echa-publishes-two-new-guidance-documents-concerning-biocides
- European biocides information network - to serve small and medium enterprises
  - http://www.europeanbiocides.net/

Fees

- Sharing the costs
  - To ensure that the costs are equally shared, all active substance manufacturers or importers must submit a letter of access or a full dossier to ECHA for each active substance they sell or use in biocidal products. ECHA will publish and maintain a list of all companies and active substances meeting this obligation.
  - Only the biocidal products containing the particular active substance from companies on the list are allowed to remain on the market after 1 September 2015.

- **COMMISSION IMPLEMENTING REGULATION 564/2013/EU of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation 528/2012/EU of the European Parliament and of the Council concerning the making available on the market and use of biocidal products :**

* http://ec.europa.eu/environment/biocides/revision.htm

Fees – according to 564/2013/EU

- To take into account the specific needs of small and medium-sized enterprises established in the Union → reduced fees
- Table 1 - Standard fees – for active substance approval (120 000,- Eur), the renewal of an approval, Inclusion in Annex I of an active substance, Notification
- Table 2 Annex II - Fee **reductions** for applications for the granting and renewal of Union authorisation of biocidal products or biocidal product families

Type of enterprise	Reduction (% of the standard fee)	
	Annex I – Active s.	Annex II - Products
Micro enterprise	60	30
Small enterprise	40	20
Medium enterprise	20	10

if the prospective authorisation holder is an SME established in the Union, except where the product contains an active substance which is a candidate for substitution

- **Refund** of amounts - to avoid penalising persons
  - launching justified appeals - where the appeal is well founded
  - partial refund of fees where applications are rejected before or during validation
- **Other Fees**
  - *Annex III-* (Technical equivalence, Appeal, Fee per item for which confidentiality is requested, Annual fee for biocidal products authorised by the Union, Mutual Recognition Submission fee, Fee per submission of a letter of access to a dossier already found)
  - Possible implementation - charges for administrative or technical services
- The Commission shall review the fees and charges. A first review shall be carried out at the latest

  January 1, 2015.

Payments

- **Mode of payment** – *Article 8*
  - The fees provided for by this Regulation shall be paid in euro.
  - Payments shall be made only after the Agency has issued an invoice.
  - By derogation from previous point, payments due under Article 4 shall be made at the time of the submission of the appeal.
  - Payments shall be made by means of a transfer to the bank account of the Agency.

- **Identification of the payment** - *Article 9*
  - Every payment, with the exception of payments referred to in Article 8(3), shall indicate in the reference field the **invoice number**.
  - Payments referred to in Article 8(3) shall indicate, the **identity** of the appellant(s) and, if available, the **number of the decision** that is being appealed against
  - If the **purpose of the payment cannot be established**, the Agency shall set a deadline by which the paying party must notify it in writing of the purpose of the payment. If the Agency does not receive a notification of the purpose of the payment before expiry of that deadline, **the payment shall be considered invalid** and the amount concerned shall be refunded to the paying party.

- **Date of payment**
  - Unless otherwise provided, fees shall be paid within 30 days from the date on which the invoice is notified by the Agency.
  - The date on which the full amount of the payment is deposited in a bank account held by the Agency shall be considered to be the date on which the payment has been made

- **Refund of amounts**
  - If an amount paid in excess is below EUR 200 and the party concerned has not expressly requested a refund, the amount paid in excess shall not be refunded..
  - The Agency shall reimburse 90 % of the fee collected where an application for active substance approval or biocidal product authorisation, is rejected before or during the validation phase.
  - Members of the Biocidal Product Committee acting as rapporteurs shall be reimbursed through the fees paid in accordance with Article 80(2) to the Member States' competent authorities acting as evaluating competent authority.

New processes comparing to BPD

Different ways to apply for product authorisation:

National Authorisation

Mutual recognition in sequence

New:

Mutual recognition in parallel

Union authorisation

Other BPR news

- Technically equivalent substances – possibility of one approve ones for technicaly equivalent active substances used in a biocidal product

  This is assessed by ECHA if:

  - the manufacturer is different from the one holding the original approval
  - the manufacturing process is different
  - just the manufacturing location of the approved manufacturer has changed

- Treated articles
  - articles can only be treated with biocidal products containing approved active substances.
  - Treated articles must be appropriately labeled according to the BPR and CLP

- Electronic submission tools
  - The main tools used when applying for active substance approval or product authorisation are IUCLID and R4BP (Register for Biocidal Products)
  - R4BP* is the central hub through which all biocides applications will be made. It will be available on ECHA's website on 1 September 2013.
  - IUCLID is used to collect, organize and store the data on your active substance and biocidal product. From this data, you will be able to create
  - a dossier that is submitted to the authorities through R4BP.
  - IUCLID software (version 5.5 or later) can be downloaded free of charge from the IUCLID website**

- Improvement of the safety of EU biocidal products market, while ensuring a high level of protection for humans and the environment
  - The most hazardous active substances are assessed before approval and the biocidal products containing them are assessed before authorisation. This is to reduce the number of e.g. carcinogens, mutagens and toxic substances on the market. If the active substance is identified as a candidate for substitution, it can only be authorized in a biocidal product if no better alternatives are available.

Mandatory data sharing

- Aim - to avoid unnecessary animal testing and, as such, testing on vertebrates for the purposes of the regulation may only be carried out as a last resort - before carrying out any tests,sending of inquiry to ECHA to find out if someone has already submitted the same test or study ⟹

  After, the applicant and the data owner must make every effort to reach an agreement on the sharing of the results of the tests or studies.

- http://ec.europa.eu/environment/biocides/revision.htm

* https://webgate.ec.europa.eu/env/r4bp2/

** http://iuclid.eu

Oportunities under Regulation 528/2012/EU

- Member state see BPR as oportunity to increase efectivity by harmonisation of EU biocidal active substances and products market
- BPR contribute to improve human health and environment
- BPR is the first piece of EU legislation to implement new Comission definition of nanomaterials
- The Commission also noted that new ways of authorisation and data sharing will save industry an estimated 2.7 billion euros during 10 years

Source: http://europa.eu/

What can be expected through to 2018 year

1/2

- Extension of ECHA's mandate on regulatory activities for biocidal active substances and biocidal products, September 1, 2013 BPR comes to apply – influence on huge number of companies
- **Increase of safety** of biocidal market and simplification of authorisation proccess for biocides which coming to or are using on EU market
- **Reduction of animal tests** by data sharing obligation and alternative test and studies support
- Use of online **Register** for biocidal products:
  - Past: applications for authorisation of product and archivation of related decisions
  - Future: information spread to **public**
- ECHA
  - Taking from European Commision program of aktive biocidal substances review programm – in cooperation with member states increase efectivity and acceleration of programm outputs
    Profetional and scientific help to Commission and member states, Cooperation with number of sujects
  - Formating statements of active substances and authorisations of biocidal products al Union level, centre for all applications, assesment of technical aquivalency, evaluation of applications about alternative importers, causes resolutions, distributing information, creating of rules and comunications platform
  - Analyses options for more speedy processing of biocidal products - experience from REACH dossier evalluation processes shared with the national authorities and the Biocidal Products Committee will be used
- **Great dubt** – Area of entries, comparing to experience and Similarity with REACH – depends on human and financial sources – expectation of time issues
- For cases felt like incorrectly applied regulatory power - a „quasi-judicial" body The Board of Appeal which takes ECHA decisions independently and impartially – decissions of this Board can have influence on have a subsequent impact on the operation and implementation of REACH and BPR
- Source: Multi-Annual Work Programme 2014-2018, DRAFT for public consultation, (MB/06/2013)

What can be expected through to 2018 year

- The aim of ECHA for the coming 5 years - **fully develop the functional interlinks** between substance evaluation and other REACH processes as well as with the CLP and BPRs. The information collected and received should lead to the identification of candidates bfor regulatory risk management.
- Information about chemicals are available on ECHA website
- Public databases are updated quarterly – cooperation with sector organisations for better data integration
- **Integrated IT system for biocidal products are in place**
  - Member states and and applicants are using consistently the IT systems
  - 2014 - All biocides processes are operational including those related to the Review Programme
    - Deliver IT support for distributed processes in Biocides, PIC, REACH - everyone and anyone can use the information, in a **responsible manner**, for the benefit of human health and the environment in Europe and throughout the world
- Maximalisation of efficiency and effectivity of agency work, particular when introducing the new legislation on biocides and export-import notifications and PIC - 649/2012/EU , also by **support and development of IT system tools and making information available quickly** - one of the four strategic aims of ECHA
- 2014 - Information from 2013 registration deadline and from existing Biocides dossiers Published
- 2015
  - Upgrade of Completeness check tool, in particular for checking safety information or biocidal information
  - Inconsistencies on intermediate dossiers addresse
- Huge change for internal market, new union way of authorisation of biocidal product – products dirrectly to whole EU market
- 2017 – First extension of the scope of Union Authorisation

Relevancy of Changes in Biocides in EU from global perspective

- Changes in EU biocidal legislation belongs to the most important aspects in current chemical regulatory policy and legislative health protection sphere

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Top International News in Chemical Policy and Regulation

- *NICNAS Changes Registration Structure For Industrial Chemicals – Australia*
- *Health Canada Seeks Comments On Proposal To Implement GHS In Canada*
- *European Union:*
  - *ECHA Seeks Comment On Draft Five-Year Strategic Plan*
  - *Harmonized Classifications According To The DSD Now Available In The C&L Inventory*
  - *EC Begins Consultation On OSH Policy Framework*
  - *EC Adopts Biocides Fee Regulation*
  - *ECHA Adds Six SVHCs To Candidate List*
  - *EC Begins Consultation On The REACH Annexes On Nanomaterials*
  - *ECHA Begins Public Consultation On Inclusion Of New Substances To The Authorization List*
  - *ECHA Holds First Biocides Stakeholders' Day*
  - *Croatia Joins EU As 28th Member State*
  - *EU Member States Publish Guidance On SVHCs In Articles*
  - *ECHA Calls For Additional Information On The Use Of Cadmium And Cadmium Compounds*
  - *EU And Industry Will Invest In Research And Innovation, Including Biobased Industries*
  - *ECHA Posts Guidance Documents Concerning Biocides*
- *FDA Issues Circular Clarifying Oversight Of Industrial Chemicals – Philippines*
- *Legislature Passes Amendments To Labor Occupation and Safety Act and Legislature Could Approve Amendments To The Toxic Chemical Substances Control Act In July* - Taiwan
- *Amendments To OSH Act Strengthen Management Of Outsourcing Hazardous Work* -South Korea
- *Thailand Proposes Combining Hazardous Substance Lists*
- *WHO Launches New Chemical Risk Assessment Network* - World Health Organisation (WHO)

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Events

- **Biocides 2013**

  November 18-20, 2013, sixteenth year of international biocides conference, on office@europeanbiocides.net

  Comprises an expert panel addressing legal issues and trade aspects of biocidal products, particularly the challenge of transforming the regime from the Directive (BPD) to the Regulation (BPR).

  2 Workshops - „Strategic overview of the biocidal products market through to 2030“ and „Overview of treated articles in relation to the BPR“

  Language: English

  Place: Hotel Park Royal Palace, Vienna, Austria

- **5. Symposium on BP authorisation**

  May 22-23, 2014

  All details about registration and place will be published in December 2013. Program will be published in January 2014

  Language: English

  Place: Bratislava, Slovakia

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Cited legal documents and used biocidal acronyms

- Commision Regulation **1451/2007/EC** about second phase of 10-year working programme
- Directive **98/8/EC**
- Regulation **528/2013/EU**
- Draft of Regulation 528/2013/EU of the European Parliament and of the Council 2013/0150 (COD), COM(2013) 288 final, Brussels,16. 5. 2013

- Biocidal acronyms:
  - BPC – Biocidal Product Committee
  - BPD – Biocidal Product Directive
  - BPR – Biocidal Product Regulation

Questions:
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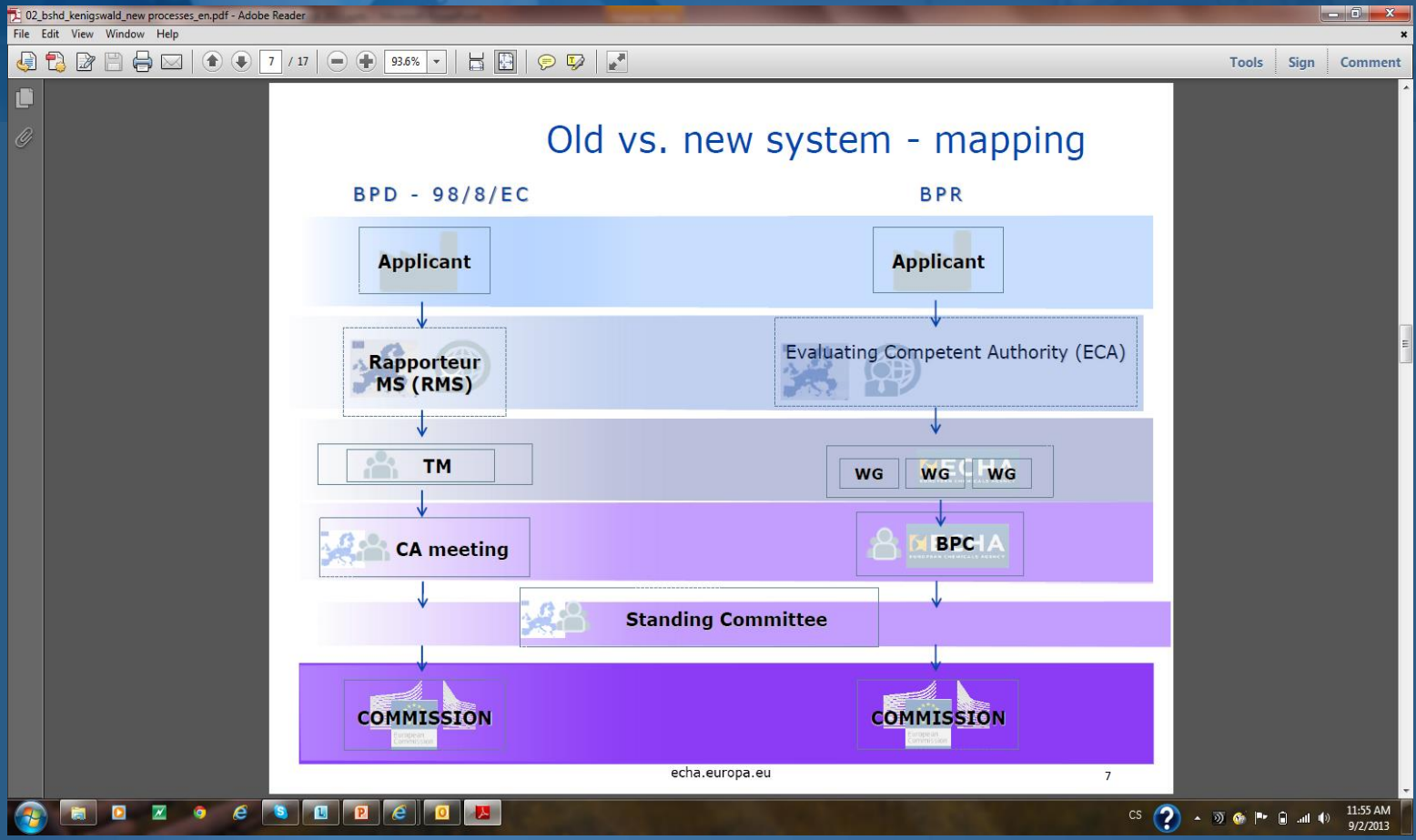
Screenshots



- Slide7, First Stakeholder Biocide day, 2.presentation Biocides new processes - Hugues Kenigswald, ECHA