Human Exposure Assessment and Risk Assessment (part 2)

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- Human Risk Assessment
- **Risk assessment in REACH (EU)**
- **Risk assessment of pesticides in EU**
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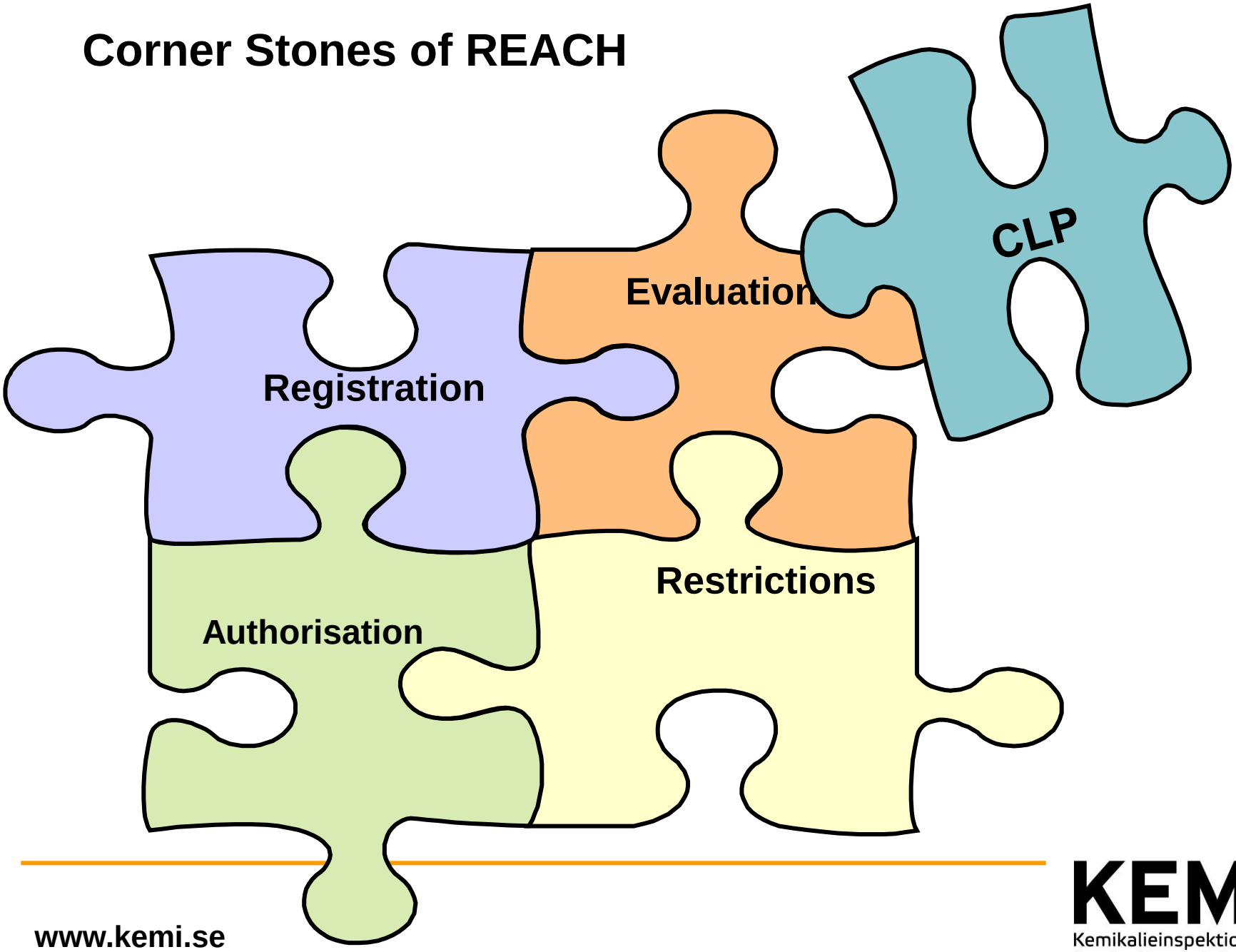
Risk assessment in REACH (EU)

REACH

- REACH is the European Community Regulation on chemicals and their safe use (EC 1907/2006).
- REACH stands for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **C**hemicals.
- REACH entered into force on in all EU countries 1 June 2007.
- In principle, REACH applies to all chemical substances.
- REACH places the burden of proof on companies.
- **Companies must identify and manage the risks linked to the substances they manufacture and market in the EU.**

- http://echa.europa.eu/web/guest/regulations/reach/understanding-reach

Corner Stones of REACH



Main features of REACH

- REACH will provide safety information about chemicals produced or imported in volumes **>1 ton/year** per manufacturer/importer
- The "Burden of proof" has been shifted to industry. It has to be able to demonstrate that the chemical can be used safely, and how.
- Industry will be responsible for assessing the safety of identified uses, prior to production and marketing.
  - **Chemical Safety Assessment (~ Risk assessment)**
    - For all substances >10 tonnes/year
    - Chemical Safety Report (CSR)
- All actors in the supply chain will be obliged to ensure the safety of the chemical substances they handle.
- Authorities will be able to focus on chemicals/issues of serious concern.

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REACH Exposure assessment

Entails two steps: Development of Exposure scenarios, and Exposure estimation.

Exposure scenario (ES):

- **Exposure scenario:** conditions under which a substance is manufactured and used
- Is meant to describe the conditions under which a substance can be used safely (= risks are controlled).
  - The **initial** ES describes the conditions of use as known at the beginning of the assessment process.
  - The **final** ES describes the conditions ensuring control of risk as a conclusion of the assessment process.

REACH Exposure assessment (2)

Exposure estimation:

- The assessment needs to cover the manufacturing and all identified uses of the substance and the life cycle stages resulting from these identified uses. Including the waste stage and, where relevant, the service-life of articles containing the substance.
- can be carried out based on modeling or based on measured data, depending on what is available.
- Exposure estimation can be carried out in a tiered process starting with conservative assumptions on emissions and exposure.

Risk characterisation

If "hazardous" or PBT/vPvB:

- **Exposure assessment** – taking into account risk reducing measures applied or recommended **[per Exposure Scenario]**
- **Risk characterisation [per Exposure Scenario]***
  - i. **Compare exposure data with DNEL**
  - ii. **Is exposure for each identified use [Exposure Scenario] "adequately controlled"? Exposure< DNEL?**
  - iii. **If not "adequately controlled": Refine hazard and/or exposure assessment or enhance risk reducing measures**

Options:

- ***Get more accurate effect data! ⇨ new data/test***
- ***Get more/better exposure data! ⇨ new model/measurements***
- ***Decrease exposure ! ⇨ new/additional risk reducing measures***

Iterations until "adequately controlled"

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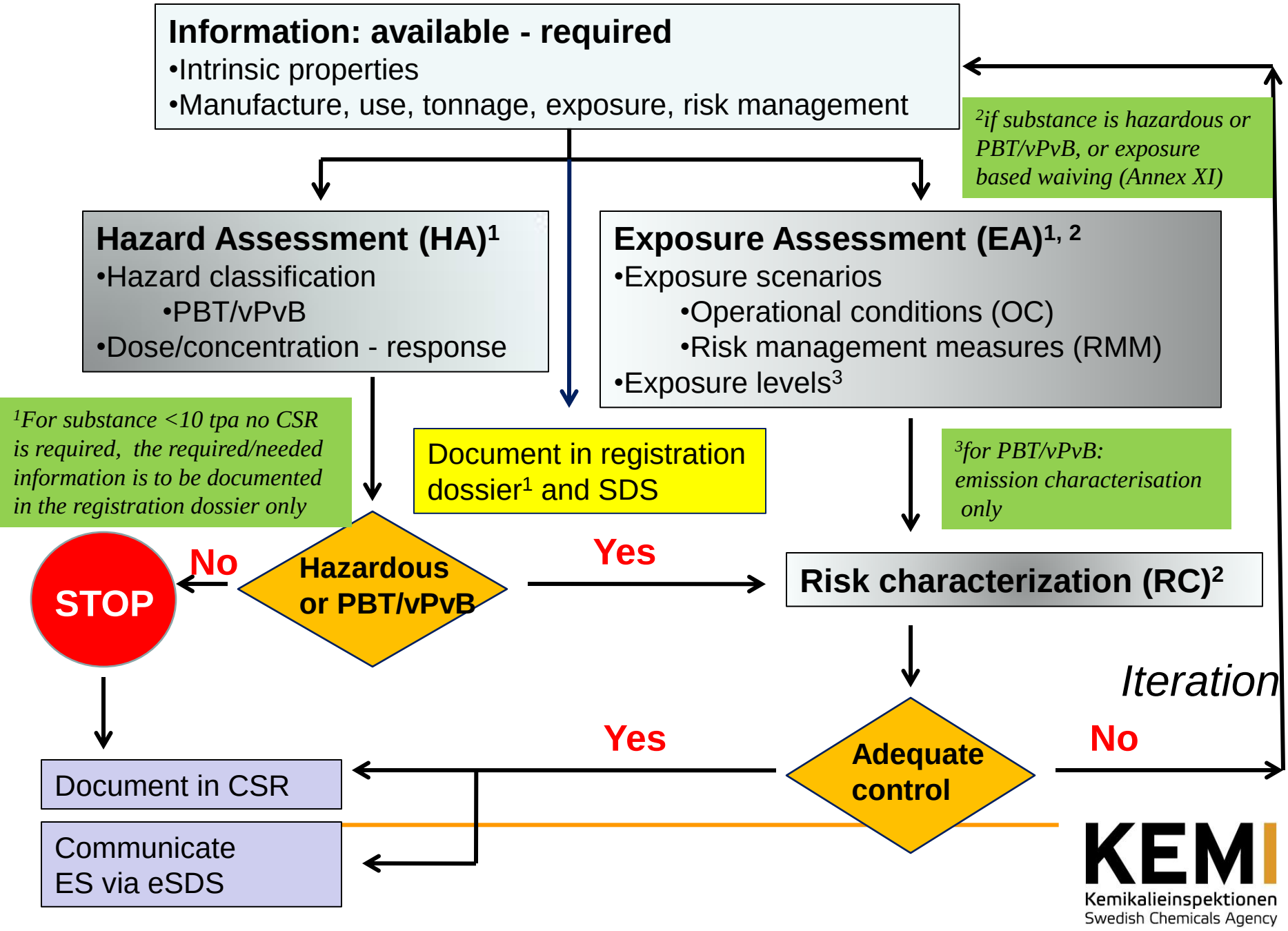
CSA and Information Requirements

- The CSA is not only a method to develop exposure scenarios and to demonstrate control of risk

  but also to support the evaluation process needed to meet the information requirements of REACH (Annex VI to X).

Based on the results in the CSA,
testing proposals can/should be made.


Information: available - required
•Intrinsic properties
•Manufacture, use, tonnage, exposure, risk management
[2]if substance is hazardous or PBT/vPvB, or exposure based waiving (Annex XI)
Hazard Assessment (HA)[1]
•Hazard classification
•PBT/vPvB
•Dose/concentration - response
Exposure Assessment (EA)[1, 2]
•Exposure scenarios
•Operational conditions (OC)
•Risk management measures (RMM)
•Exposure levels[3]
[1]For substance <10 tpa no CSR is required, the required/needed information is to be documented in the registration dossier only
Document in registration dossier[1] and SDS
[3]for PBT/vPvB: emission characterisation only
STOP
No
Hazardous or PBT/vPvB
Yes
Risk characterization (RC)[2]
Iteration
Yes
Adequate control
No
Document in CSR
Communicate ES via eSDS
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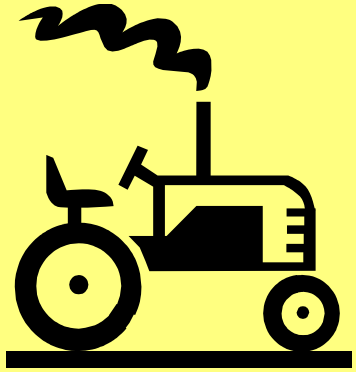
Risk assessment of pesticides in EU

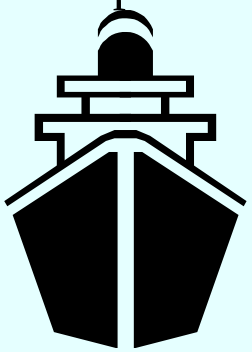
Pesticides are either

Agro-pesticides ➔
(in EU = Plant protection products, PPP) such as
* Herbicides, insecticides, fungicides
* Growth regulators
etc



or

Non-agro-pesticides ➔
(in EU = Biocidal products)
such as
* Antifouling products
* Mosquito repellent products
* Wood preservatives
* Household pesticides etc.



Pesticide regulations in EU

- **Plant Protection products (PPP)**
  Directive 91/414/EEC is replaced by a Regulation 1107/2009 on 14 June 2011 and a Frame Directive on sustainable use of PPP:s

- **Biocides:**
  Biocide Directive 98/8/EC is replaced by a Regulation 528/2012 in September 2013.

  Biocides are classified into 22 biocidal product-types, grouped in four main areas ➔ based on differences in exposure to health and the environment

  - Differences in **data requirement** for **PPPs and biocides** mainly for the **environment**

Pesticides - Exposure Assessment

Plant Protection Products (PPPs)

- Exposure assessment are usually similar between different substances but differs between e.g. substances that are
  - sprayed in field or in green-houses or
  - used as seed dressing

Biocides

- Most of the 23 different product groups are used differently ➔ leads to different methods for calculating exposure
- A substance belonging to two very different groups may have to be assessed with several methods

Exposure of Biocides

- **23 use groups; some active substances are used in several groups**

  ➔some examples
  - Household insecticides – mostly health problems

  - Rodenticides (non agricultural use) – health problems – secondary poisoning (dogs, cats, birds etc.)

  - Mosquito repellents – health problems

  - Vector pesticides – environmental problems

  - Wood preservatives - health and the environment etc. etc.

Anti-fouling application

Data requirement of a **Pesticide Product (PPP)**

- Examples of specific data requirement of products:
-

Intended uses ➔ dose, number of application, timing
➔ to be used to chose input at risk assessment

Efficacy studies on products ➔ choice of dose

Toxicology on the product: acute toxicity: oral, percutaneous, inhalation, skin and eye irritation, skin sensitization

Dermal absorption: % absorption of active ingredient
➔ used when estimating **operator exposure**.

Exposure from PPPs

- **Operator** (farmer) exposure:
  - Mixing pesticide with water and loading spray solution to spraying container (model)
  - Spraying (model)
  - Cleaning spraying container

  Worker: re-entrance into field and glass house

- **Bystander** and resident exposure:
  - from spray drift (model)

- **Consumer** exposure:
  - From food items that have been sprayed

➢ Exposure is not calculated for bad behaviour

Situation 1: Tractor-mounted boom sprayer
Exposure to health and environment

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Situation 2: Knapsack spraying
Exposure to health and environment

PPP GAP table (Good Agriculture Practice) Information on the intended uses

- Some of the information in the GAP-table give necessary data for carrying out operator exposure assessment

  - pest to be controlled and crop to be treated

  - concentration of active ingredient in product - operator exposure

  - dose per area (e.g. g/ha) - operator exposure

  - pre-harvest interval (PHI) / waiting period - exposure from residues

PPP - Operator Risk Assessment

1. **Hazard assessment**
   Effect data + dose response data ⇨ "NOAEL" ⇨ **AOEL**
   (Acceptable Operator Exposure Level)

   AOEL (mg/kg bw/day) = NOAEL/100
   (safety factor, 10x10 for inter individual x inter species variation); lowest NOAEL chosen)

2. **Exposure assessment (simulated)**
   using input data on: the type of product (solution, powder etc.), concentration of active substance in product and in spraying solution.
   % skin absorption of product/solution

⇨ **Risk assessment**

PPP Operator Risk Assessment

- **Exposure models (UK Poem Model, German Model, Europoem)** are used in a step-wise approach:
- Compare **simulated exposure** in mg/kg body weight and day (mg/kg bw/day) (body weight 60 kg) with **AOEL** (mg/kg bw/day)

  Exposure should be less than AOEL

- To reach a value less than AOEL personal protection equipments are added, one by one, in a step-wise approach:
  no protection ➔ gloves➔ overall and ➔protective mask
  a) for **mixing** and **loading** procedures
  b) during **application procedure** (mostly spraying) different types of spraying devices
- **worker** – to set an earliest time **re-entry in greenhouse / field**
  - Route of exposure: a) through inhalation b) through skin

Well protected farmer

.

Knapsack hand-held sprayer using protection equipment

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Public consultation on the Draft Guidance of EFSA on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products

Deadline: 20 May 2014

Document (1.0 Mb)

Privacy statement (0.1 Mb)

Appendix F: Exposure calculation spreadsheet (0.1 Mb)

EFSA's Pesticides Unit has launched an open consultation on the draft guidance of EFSA on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents. The Guidance Document is intended to provide guidance to applicants and authorities in the context of the review of active substances of Plant Protection Products (PPPs) under Regulation (EC) 1107/2009.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft document developed by EFSA.

Interested parties are invited to submit written comments by 20 May 2014.

Please use exclusively the electronic template provided with the documents to submit comments and refer to the line and page numbers. Please note that comments submitted by e-mail or by post cannot be taken into account and that a submission will not be considered if it is:

- submitted after the deadline set out in the call
- presented in any form other than what is provided for in the instructions and template
- not related to the contents of the document
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA working group and taken into consideration if found to be relevant.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

Published: 1 April 2014

http://www.efsa.europa.eu/en/consultationsclosed/call/140401.htm

How to interpret results from Risk Assessment

- Annex VI to the PPP regulation gives tools for decision on Plant protection Products (based on assessment of the active ingredient and relevant metabolites)

- Health:

  - Operator Exposure < AOEL
  also considering the use of protection equipment

  - ARfD (acute reference dose) is put on all pesticides with high acute toxicity, should be ≤ 100%

Risks to consumers from residues in food

- Residue levels at time of consumption (at the market, at harvest)

- Too high residues can occur
  - by using too large dose
  - application too close to harvest (after the recommended PHI)

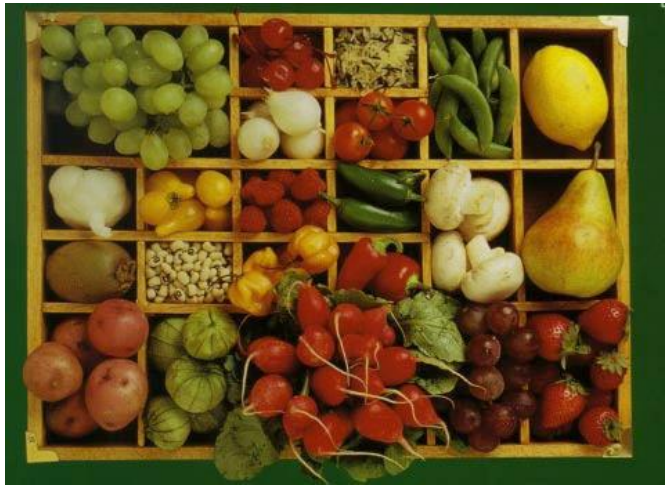
- Important endpoints based on NO(A)EL + Assessment factors:

  - **ADI** (Acceptable Daily Intake) mg a.s.kg bw/day (lifetime)

  - **ARfD** (Acute Reference Dose) set for acutely toxic substances mg a.s./meal or <24 hours

Maximum Residue Levels in EU

European diet



MRL (Maximum Residue Level) is based on field studies carried out **according to the GAP for a product**

MRL set for ca. 1100 substances and 315 agricultural products (EU)

http://www.efsa.europa.eu/en/pesticides/mrls.htm

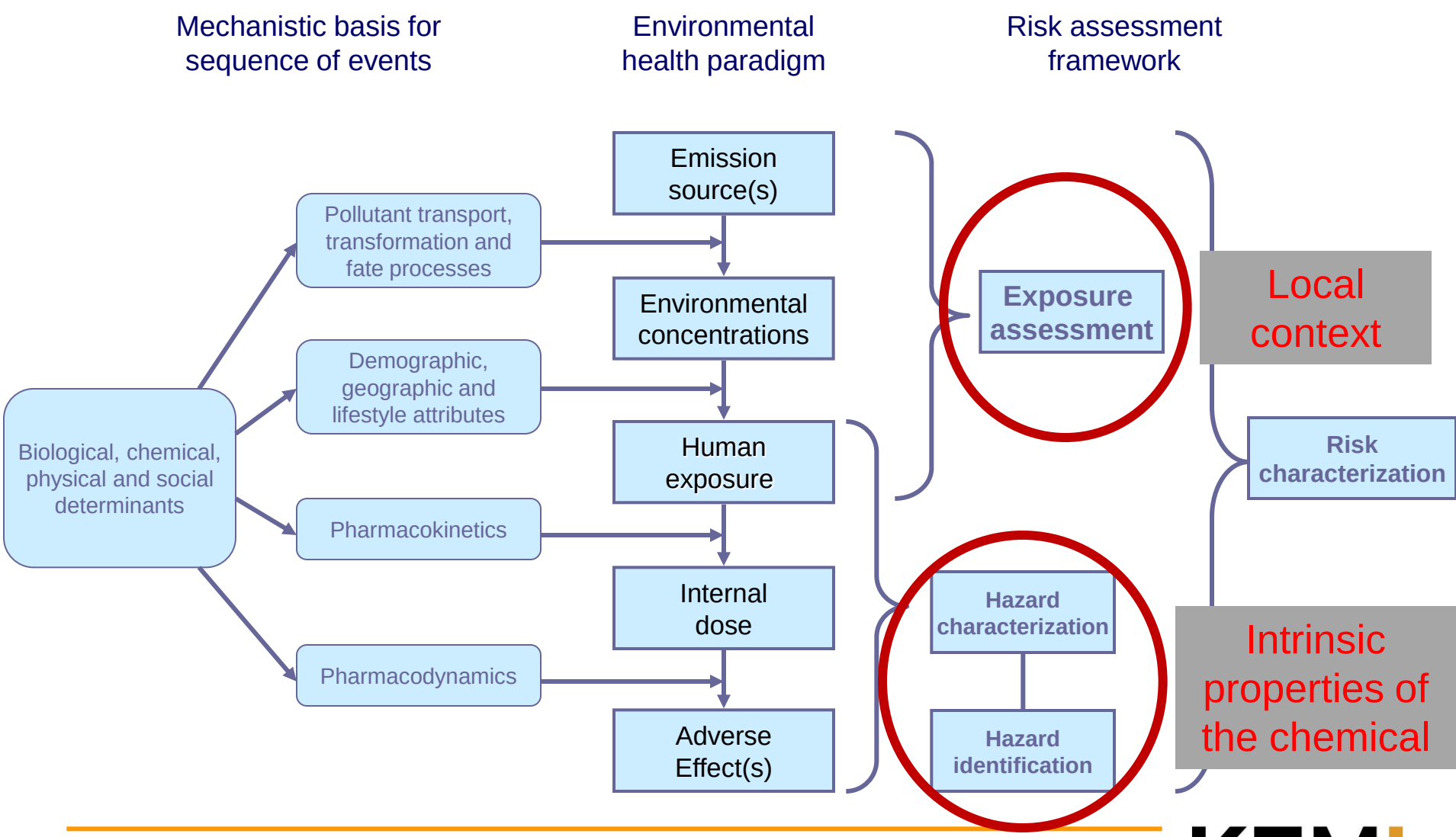
For which crops / food items is MRL set for EU?

- **MRL** is only set for crops, vegetables, fruits etc. which are included in the **GAP** for substances included in Annex I to the PPP regulation

  Import to EU:
  - For crops not included in EU GAP, importer can ask for a MRL to be set according to exporters GAP, otherwise according to WHO-codex or limit of quantification (LOQ)

  - For a substance which are not approved in EU, no GAP from exporter, MRL is set at LOQ

Information on databases/ available assessments



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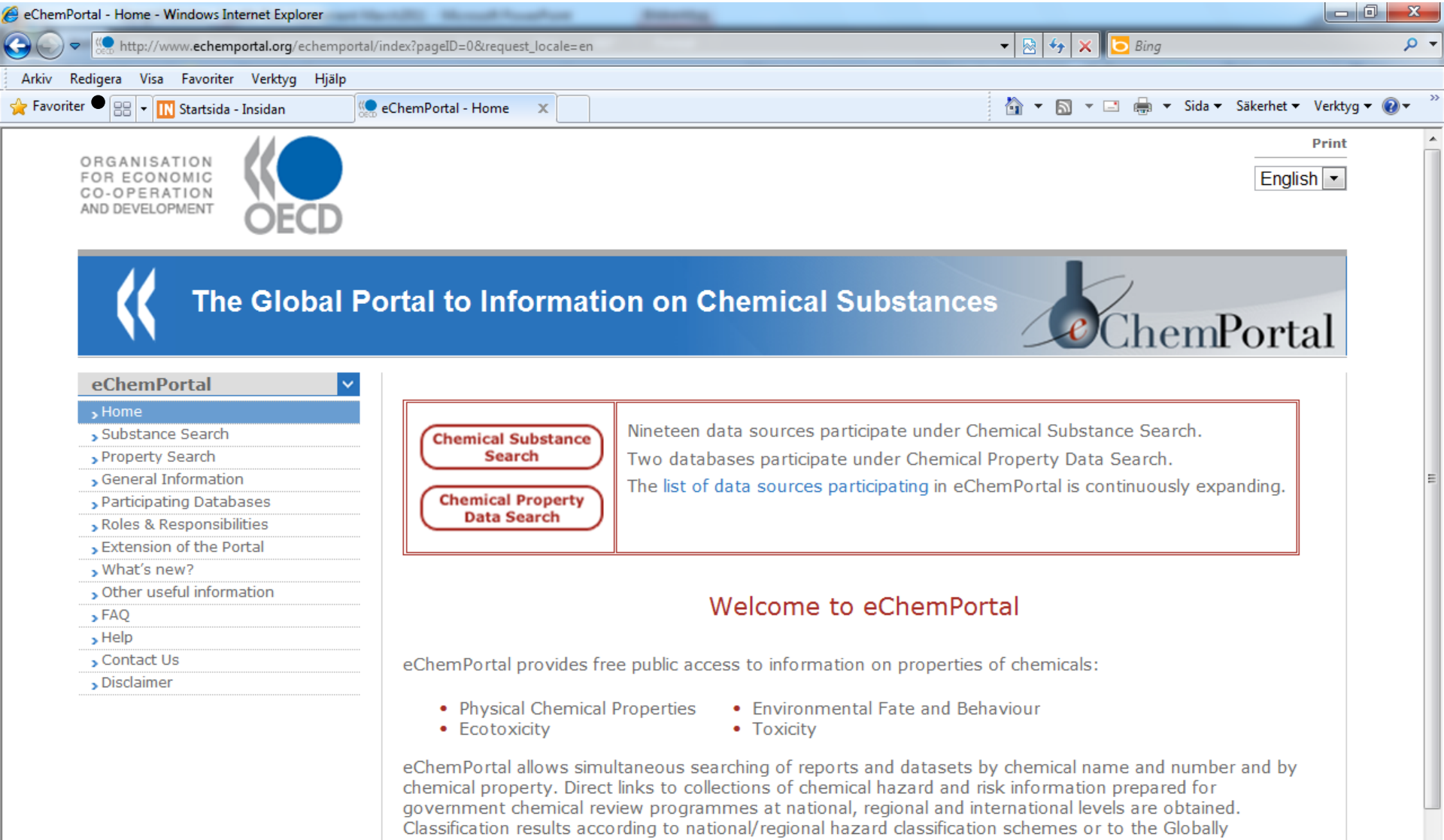
Use available Data and Assessments!

- Data on intrinsic properties **can** be used globally:
  - Toxicological and ekotoxicological testing
  - Hazard information
  - Classification & Labelling

- Exposure assessments can usually not be used globally:
  - Differences in use, handling and exposure
  - Environmental differences
  - Weather differences
- **=>Can give different risk assessment conclusions**

http://www.echemportal.org



The Global Portal to Information on Chemical Substances

eChemPortal

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- Property Search
- What's new?
- General Information
- Participating Databases
- Roles & Responsibilities
- Extension of the Portal
- Linking to eChemPortal
- Schedules of Assessments
- Other useful information
- FAQ
- Help
- Contact Us
- Disclaimer

Substance Search

Number:

CAS, EC, IUBMB, MITI, UN or NA Number.
Example: 108-88-3 for a CAS Number.
Make sure you include the number separators. Do not search on partial Numbers.

Chemical name or synonym:

Example: Use gluta* to find Glutamic acid, use *chloro* to find dichlorobenzene.
To search for * as character (non wildcard use) use ** instead.

Databases:

- [x] ACToR
- [x] AGRITOX
- [x] CCR
- [x] CESAR
- [x] Combined Exposures
- [x] ECHA CHEM
- [x] ECHA CHEM2
- [x] EnviChem
- [x] EPA HHBP
- [x] EPA OPPALB
- [x] ESIS
- [x] GHS-J
- [x] HPVIS
- [x] HSDB
- [x] HSNO CCID
- [x] INCHEM
- [x] J-CHECK
- [x] JECDB
- [x] NICNAS Other
- [x] NICNAS PEC
- [x] OECD HPV
- [x] OECD SIDS IUCLID
- [x] SIDS UNEP
- [x] SPIN
- [x] UK CCRMP Outputs
- [x] US EPA IRIS
- [x] US EPA SRS

Select All Deselect All

Select one or more of the participating databases for your search.

ECHA
EUROPEAN CHEMICALS AGENCY

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Information on Chemicals

http://echa.europa.eu/information-on-chemicals

The 'Information on Chemicals' section is the 'gateway' to ECHA's public databases on chemical substances, which contain a plethora of information about chemicals in Europe.

Search for Chemicals

I have read and I accept the legal notice

Name, EC or CAS No

REACH

- Registered substances
- Pre-registered substances
- Substances identified by industry to be registered by 31 May 2013
- Identified substances for registration in 2010
- Registration statistics
- Testing Proposals
- Transitional Measures
- Community Rolling Action Plan (CoRAP)
- Candidate List substances in articles
- Information from the Existing Substances Regulation
- Overview of downstream user reports

CLP

- C&L Inventory
- C&L Platform

Biocidal Products Regulation

- Biocidal Active Substances
- Biocidal Products
- List of active substance suppliers

Search Chemicals

Search for Chemicals

☑ I have read and I accept the legal notice

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Results

Category
Pre Registered Substances (606)
Registered Substances (30)
C&L Inventory (507)
European Priority List and Risk Assessments (1)

Information from the Existing Substances Regulation (ESR)

Before REACH entered into force, chemicals were regulated by a number of different regulations and directives. The Council Regulation (EEC) No 793/93 -- also known as the Existing Substances Regulation (ESR) -- was one of these. It introduced a comprehensive framework for the evaluation and control of "existing substances" (substances on the market before 1982).

The ESR stated that the Commission, in consultation with the Member States, would regularly draw up lists of priority substances which require immediate attention because of their potential effects to human health or the environment. Between 1994 and 2007 (the entry into force of REACH), four such priority lists were published, with a total of 141 substances.

The table gives a complete overview on the risk assessments performed by the Member States for each of the 141 substances listed in the four priority lists.

Showing 1 - 20 of 141 results. Items per Page 20 Page 1 of 8 First Previous Next Last

Substance Name	EC Number	CAS Number	Priority list	Summary	Final Risk Assessment report	Addendum	Recommendations in Official Journal	
Edetic acid	200-449-4	60-00-4	1					Details
Aniline	200-539-3	62-53-3	1					Details
Tetrasodium ethylenediaminetetraacetate	200-573-9	64-02-8	1					Details
Chloroform	200-663-8	67-66-3	2					Details
Propan-1-ol	200-746-9	71-23-8	2					Details
Benzene	200-753-7	71-43-2	1					Details
Acetonitrile	200-835-2	75-05-8	1					Details
Chlorodifluoromethane	200-871-9	75-45-6	2					Details
Methyloxirane (Propylene oxide)	200-879-2	75-56-9	2					Details
TBHP (Hydroperoxide, 1,1-Dimethylethyl)	200-915-7	75-91-2	3					Details
Hexachlorocyclopentadiene	201-029-3	77-47-4	4					Details
Acrylamide	201-173-7	79-06-1	1					Details

/echa.europa.eu/information-on-chemicals/information-from-existing-substances-regulation

Guidance on REACH

- **European Chemicals Agency (ECHA),** located in Helsinki, Finland
  http://echa.europa.eu/

- Guidance on the different processes under REACH
  http://http://echa.europa.eu/support/guidance

  ➢ Contains guidance on information requirements, hazard assessment, exposure assessment and chemical safety assessment, CLP etc.

DG SANCO - GUIDANCE DOCUMENTS

- http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm

er Verktyg Hjälp

European Commission > Food > Plant > Pesticides > Approval_active_substances

CONSUMERS | HEALTH | FOOD | ANIMALS | PLANTS

GMOS

PESTICIDES

- EU rules
- Pesticides database
- Sustainable use of pesticides
- Approval of active substances
  - Application & report
  - Guidelines
  - EFSA procedure & renewal
- Maximum Residue Levels
- Legislation

SEED & PROPAGATION MATERIAL

PLANT HEALTH - BIO-SECURITY

PLANT PROPERTY RIGHTS

STANDING COMMITEES

Guidelines on active substances

Technical guidance

[Expand All]

Phys-chem analytical methods

Efficacy

- Efficacy new active substance dossier (192 KB)
- Efficacy plant protection products - applicable from 3 April 2014 (101 KB)

Toxicity

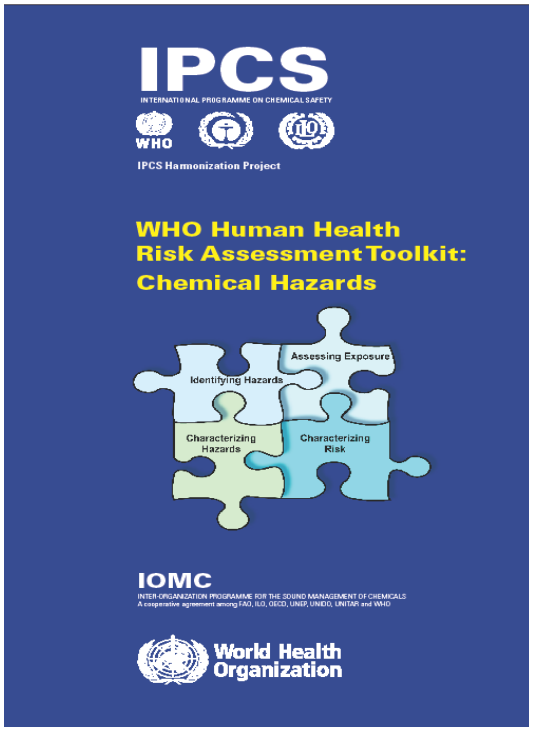
- Acceptable operator exposure levels (160 KB) - 7531 rev 10 - 7 July 2006
- Dermal Absorption (198 KB) - 19 March 2004
- Dermal absorption (256 KB) - 18 April 2012 - "Applicable from 1 December 2012/1 June 2013 depending on whether the guidance document does not trigger/triggers new studies to be submitted"
- Acute reference dose (491 KB) - 7199/VI/99 -5 July 2001

Residues

SV

WHO Human Health Risk Assessment Toolkit

- Assist with the performance of risk assessment.
- Promote the use of information developed by international organizations.
- Targeted at people with training in the principles of risk assessment.



Hard copy and web version:
http://www.who.int/ipcs/methods/harmonization/areas/ra_toolkit/en/index.html

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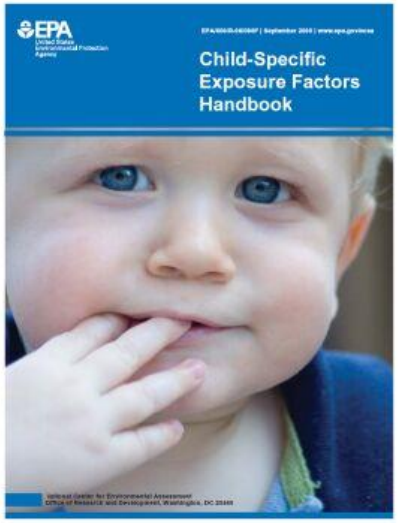
Information on Exposure factors etc. EPA

- EPA Guidance & Tools
  http://www.epa.gov/risk/guidance.htm

- Exposure factors handbook
  http://www.epa.gov/ncea/efh/report.html

- Child-Specific Exposure Factors Handbook
  http://www.epa.gov/childexpfactors/



Global Chemicals Outlook, GCO

- UNEP, in close collaboration with OECD, WHO and other organisations of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), have developed Global Chemicals Outlook to frame current understanding of trends in chemicals production, use and disposal, economic implications of these trends, and policy options.

- The GCO Synthesis document is now available in the six official UN languages:
- http://www.unep.org/chemicalsandwaste/Portals/9/Mainstreaming/GCO/GCO_SynthesisReport_UNEP.pdf
- http://www.unep.org/chemicalsandwaste/UNEPsWork/Mainstreaming/GlobalChemicalsOutlook/tabid/56356/Default.aspx

Further Links

Available Risk assessment reports

- Risk assessments from the Existing Substances Regulation (ESR): http://echa.europa.eu/web/guest/information-on-chemicals/information-from-existing-substances-regulation

- ”Risk profiles” from the Persistent Organic Pollutants Review Committee (POPRC) , a subsidiary body to the Stockholm Convention: http://chm.pops.int/TheConvention/POPsReviewCommittee/OverviewandMandate/tabid/2806/Default.aspx

- European Food Safety Authority (EFSA)
  PRAPeR - Pesticide Risk Assessment Peer Review:
  http://www.efsa.europa.eu/en/panels/praper.htm

Public information – Examples

- Cartoons: Napo in... Danger: chemicals!
  Napo is the hero of the cartoon series. He is symbolic of an employee working in any industry or sector.
  http://www.napofilm.net/en/napos-films/multimedia-film-episodes-listing-view?filmid=napo-012-danger-chemicals
- E-learning – Basic introduction to REACH
  http://ereach.dhigroup.com/
- **Focus on Pesticide Use** Movie clips on safe use of plant protection products (with english subtitles)
- http://www.sakertvaxtskydd.se/sv/In-English/

Pesticides
Links to information

- EU, DG Health and Consumers (Plant Protection Products) http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm
- Guidance Documents (Plant Protection Products) http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm
- European Food Safety Authority, EFSA (Plant Protection Products) http://www.efsa.europa.eu/en/panels/pesticides.htm
- EU, DG Environment (Biocides) http://ec.europa.eu/environment/biocides/index.htm
- Risk Assessment of Biocides http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides
- ECHA - Biocides
- http://echa.europa.eu/regulations/biocidal-products-regulation

WHO Resources http://www.who.int/ipcs/en/

- Directories of resources
- Generic resources on risk assessment
- Chemical-specific resources
  - *Hazard identification resources*
  - *Hazard characterization/ guidance or guideline value resources*
  - *Exposure assessment resources*
  - *Risk characterization resources*

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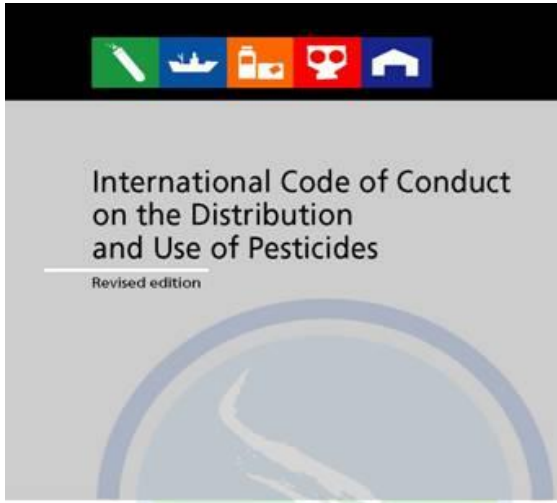
FAO Code of Conduct

- The International Code of Conduct on the Distribution and Use of Pesticides is the worldwide guidance document on pesticide management for all public and private entities engaged in, or associated with, the distribution and use of pesticides.
- The Code of Conduct is supported by a set of technical guidelines.
- http://www.fao.org/agriculture/crops/core-themes/theme/pests/code/en/



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Links

Links to information on chemical and environmental issues.

Choose by category in the list.

- Conventions
- European Union
- Finding information on chemicals on other websites
- International organisations
- National agencies in other countries
- Non-governmental organisations
- Other authorities
- Swedish research and universities

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Info

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www.kemi.se/en/ **http://www.kemi.se/en/Content/Links1/**

Thank you for your attention

Questions?