

**Experience from establishing chemicals legislation\***

# **Considering Chemicals legislation**

**Seminar of the MMA on LIRA  
Brasilia 19 March 2014**

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**\* Lessons from co-operation projects between KemI and  
authorities in other countries**

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# Chemicals legislation

**is meant to minimize risks due to the hazards from substances already when chemicals are spread for technical use (when placed on the market)**

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- **Key elements**
  - **Enable early action on possible risks from chemicals, with the use of classification, labelling and safety data sheets**
  - **Restrict the access to substances of very high concern because of the adverse effects they may have on humans, property and the environment**

# **Systems for information and restrictions give rise to activities in industry**

**Classification and labelling, the production and use of SDS as well as periods of grace before restrictions enter into force create everyday risk management activities within the ranks and files of industry and trade. Other rules are supportive to this and to enforcement**

**Compare to systems for licensing or permits**

**Chemicals legislation supports the other areas and sectors**

**Basic  
elements in  
action**

**Restrictions that limit the access to  
certain high concern substances  
or groups of substances**



**Supporting risk reduction  
everywhere chemicals are  
a concern:**

**Control of major chemical hazards,  
Consumer protection, Emission control,  
Contaminated soils remediation,  
Food safety, Protection of children,  
Public health, Waste disposal,  
Workers health & safety,  
etc.**

**Classification  
and labelling  
from suppliers**

**Safety data  
sheets from  
suppliers to  
professional  
users**



**Principle of inter-action within the supply chain**

**Chemicals legislation works up and down the chain**



**Principle driving force : Users need to know about risks**

**(More about estimating the degree of risk management)**

# **Chemical safety assessment**

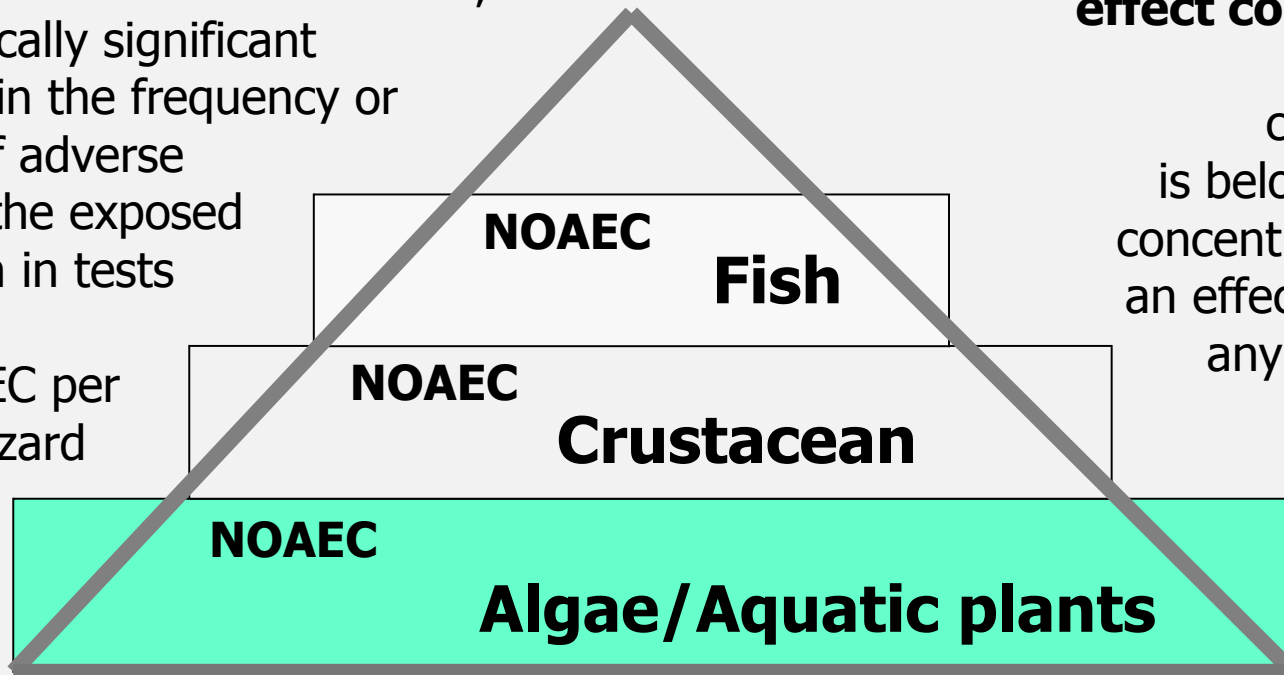
**Actual exposure for the substance  
/  
Derived no effect dose, or the predicted no  
effect concentration  
is  $\leq 1$**

**Considered adequate control**

# Data used for estimating adequate risk control, hazards to the aquatic ecosystems

**NOAEC = No observed adverse effect concentration,**  
No biologically significant increases in the frequency or severity of adverse effect on the exposed population in tests

One NOAEC per kind of hazard



**PNEC = Predicted no effect concentration**  
to the whole compartment is below the lowest concentration where an effect is found on any of the three trophic levels

One PNEC per kind of hazard

**PNEC is the NOAEC of the eco-system compartment multiplied with an uncertainty factor which depends on the quality of your data**

## **Actual exposure how to estimate?**

**Main route: Predict/Derive exposure from an exposure scenario**

**If exposure is already taking place, follow practices of sampling from representative points of the aquatic area**



**(More about estimating the degree of risk management)**

**If the conditions for use and the risk management recommendations assure that:**

$$\frac{\text{The actual exposure for the substance}}{\text{The derived no effect dose, or the predicted no effect concentration}} \leq 1$$

**it is considered adequate control**

## **Considering Chemicals legislation**

**Upstream obligations are efficient and resource effective,**

**Because manufacturers and importers are few compared to the number of downstream users, possible use and sites of handling chemicals**

**The number of chemicals is low compared to the indefinite number of applications of chemicals ( in other articles, in special chemicals or in equipments )**

# Framework primary law (on the level of the legislator)

Scope of the law

General definitions for the law purpose

Basic obligations and clear addresses of obligations

General exemptions

Regulatory mandates, tasks and powers of the ministry, the competent authority and the enforcement body

Description of possible offenses & the corresponding penalties

Transparency rules, rights of the public to know

## **Considering Chemicals legislation**

# **Secondary law, application rules (Government, ministers & mandated bodies)**

**Decree/Regulation/Ordinance/Ministerial decision**

**Subject**

**References to the law (mandate, obligations ..)**

**Precise definitions for the purpose of the application rules**

**Precise mandatory requirements and the corresponding requisites**

**Detailed exemptions**

**Leading instructions**

**Formats and templates**

# **Framework principal lines, main dispositions & main obligations**

**Administrative and technical application requisites,  
requirements, requests and instructions**

**Demands on  
administration  
Instructions  
Daily tasks**

**Detailed everyday  
demands on  
manufacturers /  
importers and users  
incl. physical persons**

**Rights of the  
general public  
in daily life**

**Framework**  
**Law on Chemicals**

Horisontal legislation,  
Parallel to legislation in other areas

**Rulebooks pursuant to the Law on Chemicals:**

|                                         |                                         |                    |
|-----------------------------------------|-----------------------------------------|--------------------|
| Bans and restrictions                   | Classification, labelling and packaging | Safety Data Sheets |
| List of substances of very high concern | Detergents                              | Import and export  |
| Criteria on PBT and vPvB                | List of surfactants                     |                    |

**Reference:** <http://shema.gov.rs/en/regulations/>

## **Special regulation on biocides and pesticides**

**Systems for permits for biocidal products and pesticide preparations could preferably be established under special legislation (Law on Biocides; Law on Plant protection products)**

**Their safe use would better be regulated in the relevant area.**

**Control of biocidal wood preservation fits for example under both the law on environmental protection and the law for workers health and safety**

## **Considering Chemicals legislation**

**See Chemicals legislation as a regulatory area of its own**

**The responsible administration would need an organisation on its own, a certain influence in the state and certain powers to act**

**It could be organised as a ministerial directorate, a bureau or an agency**

**It better should report directly to the minister in charge**



## **Considering Chemicals legislation**

### **Capacity and main competence areas of the responsible authority (central core administration)**

- Generalist competencies of staffs in hazard assessment, risk assessment and risk management**
- Some staffs with competencies in chemistry, toxicology and eco-toxicology, able to engage further expertise**
- Some competencies in law, socio-economics, environmental economy and statistics**
- Capacity to keep a chemicals registry?**

## Considering Chemicals legislation

### **The rules should lay down the clear allocation of costs**

Each actor may bear the costs for activities fulfilling her obligations

Industry's chemicals management costs may be covered, well- distributed within production and trade and successively diluted by the price-mechanism

If so, administrative costs could become more predictable and stable

Certain costs for administrative services and costs of inspection may be recovered by fees

## Considering Chemicals legislation

### **Subvention or discrimination by cost-allocation and cost-division?**

If government takes on costs for the management of hazardous chemicals – it works in real as a “state subvention” to the manufacturers and importers of those chemicals on the expense of chemical suppliers which offer less hazardous alternatives

If costs for risk management is placed on the manufacturer and importer you “level” the market in the positive sense the hazardous alternative, supporting the competitiveness of less hazardous alternatives

## Considering Chemicals legislation

### **Industry costs for compliance – main route for successive reduction of cost increases down the supply chain**

The price-mechanism is the ordinary instrument to move cost increases downstream the supply chain, the clients takes the increases as long as they find the chemical attractive

The price-mechanism make that way the cost-increase dilute, more actors are sharing it, it means less of an increase by each step since the cost of the chemical is a minor part of the total costs for the client/the downstream user

## Considering Chemicals legislation

### **Fees for administrative services & enforcement**

**– to treat everyone equally, make fees proportionate costs & to cover overhead**

- Fees are supposed to correspond to the costs for providing the service (receive applications, assess the case, prepare decisions and issue decisions)
- Fees could be calculated per day. They could be fixed fees based on some years experience from the kind of cases (you find that it on average takes x days to handle a case)
- Do include your administrative overhead costs in the fee: Salary costs of directors and staffs in supporting functions, rents and maintenance of facilities, IT-equipments, costs for internal formation of staffs, costs for air conditioning and light etc)

**Thank you for your attention**

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