

Experience from establishing chemicals legislation*

Ways to achieve the clear, effective and transparent management of chemicals

Principles and basic elements

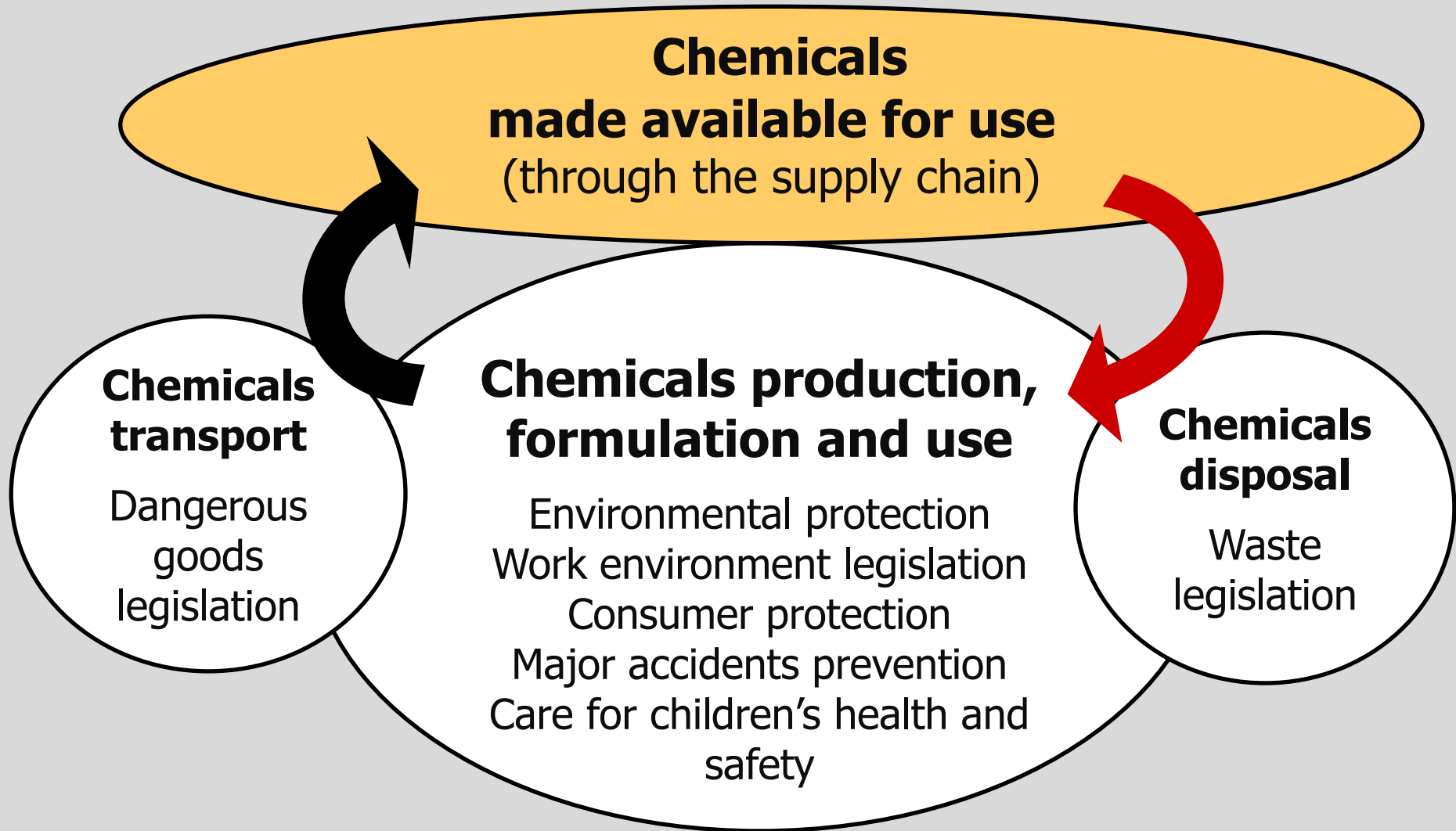
**Torbjörn Lindh
Swedish Chemicals Agency**

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

What we will touch on

- Ideas and principles of chemicals control
- Experience from establishing chemicals legislation
- Working concepts and components of legislation
- Comparative advantages & in-built incentives for a precautionary and preventive legislation
- Scope of chemicals safety in various areas of special legislation
- Legal frame and set-up of institutions following UNEP standards

**You need chemicals control
to manage the flow of chemicals in society**



Experience from establishing chemicals legislation

What principles and basic elements made colleagues in other countries open their eyes for:

- the possibilities with chemicals legislation**
- the role of other legislation in areas where chemicals safety is a concern, and**
- the possibilities to allocate mandates, obligations and basic costs in a clear, effective and transparent manner?**

Litterature

- **Lira Guidance Test version, UNEP Chemicals 2012**
- **Developing National GHS Implementation Strategy, Guidance from UNITAR et.al. 2010**
- **Capacity Building for Sound Management of Chemicals, PM 1/10 KemI 2010**
- **Legislation for Risk management at marketing of chemicals - the first step of the supply chain, PM 4/08 KemI 2008**

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)

Basic elements



Enhance early action on possible risks from chemicals, with the help 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

Main elements
of Chemicals
legislation in
everyday action

2. Systems for restrictions

to limit the free spread of
high concern-substances
or groups of substances

1. Systems for
information on
hazards and
precautions

GHS

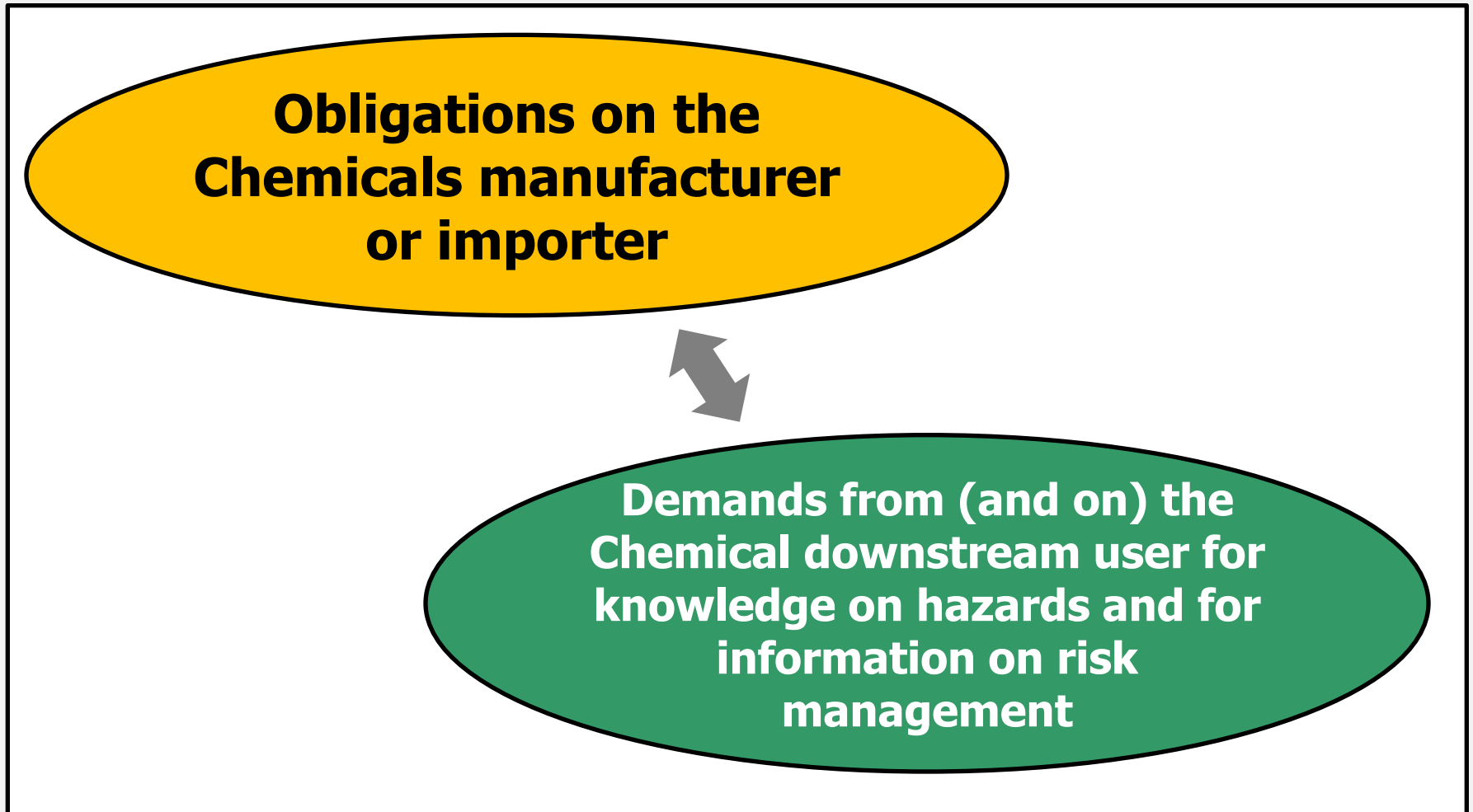
Classification &
labelling from
suppliers

Safety data sheets
to professional
users

**Support
to safe management
anywhere in society:**

**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.**

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

Impact and impuls when addressing supply with obligations

Upstream chemicals control is efficient and resource effective, it can be done

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

The number of substances used in chemicals is high

but the number of mixtures is much higher and the possible articles containing or treated with chemicals are an indefinite number over time

Most chemicals legislation treats the importer equally to the domestic manufacturer

Once you are the importer, you stay the importer and are responsible as such

The imported chemical stays an imported chemical through its whole life-time

Import is not reduced to the passage of a checkpoint at the national border

The concept "Placing on the market"

Definition in CLP-REACH

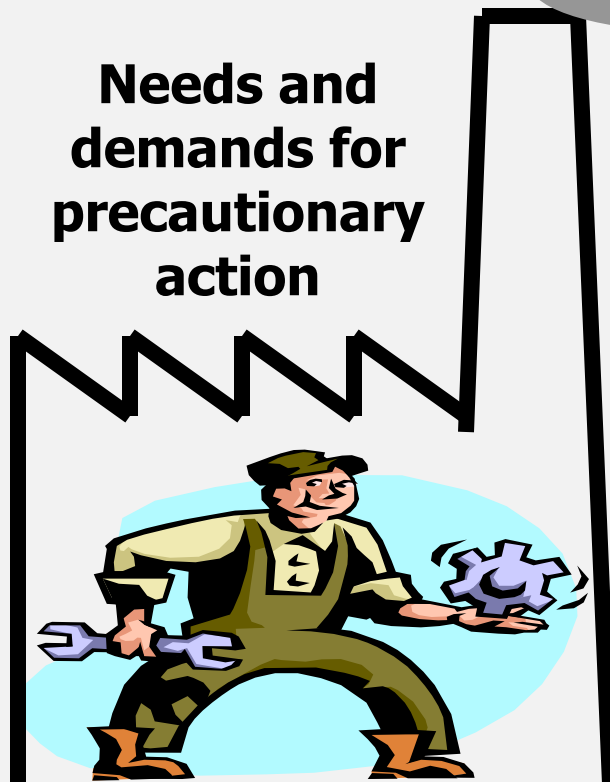
... supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

Definition in the "Biocide regulation" BPR

..... the first making available on the market of a biocidal product or of a treated article;

Chemicals legislation is meant to promote early action

Prevent risks from the very beginning



Needs and demands for precautionary action

Eliminate adverse effects

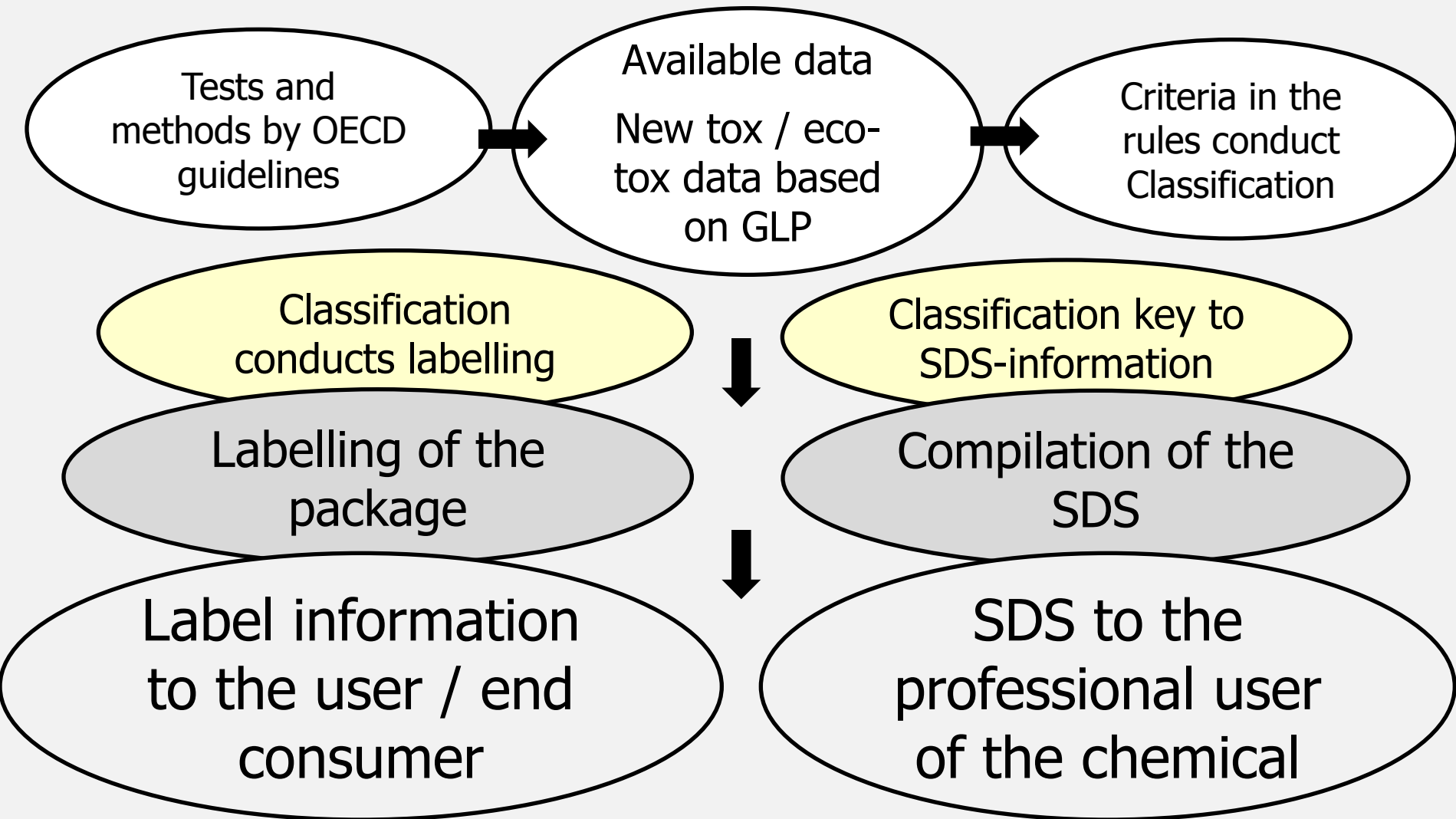


Relax burdens of cure and repair

Principles of prevention and precaution

"Prevention is better than cure" Bernadino Rammazzini (1633-1714)

The Generic principle: From Laboratory data to Labels on the cans

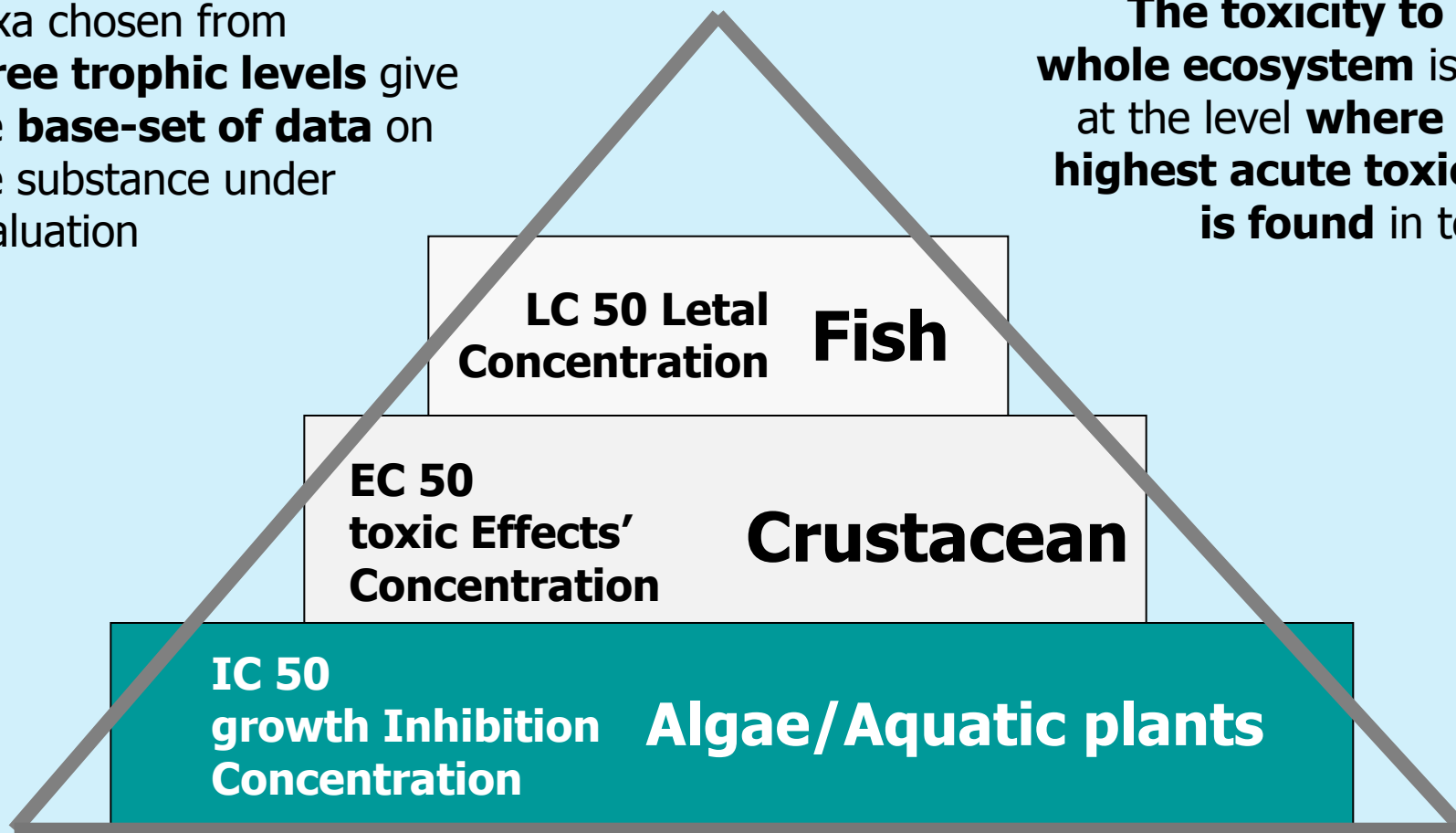


Basic elements of the generic approach: Hazard criteria

Example: to assess acute toxicity as a hazard to the aquatic environment

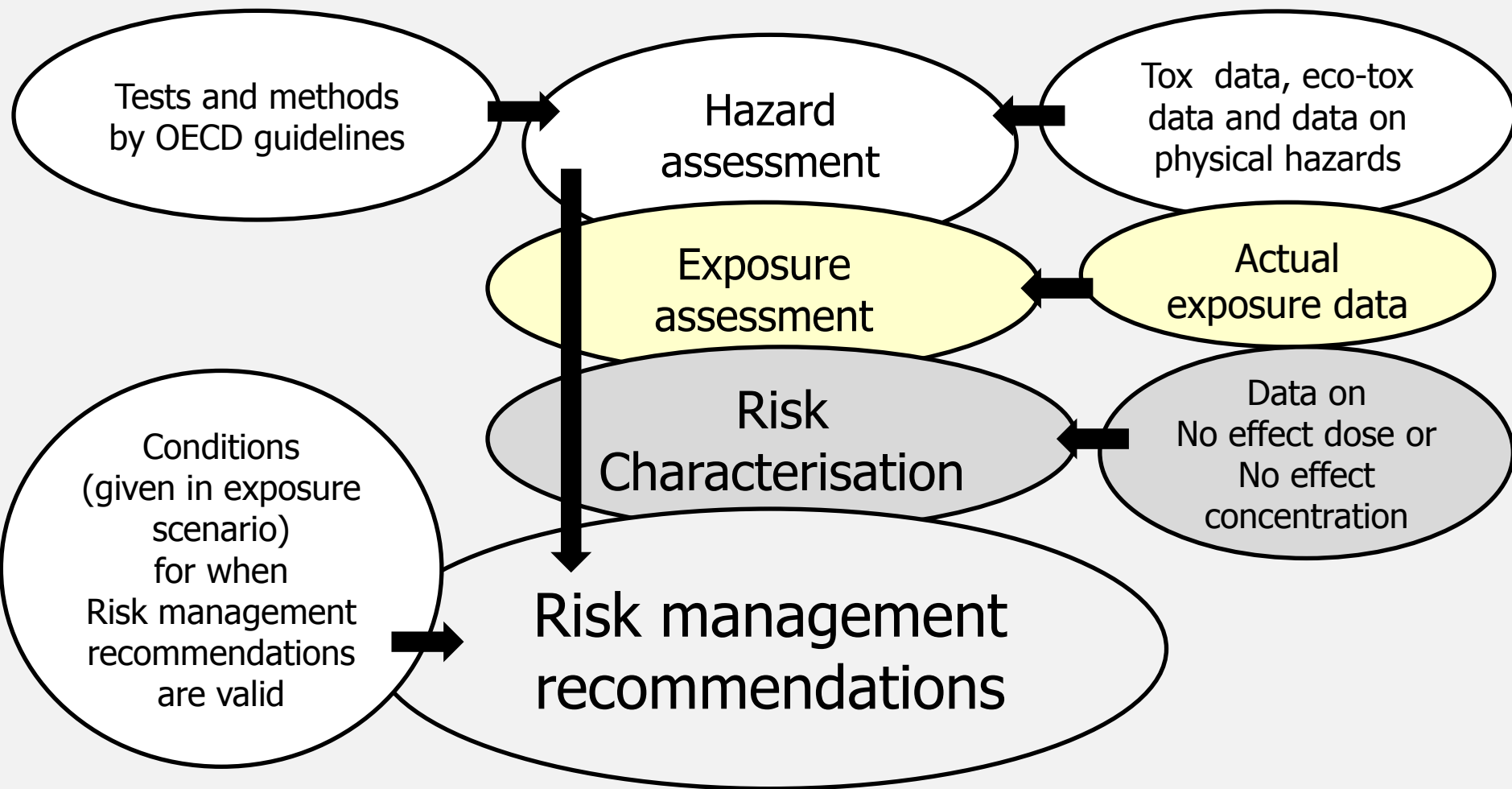
Taxa chosen from **three trophic levels** give the **base-set of data** on the substance under evaluation

The toxicity to the whole ecosystem is set at the level **where the highest acute toxicity is found** in tests



Acute toxicity, category 1 : LC_{50} or EC_{50} or $IC_{50} \leq 1$ mg/l

The Generic principle: From lab data and exposure data to Chemicals safety assessment (REACH Annex I)

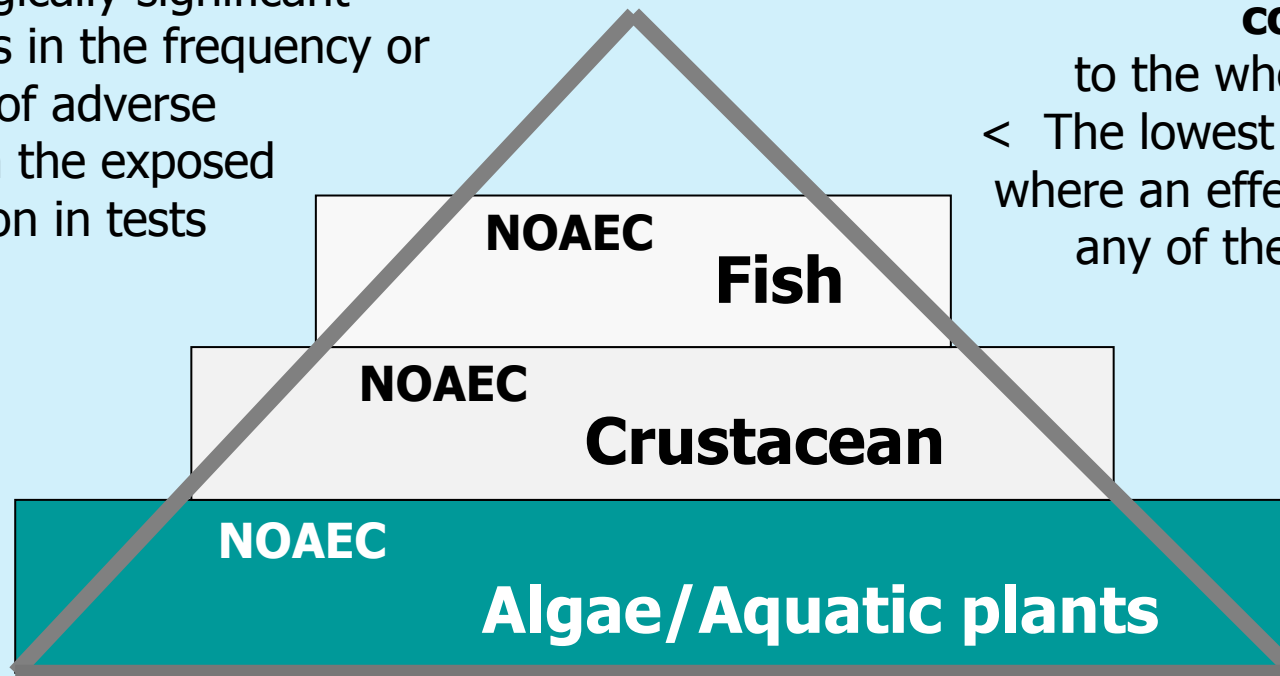


Basic elements of the generic approach:

No effect concentration

NOAEC = No observed adverse effect concentration,

No biologically significant increases in the frequency or severity of adverse effect on the exposed population in tests



From NOAECs, you may assess **PNEC**, the **Predicted no effect concentration** to the whole ecosystem
< The lowest concentration where an effect is found on any of the three trophic levels

REACH Chemical safety assessment method

Human risk

Adequate control if: *The actual health exposure* for a certain substance / *The Derived no effect dose level* of the substance for the way of exposure as documented in tests , is

$$\leq 1$$

Environmental risk

Adequate control if: *The actual environmental exposure* for a substance / *The Predicted no effect concentration* of the substance for the way of exposure as documented in tests , is

$$\leq 1$$

REACH Chemical safety assessment method

Stricter conditions or stricter measures

- 1) Stricter conditions for the risk management recommendation at the one hand, and
- 2) Stricter risk management measures as such, at the other hand

are supposed to interact to guarantee the adequate control
(bring the quota down to ≤ 1)
in regard to the actual scenario (the substance, the hazard, the use
and the situation of exposure)

If no adequate control the use should better be replaced

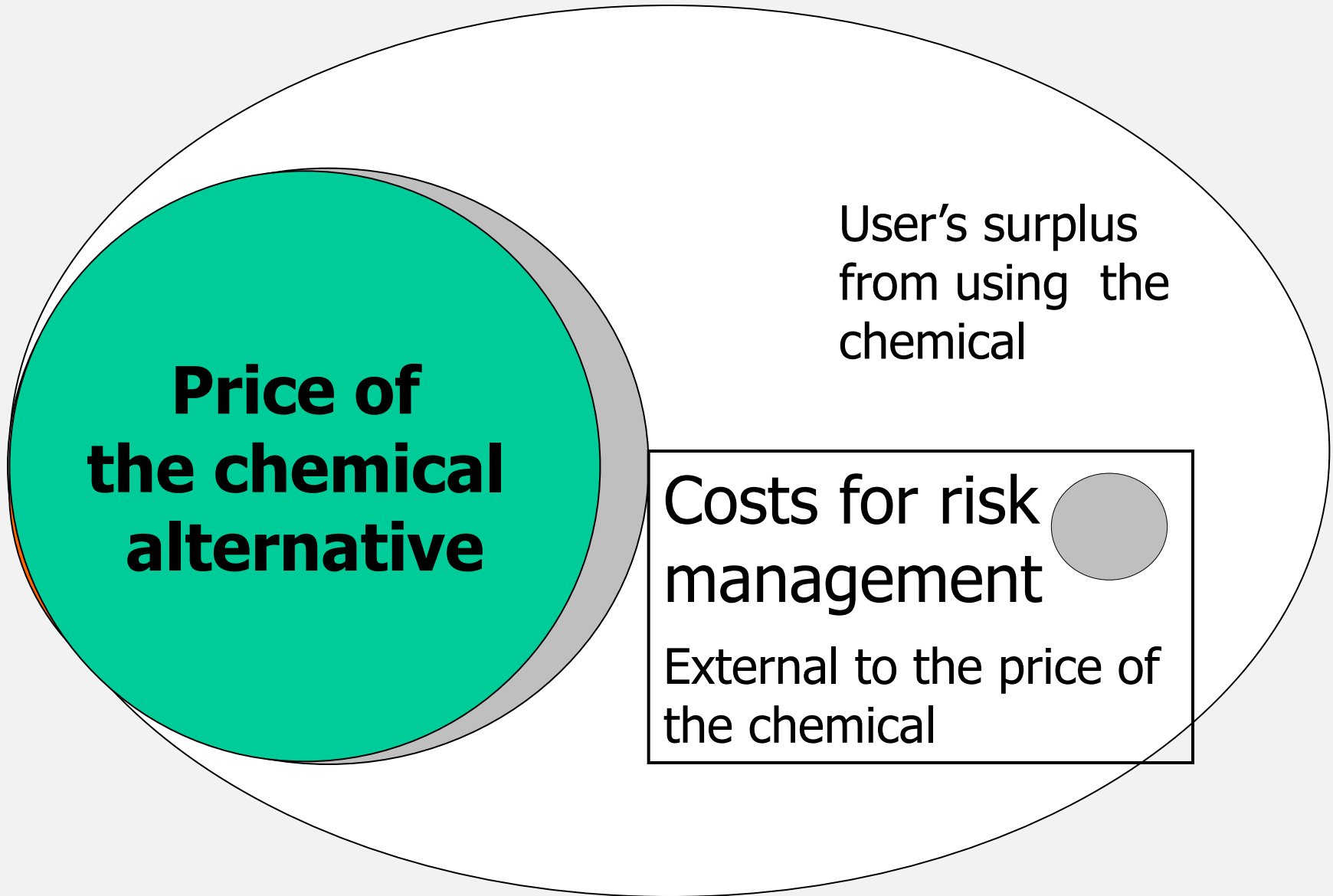
Principle of managers' responsibility

Build on everyday Industry concern for the Sound management of chemicals

When main obligations are placed on industry - everyday responsible actions and activities will be undertaken in the ranks and files of the enterprises

It establishes chemicals management where it belongs and where there are true economic incentives on the long term

Principles of informed choices, substitution and innovation

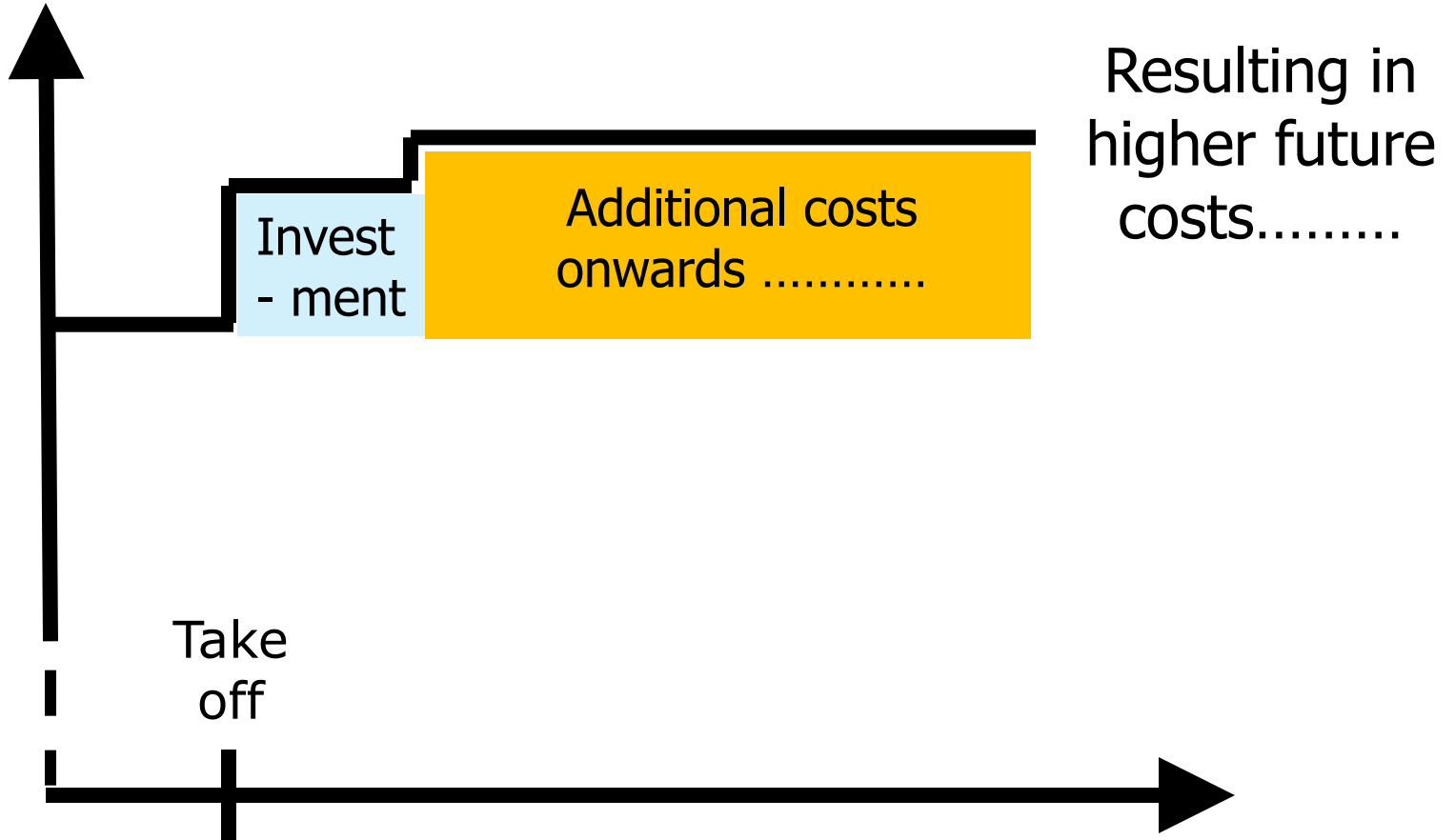


Chemicals legislation makes you able to judge the true costs of choosing a chemical

Costs pattern

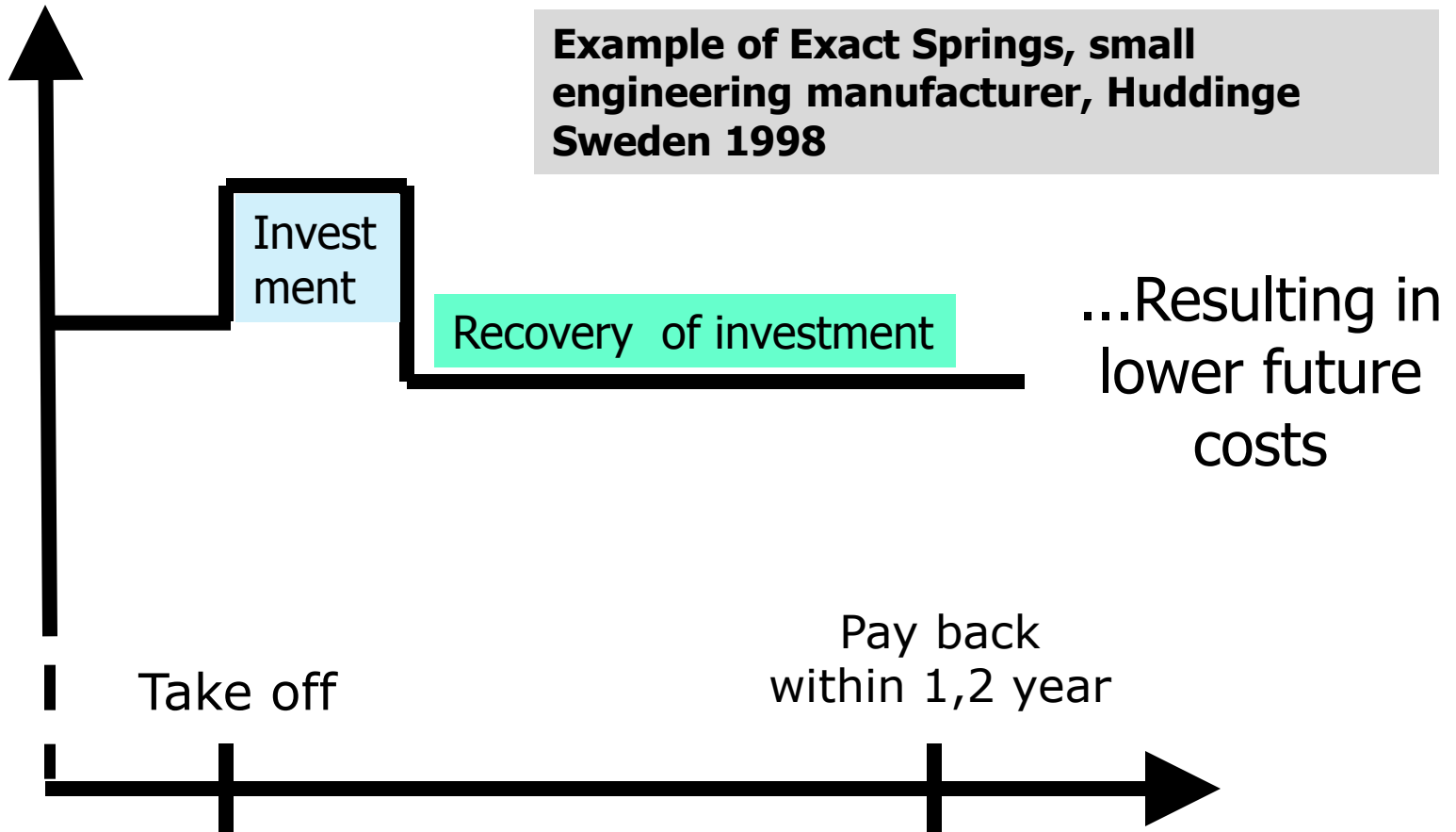
of traditional workers' or environment protection measures

Costs



Costs pattern of chemicals risk management programmes

Costs



Experience from establishing chemicals legislation

Scopes & addresses of legislation are of principle concern

Chemicals legislation addresses supply; no adverse effects from the chemicals made available for use

Other areas of legislation address

- the safe transport,**
- the safe use from various points of view,**
- the safety of finished products in special areas**

Transport of dangerous goods

All sort of goods classified as dangerous under transport on land, over sea or by air

Transports should be in safe hands

Adresses the transporter

Costs mainly on the salesman and the buyer

Mandates for supervision and inspection on ministry and agencies responsible for transport

Major chemicals accidents

Prevention and control in areas classified as sites of hazardous installations (Seveso-establishments)

Addresses the operator of the hazardous installation

Costs placed on industries at the site (internal emergency plans) and society (external rescue planning)

Mandates for supervision and inspection on ministries and agencies for civil defence and physical planning

Workers' health and safety

Dangers from chemical agents at work (also hot water vapour, glowing metals, dust from minerals and ore, all kinds of unhealthy mist etc)

Addresses the employer

Main costs on the employer

Permits, supervision and inspection on the ministry of labour and state agencies in the field of the work environment

Example of area of legislation	Scope of chemicals safety	Scope of obligations	Responsible ministry (-ies)
Major accidents prevention and control	Hazardous chemical installations	The operator in the area	Defence; Physical planning; Interior
Protection of workers from chemical agents	All kind of dangerous agents (hot vapour; dust)	The employer	Labour; Health; Social Affaires
Safe transport of dangerous goods	Classified goods (including radioactive and biological material)	The transporter	Transport; Interior

Pollution prevention and control

Emissions to air, soil and water; The safe disposal of waste; Soil and water remediation

Addresses the producer / polluter

Costs most often placed on industries according to the polluter pays' principle

Mandates for supervision and inspection on the ministry and agencies in the area of environment protection and the preservation of natural resources

Consumer protection

All sort of goods aimed for the general public

Adresses the liability of the trader/salesman of the article/brand

Liability costs placed on the responsible company

Supervision and inspection on ministries of economy and trade, social affaires or.....?

Special legislation on products placed on the market

Addresses the product as such on the market

Biocides; Pesticides; Cosmetics and hygiene care; Pharmaceuticals and veterinary products; Electric and electronic equipments

Mandates for regulation, supervision and enforcement on ministries and agencies of close concern

Chemicals made available for use / placed on the market

**Knowledge and communication demands ;
Restrictions on the access to certain substances**

**Addresses the manufacturer, importer and further
distributors of chemicals**

Main costs on the actors in the supply chain

**Mandates for supervision and inspection on ministry
of environment, health, industry, social affaires?**

Experience from establishing chemicals legislation

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

Experience from establishing 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

Principle of frame work legislation

Framework law, principal lines, main dispositions & main obligations

Administrative and technical application requisites,
requirements, requests and instructions

**Demands on
administration
Daily tasks**

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

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

Serbian scheme of Chemicals legislation

Law on Chemicals

Horizontal 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/>

Experience from Developing Government Administration

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

What institutional set-up is necessary?

Which elements have shown indispensable?

What principles have shown most crucial?

Experience from Developing Government Administration

It is of importance to recognize “Chemicals placed on the market” as a regulatory area of its own

The responsible administration would need a certain influence in the state and certain powers; It should report directly to the minister in charge

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

Principles of having a legislation that is horizontal, parallel to other legislation and sector over-powering

Sector: Legislation:	Agriculture	Forestry	Industry	Mining / ETC
Chemicals placed on the market				
Transport of dangerous goods				
Chemical agents at work				
Chemical emissions to Environment				
ETC				

Elements which show indispensable

- A **lead ministry** in the area of chemicals legislation (MoE, MoH, MoI, MoSA?)
- A **central core administration** responsible for competent authority tasks; seated in or underneath the lead ministry
- A wider cluster of **engaged national experts**
- **Inter-ministerial coordination** and co-operation
- Secure **enforcement capacity** with well trained and experienced inspectors

Further elements which are crucial

- The steady **involvement of the most interested parties**, f.e. through a Roundtable / meeting each six months; with guidance from national strategy

- A working **financing solution:**

Division of tasks and costs between industry and administration; General taxation; targeted taxation; fees on administrative services, fees including administrative overhead costs?

Elements for the institutional set-up

Framework horizontal law

Main obligations, mandates, powers, financial system etc

Secondary legislation / application rules

Ministry in charge

.....Inter-ministerial coordination.....

Sustainable financing
(State treasury,
regulatory fees)

Core
administration
Access to
further expertise

Involvement of interested
parties and the public

Enforcement capacity

Competent inspectors, Efficient supervisory means

Thank you for your attention