



## EU legislation on reproductive risks and EU practical guidance relevant for exposure at work

**Analysis at EU-level of health, socioeconomic and environmental impacts  
from a possible amendment to the Carcinogens and  
Mutagens Directive 2004/37/EC to extend the scope to include  
category 1A and 1B reprotoxic substances**

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**EU-OSHA Workshop**

**Workplace risks to reproductivity: from knowledge to action**

**ANSES, French Agency for Food, Environmental and Occupational Health & Safety  
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# Presentation outline

- Project details & objectives
- Policy options for analysis
- Problem definition
- Baseline scenario
- Impact assessment

# Project Details

- **Project for DG EMPL delivered by Milieu and RPA carried out from December 2009 to June 2012**
- **Report on impacts of 4 policy options**
- **Model guidance on working with reprotoxic substances**

# Project Objectives

Evaluate 4 policy options for controlling R1A and 1B in the workplace in terms of:

- Health impacts
- Environmental impacts
- Socio-economic impacts

With the aim of improving workers' protection from R1A and 1B

# Policy options

1. No action at EU level
2. Binding legislative action at EU level, Directive 2004/37/EC amended to include category 1A and 1B reprotoxic substances
3. Non-binding action at EU level: Guidance document and supporting awareness raising information
4. Combination of binding and non-binding action at EU level (combination of options 2 and 3)

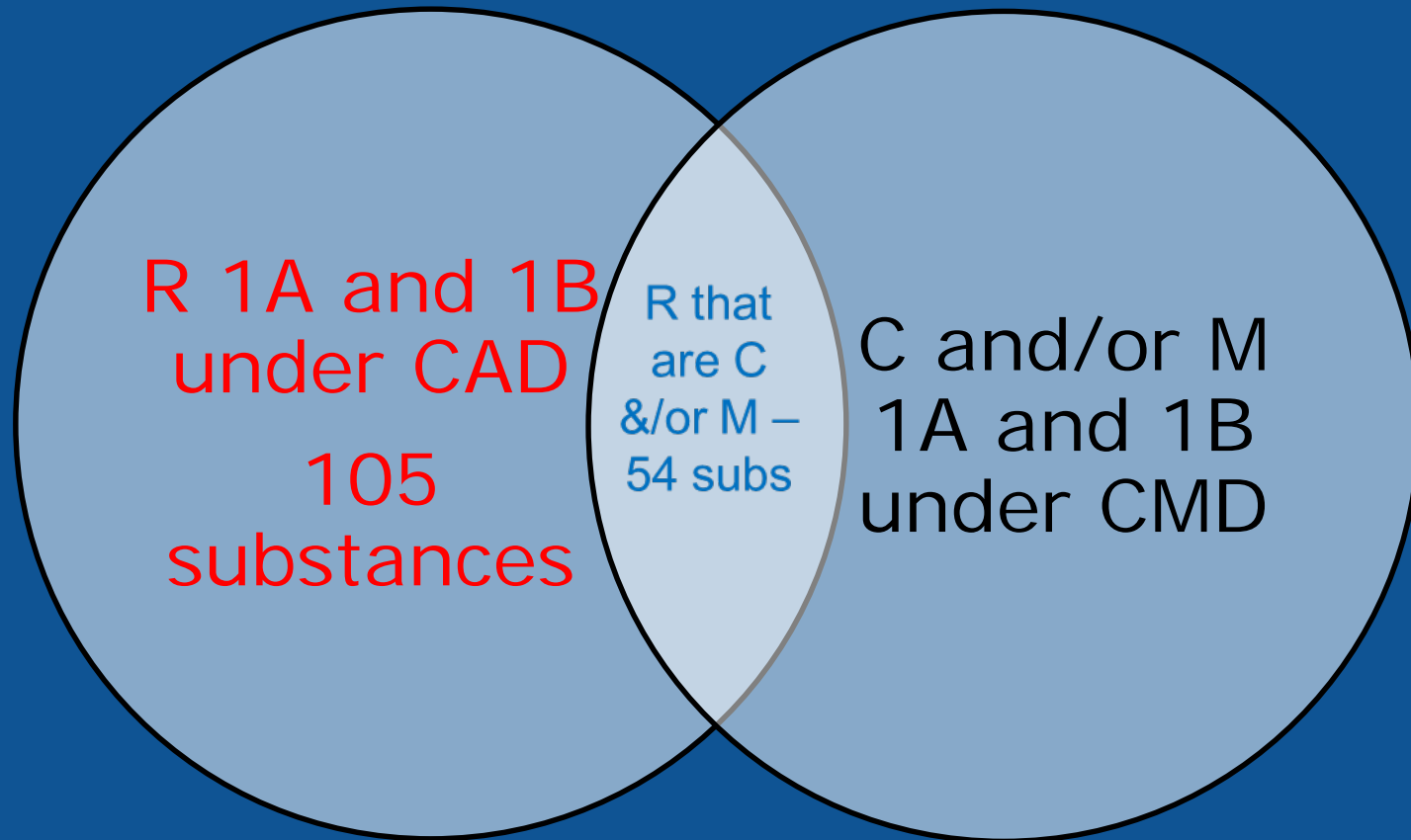
# Problem Definition

- Mapping the substances of concern
- Impacts on human health
- Economic sectors where reprotoxins are used
- Available exposure data

# Substances of concern

- **Category 1A and 1B reprotoxins classified according to Annex VI of CLP Regulation 1272/2008 or to its 1<sup>st</sup> ATP: 151 substances, 97 R ONLY**
- **9 substances or groups of substances have provisionally been proposed by ECHA as Repro. Cat 1B, 8 R ONLY**

# Substances of concern





# CAD versus CMD

Chemical Agents Directive 98/24/EC	Carcinogens and Mutagens Directive 2004/37/EC
R 1A, 1B and 2	R that are C and/or M 1A and 1B
Risk assessment	Risk assessment
Eliminate risk or reduce to a minimum, preferably by substitution	Prevent exposure through substitution, closed systems, or reduce to a minimum
Health surveillance – biological monitoring	Health surveillance
Binding OELVs and BLVs for lead & lead compounds	Binding OELVs for benzene, vinyl chloride and hardwood dusts

# Substances of concern

Legislation	Impacts
REACH	<p>Authorisations: 8 R substances approved for inclusion in Annex XIV, 5 R only: DEHP, BBP, DBP, DIBP, TCEP</p> <p>Restrictions: on specific uses of lead compounds, mercury, DEHP, DBP and BBP; 1A and 1B on use and sale to the general public</p>
PPP Regulation	Approvals sought for 2 R1A & 17 R1B substances, 7 approvals granted
Biocidal Products Directive	
RoHS	Restrictions on mercury & lead in electrical and electronic equipment above 0.1% conc.
ELV Directive	No mercury or lead

# EU OELVs

Legislation	OELVs
CAD	Binding OELVs for lead & lead compounds
Directives 2000/39/EC & 2009/161/EC	Indicative OELVs for 7 R ONLY substances & mercury compounds
CMD	Binding OELVs for benzene, vinyl chloride and hardwood dusts

# Health impacts on workers

Review of evidence of adverse reproductive effects in human populations from occupational exposure in epidemiological studies

# Evidence of adverse reproductive effects: substances

Lead	Cobate compounds	Warfarin
Mercury	Nickel compounds	Glycol ethers
Cadmium	1, 2-Dibromo-3-chloropropane (DBCP) and 2-Bromopropane	Borates
Chromates and dichromates	Carbon monoxide	phthalates

# Evidence of adverse reproductive effects: industries

Hairdressing	Agriculture
Healthcare	Wood and wood products
Plastics	Rubber
Copper and copper electrolyte refining	Exposure to organic solvents
Construction	Exposure to metals

# Thresholds for R substances

Effects of R substances are considered to show a threshold (although many thresholds are not yet known)

## Exceptions:

Mutagenic effects, already under CMD

Very low thresholds, i.e. lead and impacts on neurodevelopment in children?

Endocrine disruptors (included in very low threshold)

# EU workers exposed to chemicals, dusts, fumes, smoke or gas in 2007

Member State	% of labour force reporting exposure	Member State	% of labour force reporting exposure
Austria	15.3	Latvia	5.6
Belgium	5.6	Lithuania	7.2
Bulgaria	9.3	Luxembourg	2.5
Cyprus	8.2	Malta	10.7
Czech Republic	6.1	Netherlands	7.5
Denmark	3.3	Poland	9.3
Estonia	10.5	Portugal	10.3
Finland	11.1	Romania	5.4
France	15.2	Slovakia	5.1
Germany	2.7	Slovenia	28.3
Greece	12.0	Spain	8.2
Hungary	5.8	Sweden	7.5
Ireland	9.2	United Kingdom	9.5
Italy	8.0	EU-27	8.4





## France: Workers exposure to reprotoxicants

- 180,000 workers exposed to reprotoxicants
- 4% of workers exposed to reprotoxicants work in a closed system
- Production and maintenance jobs are the most likely to be exposed & at highest risk
- Men 3x more likely to be exposed than women
- Lead accounts for 2/3 of all exposures

French 2002-2003 data from Sumer Report

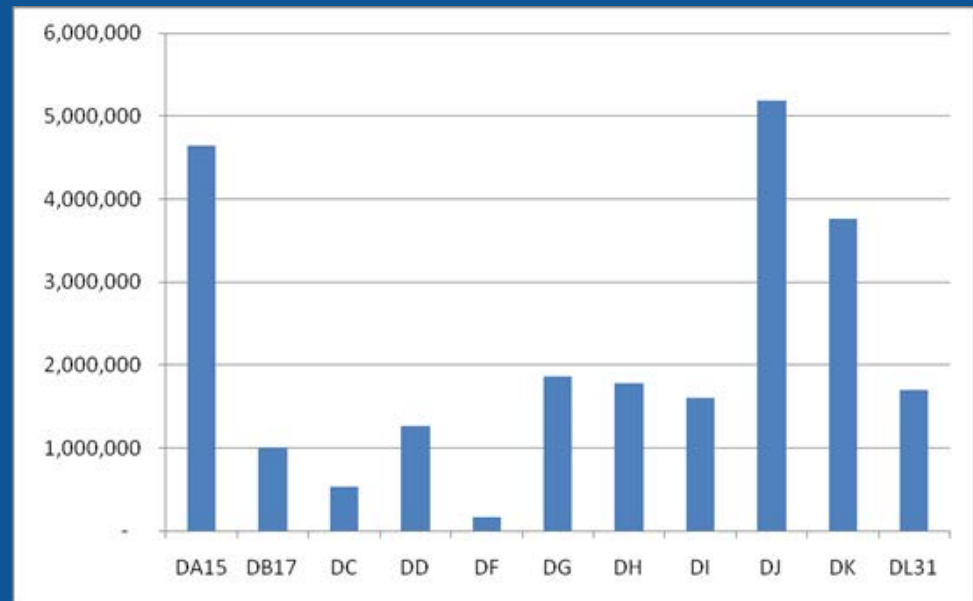


## Industrial sectors where R1A and 1B are used most

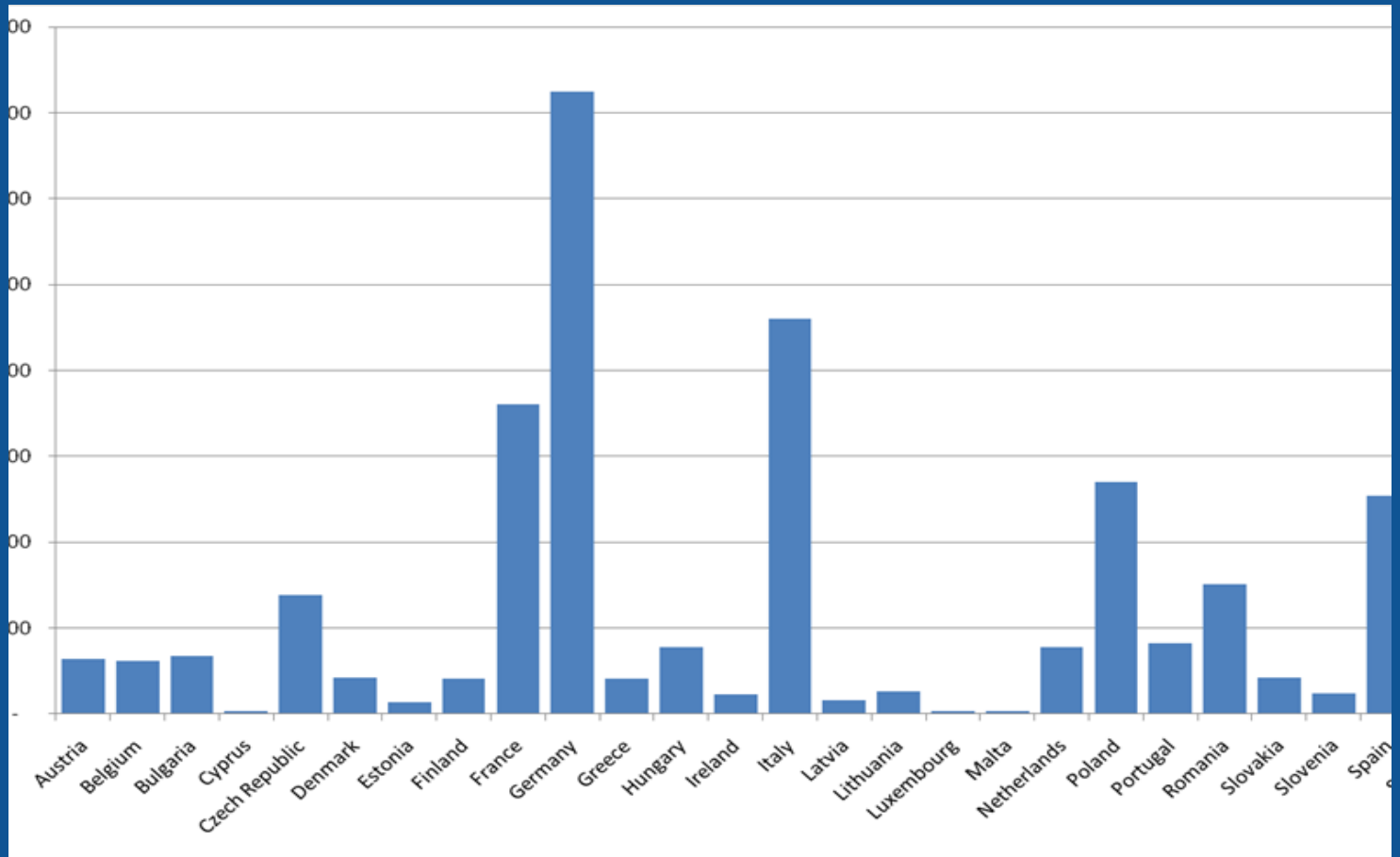
Manufacture or use of paints, inks and coatings.	Agriculture	Manufacture of plastics
Manufacture of PVC (for outdoor applications).	Manufacture of one-component and two-component adhesives	Manufacture of construction materials
Manufacture or use of one-component and two-component sealants.	Production of metals/alloys/plating	Wood treatment
Manufacture or use of biocides	Manufacture of cosmetics	Pyrotechnics/explosives
Manufacture of flame retardants	Manufacture of textiles	Petroleum refining/fuels
Manufacture of glass/glazing	Manufacture of ceramics	Electronics/lighting manufacture
Manufacture or use of detergents and cleaning agents	Organic compound synthesis	Manufacture of batteries
Manufacture of one-component and two-component adhesives	Manufacture of photographic film	Refrigeration systems
Production of metals/alloys/plating	De-icing solutions	Fire fighting foams

# Numbers of workers in manufacturing sectors using R1A and 1B

DA15: food products and beverages	DH: rubber and plastic products
DB17: textiles	DI: other non-metallic mineral products
DC: leather and leather products	DJ: basic metals and fabricated metal products
DD: wood and wood products	DK: machinery and equipment
DF: coke, refined petroleum products and nuclear fuel	DL31: electrical machinery and apparatus
DG: chemicals, chemical products and man-made fibres	



# Variation in numbers of workers in manufacturing sectors across the EU





# Profiling the exposed population by gender & reproductive age

- Men of reproductive age, 15-59
- Older males, 60-64
- Females of reproductive age, 15-49
- Older females, 50-64

# Number of workers in 1000s

	Male			Female		
	15-59	60-64	Total	15-49	50-64	Total
<b>Agriculture, forestry and fishing</b>	5,569.0	515.3	6,084.30	2,173.5	1,315.5	3,489.0
<b>Mining and quarrying</b>	707.8	19.6	727.40	59.5	21.6	81.1
<b>Manufacturing</b>	22,867.3	903.7	23,771.00	7,757.5	2,275.6	10,033.1
<b>Human health and social work</b>	4,468.9	301.2	4,770.10	12,276.0	5,034.9	17,310.9
<b>Construction</b>	13,702.4	583.4	14,285.80	1,080.2	363.9	1,444.1

Source: Eurostat, data for 1<sup>st</sup> quarter of 2011

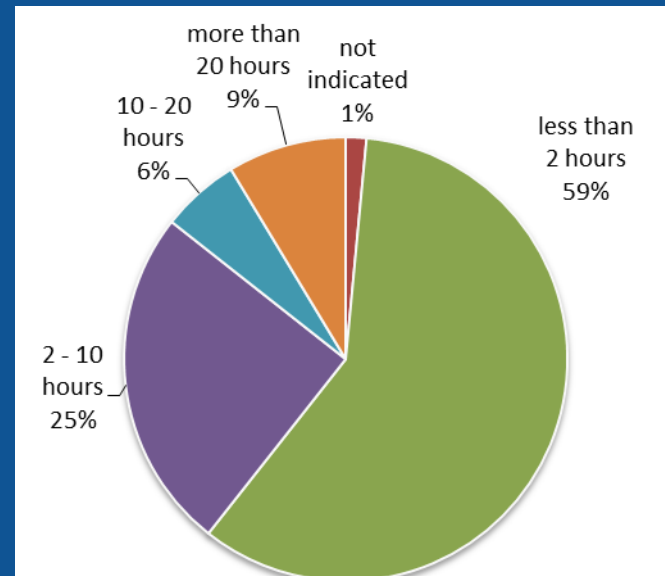
# France: workers exposure to glycol ethers

213,400 workers, 1.2% of the working population

70% male, 30% female

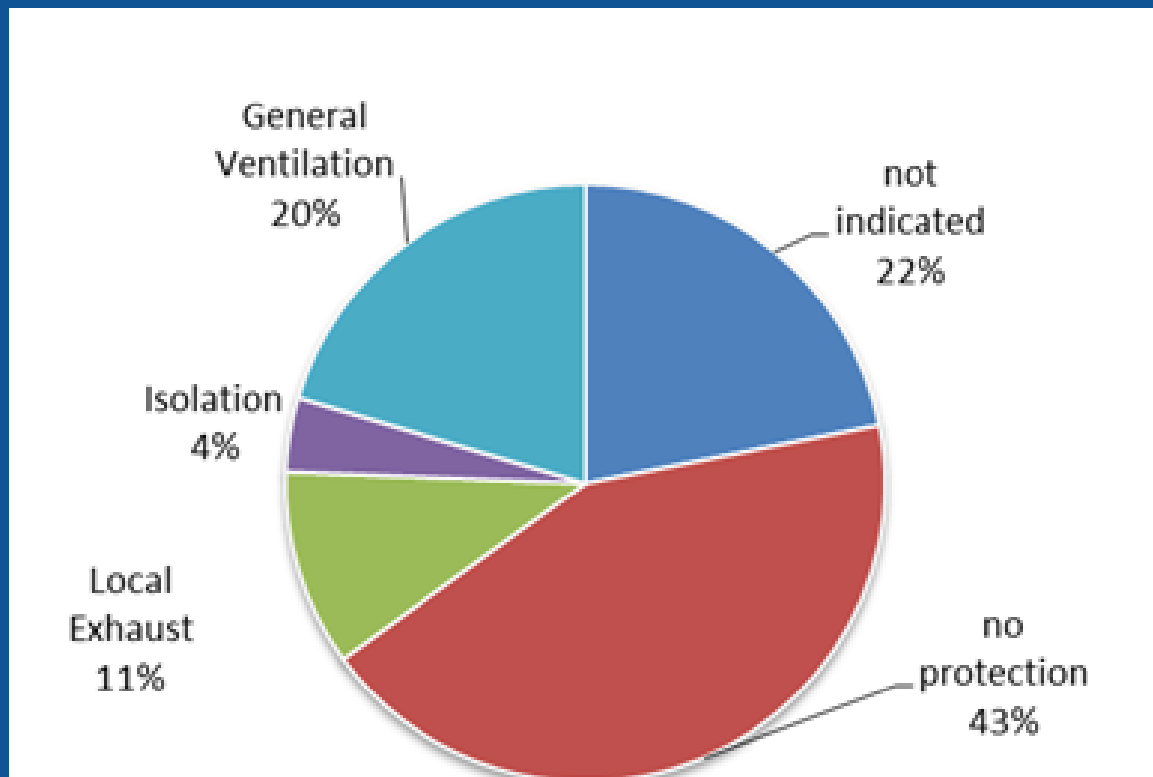
## Intensity of exposure:

- 1% very strong
- 8% strong intensity
- 35% low intensity
- 49% very low intensity



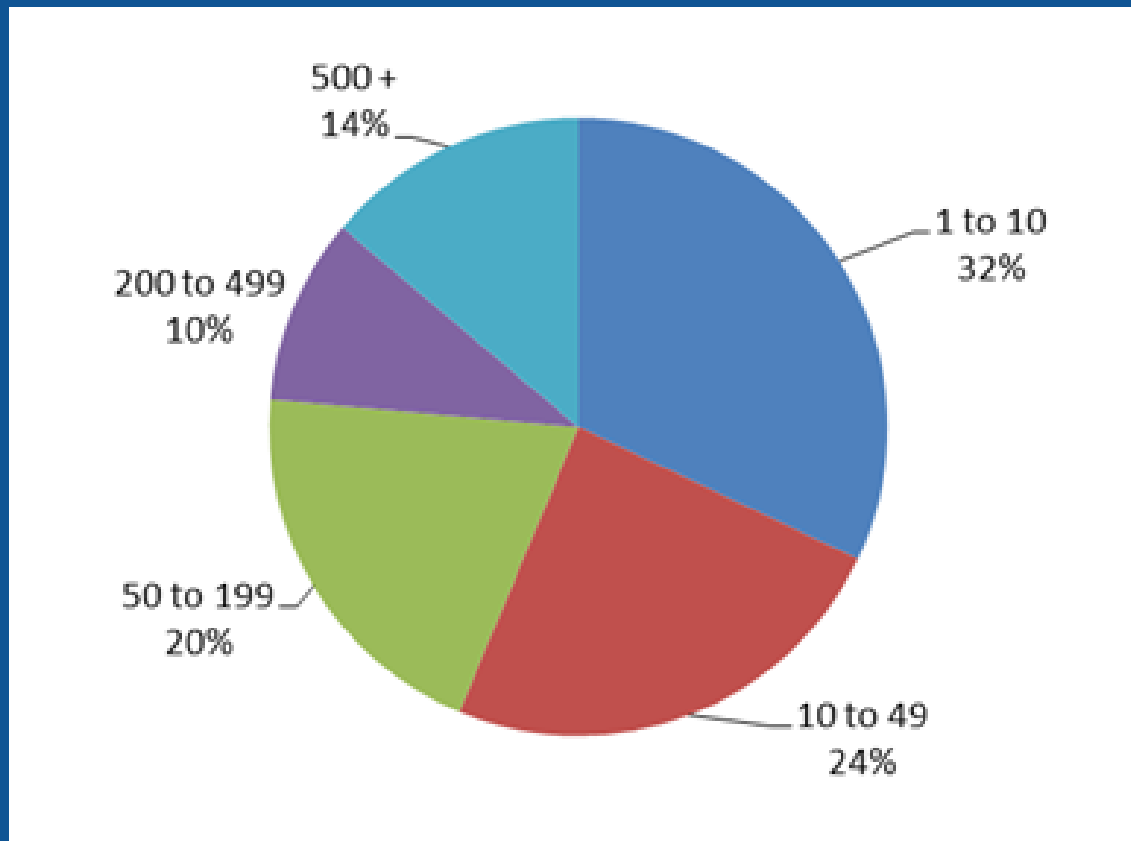
Duration of exposure

# France: Protective measures





# France: Company size





# Baseline Scenario

- EU legislation
- Member State implementation
- Other factors affecting implementation

# EU Legislation

Leg	Coverage	Requirements
CAD	All R1A and 1B	Eliminate risk or reduce to a minimum, preferably by substitution Binding OELVs for lead & lead compounds
CMD	54 R1A and 1B covered due to C and/or M	Substitution; closed system; protection measures Binding OELVs for benzene, vinyl chloride and hardwood dusts
PWD	R60-64, R40, R45, R46	Exposure to risk must be avoided Prohibition on work with lead and lead derivatives <i>Limitation: women only declare pregnancy after most vulnerable window</i>
YPD	R-Phrases R60, R61	Prohibition on harmful exposure to chemical agents
IOELVS	7 R & mercury & its compounds	

## Additional protection at MS level:

Member State	Additional protection
France	All CMRs under CMD
Austria	R1A and 1B under CMD
Czech Republic	R1A and 1B under CMD
Germany	R for which there is a OELV: <ul style="list-style-type: none"> <li>•Exposure below OELV – CAD</li> <li>•Exposure above OELV – CMD</li> </ul> R without OELV – CMD
Netherlands	R1A and 1B under CMD
Finland	R1A and 1B, identified biological and physical reprotoxicants
Sweden	Some reprotoxicants include, not all R1A and 1B

## Additional considerations:

- Challenges for SMEs
- Compliance issues
- Stakeholder consultation
- Challenges in substituting substances
- General support for guidance
- R non-thresholded substances
- Need for clarity regarding role of DNELs under REACH / relationship with OELVs

# Stakeholder consultation:

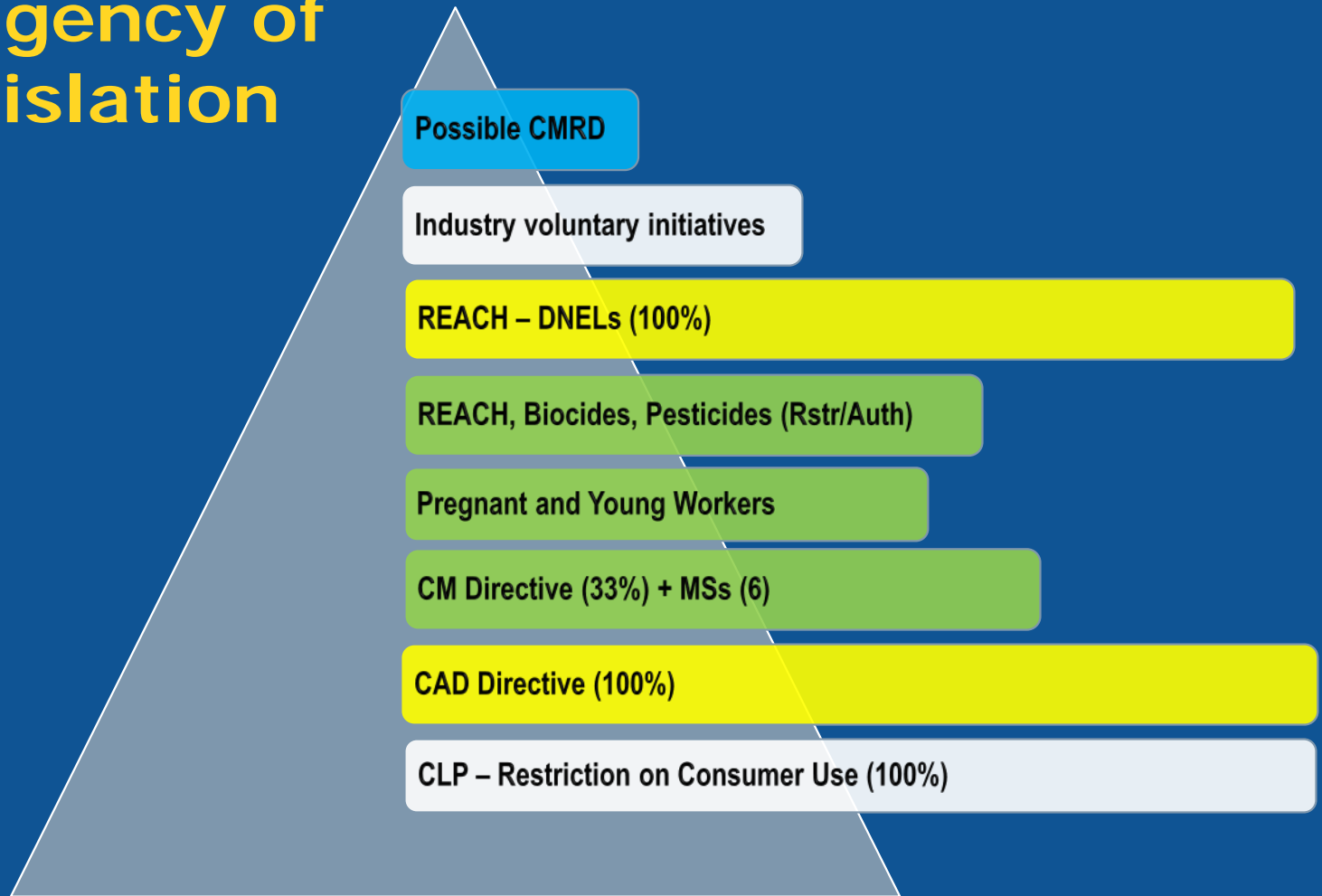
Industry	Trade Unions
<ul style="list-style-type: none"><li>• R thresholded substances, not under CMD</li><li>• Challenges in substituting substances, suppliers, confidentiality</li><li>• Technical limitations in implementing close systems</li><li>• General support for guidance</li><li>• Need for clarity regarding role of DNELs under REACH / relationship with OELVs</li></ul>	<ul style="list-style-type: none"><li>• General support for R1A and 1B under CMD</li><li>• Compliance issues</li><li>• General support for guidance</li><li>• Vulnerability of pregnant workers in critical first weeks</li><li>• Need to improve classification of R</li></ul>



# Inclusion of Cat 1A and 1B Reprotoxins in CMD

## Summary of IA Findings

# Stringency of Legislation





# Methodologies Applied (1)

- **Calculation of the worker sub-populations that would most benefit under each policy option in respect of changes in exposures**
- **Difficulties include** →
  - **No comprehensive dataset setting out all Cat 1A and 1B reprotoxins and the sectors/applications they are used in**
  - **Data gaps as to the number, age, sex, etc. of workers actually exposed to each substance and level of exposure**
  - **Gaps in understanding with regard to the nature of the adverse effects elicited by these substances (particularly where no robust human data are available) and their precise dose-response characteristics in humans**

## Data Sources

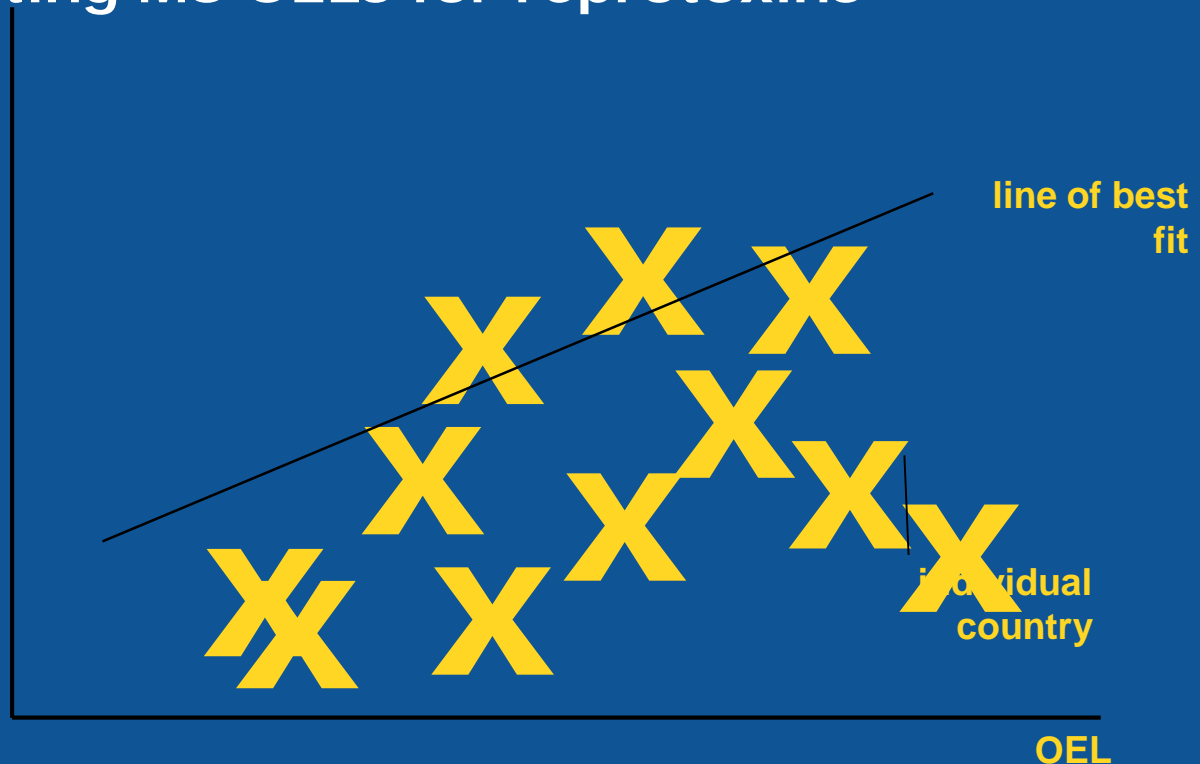
- INRS COLCHIC database – *exposure, few chemicals*
- INRS fiches DEMETER – *reprotoxic health effects, some law*
- INRS fiches toxicologiques – *reprotoxic health effects, some law*
- EASHW (2009) – *survey of national legislation*
- DARES (2006) – *exposure in French industries by chemical*
- EUROCAT database – *congenital anomaly prevalence by country*
- HEIDI data tool, DG SANCO – *low birth weight incidence by country*

## Methodologies Applied (2)

- Identifying correlations between health effect prevalence rates and existing MS OELs for reprotoxins

- We hoped for:

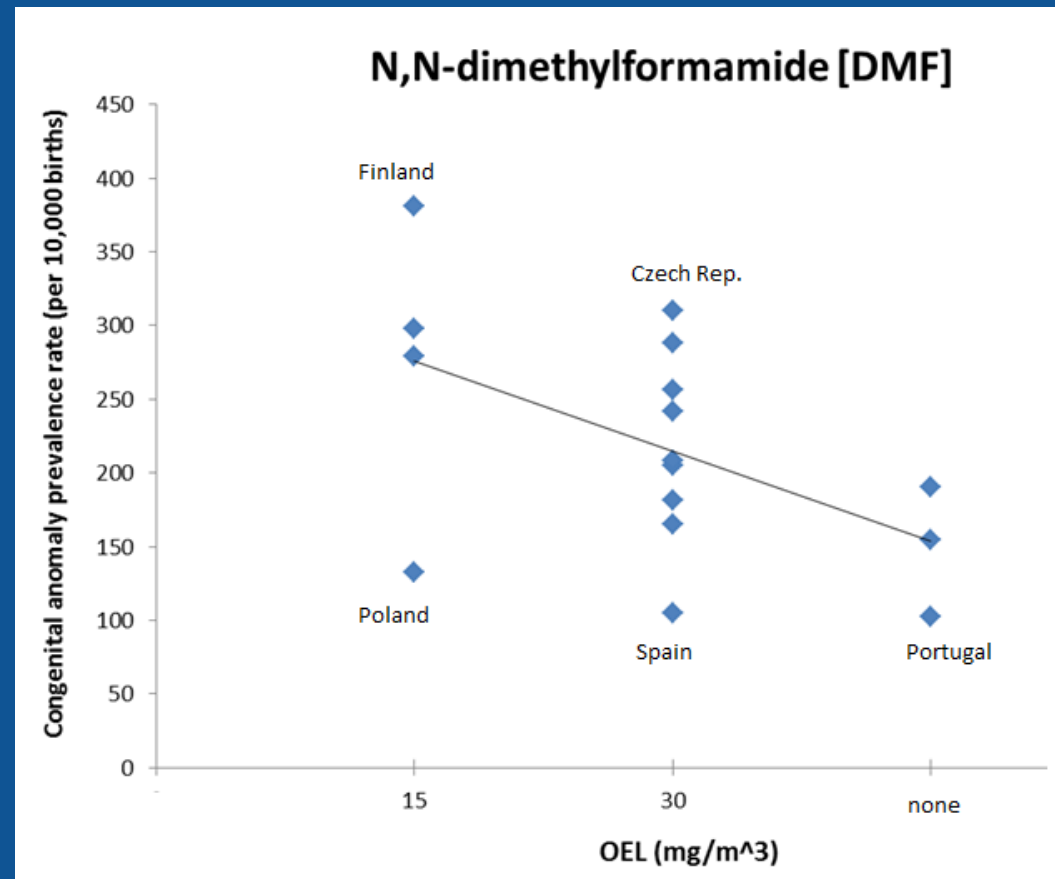
Health effect prevalence



## Methodologies Applied (2)

We got:

- Countries with stricter (lower) OELs can have *higher* prevalence rates
- Many confounding factors
- No reliable basis for extrapolation



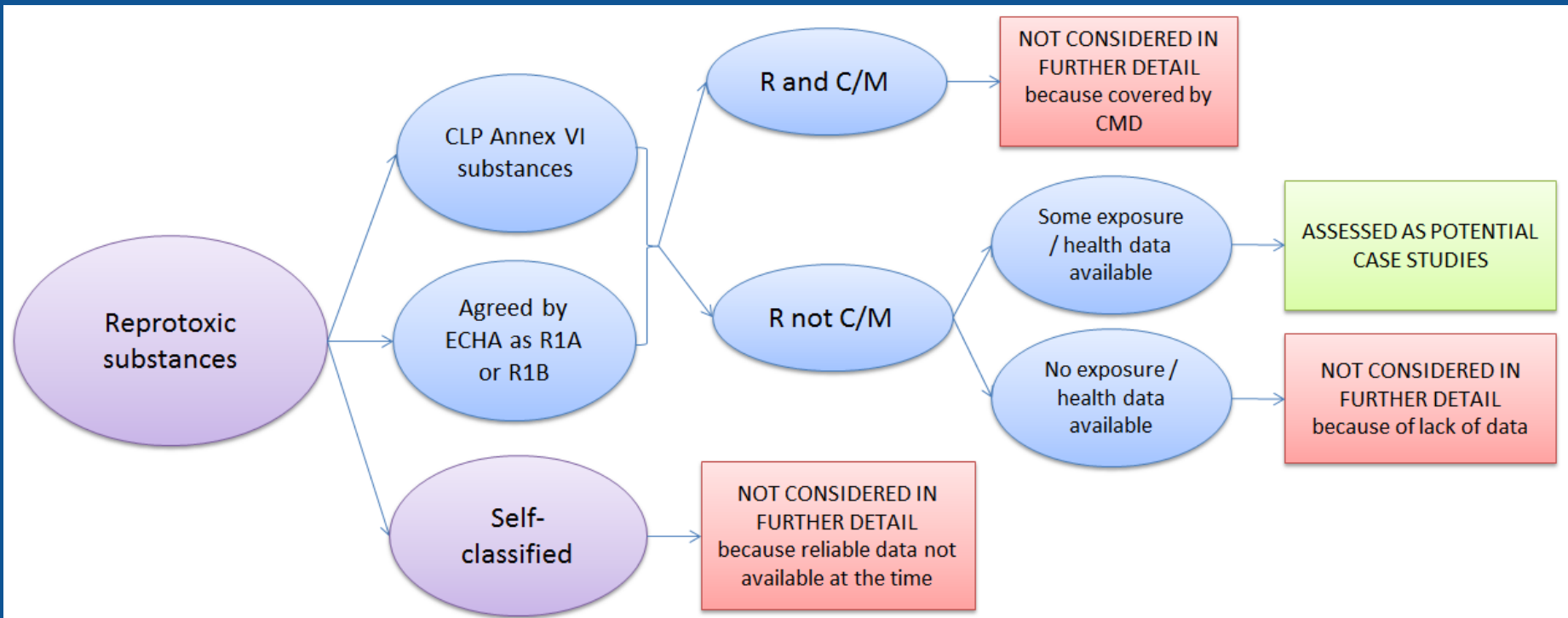
# Methodologies Applied (3)

## Case study approach (Taken Forward)

- Select substances for which exposure, dose-response and effects data are available, thereby avoiding data limitations
- Use actual examples to exemplify actual business responses, costs and benefits, and regulatory implications

**Key issue is Case Study selection**

# Case Study Selection



# Case Study Selection

Carcinogen Cat 1A/1B substances + Other Concerns*	Restricted use under legislation + Measures in pipeline	On-going Regulatory Initiatives + Data availability**
Nickel (Ni) compounds (sensitisation*)	Inorganic Lead (Pb) compound	Glycol Ethers (Industry initiative)
Chromium (Cr) compounds (resp./immune system*)	Pesticides (PPP/Biocides legislation)	Borates**
Cadmium (Cd) compounds (renal/cardio/immune*)	Phthalates (restriction/ authorisation)	Formamides**
Cobalt (Cb) compounds		

# Data Availability

## Borates → *lack of data*

- Male exposure → risk from exposure (*odds ratio unknown*) → *sperm quality and numbers* → *infertility*
- Female exposure → *unknown*

## Formamides → *lack of data*

- Male exposure → *unknown*
- Female exposure → risk from exposure (*odds ratio unknown*) → *embryo toxicity/congenital malformation* → *unknown*

## Glycol ethers → *Chosen Case Study*

- Male exposure → risk from exposure to GE (odds ratio of 1.46-2.25) → affecting sperm quality and numbers → **infertility**
- Female exposure → congenital malformations → neural tube defect → **spina bifida**



## Pre-REACH Health Costs

	Cost per affected worker	Cost per family of substances	EU-wide costs (assuming 5 families*)
Direct Costs - Medical Costs	€9,000 (infertility) €630,000 (disability)	€9.4 million - €15.4 million	€83 million - €125 million
Indirect Costs - Lost Output	€2,100 (infertility) €1.3 million (spina bifida carer)	€19.8 million - €20.3 million	€176 million - €178 million
Indirect Costs - Stress, Grief and Suffering	€17,000 (infertility) - €1.3 million (disability)	€35.2 million	€188 million
<b>TOTAL</b>	<b>€28,100 - €2.7 million</b>	<b>€64.4 million - €70.9 million</b>	<b>€447 million - €490 million</b>

## Option 1 - Baseline

- Expected that health costs will reduce as REACH is implemented
  - **DNELS generated**
  - **Self-classification**
  - **Exposure scenarios and safe use**
- Allows employers to react and adopt least cost measures of control to ensure safe use
- Reinforced by CAD, Pregnant Workers, Young Workers obligations and duties



## Option 2 Vs. Option 3 – Legal Clarity

- An additional legislative instrument to cover the regulation of reprotoxins → more stringent
- CMD will act in parallel to the existing legislative instruments (CAD, PWD, YWD, REACH, CLP etc.), thus adding to the existing legislative overlap
- Option 2: More complexity, especially for SMEs, with cost implications → **Additional legal costs of up to €660k**
- Option 3: Clarification of existing legal overlaps and harmonisation → **Benefits from clarity up to €1.35 million**

## Option 4: Merging Options (One Family Only)

	Option 2	Option 3	Option 4
Legal Complexity and Clarity	- €167,000 to €660,000 <i>Less clarity → ≤ compliance</i>	+ €330,000 to €1.3 million	<i>More complexity, yet clarified by guidance</i>
Compliance Costs	- €9 to €27 million <i>More stringent reqs</i>	<i>More clarity → &gt; enforcement and compliance</i>	- €9 to €27 million
<b>TOTAL</b>	<b>- €9 to €28 million</b>	<b>+ €330,000 to €1.3 million</b>	<b>- €9 to €27 million</b>

# Comparative Rating of Policy Options

	PO 2	PO 3	PO 4
Costs	-- / 0	0	-- / 0
Benefits	+	+	+ / ++?
Costs + Benefits	- / 0	+	+?



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HEALTH

Are there currently effects on workers due to reprotoxins?

YES

NO

Is legislation weak or lacking stringency?

No further action required  
(Option 1)

LEGISLATION

YES

NO

Is there also a lack of compliance with existing legislation?

Is there a lack of compliance with existing legislation?

COMPLIANCE

YES

NO

YES

Extend CMD and introduce guidance  
(Option 4)

Extend CMD  
(Option 2)

Introduce guidance  
(Option 3)



# Guidance document

## Contents

1. Introduction
2. How can chemicals affect your reproductive health?
3. Identifying reprotoxicants
4. Protecting workers: the legal framework
5. How to do a risk assessment for reprotoxicants
6. Risk management
7. Case studies
8. Other sources of information and guidance

**Annex I:** Glossary

**Annex II:** EU Legal Framework for the Protection of Workers from Chemicals

# This guidance aims to provide practical and useful information for employers and workers in industries where workers may be exposed during the course of their work to chemicals that can damage their reproductive health

Chemicals that can damage reproductive health are known as reproductive toxicants or reprotoxicants, and include heavy metals, solvents, pesticides and other industrial chemicals. In terms of their negative health effects, reprotoxicants can:

- damage the reproductive systems of men and women and reduce their chances of having children;
- cause damage to unborn children whose mothers are exposed during pregnancy; and
- damage the health of breastfed babies whose mothers are exposed.





The guidance document aims to inform workers and employers of the risks from reprotoxicants and to support them in improving protection in the workplace.

It begins by summarising in **Chapter 2** the **possible negative effects that reprotoxicants** can have on men and women's ability to have children, and on the health of those children.

**Chapter 3** then explains **how reprotoxicants are classified** and how they can be identified by looking at the labels on chemical containers and at the Safety data Sheets. The legal principles that serve to protect workers from chemicals in the workplace are laid out in **Chapter 4**.

The **process of conducting a risk assessment for reprotoxicants** is described in **Chapter 5**, while **Chapter 6** discusses risk management and identifies **prevention and protective measures** that should be taken to protect workers exposed to reprotoxic substances.

**Chapter 7** includes **two case studies** that serve to provide examples of how individual employers have acted to manage the risks to workers from exposure to specific reprotoxicants, namely lead and N-methylpyrrolidone (NMP).

Finally, **other information sources and guidance materials** that may be of interest are identified in **Chapter 8**.

A **glossary of key terms** is provided in **Annex I** and an **overview of the legal framework** at European Level for the protection of workers from chemicals is provided in **Annex II**.

How can reprotoxicants interfere with my reproductive system?	How can reprotoxicants affect my unborn child?
<p>Working with certain chemicals may:</p> <ul style="list-style-type: none"> <li>• Lower my fertility</li> <li>• Make me infertile</li> <li>• Lower my sex drive</li> <li>• Alter sex hormones in my body</li> </ul>	<p>Working with certain chemicals during pregnancy may:</p> <ul style="list-style-type: none"> <li>• Cause problems with the normal growth and development of my baby</li> <li>• Cause birth defects such as heart malformations, cleft palate, limb abnormalities</li> <li>• Impair the ability of my child to learn, change their behaviour or their sexual development later in life</li> </ul>
<p>Chemicals may also pass into a mother's breast milk and adversely affect the baby.</p>	
<p><u>BUT-</u> these effects can be influenced by my lifestyle, not just the chemicals I work with.</p> <p>Do I drink or smoke or take drugs?</p> <p>Do I have a healthy diet?</p>	



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Chemical	Reproductive Effects Reported	Example(s) of Exposure
Anesthetic gases	Spontaneous abortion, low birth weight in offspring , minor and major malformations	Medical, dental, veterinary
Carbon disulfide	Decreased libido in men, impotence, abnormal sperm morphology and count	Viscose rayon, production, fumigant chemical production
Carbon monoxide	Retarded foetal growth of offspring	Combustion byproduct
DBCP (1,2 dibromo-3-chloropropane)	Infertility in men due to azoospermia and oligospermia	Pesticide
Ethylene oxide	Spontaneous abortions	Healthcare, food sterilisation, chemical production
Glycol ethers	Infertility in men	Widely used solvents
Kepon	Decreased libido in men, decreased sperm count, motility, and morphology	Pesticide
Organic solvents (e.g. toluene, xylene)	Menstrual disorders, spontaneous abortions Infertility in men	Industry, laboratories
Lead and lead compounds, smelter emissions	Decreased sperm count and motility in men menstrual disorders and spontaneous abortions in women, premature delivery, increased neonatal mortality in offspring, neurological defects	Smelting, battery production, use of leaded paint, electronics industry
Methyl mercury	Neurological defects in offspring	Chemical wastes
Poly chlorinated biphenyls (PCBs)	Menstrual disorders, stillbirth, malformations and low birth weight in offspring	Capacitors in telephone/electrical equipment
Vinyl chloride	Sperm abnormalities in men, miscarriages, stillbirth,, birth defects	PVC industry

# Identifying reprotoxicants

Given the potential risks associated with exposure to reprotoxicants in the workplace, it is essential that if such chemicals are used in the workplace they are **clearly identified** and **properly labelled** according to a system with which workers and employers are familiar.

**Information on whether a chemical has reprotoxic properties can be obtained from**

- a. The label on the container of the chemical,
- b. The Safety Data Sheet (SDS).

The CLP Regulation defines reproductive toxicity under two main headings as including:

a) Adverse effects on sexual function and fertility: This includes effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, and pregnancy outcomes.

b) Adverse effects on development of the offspring: i.e. adverse effects induced during pregnancy, or as a result of parental exposure, resulting from exposure of either parent prior to conception, or exposure of the developing offspring during prenatal development, or postnatally, to the time of sexual maturation. Effects on or via lactation: Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes such effects are treated separately.

For classification purposes, reproductive toxicity does not include chemicals that cause health impacts that children will then pass on to their children (heritable genetic disorders). Such impacts are included under Germ Cell Mutagenicity.



**Under the CLP Regulation, reprotoxic substances are divided into categories according to the strength of evidence from humans and/or experimental animals that they can cause such effects, as follows:**

**CATEGORY 1: Known or presumed human reproductive toxicant.**

Substances known to have produced an adverse effect on sexual function and fertility, or on development in humans or where there is a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a category 1 substance is subdivided into:

**Category 1A: Known human reproductive toxicant**

Classification is based on reliable evidence of an adverse effect on reproduction in humans, for example, well conducted studies of patterns of ill health in groups of people. If less rigorous data from studies in humans is supplemented with adequate data from studies in experimental animals, classification in Category 1B shall be considered.




**Category 1B: Presumed human reproductive toxicant**

Classification is largely based on data from animal studies which provide clear evidence of an adverse effect on sexual function and fertility or on development.

**Category 2: Suspected human reproductive toxicant**

Classification is based on some evidence from studies on groups of humans or test on animals, possibly supplemented with other information, of a negative effect on sexual function and fertility, or on development but where the evidence is not sufficiently convincing to place the substance in Category 1.

## Reprotoxicants can be identified from the labels affixed to their containers as follows:

Category 1A	Category 1B	Category 2	Additional category on effects on or via lactation
 <p>Danger</p> <p><i>H360: May damage fertility or the unborn child</i> (specific effect if know) (route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p>Danger</p> <p><i>H360: May damage fertility or the unborn child</i> (specific effect if know) (route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	 <p>Warning</p> <p><i>H361: Suspected of damaging fertility or the unborn child</i> (specific effect if know) (route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)</p>	<p>No pictogram</p> <p>No signal word</p> <p><i>H362: May cause harm to breastfed children.</i></p>

# How to do a risk assessment for reprotoxicants

<b>Hazard identification:</b>	What is the hazard
<b>Hazard characterisation:</b>	Determining what the dose or exposure is that causes the effect (e.g. is there an OEL or BLV for the chemical), through what route does it cause its effect (e.g. inhalation)
<b>Exposure assessment:</b>	What is the degree, route and duration of exposure (exposure assessment)
<b>Risk characterisation:</b>	Given the above 3 steps, is there a risk (risk characterisation)?





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SAFETY DATA SHEET section	Relevant information
<b>SECTION 1: Identification of the substance/mixture and of the company/undertaking</b>	This section contains information on the chemical including its REACH registration number (if there is one), plus the supplier details for further information.
<b>SECTION 2: Hazards identification</b>	This section contains the classification of the chemical (important for hazard identification), its label and hazards that don't lead to classification but that may still need to be assessed (e.g. dustiness).
<b>SECTION 3: Composition/information on ingredients</b>	This section gives information on ingredients of mixtures (along with their hazards) that might be useful for risk assessment if they have a higher volatility to the other components.
<b>SECTION 4: First aid measures</b>	This section will not normally have so much relevance to risk assessment
<b>SECTION 5: Firefighting measures</b>	This section gives some information on hazardous thermal decomposition products.
<b>SECTION 6: Accidental release measures</b>	This section contains useful information on spills and precautions for such situations.
<b>SECTION 7: Handling and storage</b>	This is one of the key sections that details safe handling and storage precautions that will guide the possible risk management measures for the chemical.
<b>SECTION 8: Exposure controls/personal protection</b>	Another key section that contains information on applicable national OELs and BLV for the chemical or its ingredients. Also contained here are details of risk management measures and Personal Protective Equipment relevant for uses of the chemical.
<b>SECTION 9: Physical and chemical properties</b>	This section contains information on properties that might give rise to physical hazards e.g. flammability and that influence exposure such as boiling point/volatility and granulometry.
<b>SECTION 10: Stability and reactivity</b>	This section contains information on the reactivity of a chemical, how stable it is, if there are any hazardous reactions and what conditions or materials to avoid.
<b>SECTION 11: Toxicological information</b>	This section contains information on the health effects of the chemical, such as its effects on reproduction.
<b>SECTION 12: Ecological information</b>	This section contains environmental information.
<b>SECTION 13: Disposal considerations</b>	This section contains information on how to dispose of the product and its packaging safely.
<b>SECTION 14: Transport information</b>	This section contains information on safe transport of the substance.
<b>SECTION 15: Regulatory information</b>	This section contains information on relevant safety and health regulations/legislation specific for the chemical.
<b>SECTION 16:</b>	Other information can be included in this section.

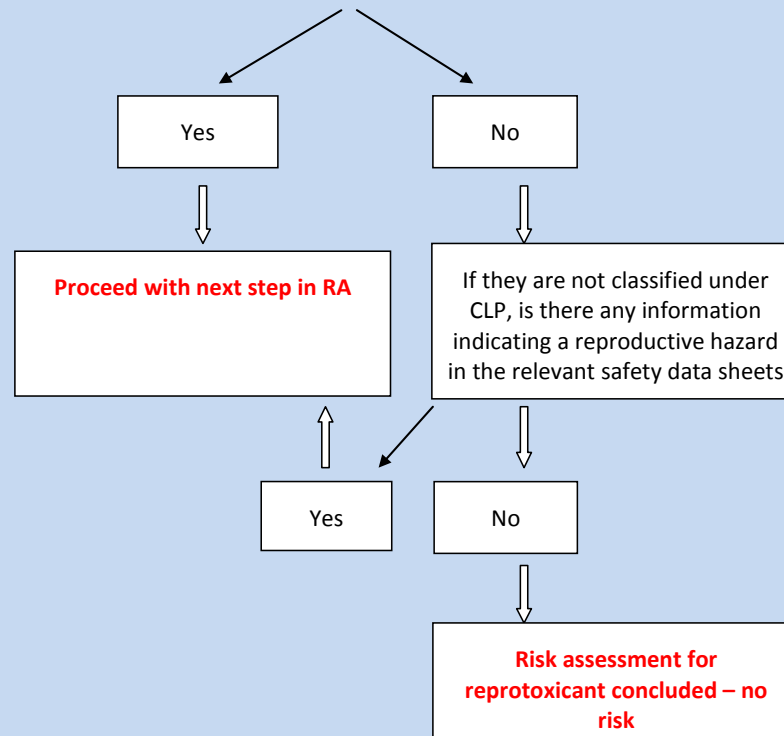
### Step 1: Hazard identification



What chemicals are you using in your workplace (chemical inventory)?

Consult an up-to-date Safety Data Sheet for each chemical involved, and other sources of information (see Chapter 6).

Are any of the chemicals classified as reproductive toxicants under CLP (Regulation 1272/2008, see chapter 3)?



## The outcome of the hazard identification step is one of the following:

- There are no reproductive hazards (known or suspected) from chemicals used in the workplace, in which case the risk assessment can be concluded at this step (although it may need to be continued for other hazards).
- One or more chemicals classified as reproductive toxins are in use in the workplace, in which case proceed to the next stage (see below)
- There is information from the Safety Data Sheet or other sources that indicates that the substance may have effects on reproduction.

## Step 2: Hazard Characterisation

1. What is the nature of the reproductive hazard (classification category, are men, women or both at risk, are pregnant or lactating women affected, is the effect reversible, long-term consequences, etc)?
2. Has an OELV been assigned or can a NOAEL/NOAEC/NOEL be identified?
3. Has an exposure standard been derived, e.g a DNEL under REACH or an OES, or can one be derived?

### **Step 3: Exposure Assessment**

1. Who is exposed (men, women, young and/or pregnant and /or lactating workers)?
2. How often are they exposed?
3. What is their level of exposure (requires measurement of exposure levels)?
4. How are they exposed (by inhalation, oral or by the dermal route)?
5. What control measures are already in place to minimise exposure?

#### Step 4: Risk Characterisation

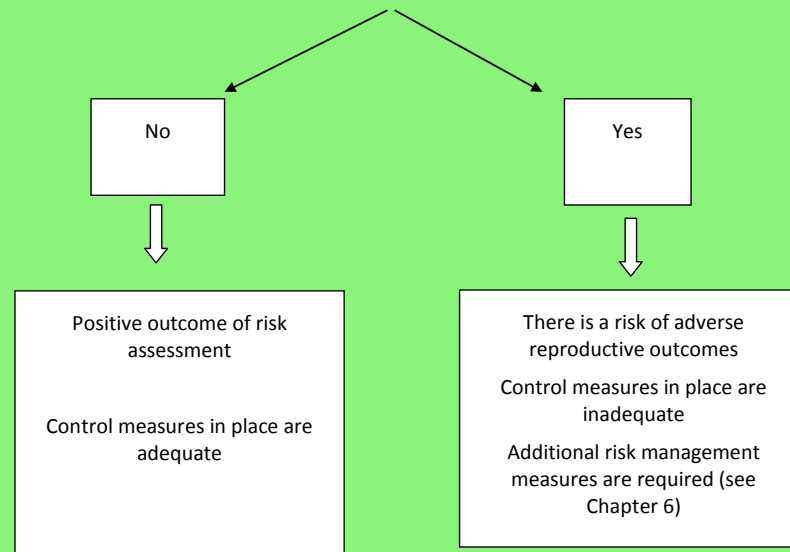
What is the hazard/how serious is it/what are the long-term consequences?

Can/has a safe level of exposure been determined for humans?

What is the (individual) exposure level in the workplace?

Who is exposed (men, women, pregnant and/or young workers)

Is their exposure greater than the established safe level of exposure (DNEL, OES)?





# Risk management

Substitution of the chemical, or

Introduction of protection and prevention measures, in order of priority:

- a.** Design of appropriate work processes and engineering controls and use of adequate equipment and materials to clean up the workplace and reduce exposure levels;
- b.** Application of collective protection measures at the source of the risk;
- c.** Application of individual protection measures including personal protective equipment.



# Protection and Prevention Measures

## Relevant measures include:

- The design and organisation of systems of work at the workplace,
- The provision of suitable equipment for work with chemical agents and maintenance procedures which ensure the health and safety of workers at work,
- Reducing to a minimum the number of workers exposed or likely to be exposed,
- Reducing to a minimum the duration and intensity of exposure,
- Appropriate hygiene measures, reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned,
- Suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents



### *Risk Management Example: Dibutyl phthalate (DBP)*

DBP is used mainly as a plasticiser in resins and polymers such as polyvinyl chloride (76%). It is also used in printing inks (7%), adhesives (14%), sealants/grouting agents, nitrocellulose paints, film coatings and glass fibres.

The substance is classified as Repr. Cat. 2; R61 (May cause harm to the unborn child) and Repr. Cat. 3; R62 (Possible risk of impaired fertility).

Production of DBP is carried out in closed systems, however, exposure can occur due to filling of tankers and drums, sampling, changing of filters and other maintenance activities. In these cases either Local Exhaust Ventilation or respiratory protective equipment or personal protective equipment (RPE/PPE) is used.

The formulation of products containing up to 15% of DBP leads to inhalation exposure and dermal exposure mainly due to adding of the substance to mixers, mixing and forming of the products by processes such as extruding and calendaring.

Sources of exposure related to further compounding are: opening of the mixer (usually equipped with LEV), the exit of the extruder (LEV), emission from the nozzle on retraction at injection moulding (usually in rooms with dilution ventilation), the exit of (the second) extruder (dilution ventilation) and the calender mill (dilution ventilation).

## Maintenance of control measures

- All control measures must be regularly maintained. This includes the regular testing of control measures, for example exhaust ventilation, to check that they are working effectively and repaired as necessary.
- If personal protective equipment (PPE) is used, it should be maintained on a regular basis and properly cleaned and checked before it is used again.



**Thank you !**