Change of Classification for Chemicals moving from EU to GHS

Consequences for the Scope of Seveso II Directive in Germany

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Starting Point

- Replacement of EU Chemicals- Classification System by UN Globally Harmonised System (GHS)
- „Down stream“ consequences for the scope of SEVESO II Directive by analysing the frequently used chemicals
- Assessment of practical consequences in Germany

Project steps

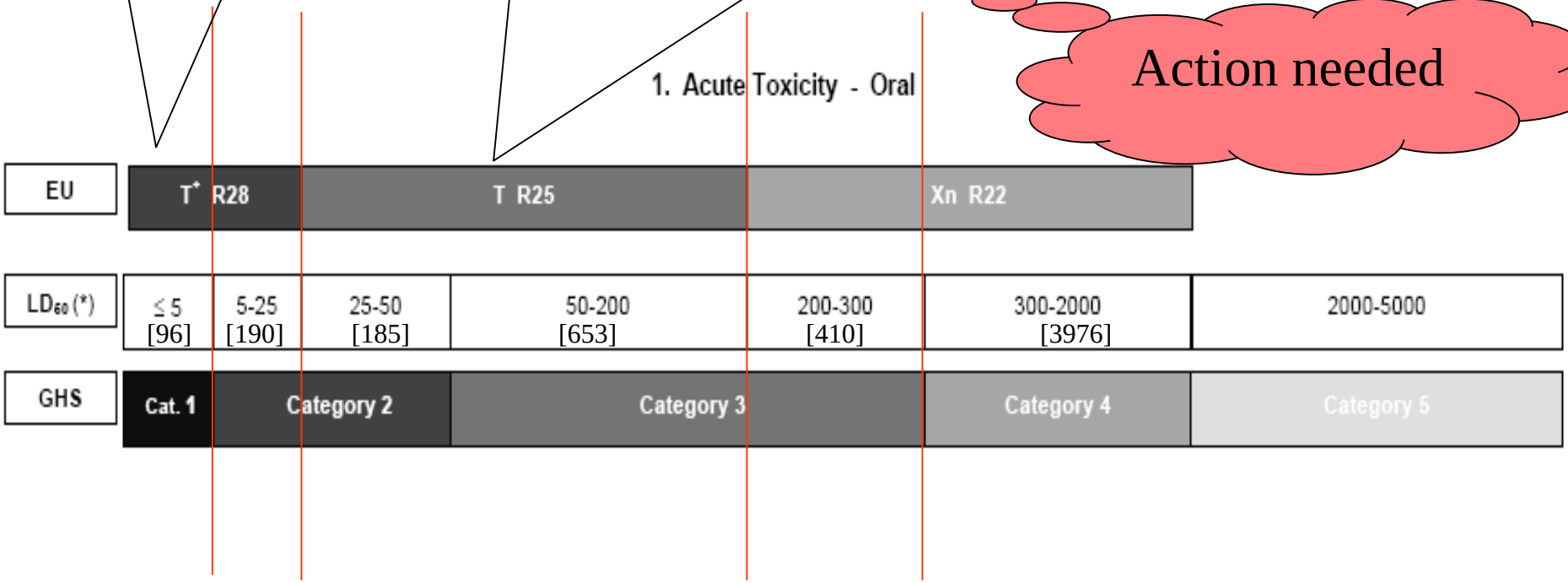
- Analysis of substances concerned
- Identification of practical use in chemical industry
- Analysis of consequence

EU T+ = Cat 1 + Cat 2 -$S_{LD\ 25\text{-}50}$

Action needed

EU T = (Cat 2- $S_{LD\ 5\text{-}25}$) + (Cat 3 - $S_{LD\ 200\text{-}300}$)

Action needed



Exposition path: Oral

Substances investigated:

- Substances with LD_{50} 5-25 mg/kg (oral)
- Substances with LD_{50} 200-300 mg/kg (oral)
- Substances with LD_{50} 400 – 1000 mg/kg (dermal)
- Substances with LC_{50} 0,25 – 0,5 mg/l/4h (inhale) ref. dust & mist

Step 1 Selection of Substances from Database (GSBL) by UBA

Criteria:

- Looking for substances with toxic potential for humans (R-phrase 22-28) only.
- Preparations were not considered.
- Selection of substances with high production volume >1000 t/a according EU list only.
- Classification to GHS Acute 1-3 according to individual toxicological data.
- All substances which are only characterized by oral toxicological data will be taken to GHS Acute 3 according Annex 6 GHS-V (Draft June 2005)

Results from Analysis

Classification	Number	Remarks (SEVESO)
T+(R 26,28) ➔ GHS Acute 2	**-6**	Decrease of QQ
T (R 23,24,25) ➔ GHS Acute 2	**24**	No change
T (R 23,24,25) ➔ GHS Acute 3	**-62**	Out of scope if GHS Acute 3 is not incorporated
Xn (R 20,21,22) ➔ GHS Acute 3	**+31**	New substances if GHS Acute 3 is incorporated

6 Substances Reclassification T+ ➔ GHS Acute 2

(Decrease of QQ)

	Name	CAS	R-prase	Tox	Seveso MS (alt)	Seveso MS (neu)	Remarks
1-Reclassification T+(R26,28) ➔ GHS Acute 2							
	arsenic trioxide	1327-53-3	45-**28**-34-50/53	**O**	**5/20**	**50/200**	
	Methylparathion	298-00-0	5-10-24-26/**28**-48/22-50/53	**O**	**5/20**	**50/200**	
	O,O-Dimethyl-S-(4-oxo-3H-1,2,3-benzotriazin-3-yl) methyldithiophosphorsäureester	86-50-0	24-26/**28**-43-50/53	**O**	**5/20**	**50/200**	
	Neodecanoylchlorid	40292-82-8	22-**26**-34	**I**	**5/20**	**50/200**	
	sodium dichromate anhydrate	10588-01-9	45-46-60-61-8-21-25-**26**-34-42/43-48/23-50/53	**I**	**5/20**	**50/200**	
	STICKSTOFFMONOXID	10102-43-9	**26**-34	**I**	**5/20**	**50/200**	

62 Substances Reclassification T ➔ GHS Acute 3

(out of scope ?)

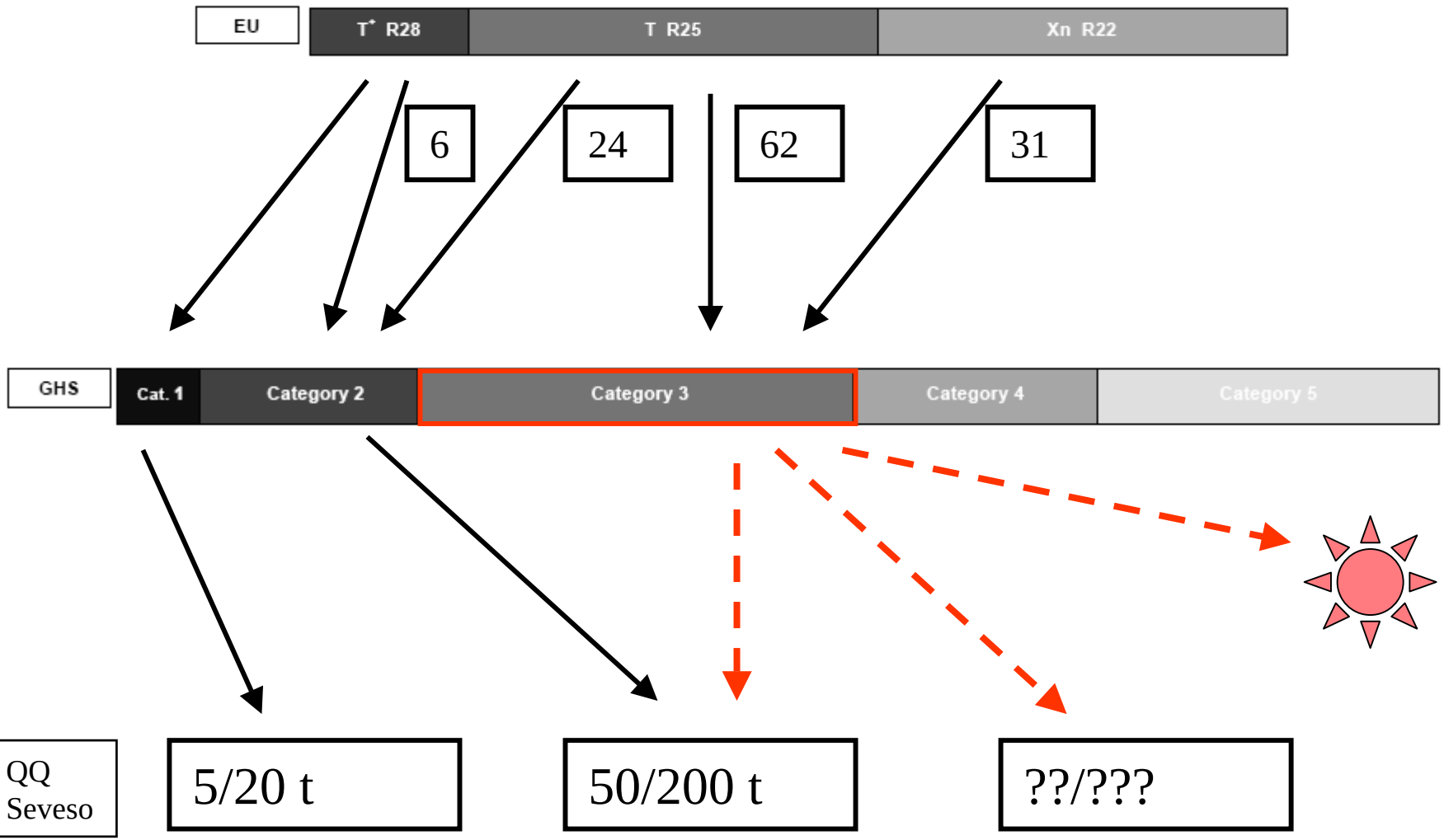
- **chloroacetic acid**
- ethyl estero-toluidine2,6-xylenol
- Propoxur
- **Toluene, 2,4-dinitro-**
- Ammoniumhydrogendifluorid
- Chloroacetic acid sodium salt
- O,O-Dimethyl-O-(3-methyl-4-methylthio-phenyl)-thiophosphatbenzene,
- 1,1'-(2,2,2-trichloroethylidene)bis(4-chloro-1,1'-dimethyl-4,4'-bipyridiniumBis(tributylzinn)oxid
- **Nitrobenzene**
- **Aniline**
- o-phenylenediamine
- 2,6-Dimethyl-1-aminobenzolacrylamide
- 2-Chloracetamid
- 2,2,2-trichloroethane-1,1-dioldiphenylamine
- 2-BUTIN-1,4-DIOL
- **Natriumnitrit**
- **Kaliumfluorid**
- **Dischwefeldichlorid**
- Bariumchlorid
- 2,4-Dimethylaminobenzol
- Natriumpolysulfid
- Aminoguanidin
- Hydrogencarbonat
- 3-Methylaminobenzol
- Natriumfluorsilikat
- CHLORESSIGSÄURE
- sodium sulfide(Na2S4)
- KALIUMFLUORSILIKAT
- 1,3-Dichlorpropen, techn.Isomerengemisch (cis- u.trans-Form)
- KRESYLSÄURE
- O,O-Diethyl-O-(3,5,6-trichlorpyrid-2-yl)thiophosphorsäureester
- **Cyanamid**, stabilisiert.
- gamma.-**HCH** or .gamma.-BHC
- 1,2-dibromoethane1-chloro-4-nitrobenzenediaminotoluene, technical product - mixture of [2] and [3]
- **Phenol**
- Phenylhydrazine
- 2-Nitro-1-aminobenzol
- **N-Ethylanilin**
- 4-nitroaniline4-methyl-aniline3,5-dimethyl-phenol
- **Tetrachlorkohlenstoff**
- 4-Ethoxy-1-aminobenzolo-anisidine
- Chlorpyrifos Methyl
- A mixture of: butan-2-one oxime, syn-O,O'-di(butan-2-one oxime)diethoxysilane
- **Benzol**
- **Methanol**
- 3,4-dichloroaniline4-methyl-o-phenylenediamine
- N,N-dimethylanilinehexachlorobenzene
- **2,3-Diaminotoluol**
- **m-(meta-)Kresol**
- **o-(ortho)Kresol**
- **p-(para)Kresol**

31 Substances Reclassification Xn ➔ GHS Acute 3

(new in scope ?)

- Diazinon (ISO);
- O,O-Diethyl-O-2-isopropyl-6-methylpyrimidin-4-ylthiophosphat
- **1,2-Dihydroxybenzol;**
- Brenzcatechin
- **Isobuttersäure**
- 2-Butoxy-ethanol;
- Butylglykol
- **Furfurylalkohol**
- 2-Hexyloxyethanol;
- Ethylenglycol-
- Monohexylether;
- n-Hexylglycol
- **Chlorkresol;**
- 4-Chlor-3-methylphenol
- 1-Naphtol
- **Acrylsäure**
- **Methacrylsäure**
- **Diethylamin**
- **Triethylamin**
- **Butylamin;**
- 1-Amino-butan
- **Ethylendiamin**
- 1,2-Diamino-ethan
- Cyclohexylamin
- 3,6,9-Triazaundecan-1,11-diamin;
- Tetraethylenpentamin
- 1,2-Propylendiamin
- 2-Piperazin-1-ylethylamin
- Morpholin
- 2-Methylpyridin;
- **2-Picolin**
- **Kaliumhydroxid;**
- **Ätzkali**
- **Kupferchlorid**
- **Kupfersulfat**
- **Zinkchlorid**
- 2,4,6,8-Tetramethyl-1,3,5,7-tetraoxacycloctan;
- Metaldehyd
- **Methylacrylat**
- **Acetonitril**
- **4-Nitrophenol;**
- **p-Nitrophenol**
- **Benzylamin**
- Dazomet (ISO);
- Tetrahydro-3,5-dimethyl-1,3,5-thiadiazin-2-thion
- Coffein;
- Trimethylxanthen

Summary of reclassification effects



Step 2 Results from „Länder“ investigation

- Upper tier:

  437 ES from survey➔ ca. 53 % from total Germany
- Lower tier:

  484 ES from survey➔ ca. 27 % from total

Scenario A

- T+ ➔ Acute 1 QQ: 5/20 t
- T ➔ Acute 2&3 QQ: 50/200 t

Result from „Länder“ survey:

- T+ ➔1 ES to GHS Acute 2;
- Xn ➔6 ES to GHS Acute 3 (new in scope Störfallverordnung)

Scenario B

- T+ ➔ Acute 1 QQ: 5/20 t
- T ➔ Acute 2 QQ: 50/200 t

Result from „Länder“ survey :

- T+ ➔1 ES to GHS Acute 2 ;
- T ➔5 ES out of scope of Störfallverordnung

Scenario C

• T+ ➔ Acute 1	QQ: 5/20 t
• T ➔ Acute 2	QQ: 50/200 t
• Xn ➔ Acute 3	QQ: 100/500 t (new)

Result from „Länder“ survey :

- T+ ➔1 ES to GHS Acute 2;
- T ➔3 ES to GHS Acute 3;
- Xn ➔3 ES to GHS Acute 3 – new in scope Störfallverordnung

Step 3 Analysis of Consequences

Scenario	Establishments involved (total of Germany)			
	LT (Number)	LT (%)	UT (Number)	UT (%)
A	+24	+1,4	+12	+1,5
B	-20	-1,1	-10	-1,2
C	+12	+0,7	+6	+0,75

Uncertainty

- Insufficient data because the registration of activities with hazardous chemicals are only available at the scattered competent authorities.
- Low total amount in the investigation, requires big failure limits.
- Addition rule could not be taken into account.

Facit

- Regardless the big failure rate the effect of reclassification will be very limited (under 5 %) in the practical consequences.
- The formal adoption of the new GHS classification will trigger an immense bureaucratic burden, both to authority and industry
- To limit the bureaucratic effect and to reach as much harmonisation as possible a clear cut and identity of the old in to the new classes is required. The best fit seems to take over GHS 1-3 as a whole.

Classificaton Directive 67/548/EWG	Physical state	Classification GHS V, Draft June 2007	
		Classification	H -phrases
T; R23 (inhale)	gas	Acute Tox. 3	H331
T; R23 (inhale)	vapour	Acute Tox. 3	H331
T; R23 (inhale)	dust/mist	Acute Tox. 3	H331
T; R24 (dermal)		Acute Tox. 3	H311
T; R25 (oral)		Acute Tox. 3	H301
T+; R26 (inhale)	gas	Acute Tox. 2	H330
T+; R26 (inhale)	vapour	Acute Tox. 1	H330
T+; R26 (inhale)	dust/mist	Acute Tox. 2	H330
T+; R27 (dermal)		Acute Tox. 1	H310
T+; R28 (oral)		Acute Tox. 2	H300

Annex VII (partly) GHS V [KOM(2007) 355 final]

State of recent discussion

Considering in addition:

- Draft of GHS VO from June 27th, 2007
- Results of investigation HSL April 2007
- Preliminary discussion in German Commission on Process Safety (KAS)

➔Preference of „Precautionary Alignment“ (EU T+ equal GHS Acute 1&2; EU T equal GHS Acute 3)