Prioritization in REACH

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REACH

Registration
Evaluation
Authorisation
Restrictions
Chemicals

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REACH: the legal text

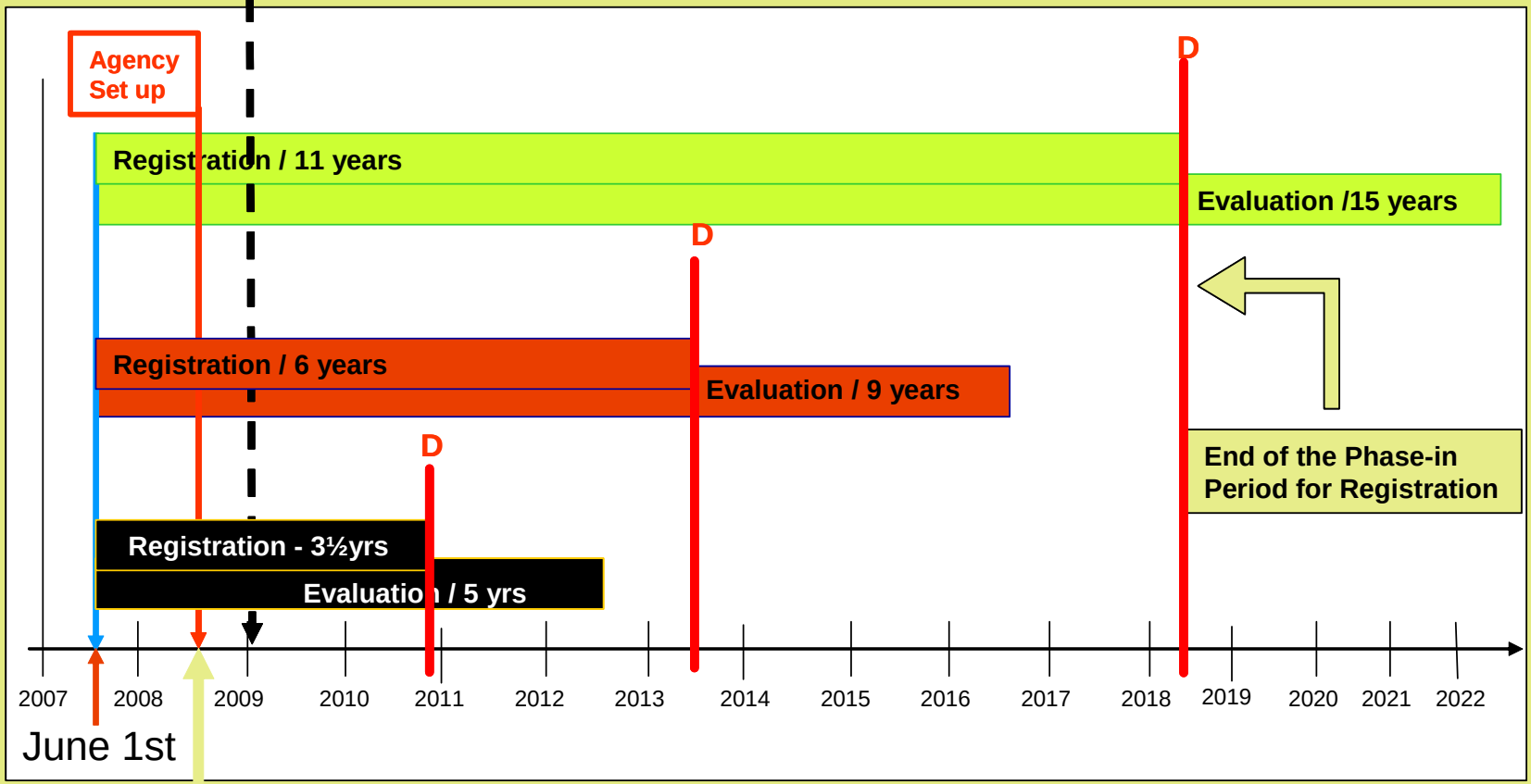
- Title II: Registration of substances
- Title III: Data sharing and avoidance of unnecessary testing
- Title IV: Information in the supply chain
- Title V: Downstream users
- Title VI: Evaluation
- Title VII: Authorisation
- Title VIII: Restrictions

Impact REACH

- It is estimated that around 27 000 chemical companies will fall under REACH Regulation.
- It is estimated that around 30 000 chemicals will fall under REACH Regulation

Jan 2009: List of Pre-registered substances

D=Deadline for (Pre-)registration



12-18 months Pre-registration > 1 t/y

> 1000 t/year + R50-53 > 100tons/y + CMR 1+2 (> 1 t/year)

> 100 t/year

> 1 t/year

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Report “Prioritering in processen van de Europese stoffenwetgeving REACH en CLP”

DRAFT (October 2009)

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NB IN DUTCH

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Prioritization in processes of the European substances legislation REACH and CLP

Content

List with abbreviations

Summary

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Introduction prioritization

For the Ministry of Health, Welfare and Sports in the Netherlands the following aspects have priority:

- Hazard properties: CMRS (carcinogenic, mutagenic, reproduction-toxic and respiratory sensitizing)
- Exposure via consumer products, especially those meant for children

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Approach

Point of departure is risk, the combination of hazard and exposure

NB1: Ministry of Health also wants further completion of the European CMR- list (= hazard)

NB2: Prioritization is a more systematic approach of future work. Next to that, ad-hoc prioritization because of incidents

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1. Prioritization on hazard and exposure

   → list with substances ranked on their risk

2. process-specific prioritization

(3. available capacity/ timing)

Hazard properties

- Carcinogenic (C)
- Mutagenic (M)
- Toxic for the reproduction (R)
- Sensitizing; respiratory (S)

- Category 1 and 2
- Category 3

Choices
prioritization of hazard properties

- A priori no weight difference in the properties C, M, R of S
- Cat 1/2 C/M/R of higher priority than cat 3 C/M/R
- No-threshold effect of higher priority than effect
- Substance of higher priority when its potency is higher

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Consequences of the choices

Using CMRS properties results in no prioritization on:

- Serious effects after chronic exposure (R48)
- Neurotoxicity
- Immunotoxicity
- Hormone-disturbing properties (if not already expressed in reproduction toxic properties)
- Dermal sensitization (R43)

Questions to be asked in prioritization for hazard

Question 1. CMRS substance? Yes = 1 point, no = 0 points

Question 2. Distinction CMR or S

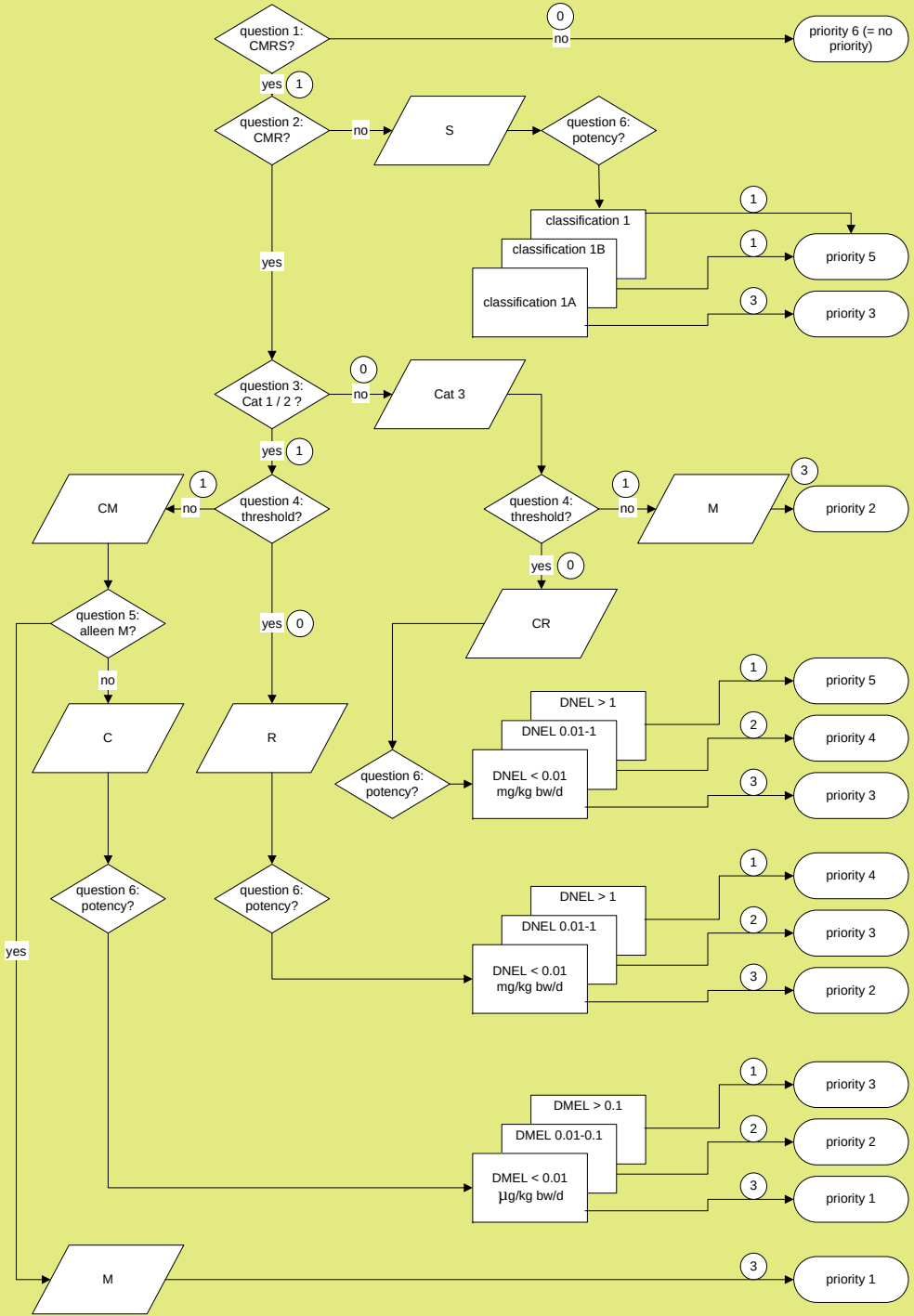
Question 3. CMR category 1 and 2 (1 point)

CMR category 3 (0 point)

Question 4. no threshold (1 point), threshold (0 point)

Question 5. distinction between C and M

Question 6. potency (3 classes, on the basis of DNEL or DMEL)


question 1: CMRS?
0
no
priority 6 (= no priority)
yes
1
question 2: CMR?
no
S
question 6: potency?
classification 1
classification 1B
classification 1A
1
1
priority 5
3
priority 3
yes
question 3: Cat 1 / 2 ?
0
no
Cat 3
yes
1
CM
1
no
question 4: threshold?
question 4: threshold?
1
no
M
3
priority 2
yes
0
CR
question 5: alleen M?
yes
0
no
C
R
question 6: potency?
DNEL > 1
DNEL 0.01-1
DNEL < 0.01 mg/kg bw/d
1
priority 5
2
priority 4
3
priority 3
question 6: potency?
question 6: potency?
DNEL > 1
DNEL 0.01-1
DNEL < 0.01 mg/kg bw/d
1
priority 4
2
priority 3
3
priority 2
yes
DMEL > 0.1
DMEL 0.01-0.1
DMEL < 0.01 µg/kg bw/d
1
priority 3
2
priority 2
3
priority 1
M
3
priority 1

priority	C		M		R		S	Score
	Cat 1+2	Cat 3	Cat 1+2	Cat 3	Cat 1+2	Cat 3		
1	YES No threshold high potency		YES No threshold					6
2	YES No threshold middle potency			YES No threshold	YES threshold high potency			5
3	YES No threshold low potency	YES threshold high potency			YES threshold middle potency	YES threshold high potency	YES threshold classification 1A	4
4		YES threshold middle potency			YES threshold low potency	YES threshold middle potency		3
5		YES threshold low potency				YES threshold low potency	YES threshold classification 1/1B	2
6 (= No priority)	NO	NO	NO	NO	NO	NO	NO	0

Consequenes of the decision scheme for hazard properties

- Point of departure: identified CMRS substances Thus potential CMRS will not be included
- Not all possible situations are described, only the most current ones. In case of exceptions, choices for worst case are made:
  - M substances with threshold
  - category 1/2 C substances with threshold
  - Reproduction-toxic germ cell mutagens

Exposure

For the Ministry of Health:

Substance in consumer products is important

Assumption:

IND registers the use of 1 product well (and thus safe)

Aggregated exposure is important in prioritization!

Choices in prioritization on exposure

- Only substances in non-food consumer products
- A substance is of higher priority when it is present in more product categories
- A substance if of higher priority when it is (also) applies in child-specific product categories
- A substance is of higher priority when its exposure is higher and longer, estimated using :
  - height of 1st tier exposure estimate
  - frequency of exposure
  - frequency of use

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NB. There is still discussion on the tool for REACH for the "first tier" estimate of consumer-exposure

(SIR – ECETOC – EChA)

ProductSubCategory	estimate	adult	child	type	freq/year		height	freq exp	freq use	sum
A01; waterborne latex wall paint	40,44	y	n	V	2		1	2	0	3
A02; solvent rich, high solid, water borne paint	37,36	y	n	V	1		1	2	0	3
A03; aerosol spray can	0,06	y	n	V	2		0	2	0	2
A04; Hardened dried paint	17,28	y	n	G			1	0	1	2
A05; Finger paint, face paint	194,7	n	y	V	12-100		2	2	1	5
A06; Fillers and putty	10,52	y	n	V	1-3		1	2	0	3
A07; Plasters and floor equalizers	200,04	y	n	V	0.2-0.5		2	2	0	4
A08; Removers (paint-, glue-, wall paper-, sealant-remover)	136,86	y	n	V	0.25-1		2	2	0	4
B01; Glues, hobby use	1,8	y	n	V	52		0	2	2	4
B02; Glues DIY-use (carpet glue, tile glue, wood parquet glue)	73,72	y	n	V	0.125-2		2	2	0	4
B03; Glue from spray	2,14	y	n	V	12		0	2	1	3
B04; Sealants	2,32	y	n	V	1-3		0	2	0	2
C01; Laundry and dish washing products	85,78	y	n	V	128-426		2	2	2	6
C02; Cleaners, liquids (all purpose cleaners, sanitairy products, ….)	71,51	y	n	V	2-365		2	2	2	6
C03; Cleaners, trigger sprays (all purpose cleaners, sanitairy ….)	28,61	y	n	V	6-365		2	2	2	5
D01; Clothing (all child of mat., rubber and plastic clothing too), towel	1027,87	y	y	G			1	0	2	4
D02; Bedding, mattress	46,71	y	y	G			1	0	2	3
D03; Toys (cuddly toy)	55,68	n	Y	G	365		2	0	2	4
….										
…..										

classes height exposure	classes freq of exposure	Classes frequency of use
0= <5 mg/kg bw/d	0= G	0 = accid/infreq
1= 5-50 mg/kg bw/d	-	1 = occasional
2= >50 mg/kg bw	2= V	2= cont/freq

Exposure, frequency and height

- height of 1st tier exposure estimate (ECETOC-TRA tool vs2)

- frequency of exposure
  use of products give similar exposure every time they are used, or not??
  for example:
  cleaning product, exposure similar every time (G)
  mattress, exposure decreasing in time (V)

- frequency of use

how often consumer products are used (everyday, twice a year, …)

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Questions regarding the exposure

Question 1. Consumer use? YES = 1 point, NO = 0 points

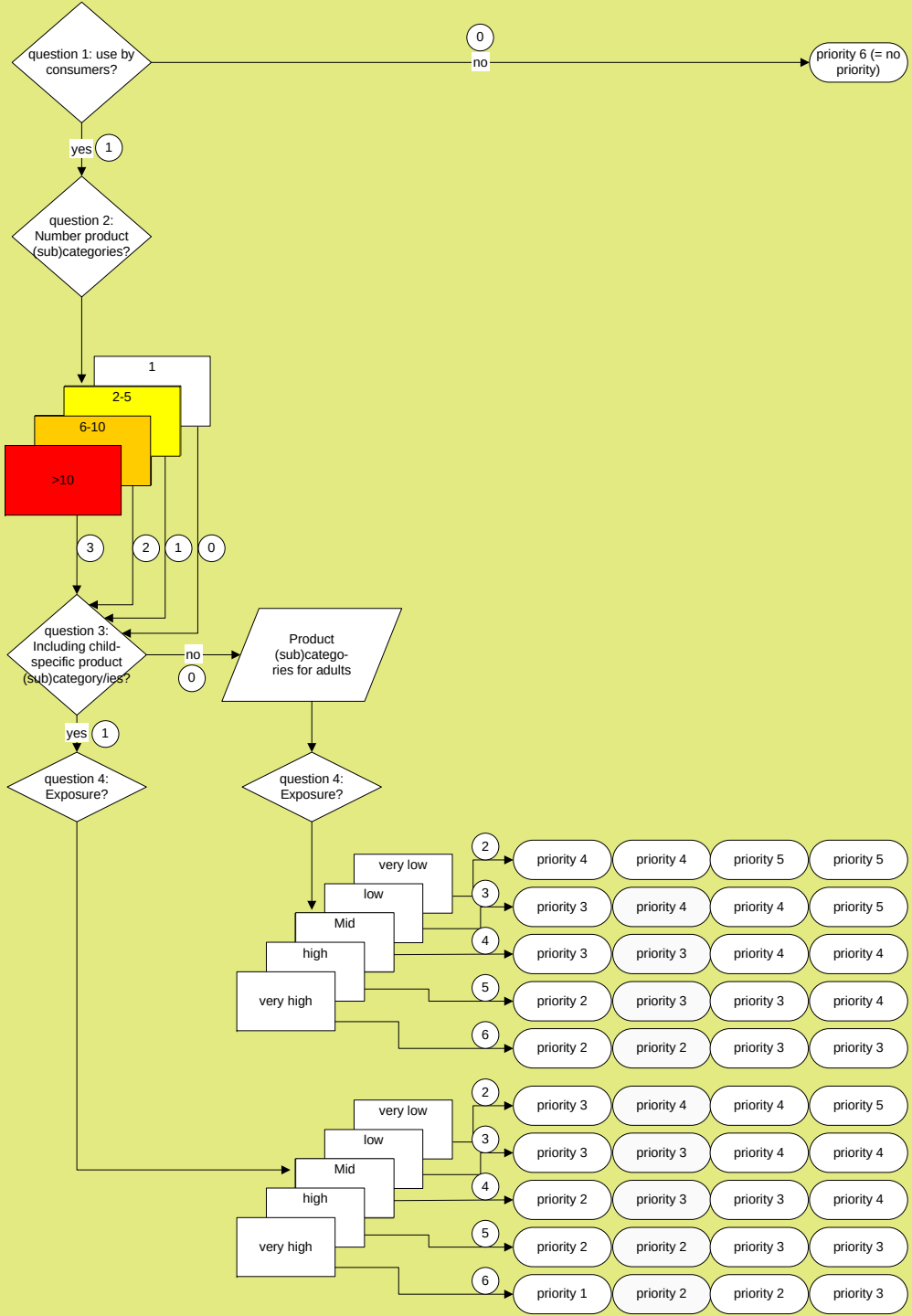
Question 2. Number of product (sub)categories?

4 classes; 0, 1, 2, or 3 points

Question 3. Specific for children? 1 point

Question 4. What is the exposure? How high and how often?

5 classes; very low, low, middle, high, very high


question 1: use by consumers?
0
no
priority 6 (= no priority)
yes
1
question 2: Number product (sub)categories?
1
2-5
6-10
>10
3
2
1
0
question 3: Including child-specific product (sub)category/ies?
no
0
Product (sub)catego-ries for adults
yes
1
question 4: Exposure?
question 4: Exposure?
very low
low
Mid
high
very high
2
3
4
5
6
priority 4
priority 4
priority 5
priority 5
priority 3
priority 4
priority 4
priority 5
priority 3
priority 3
priority 4
priority 4
priority 2
priority 3
priority 3
priority 4
priority 2
priority 2
priority 3
priority 3
very low
low
Mid
high
very high
2
3
4
5
6
priority 3
priority 4
priority 4
priority 5
priority 3
priority 3
priority 4
priority 4
priority 2
priority 3
priority 3
priority 4
priority 2
priority 2
priority 3
priority 3
priority 1
priority 2
priority 2
priority 3

priority	Number of product(sub)categories								Score
	1		2-5		6-10		>10		
1							YES child VH		11
2					YES child VH		YES child H	YES adult VH	10
			YES child VH		YES child H	YES adult VH	YES child M	YES adult H	9
3	YES child VH		YES child H	YES adult VH	YES child M	YES adult H	YES child L	YES adult M	8
	YES child H	YES adult VH	YES child M	YES adult H	YES child L	YES adult M	YES child VL	YES adult L	7
4	YES child M	YES adult H	YES child L	YES adult M	YES child VL	YES adult L		YES adult VL	6
	YES child L	YES adult M	YES child VL	YES adult L		YES adult VL			5
5	YES child VL	YES adult L		YES adult VL					4
		YES adult VL							3
6 (= No priority)	NO		NO		NO		NO		0

Not included

- tonnage
- Number of registrants
- Article or substance/mixture
- Size of the population

The combination: risk

hazard / exposure	1	2	3	4	5	No
1	2	3	4	5	6	No
2	3	4	5	6	7	No
3	4	5	6	7	8	No
4	5	6	7	8	9	No
5	6	7	8	9	10	No
No	No	No	No	No	No	No

More in the report

Prioritization schemes

- Exposure of the environment
- Exposure of humans via the environment
- Exposure of workers

Planning of the report

Review round was in September

Taking into account comments October/November

Printing January

An extensive summary (including chosen criteria) will be written in english!

Thanks

For your attention!

To all the co-workers of the report (see earlier)!

Information sources hazard properties

1. regarding (potencial) CMRS substances

- Annex VI
- IUCLID (2.2)

  after 2010 for CMR cat 1/2 substances
- C&L inventory (after 2010)
- IARC, GR, EPA (convert to EU classification)
- draft advisory list for self-classification of dangerous substances" (Danish EPA, 2001)

2. Regarding assessment of potency

- T25/NOAELs underlying uptake on C&L list

  → convert to DNEL/DMEL
- M?
- S?

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Information sources on exposure

After 2010:

• IUCLID5:

- 3.4 form in supply chain

- 3.5 identified uses and exposure scenario

- 3.8 exposure estimates

Before 2010:

• SPIN database

• NVIC database

• Household Product database

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