HOW HAS AUTHORISATION PROCESS REDUCED RISKS: RESULTS OF THE STUDY ON THE IMPACTS OF AUTHORISATION

Stock-taking conference on the implementation of REACH authorisation

13th November 2017

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eftec
Economics for the Environment Consultancy

Apeiron
where Strategy, Science and Efficiency meet

Peter Fisk Associates

The Economics Interface

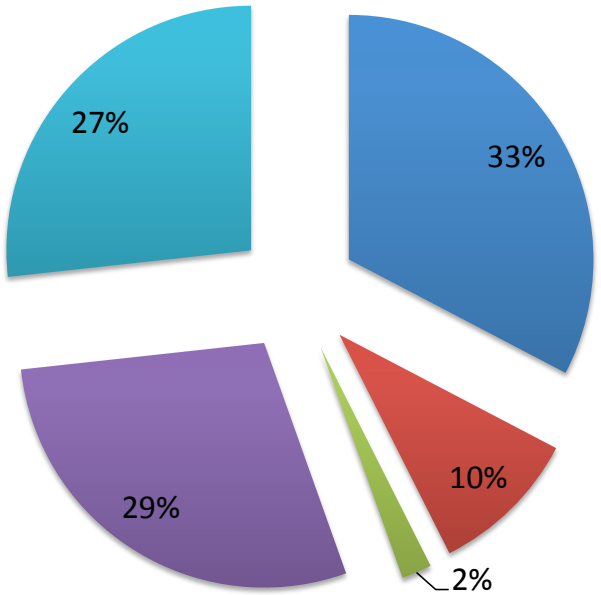
RISK REDUCTION

Substitution

Improved RMM

Reduced exposure
Reduced risk

SUBSTITUTION AS TRIGGER FOR REDUCTION OF RISK



- Yes, partly due to the REACH authorisation process
- Yes, but not due to the REACH authorisation process
- No, but we are aware of substitution in our supply chain
- No, but we are investigating possibilities to substitute
- No

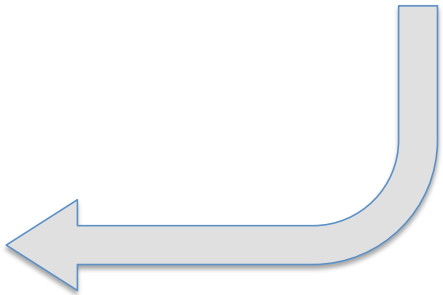
HAS THE RESPONDENT SUBSTITUTED A (POSSIBLE) SVHC WITH AN ALTERNATIVE SUBSTANCE AND/OR TECHNOLOGY

Q8

CEASED MANUFACTURING AS INDICATOR FOR REDUCTION OF RISK

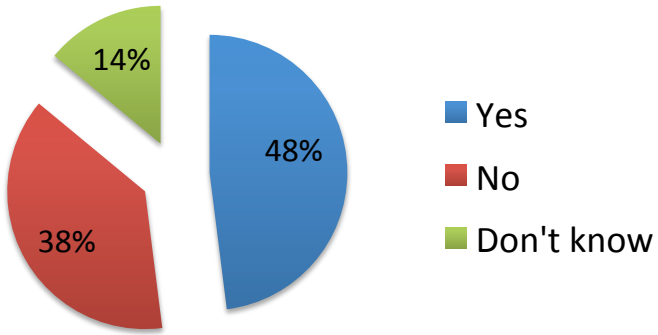
Registrant type	On Candidate List	On Authorisation List	Total
Total number of dossiers "ceased manufacturing or importing"	69	34	**103**

Substance on Authorisation List	Remaining active registrations	Ceased manufacturing
Trichloroethylene	5	1
Diisobutyl phthalate (DIBP)	7	3
Dibutyl phthalate (DBP)	8	3
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	5	1
4,4'- Diaminodiphenylmethane (MDA)	10	3
1,2-dichloroethane (EDC)	36	6
Bis(2-ethylhexyl) phthalate (DEHP)	17	7
Diarsenic trioxide	6	1
Chromium trioxide	26	2
Lead sulfochromate yellow	7	1
Ammonium dichromate	1	1
Sodium dichromate	17	2
Lead chromate molybdate sulfate red	7	1
Hexabromocyclododecane	6	2
TOTAL	158	34



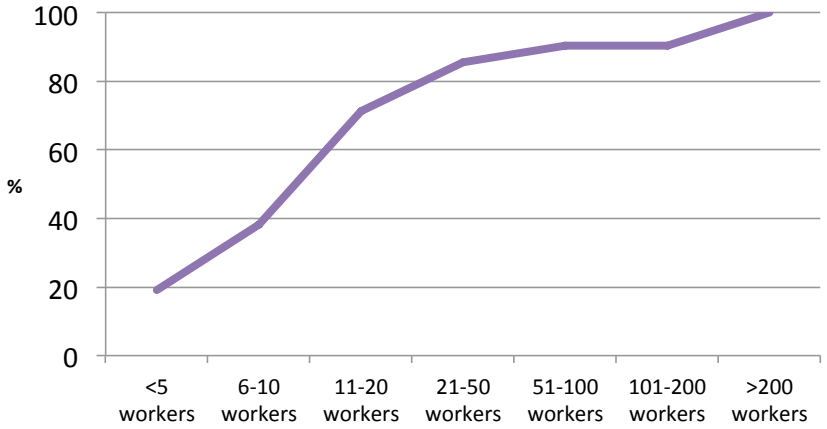
Change of registration status for substances on the Authorisation List

SUBSTITUTION AS REDUCTION OF RISK



REDUCTION IN WORKER EXPOSURE LEVELS

Q40



NUMBER OF WORKERS WITH REDUCED/NO EXPOSURE

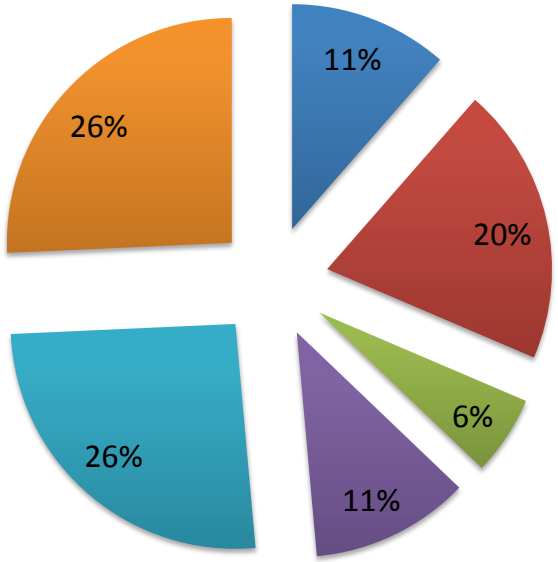
Q41

Apeiron-Team: Results of the study on the reduction of risks

EVIDENCE OF IMPROVED RISK MANAGEMENT MEASURES

Automating production process(es) to minimise worker exposure	1
Confinement of production process(es) to minimise exposure, reduced use of SVHC to limit their prevalence in final products	1
Employee training and examination	1
Exposure controls and new procedures	1
Improved information to workers, continuous monitoring of exposure	1
Improved ventilation and closed production systems	1
Improvements to containment and monitoring measures	1
Personal protective equipment	1
Personal protective equipment, improved monitoring	1
Protection against inhalation, training workers, development of safety documents	1
Use of alternative substances to modify the production process	1
Not stated	14

AUTHORISATION STAGE THAT TRIGGERED REDUCTION OF RISK



- Screening of substance and Risk Management Option Analysis (RMOA)
- Inclusion of substance in Candidate List
- Recommendation for inclusion of substance in Authorisation List (Annex XIV)
- Inclusion of substances in Annex XIV
- Applications for authorisation (AfA)
- Not sure

75% of the RAC decisions contain additional RMM,

Questions 80, 98

EVIDENCE OF IMPROVED RISK MANAGEMENT MEASURES

	Improved RMM
Survey (Q67)	37%
AfA	35%
ECHA	"most"
Draft opinions (Q98)	75%
Case Studies (AfA)	
Chromium trioxide	24%
TCE	37%
DBP	33%

Interviews:

"application for authorisation has proven to be a driver for the review of exposure and emissions situation of the SVHC "

EVIDENCE OF REDUCED EXPOSURE

Historical sources for Cr(VI)

Country	Publication	Period
Italy	Hexavalent Chromium Compounds in the Workplace: Assessing the Extent and Magnitude of Occupational Exposure in Italy	1996-2009
Germany	MEGA-auswertungen zur Erstellung von REACH-Expositionsszenarien für Chrom(VI)-Verbindungen (2000-2009) in Deutschland	2000-2009
	Galvanotechnik und Eloxieren Empfehlungen Gefährdungsermittlung der Unfallversicherungsträger (EGU) nach der Gefahrstoffverordnung (DGUVI 213-716)	2001-2011
France	Occupational Exposure to Chrome VI Compounds in French Companies: Results of a National Campaign to Measure Exposure (2010–2013)	2010-2013
Belgium	Resultaten Inspectiecampagne Chemische Agentia in de sector van de oppervlaktebehandeling van metalen	2015

EXPOSURE LEVELS TO Cr(VI)

Exposure to Cr(VI)	< 1 µg/m³	1 - 10 µg/m³	> 10 µg/m³
Italy - Metal finishing-, plating-, and coating-machine operators (1996 - 2009)	0.001- 1000 µg/m³ 1.79 µg/m³(GM)		
Germany - Electroplating (2000- 2011) P90 values	32.6 µg/m³		
France (2010 – 2013) Hard chrome plating Chrome plating	<0.03 – 23 µg/m³ <0.02 – 1.71 µg/m³		
Belgium: Inspection Q4 2015 (Chrome plating)	44%	51%	5%
AFA dossiers (all uses)	53%	43%	4%

EFFECT OF THE REDUCED EXPOSURE

Before	After
How many people were exposed at what level $Effect = \left(\sum_{before} Exposure \times \#exposed - \sum_{after} Exposure \times \#Exposed \right)$	
- Trade statistics: production / import / export volumes - Member state monitoring programs: exposure levels – details on tasks ? - Registration dossier: exposure level & production volume	CSR's in AfA's contain this information
Information Gaps	Information available

EXPOSURE MEASUREMENTS AVAILABLE ?

80% of the visited companies use substances where measurements are required
Belgian inspection program on SVHC; Q4 2015

N° FTE	1-9	10-19	20-50	>50	Total
Measurements done for Cr(VI)	9%	14%	7%	40%	19%
Measurements other substances	5%	9%	29%	36%	19%
No measurements	86%	77%	64%	24%	61%

EFFECT OF THE REDUCED EXPOSURE: TCE

Before	After
How many people were exposed at what level $Effect = (Average\ Exposure_{Before} - Average\ Exposure_{After}) \times \#Exposed$	
- Data source: France (COLCHIC) - Period: 2002 – 2008 - Average exposure level: 74 mg/m^3 - ➔Risk: 10^{-2} - Number of workers exposed: 200.000*	Assumed exposure level: 32 mg/m^3 ➔Risk: 4 10^{-4} Number of workers exposed: 200.000
For post-AfA exposure level of 32 mg/m^3 ➔ 1137 cases	

*Extrapolation based on: **Risk of Cancer Among Workers Exposed to Trichloroethylene: Analysis of Three Nordic Cohort Studies**

SUMMARY

Authorisation process results in a reduction of risks

- Substitution
- Improved risk management measures

The reduction of risks leads to

- Less people exposed
- Lower exposure levels

The overall effect is difficult to estimate because baseline data is incomplete

The detailed CSR's and the monitoring obligations associated with AfA's will allow further follow up

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