REACH Regulatory Trends
&
SIEF & Consortia Approach

Tokyo, Japan

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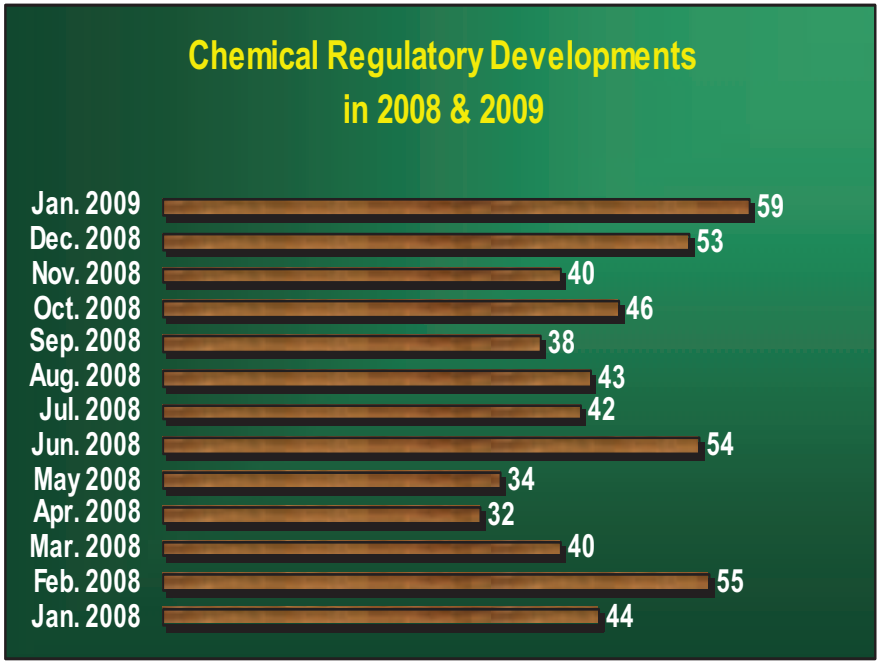
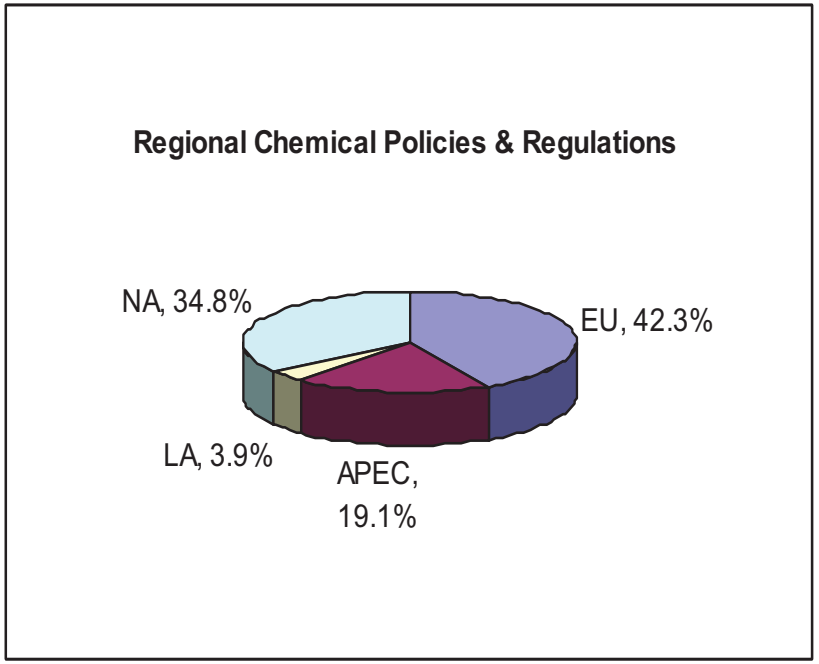
Overview

What Happened on Chemicals in 2008 - 2009

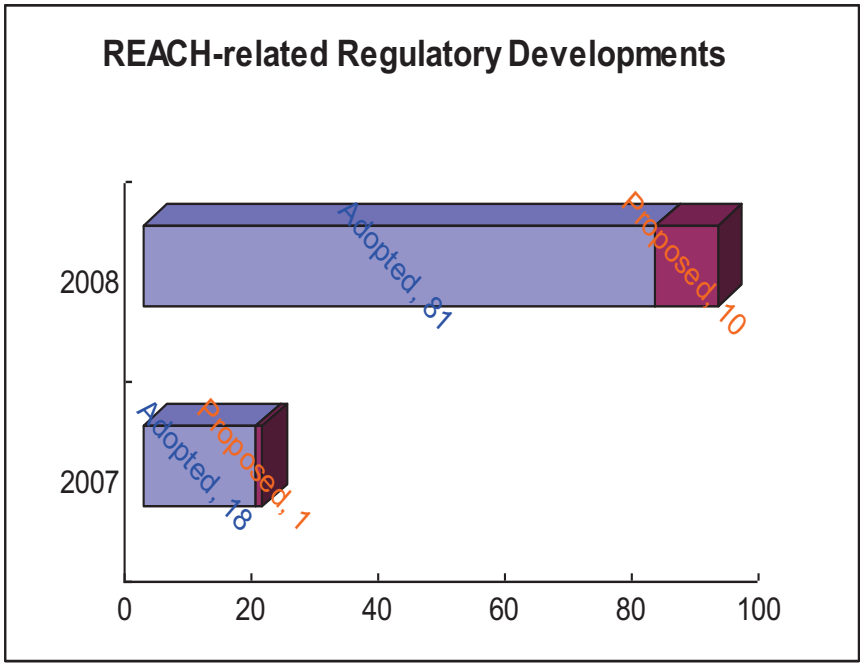
- Globally, around **580** chemical policies & regulations amended & adopted between Jan. 2008 and Jan. 2009.
- Namely, **44** chemicals policy & regulatory issues are out each month.
- Amongst others, more than **42%** of chemical policy and regulatory issues from EU & Member States.





EU Chemical Policies & Regulations in 2008 - 2009

- **Highest Regulatory Development in EU & MS is due to REACH- & GHS-related Policies & Regulations.**
- **Around 110 chemical-related policies & regulations in EU & MS adopted, amended & proposed between 2007 - 2009.**
- **In 2008, 81 REACH-related policies & regulations amended or adopted, and 10 proposed.**



Amongst others, Member States having REACH-related enforcement regulations include:

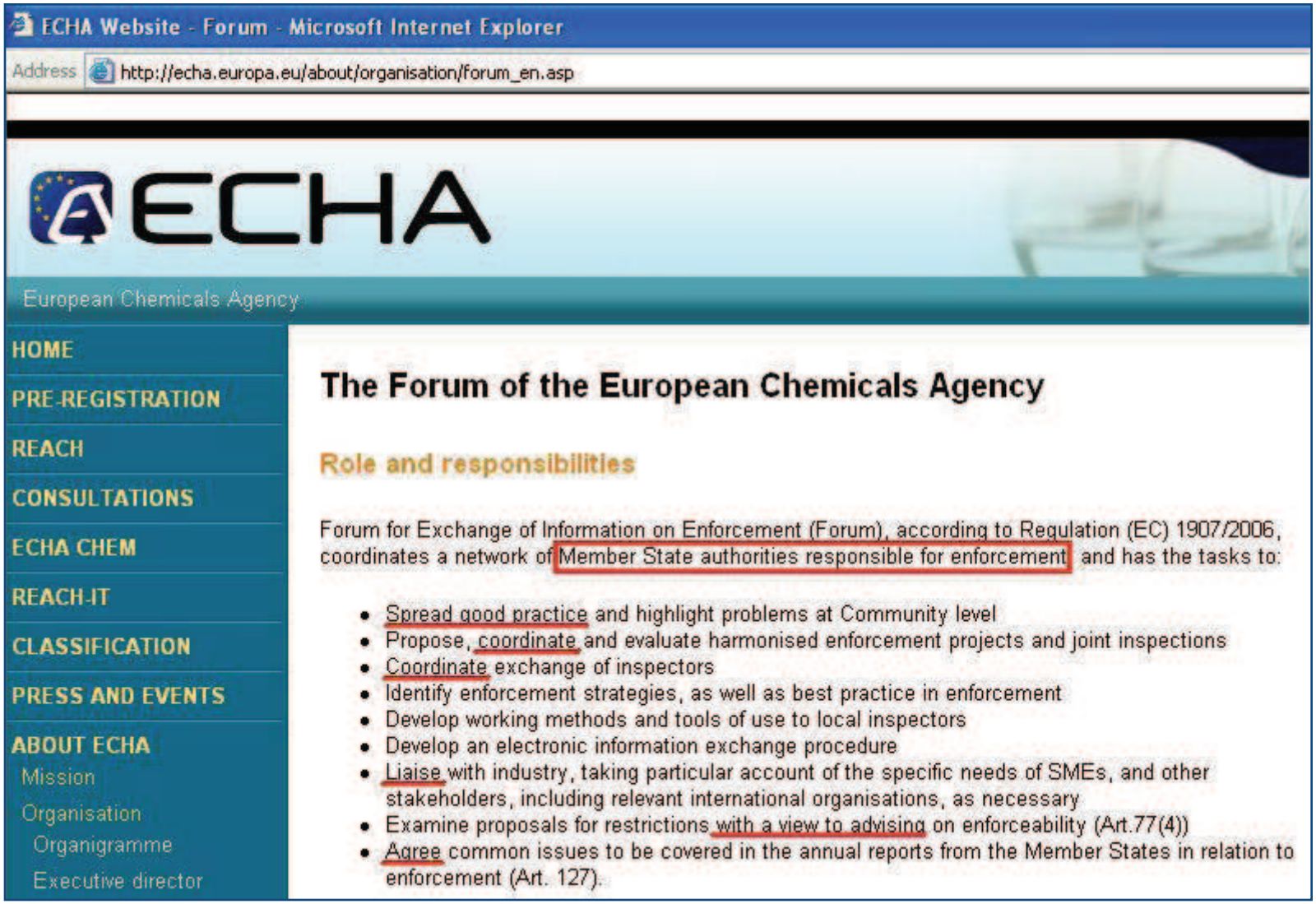
Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, United Kingdom

REACH Enforcement Regulations in MSs

Country	Legislation	Date
Croatia	Law on Adoption of the Regulation EC/1907/2006 of European Parliament and the Council of the EC registration, evaluation, authorization and limitation of chemicals (NN 53/08)	25-Apr-08
Latvia	Chemical Substances and Chemical Preparations Law	01-Nov-07
Malta	Dangerous Substances Regulations, 2008	21-Nov-08
Austria	Chemicals Ordinance	13-Nov-08
Lithuania	Resolution No. 687 on the Registration, Evaluation, A	11-Jul-07
Slovakia	Government Regulation N Articles	06-Nov-08
Spain	Royal Decree 1802/2008 and classification, packaging and labeling of dangerous substances	03-Nov-08
United Kingdom	REACH Enforcement Regulations 2008 (SI No. 2852)	10-Nov-08
Hungary	Act XXVIII. of 2008 on the amendment of several Acts related to health	01-Sep-08
Romania	Decision No. 1238/2008 stating new inspection competencies of the National Environmental Guard	01-Oct-08
Czech Republic	Act Amending Act No. 356/2003 on Chemical Substances and Preparations	23-Sep-08
Hungary	Government Decree No. 224/2008. (IX. 9.) on detailed rules of the application of chemical fines (224/2008. (IX. 9.)	09-Sep-08
Finland	Act 491/2008 amending the Chemicals Act 744/1989	18-Jul-08
Ireland	Chemicals Act 2008 (S.I No. 13 of 2008)	09-Jul-08
Italy	Draft Legislative Decree including: Sanctions for the violation of the provisions of REACH Regulation EC/1907/2006 (n. 55)	22-Jan-09

Up to EUR 120.000 for placing on the market a substance of very high concern (SVHC) without obtaining an authorization.

“REACH Enforcement”= MS, not ECHA!



SIEF – Unknown Animal in Asia

China	Measures on the Management of New Chemical Substance (新化学物质环境管理办法)	No SIEF or Consortia Mechanism
Japan	Law on the Control of Examination and Manufacture of Chemical Substances (化学物質の審査及び製造等の規制に関する法律)	No SIEF or Consortia Mechanism
Korea	Toxic Chemicals Control Act (유해화학물질관리법)	No SIEF or Consortia Mechanism

- **Japanese companies have some experience in joint or cooperative data sharing through the HPV Program in ICCA and the Japan Challenge Program.**
- **The Ministry of the Environment (Korea) sponsored around 10 substances in the OECD HPV Program.**

SIEF Formation Facilitator – Whom to believe?

Example 5

TOLUENE
EC NUMBER: 203-625-9

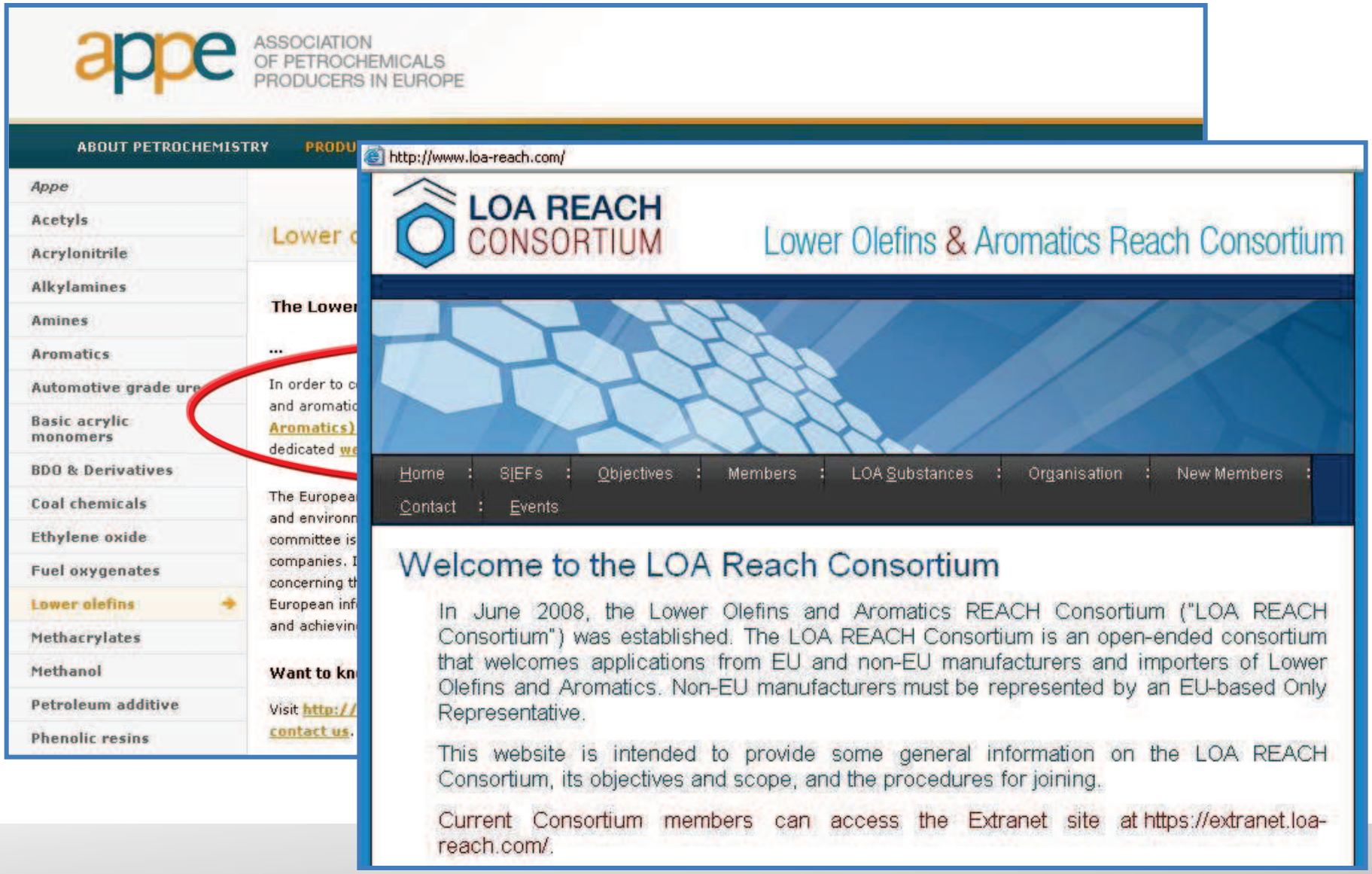
CAS No: 108-88-3
Dear Sir / Madam,
We are acting on behalf of the LOA REACH Consortium (http://www.loa-reach.com/), which represents the vast majority of the EU manufacturing and import capacity for the substances covered by the Consortium.
This email is addressed to all potential participants in the Substance Information Exchange Fo on the European Chemicals A
The LOA RE e in meeting the registration r f substances covered by t
This communication does not require an immediate response, as it seeks to inform and provide information on which organisations can base decisions. An open letter from the Chairman of the LOA REACH Consortium's General Assembly (click here) sets out the measures taken by the EU olefins and aromatics industry to comply with the REACH registration requirements, and describes how companies can become involved in the work of the LOA REACH Consortium and gain access to the registration dossiers which are in preparation. Please click on the link and review the letter. Future communications in the coming weeks will ask you to indicate specifically how your organisation wishes to engage in the activities of the LOA REACH Consortium.
Yours faithfully,
Helen Penman, SIEF Manager
LOA REACH Services Team

Yes. I know them very well & they are a competent SFF & Consortia. However, I am not the one who can directly respond to them by my own decision.

1061 Budapest

Regards

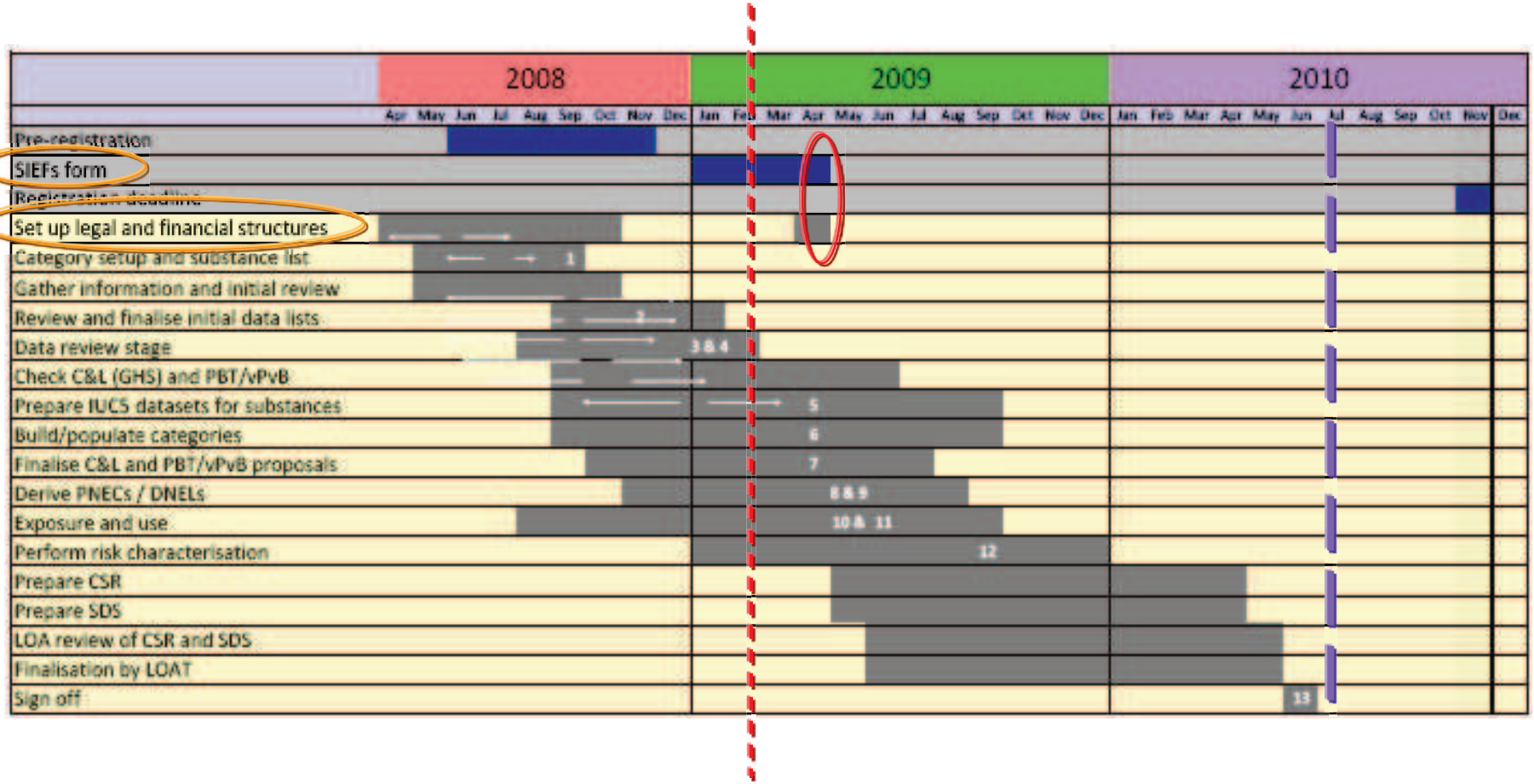
SIEF & Consortia - Eligibility



CSR is Optional in SIEF

Mandatory Joint Submission	Individual Submission	Optional
• Classification and Labelling • Study Summaries • Robust Study Summaries • Proposal of Testing	•Identify of manufacturer or importer of the substance •Identity of substance •Information on the manufacture and use of the substance •For substances in quantities of 1 to 10 tons, exposure information	• Chemical Safety Assessment (CSA) • Chemical Safety Report (CSR) • Guidance on Safe Use

SIEF & Consortia on CSA & TD



25 February 2009, Current Status

Source: LOA Consortium

SIEF & Consortia on CSA & TD

- Core data set
- IUCLID 5 file - Common elements of the registration dossier to the level required by the registration type
  - ☞ Classification and Labelling proposals
  - ☞ Derivation of DNELs and PNECs
  - ☞ Chemical Safety Report
- As necessary (Optional)
  - ☞ Exposure scenarios for hazardous substances
  - ☞ Risk characterisation for agreed common uses
  - ☞ Elements of a Safety Data Sheet that need change to reflect the conclusions of the dossier and the Chemical Safety Report
- Detailed guidance on how to use the information

Source: LOA Consortium

Difficult Part – Exposure Scenario in CSR

PART A	1. Summary of Risk Management Measures 2. Declaration that Risk Management Measures are Implemented 3. Declaration that Risk Management Measures are Communicated
PART B	1. Identity Of The Substance And Physical / Chemical Properties 2. Manufacture & Uses 3. Classification And Labelling 4. Environmental Hazard Assessment (e.g. degradation, bioaccumulation) 5. Human Health Hazard Assessment 6. Human Health Hazard Assessment of Physicochemical Properties 7. Environmental Hazard Assessment (e.g. acquatic, atmospheric compartment) 8. PBT & vPvB Assessment **9. Exposure Assessment (9.1 Exposure Scenario, 9.2 Exposure Estimation)** 10. Risk Characterisation

* China, Japan and Korea – Traditionally Hazard-based Chemical Management

Exposure Scenario – Use & Application, e.g. Methnol

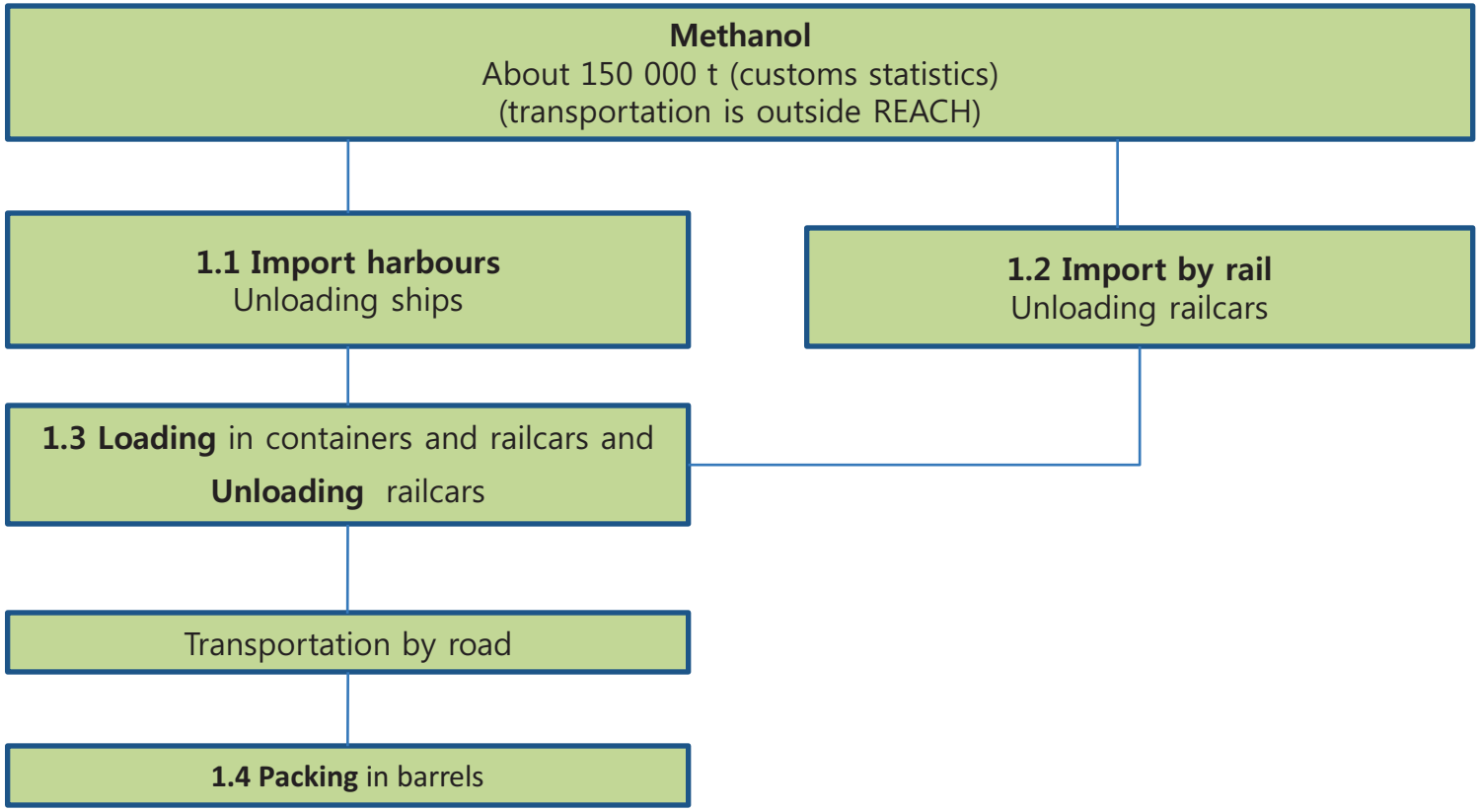
- **55 applications were in worker use**
  - 31 applications were found from the measurement register of TTL (1994-2006)
    - 21 branches, 475 measurements
  - In the project measurements were made in 12 new applications
    - 5 branches, about 200 measurements
  - No information from 12 applications
  - The scenarios cover the applications where methanol is actually sold and loading and unloading tasks , i.e. together 33 applications
  - Not included in this project: manufacturing and use of products including methanol, because there was so little information (except manufacturing of windshield washer fluid)

- 7 applications in c**onsumer use** were found, 2 were taken in exposure scenarios
- Information about amounts was achieved from KETU as additional service

Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

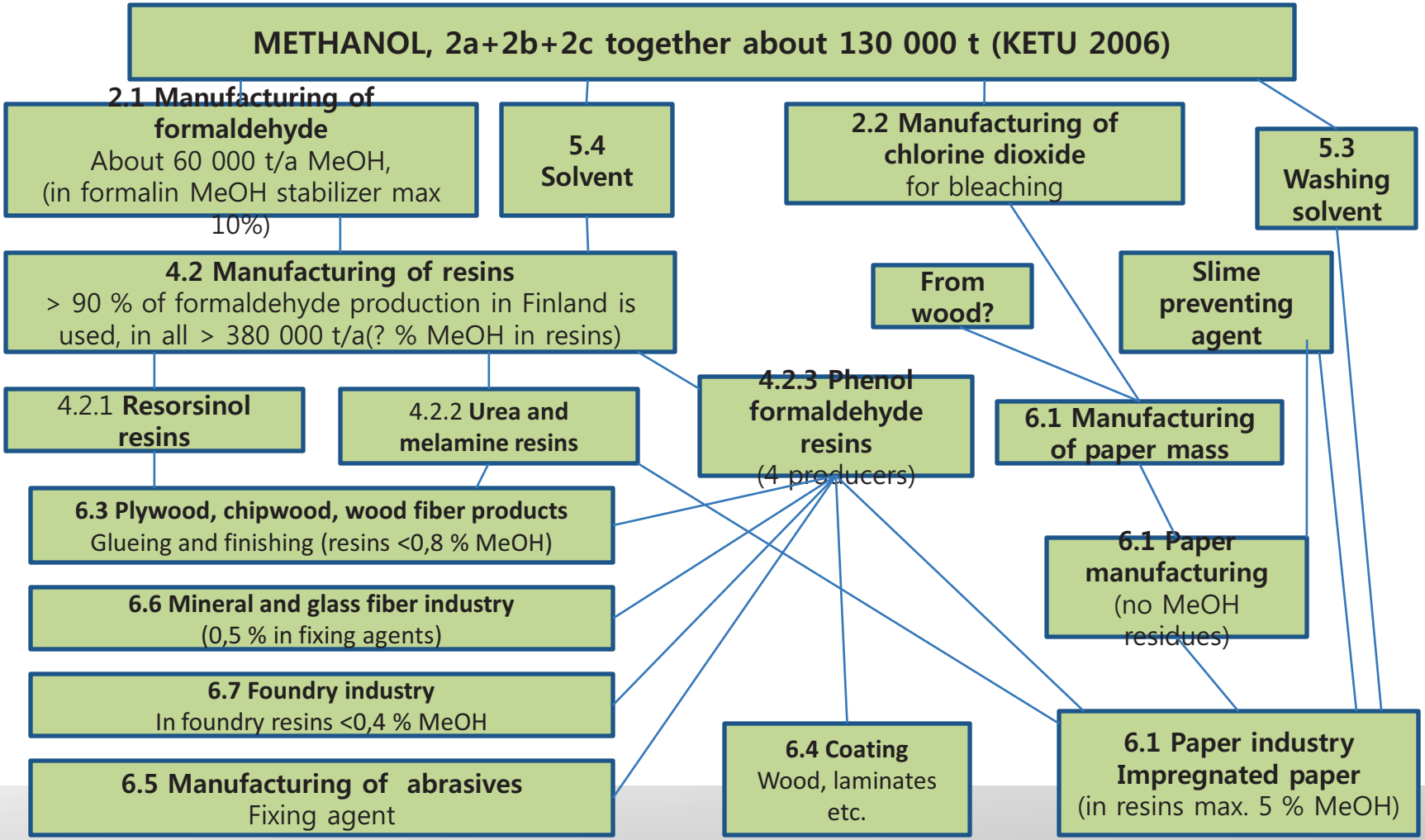
1. Loading, unloading and packing in vessels



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

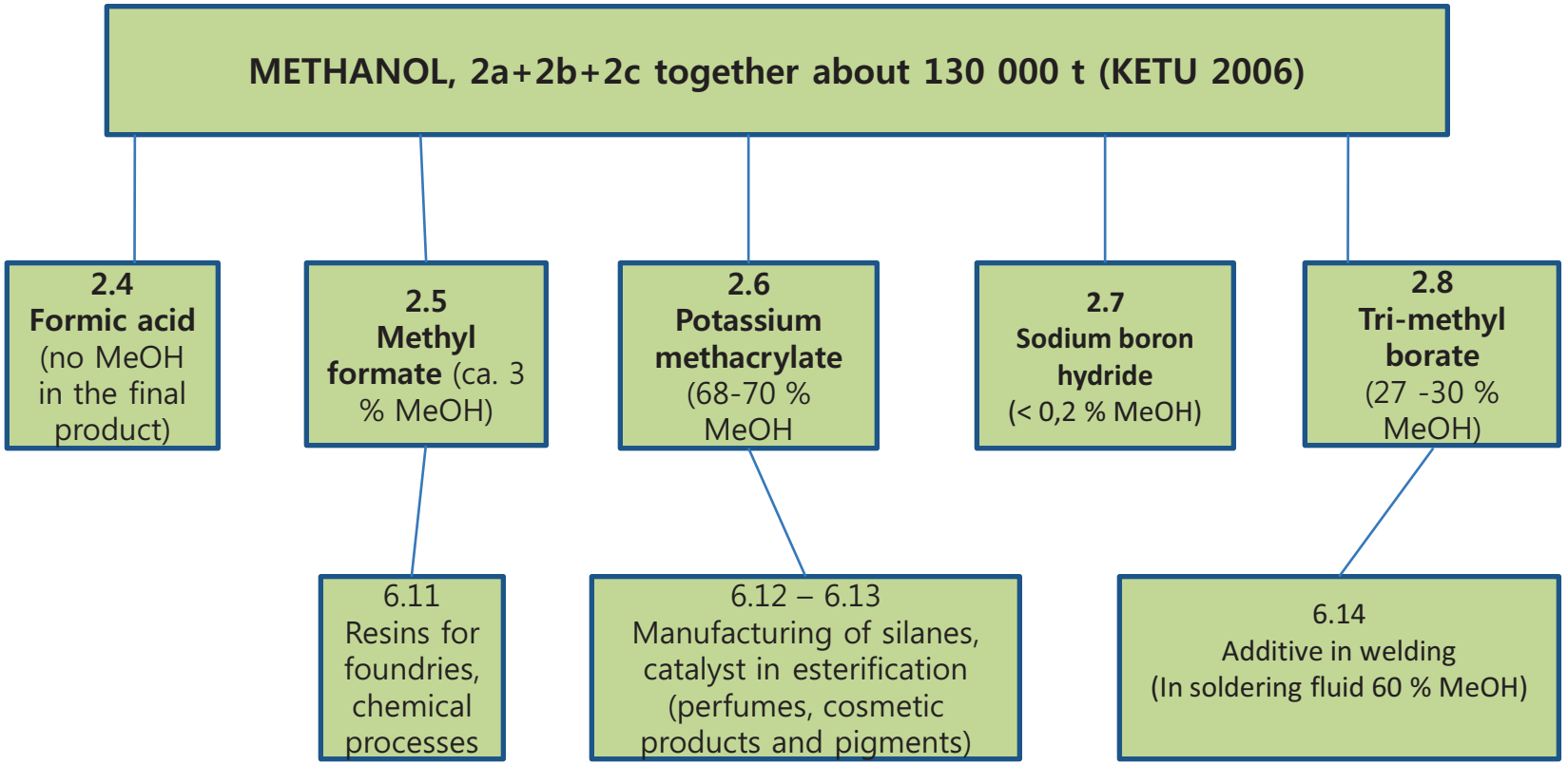
2. Manufacturing of chemical products: formaldehyde and chlorine dioxide and slime preventing agent



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

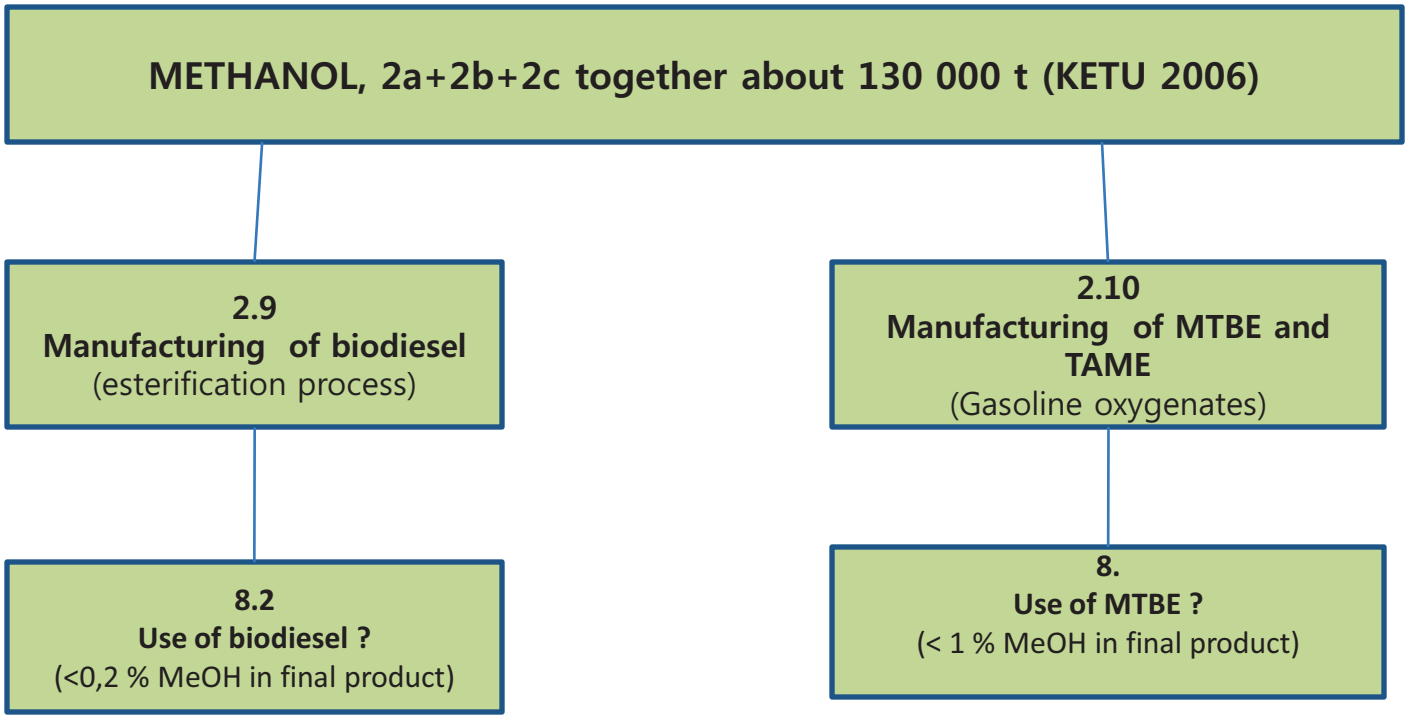
3. Manufacturing of chemical products



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

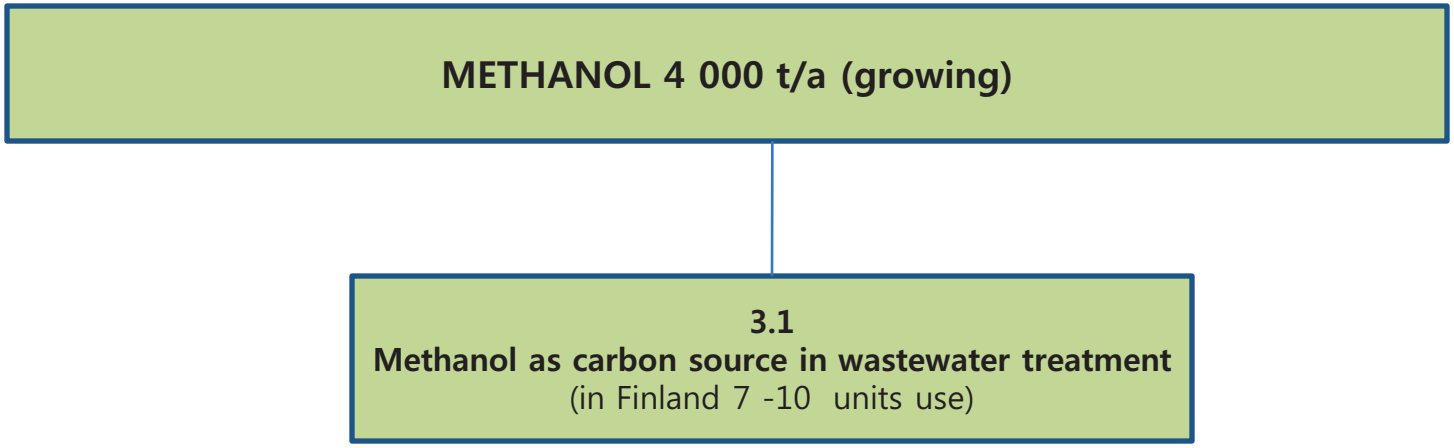
4. Manufacturing of chemical products



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

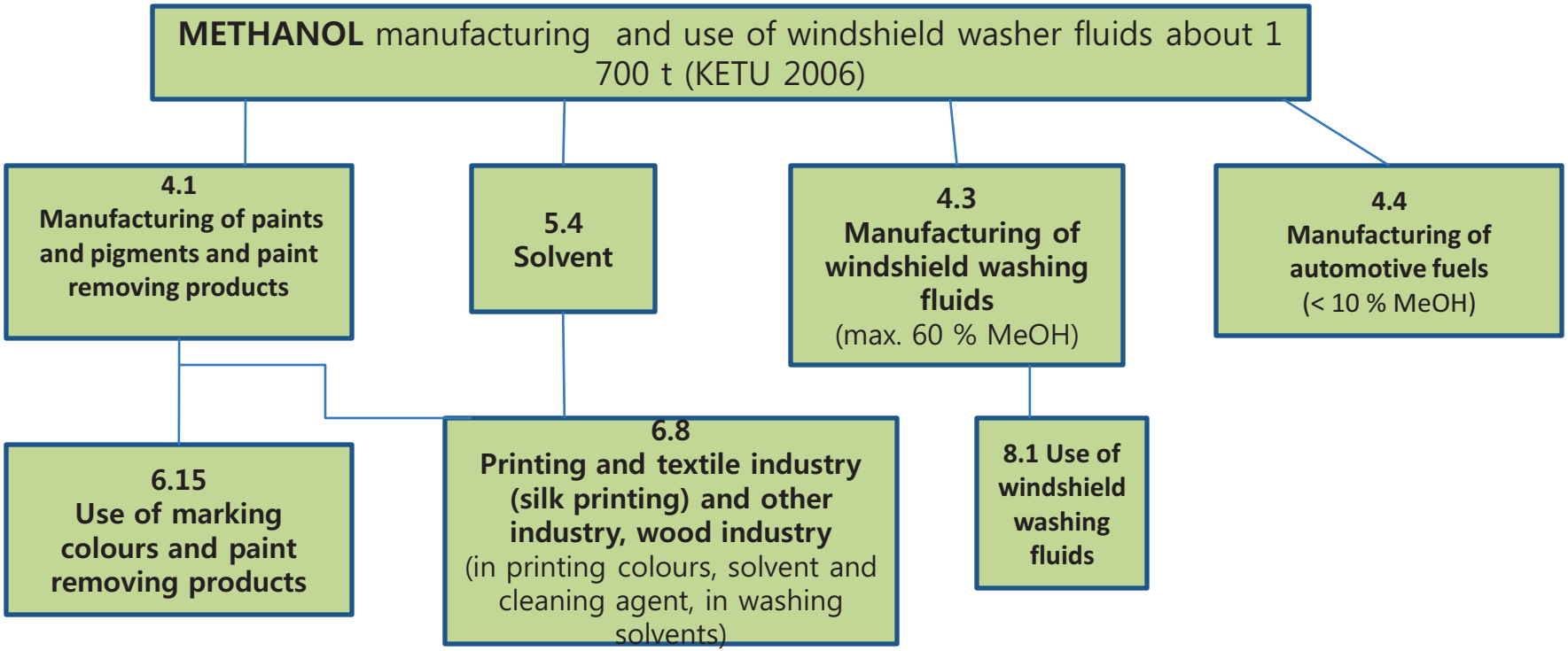
5. Use as a process chemical



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

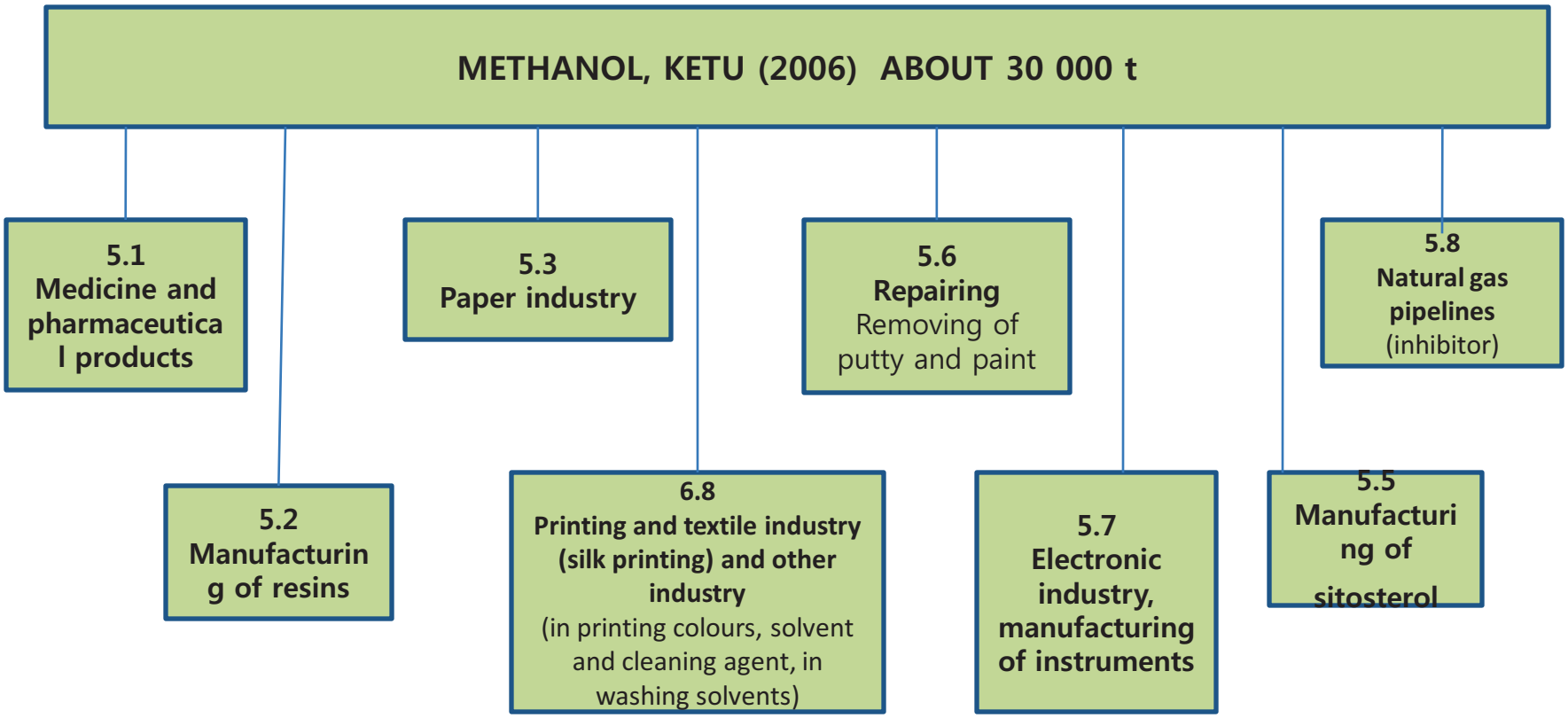
6. Manufacturing of products containing methanol as a solvent



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

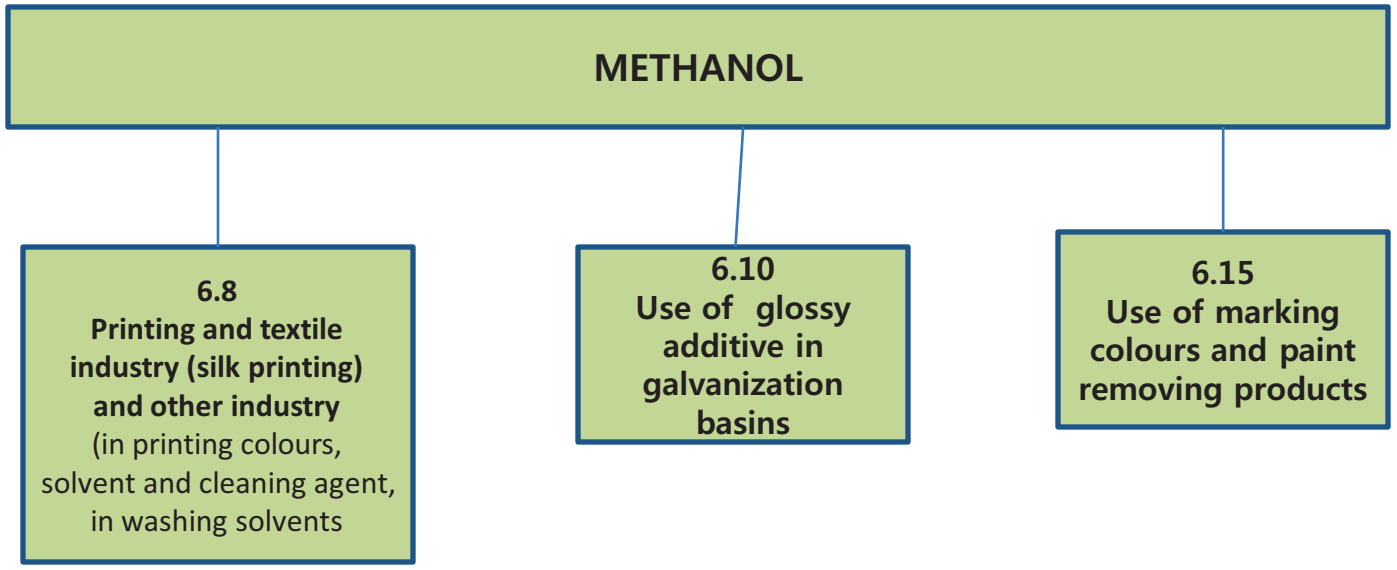
7. Use of methanol as solvent in industry



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

8. Use of methanol and products containing methanol in industry and workplaces (this includes products having methanol as solvent)



Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

9. Laboratory use of methanol

METHANOL about 50 t/a (KETU 2006)

7.1 preparation of reagents, purification of methanol
7.2 manufacturing mediciinal products at the chemists´
7.3 various analysis (like ocratoxines, ligniine, PAH-analysis, fatty acid, vitamines)
7.4 use as cooling agent
7.5 colouring of tissues
7.6 HPLC-analysis (high pessure liquid chromatography)
7.7 cleaning agent in glue removing
7.8 tasks in mass spectrometry

Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

10. Use of products containint methanol in professional traffic

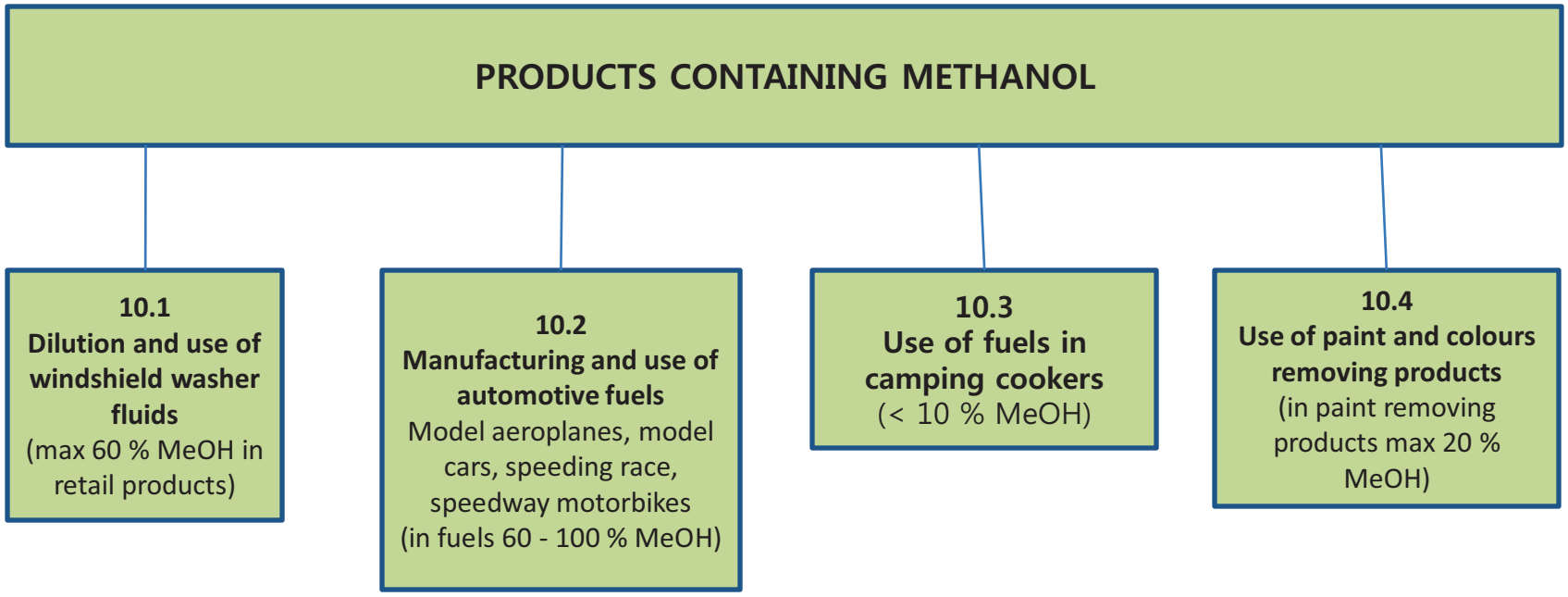
METHANOL in manufacturing and use of windshield washer fluids about 1 700 t (KETU 2006)

8.1
Use of windshield washer fluids

Source: RV Chem Oy

Exposure Scenario - Use, e.g. Methnol

11. Consumer exposure to products containing methanol



Source: RV Chem Oy

Exposure categories (EC) and exposure scenarios (ES) - Methnol

1. Transportation of methanol (work during loading and unloading) (EC)
2. Methanol as the raw material in manufacturing of chemical products: the process itself, maintenance, process sampling, packing, waste treatment, regeneration of methanol (EC)
   - Formaldehyde, Chlorine dioxide
   - Formic acid, Methyl formate
   - Potassium methylate, Sodium methylate
   - Sodium boron hydride, Trimethyl borate
   - MTBE, TAME
   - Bio diesel (RME etc.)

3. Methanol as carbon source in wastewater treatment (ES)

4. Manufacturing of products containing methanol as solvent :
   -production of windshield washer fluids (ES)

Source: RV Chem Oy

Exposure categories (EC) and exposure scenarios (ES)

5. Use of methanol as an industrial solvent in extraction processes (e.g. medicins) (EC)

6. Use of methanol as solvent in different fields of industry (EC)

7. Laboratory use of methanol (EC)

8. Use of products containing methanol in professional traffic (ES)
   - Use of windshield washer fluids

9. Consumer use of products containing methanol (ES)
   - Use of windshield washer fluids

10. Consumer use of products containing methanol (ES)
    - Use of methanol as automotive fuel

Source: RV Chem Oy

Example: Laboratory use of methanol, preliminary exposure scenario (only worker exposure)

1. Short title	Branch: Research (Natural science and technology) Process category: PROC 15 use as laboratory reagent, professional use
2. Description of activities and processes covered	Use of methanor in various laboratory functions: Preparation of reagents, preparation of medical agents in the chemist´s shop, various analysis, use as refrigerant, colourant for tissues, HPLC-analysis, use for glue cleaning and MS-tasks. Maintenance of laboratory equipment and waste handling in the laboratory
Conditions of use	
3 Duration and frequency of use	8h, 200 d/a. (Needs more specification?)
4.1 Physical form of the substance	Liquid solvent, flammable, volatile
4.2 Concentration of substance in the product (% substance in the mixture or preparation)	Maximum 100 % methanol
4.3 Amount used per time	Variable use depending on the function (needs specification?)
5. Other operational conditions Temperature, pressure, volume of the environment/room size	Temperature inside about 20 °C

Source: RV Chem Oy

Example: Laboratory use of methanol, preliminary exposure scenario (only worker exposure)

Risk management measures (RMM) which together with the conditions of use guarantee safe use.	
6.1. Worker exposure RMM (The details are found in the RMM library, effectiveness must be desribed, also details of exposure from various ways of exposure)	Handling of methanol should always be in fume cupboard. Use of protective gloves (buthyl rubber, fluorinated rubber, teflon, laminated plastic materials) in all tasks where skin contact is possible. Use of goggles during all methanol tasks. Beware of flammSuojalasien käyttö kaikissa metanolitöissä. Beware of inflammability.
6.2 RMM in environmental exposure (wastewater, air and soil)	Not handled in this exposure scenario
7. Waste handling and RMM	Worker exposure during waste handling in one target was <27 mg/m3. Total exposure to all solvents is however above the occupational limit values. How is this dealed in REACH?

Source: RV Chem Oy

Example: Laboratory use of methanol, preliminary exposure scenario (only worker exposure)

Exposure assessment and the methods how the downstream user can estimate that he/she follows the conditions of the use described in the exposure scenario	
8.a Estimation of the exposure level (e.g. mg/l tai mg/m^3) and reference to the source of information	Based on the measured concentrations the estimated mean concentrations of the whole workday exposures were below 27 mg/m3 (except the work of glue removal). In this case the dose would be lower than the DNEL value (see previous risk characterisation). According to modelling of the dermal exposure (?) protective gloves should be used to reduce the exposure (so far no good model, development is continuing).
9. Guidance to the downstream user to assess the exposure and circumstances	In the final exposure scenario guidance is given e.g. about the correlation between the amount of use and exposure time to the exposure.

Source: RV Chem Oy

CSA & ES in China, Japan and Korea

China	• 2008: Comprehensive chemical test standards, e.g. Chemicals - Test Method of Toxicokinetics Studies (GB/T 21750-2008), Chemicals - Test Method of In-Vivo Mammalian Erythrocyte Micronucleus (GB/T 21773-2008), Testing of Chemicals - Alga Growth Inhibition Test (GB/T 21805-2008
Japan	• Dec. 2008, Review Report of Public Consultation on the Revision of the Law on the Control of Examination and Manufacture of Chemical Substances (e.g. risk assessment on priority chemicals (優先評価化学物質)) • NEDO Comprehensive Chemical Substance Assessment and Management Program (Development of Chemical Risk Assessment, Preliminary Risk Assessment, Exposure Route Data Sheets) • Japan Challenge Program
Korea	• Feb. 2009: Chemical Release and Transfer Survey in Life Cycle (Ministry of the Environment) • Feb. 2009: Development and Operation of Chemical Test Data Search System (Ministry of the Environment) • Jan. 2009: Exposure Scenario Development (Korea Institute of Industrial Technology) • Jun. 2008: Chemical Information Exchange System in Supply Chain (Ministry of the Environment) • Feb. 2008: Guidance on the Development of Integrated Exposure Assessment (Ministry of the Environment)

Thank you.

구주산업환경협의회
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