Olefins and Chemical Regulation in Europe: REACH

5th November 2014 - Austin, Texas

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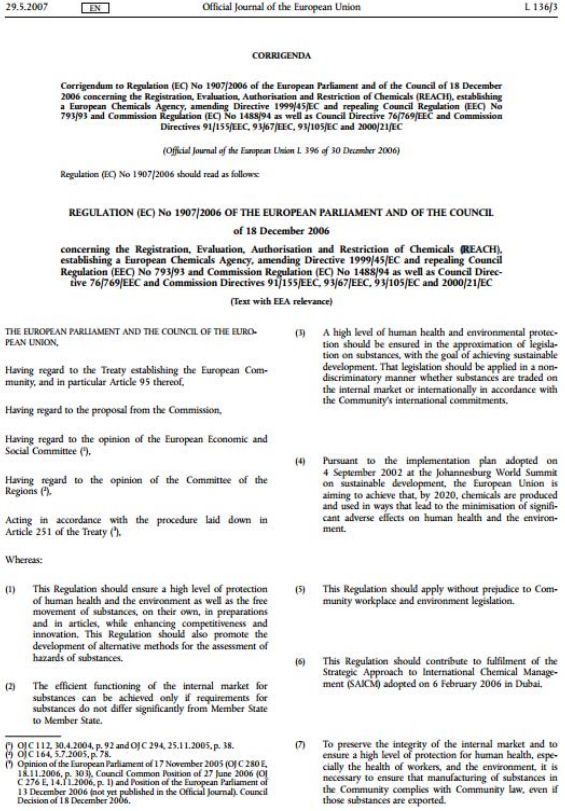
Slides Prepared for the 2014 Symposium on Understanding the Health Risks of Lower Olefins

Presentation Outline

- REACH Basic Process
- Formation of the Lower Olefins and Aromatics Reach Consortium and activities
  - Example: 1,3-Butadiene
- Post registration activities and outlook

REACH Overview

- REACH – 18th December 2006
- Replaced a number of other legal instruments
- Amongst the longest and most complex EU Regulations
- Extensive guidance proposed
  - Not immediately available for some aspects
- Formation of new European Chemicals Agency (ECHA)



29.5.2007 EN Official Journal of the European Union L 136/3

CORRIGENDA

Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

(Official Journal of the European Union L 396 of 30 December 2006)

Regulation (EC) No 1907/2006 should read as follows:

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 December 2006

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Having regard to the opinion of the Committee of the Regions (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.

(2) The efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State.

(3) A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development. That legislation should be applied in a non-discriminatory manner whether substances are traded on the internal market or internationally in accordance with the Community's international commitments.

(4) Pursuant to the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, the European Union is aiming to achieve that, by 2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment.

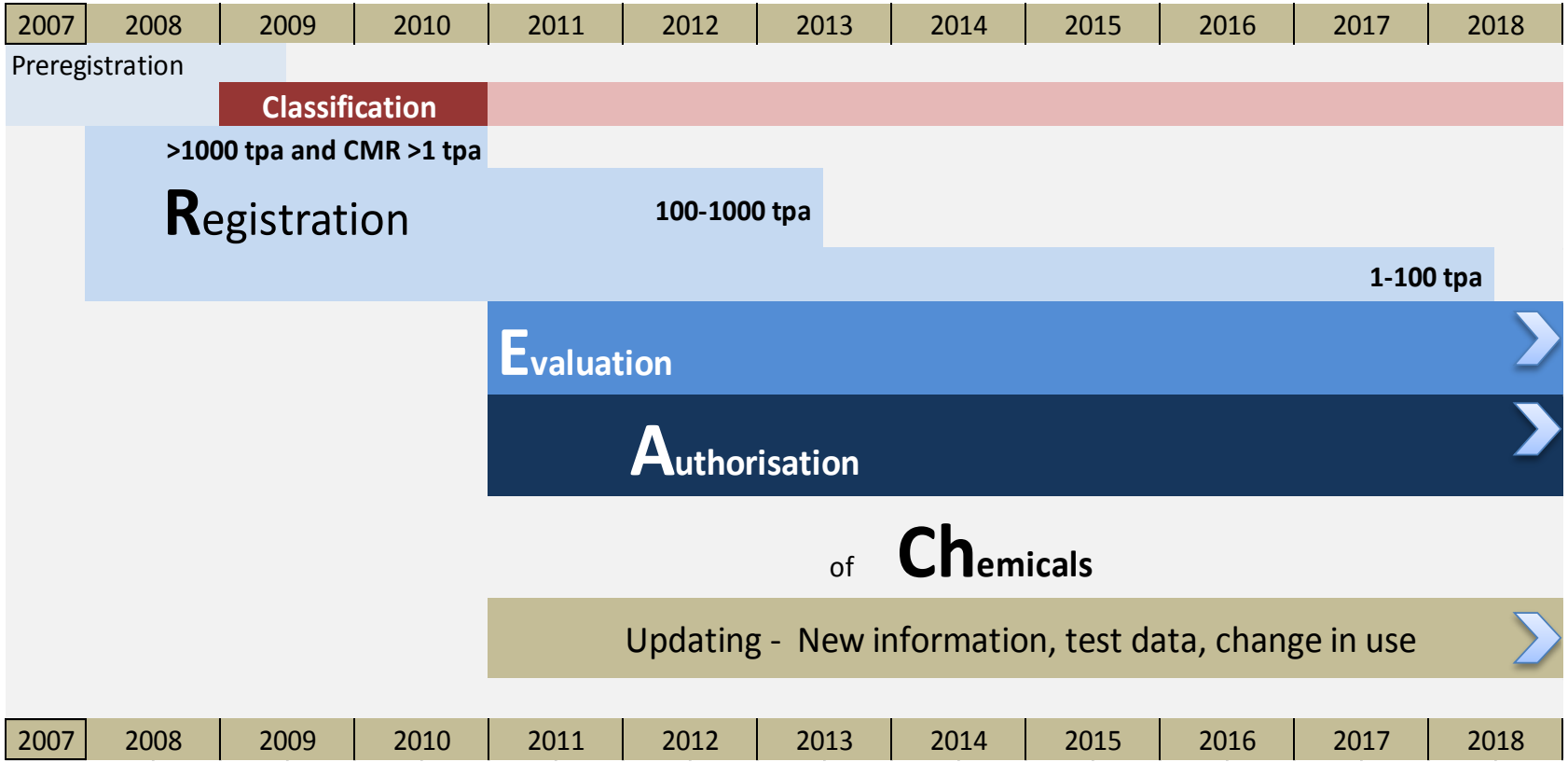
(5) This Regulation should apply without prejudice to Community workplace and environment legislation.

(6) This Regulation should contribute to fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.

(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that manufacturing of substances in the Community complies with Community law, even if those substances are exported.

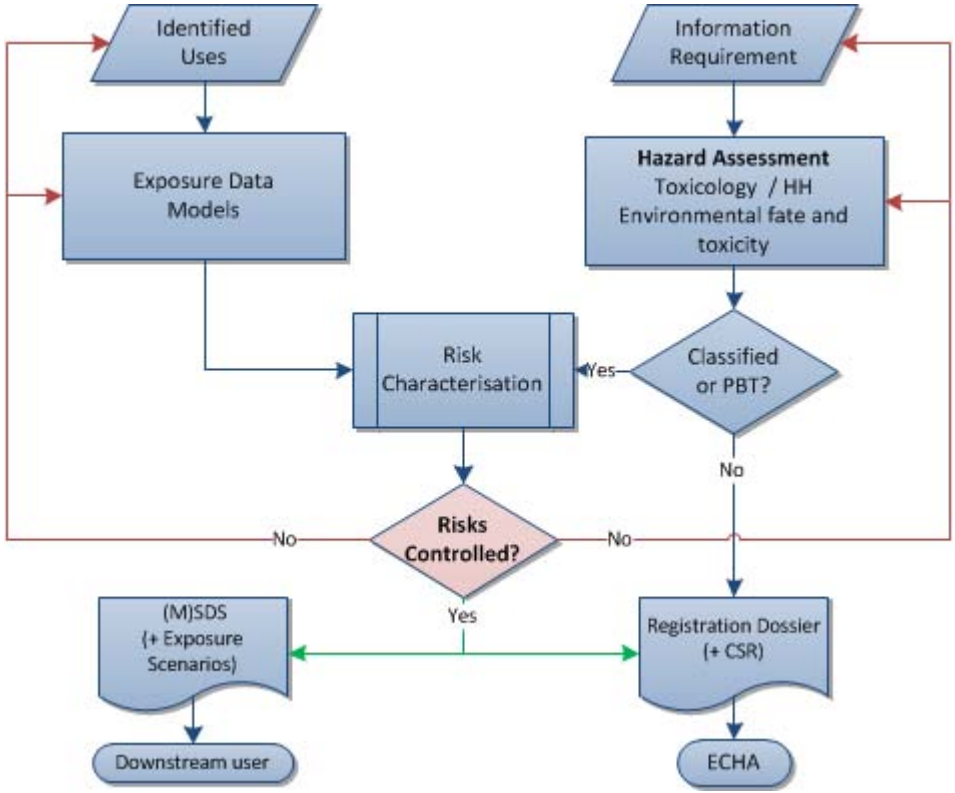
(1) OJ C 112, 30.4.2004, p. 92 and OJ C 294, 25.11.2005, p. 38.
(2) OJ C 164, 5.7.2005, p. 78.
(3) Opinion of the European Parliament of 17 November 2005 (OJ C 280 E, 18.11.2006, p. 303), Council Common Position of 27 June 2006 (OJ C 276 E, 14.11.2006, p. 1) and Position of the European Parliament of 13 December 2006 (not yet published in the Official Journal). Council Decision of 18 December 2006.

REACH Basics 1



*CMR = substances >1 tpa classified carcinogen, mutagen or reprotox. cat. 1A or 1B (EU GHS)

Process Towards REACH Registration - per Substance



Substance Types and Information requirements

	Information Requirement by Annex*			
Tonnage band	1-10 tpa	10-100	100-1000	>1000
Substance	VII	+ VIII	+ IX	+ X
Non Isolated Intermediate				
On-site Intermediate	Available information			
Transported Intermediate	Available information			VII
Monomer	VII	+ VIII	+ IX	+ X
Polymer				

* + Annex 3

REACH Information Requirements …. Toxicology

	Provide data		Test proposal if no data	
TOXICOLOGICAL INFORMATION - by Annex	**VII**	**VIII**	**IX**	**X**
Skin irritation/corrosion- in vitro	X			
Skin irritation – in vivo		X		
Eye irritation – in vitro	X			
Eye irritation – in vivo		X		
Skin sensitisation	X			
in vitro gene mutation study in bacteria	X			
in vitro cytogenicity study in mammalian cells	(X)	X		
in vitro gene mutation study in mammalian cells	(X)	X		
in vivo mutagenicity studies	(X)	(X)	(XX)	(XX)
Acute oral toxicity or		X		
Acute inhalation toxicity or				
Acute dermal toxicity				
Short-term repeated dose toxicity study (28 days)		X	XX	
Sub-chronic toxicity study (90 days) (408)		(XX)	XX	
Long term toxicity study (≥ 12 months)				[XX]
further studies		(XX)	(XX)	(XX)
Screening for reproductive/developmental toxicity (422)		X		
Developmental toxicity study (414)		(X)	XX	
Two-generation reproduction toxicity study (416)		(XX)	(XX)	XX
Assessment of toxicokinetic … derived from.. available information				
Carcinogenicity				[XX]

Mandatory requirement

X study shall be conducted, unless ….
(X) study shall be considered, if ….
XX study shall be proposed, unless ….
(XX) study shall be proposed, if …./in case of …
[XX] study may be proposed, if ….

Ways To Meet the Information Requirements

- **Current Data - Reports / publications**
- **Annex XI – Adaptation of the Annexes**
  1. **Testing does not appear scientifically necessary**
     - **1.1. Use of existing data**
       - **1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the test methods referred to in**
       - **1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3)**
       - **1.1.3. Historical human data**
     - **1.2. Weight of evidence**
     - **1.3. Qualitative or Quantitative structure-activity relationship ((Q)SAR)**
     - **1.4. *In vitro* methods**
     - **1.5. Grouping of substances and read-across approach**
  2. **Testing is technically not possible**
  3. **Substance-tailored exposure-driven testing**
- **Testing Proposals**

DNELs, DMELs and PNECs

- **Derived No Effect Level**
  - Level of exposure above which humans should not be exposed
    - Based upon dose descriptor from studies
    - Application of an assessment factor with justification
      - Sources: ECETOC, ECHA guidance
    - Derived for different populations - worker, general population
- **Derived Minimal Effect Level**
  - Reference risk level which is considered to be of very low concern for certain exposure scenarios
  - For non threshold modes of action or where the threshold cannot be determined
- **Potential No Effect Concentration (Environment)**
  - Experimental data or QSAR
    - Application of an assessment factor with justification

REACH Basics 2

- Requires reporting of Uses as well as Intrinsic Hazard
- Risk characterisation for substances that are
  - Dangerous
    - Classified under the Classification, Labelling and Packaging Regulation (EU GHS)
- All dossiers submitted via REACH IT
  - Format IUCLID 5 INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE
    - Proprietary software managed by ECHA

Impact on Industry

- Concept of *'No data, no market'*
  - *License to operate in the EU*
- Large amount of information to collate in a short timescale
- Resources limited within many companies
- Obligation to cooperate to minimise animal testing
- Complex data sharing agreements required with co-producers / importers

Impact on Industry

- **Seen as significant challenge for Olefins and Aromatics**
  - **Many data rich substances with history of regulatory dialogue**
  - **Many complex production streams of unknown / variable composition**
- **17 Member companies of Cefic Lower Olefins Sector Group and Aromatics Producers Association**
  - **Agreed to form consortium to ensure industry meets challenge**
  - **February 2008, call for tender to set up and run consortium**

Lower Olefins and Aromatics REACH Consortium

- **Consortium Contract signed by all Members**
  - **Defines Legal framework for cooperation**
    - **Purpose: "The Members undertake to cooperate and share human and financial resources in order to comply with the requirements of the REACH Regulation"**
    - **Method of working - Allocation of Authorities - Committees**
    - **Operating rules**
    - **Financial and Compensation rules**
    - **Relationship with Producers / importers who do not join**
- **Financed by subscription**

Basis of Categories

- **Structural similarity and physical-chemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern - may be considered as a group, or 'category'**
  - Common functional group(s)
  - A common mode or mechanism of action
  - Common constituents or chemical classes, similar carbon range numbers
  - The likelihood of common precursors and/or breakdown products via physical or biological processes that result in structurally similar chemicals (e.g., the "metabolic pathway approach" examining related chemicals such as acid/ester/salt)
- **Document basis for read across in "Category Justification Document"**
  - Category hypothesis - why it applies to the various endpoints points given
  - Applicability domain - based upon structural / compositional information
  - Category Members
- **LOA – defined 13 categories with > 100 substances**

LOA >135 Substances under Management

Substances
1,2,4-trimethylbenzene
1,3,5-trimethylbenzene (Mesitylene)
1,3-butadiene
2,4,4 trimethylpent-1-ene
2,4,4-Trimethylpentene
2-Butene
2-methylbut-2-ene
2-methylbutene (Isoamylene)
2-Methylpropene (Isobutene)
3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-indene
Acetylene
Benzene
But-1-ene
buta-1,2-diene
Butene
Cyclohexane
Cyclopentene
DCPD (3a,4,7,7a-tetrahydro-4,7-methanoindene)
Ethylene
Isooctene
Isoprene
m-xylene
o-xylene
propene
p-xylene
Toluene

Categories	Number of Substances
Aliphatics C5 & higher	6
Butylene Oligomers	11
C4, low 1,3-butadiene (<0.1%)	4
C4, high 1,3-butadiene (>=0.1%)	5
C5 non-cyclics	5
Fuel Oils	12
High Benzene Naphthas	26
Low Benzene Naphthas	6
Other Petroleum Gases*	8
Resin Oils & Cyclic Dienes	8
Resin Oils & Cyclic Dienes (DCPD-rich)	8
Xylenes	5
Petroleum Gases	5

Categories - used for data sharing between substances with similar intrinsic properties. However, each substance needs to be registered and managed separately.

* Category managed by LOA for joint CONCAWE / LOA interests. Total number of substances 45

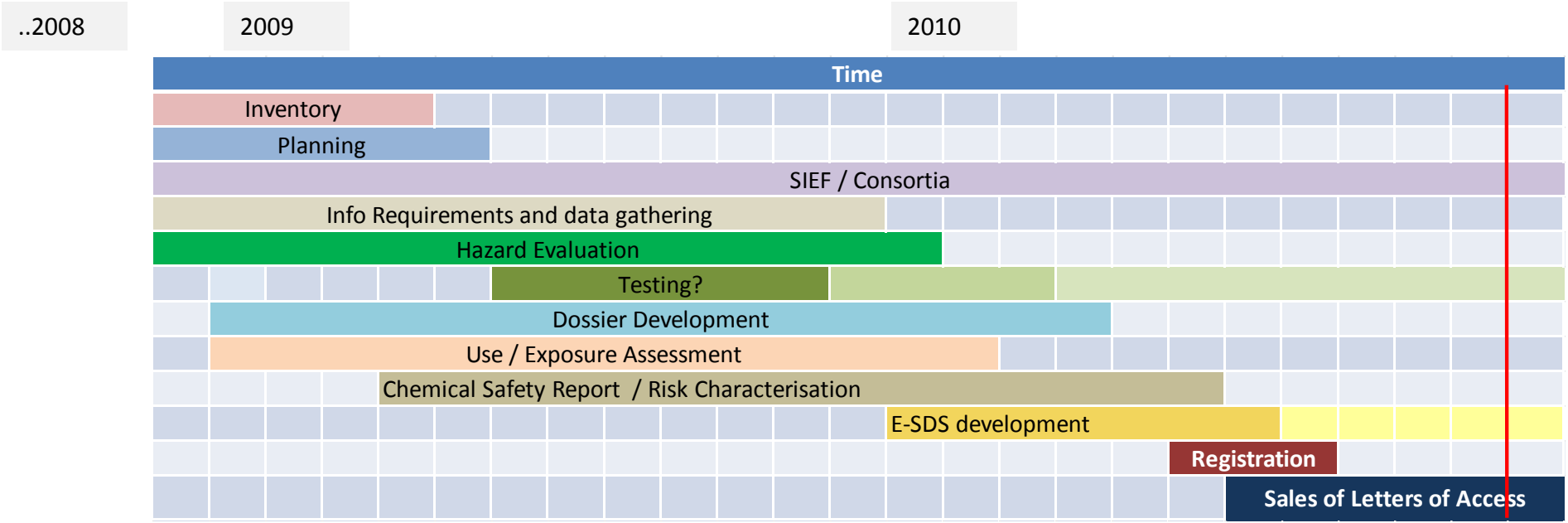
Scope of Activities

- **Technical**
  - Dossier development within Consortium and maintenance
    - Agreed positions for each substance
- **Operational**
  - Management of all those who want to register a substance
    - Substance Information Exchange Fora
      - E.g. 1550 with an interest in ethylene - 400 active
  - Data rights management for proprietary data
    - Who owns what, who pays whom for every study
  - Contractual systems
    - Co-registrant contracts
    - Payments for Letters of Access
  - Financial management
    - Tax position
  - Specialised IT systems to do the work efficiently

52 Consortium Members 2014

Arsol Aromatics GmbH
Asahi Kasei Chemicals Corporation
Braskem SA
BASF SE
Borealis AG
BP Europa SE
Cepsa Quimica S.A.
Chevron Phillips Chemicals International NV
China National Petroleum Corporation
Deutsche BP AG
Dow Europe GmbH
Eastman Chemical BV
Evonik Oxeno GmbH
ExxonMobil Petroleum & Chemical BVBA
Gazprom Marketing & Trading France SAS (for Gazprom)
Gazprom Marketing & Trading France SAS (for Sibur)
Glencore Energy UK Ltd
Goodyear Tire & Rubber Company
Hellenic Petroleum SA
Ineos Europe Ltd
Infineum UK Ltd
InterChem Logistics BV
JSR Corporation
JX Nippon Oil & Energy Corporation
Kolon Industries Inc.
Kuraray Europe GmbH
LG Chem Ltd
Lukoil Neftochim Bourgas AD
LyondellBasell Industries
Maruzen Petrochemical Co., Ltd
Mitsubishi Chemical Corporation
Mitsui Chemicals, Inc.
MOL Hungarian Oil & Gas Public Company Limited
OMV AG
Oy Nizhex Scandinavia Ltd
Petkim Petrokimya Holding A.S.
Petrochemia - Blachownia SA
Petrogal SA
Phillips 66 Ltd
PKN ORLEN S.A.
Rabigh Refining and Petrochemical Company
Repsol Química
Rütgers Chemicals GmbH (VFT)
Sabic Petrochemicals BV
Shell Chemicals Europe BV
Sinopec Europa Handels GmbH
Sumitomo Chemical Co., Ltd.
Synthos Dwory Sp. z o.o.
Total Petrochemicals & Refining (Total Research & Technology Feluy)
TPC Group
Versalis
Zeon Corporation

Inception to First Registration



Example 1,3-Butadiene

- **All available date collated**
  - Intrinsic properties – tox, env and physchem
  - Information on use and tonnage
- **Information requirements - for Annex X (> 1000tpa)**
  - Met by existing data in publications and reports
  - Waived reproductive toxicity requirement as the substance is a genotoxic carcinogen and germ cell mutagen
    - Annex IX Column 2 adaptation
  - Data scored for quality and for purpose entered into IUCLID - Robust Study Summaries
  - Endpoint study summaries developed
- **Data rights tracked**
  - Contracts developed to acquire data rights for information not in the public domain
    - Compensation agreed
- **Classified (EU GHS) as a Category 1A Carcinogen**
  - Risk Characterisation required

1,3-Budiene DNEL / DMEL – Workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	**Systemic effects - Long-term**	**DMEL (Derived Minimum Effect Level): 2.21 mg/m³ (1 ppm)**	**carcinogenicity (by inhalation)**

DMEL basis

Systemic long term - Cox regression model for leukaemia reported by Cheng et al (2007)

Model can be adapted to account for high intensity tasks and other exposure covariates described by Sielken et al. (2007) and Sielken & Valdez-Flores (2013)

Exposure of workers (40 years) to the DMEL of 2.21 mg/m3 (1 ppm), results in a risk estimate for excess leukaemia deaths (all cell types combined) of or less than 4 in 100,000

Inhalation	Systemic effects - Acute	No hazard identified	
Inhalation	Local effects - Long-term	No hazard identified	
Inhalation	Local effects - Acute	No hazard identified	
Dermal	Systemic effects - Long-term	No hazard identified	
Dermal	Systemic effects - Acute	No hazard identified	
Dermal	Local effects - Long-term	No hazard identified	
Dermal	Local effects - Acute	No hazard identified	
Oral	Systemic effects - Long-term	No hazard identified	

DNEL cannot be derived as no LOAEL or NOAEL can be determined due to absence of adverse effects relevant to humans

1,3-Budiene DNEL / DMEL – General Population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	**Systemic effects - Long-term**	**DMEL (Derived Minimum Effect Level): 0.265 mg/m³ (0.12 ppm)**	**carcinogenicity (by inhalation)**

DMEL basis

Systemic long term - Cox regression model for leukaemia reported by Cheng et al (2007)

Model can be adapted to account for high intensity tasks and other exposure covariates described by Sielken et al. (2007) and Sielken & Valdez-Flores (2013)

Exposure of general population (lifetime) to the DMEL of 0.265 mg/m3 (0.12 ppm), results in a risk estimate for excess leukaemia deaths (all cell types combined) of or less than 1 in 100,000

Inhalation	Systemic effects - Acute	No hazard identified	
Inhalation	Local effects - Long-term	No hazard identified	
Inhalation	Local effects - Acute	No hazard identified	
Dermal	Systemic effects - Long-term	No hazard identified	
Dermal	Systemic effects - Acute	No hazard identified	
Dermal	Local effects - Long-term	No hazard identified	
Dermal	Local effects - Acute	No hazard identified	
Oral	Systemic effects - Long-term	No hazard identified	

DNEL cannot be derived as no LOAEL or NOAEL can be determined due to absence of adverse effects relevant to humans

Butadiene Uses / Exposure Scenarios

Exposure scenarios	Tonnage (tonnes per year) used for env assessment
Manufacture - Manufacture	**5,000,000**
Contributing scenarios **(example)** - General exposures (closed systems) [CS15]. (PROC 1) - General exposures (closed systems) [CS15]. With sample collection [CS56]. With occasional controlled exposure [CS137] (PROC 2) - General exposures (closed systems) [CS15]. Use in contained batch processes [CS37]. (PROC 3) - Process sampling [CS2]. (PROC 8b) - Laboratory activities [CS36]. (PROC 15) - Bulk transfers [CS14]. (open systems) [CS108]. With potential for aerosol generation [CS138]. (PROC 8b) - Bulk transfers [CS14]. (closed systems) [CS107] (PROC 8b) - Equipment cleaning and maintenance [CS39]. (PROC 8a) - Storage [CS67]. With occasional controlled exposure [CS137] (PROC 2)	
Formulation - Formulation	750,000
Use at industrial site - Intermediate use of the substance	250,000
Use at industrial site - Distribution	5,000,000
Use at industrial site - Uses in Rubber production and processing	3,000,000
Use at industrial site - Use as laboratory reagents	1000
Use at industrial site - Use as a fuel	500,000
Use at industrial site - Polymer Production	1,000,000
Use at industrial site - Polymer Processing	250,000
Use by professional worker - Polymer Processing	25,000

Risk Characterisation

- **For each Exposure scenario / contribution scenario**
  - **Generation of exposure estimate detailing all assumptions**
    - **Human Health - TRA V3**
    - **Environmental - European Union System for the Evaluation of Substances (EUSES)**
  - **Calculation of Risk Characterisation Ratio**

$$\frac{\text{Exposure – measured or estimated}}{\text{DNEL, DMEL or PNEC}} = < 1$$

to demonstrate “Risks controlled”

Detail in Chemical Safety Report, append to REACH Dossier

Risk Characterisation Reporting - HH and Env

9.1.5. Worker contributing scenario 4: Process sampling [CS2]. (PROC 8b)

9.1.5.1. Conditions of use

	Method
Product (article) characteristics	
• Concentration of substance in mixture: Substance as such	TRA Worker v3
Amount used (or contained in articles), frequency and duration of use/exposure	
• Duration of activity: < 15 minutes	TRA Worker v3
Technical and organisational conditions and measures	
• General ventilation: Good general ventilation (3-5 air changes per hour)	TRA Worker v3
• Containment: Semi-closed process with occasional controlled exposure	TRA Worker v3
• Local exhaust ventilation: yes [Effectiveness Inhal: 95%] *For safe use to be achieved either the above LEV effectiveness needs to be in place or the following RMM is required: Sample via a closed loop or other system to avoid exposure [E8]*	TRA Worker v3
• Occupational Health and Safety Management System: Advanced	TRA Worker v3
• Obtaining samples from process plant: Sample via a closed loop or other system to avoid exposure [E8] [Effectiveness Inhal: 95%]	
Conditions and measures related to personal protection, hygiene and health evaluation	
• Respiratory Protection: No [Effectiveness Inhal: 0%]	TRA Worker v3
Other conditions affecting workers exposure	
• Place of use: Indoor	TRA Worker v3
• Process temperature (for liquid): <= 40 °C	TRA Worker v3

9.1.5.2. Exposure and risks for workers

The exposure concentrations and risk characterisation ratios (RCR) are reported in the following table.

Table 51. Exposure concentrations and risks for workers

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	**1.183 mg/m³** (TRA Worker v3)	Exposure/DMEL = 0.535 Qualitative risk characterisation (see below)

Conclusion on risk characterisation

If conditions detailed in Section 9.0.2.3 are adhered to risks are minimised and safe use has been achieved.

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the table below. This is the sum of the releases to the environments from all exposure scenarios addressed.

Table 180. Total releases to the environment per year from all life cycle stages:

Release route	Total releases per year
Water	5.465E6 kg/year
Air	2.591E7 kg/year
Soil	1.478E6 kg/year

10.2.1.2. Regional exposure

Environment

Risk characterisation is not required for environment.

Man via environment

The exposure to man via the environment from regional exposure and the related risk characterisation ratios are presented in the table below. The exposure concentration via inhalation is equal to the PEC air.

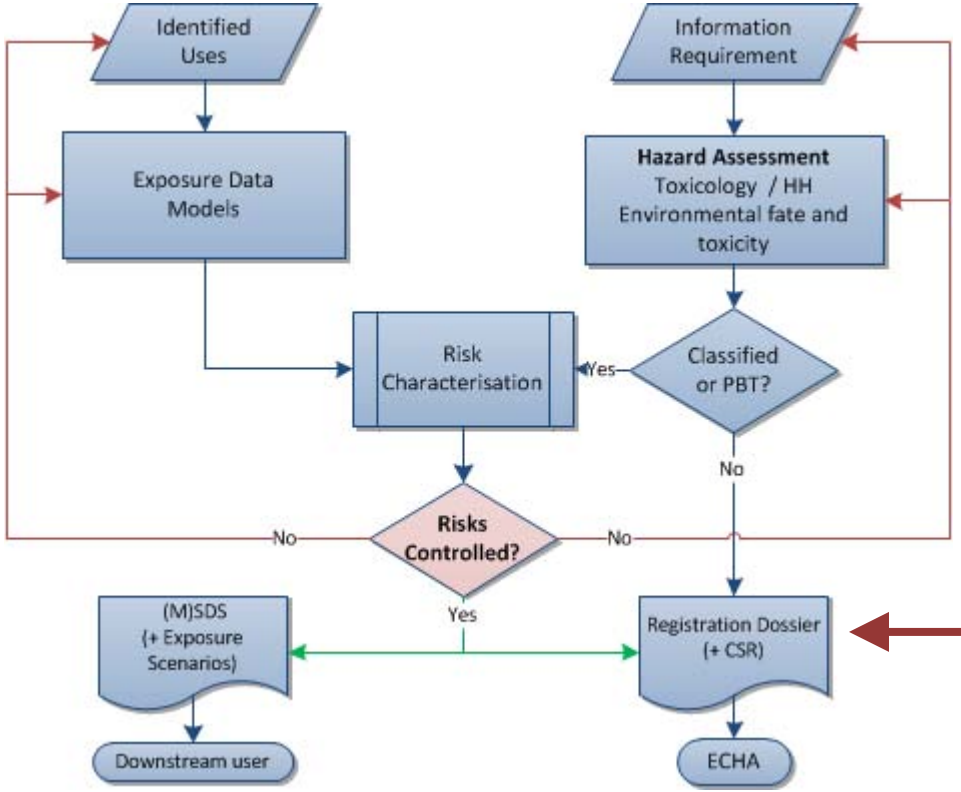
Table 181. Regional exposure to man via the environment

Route	Regional exposure	RCR
Inhalation	5.648E-5 mg/m³	< 0.01
Oral	2.708E-5 mg/kg bw/day	
Combined routes		< 0.01

10.2.2. Local exposure due to all wide dispersive uses

Not relevant as there are not several wide dispersive uses covered in this CSR.

Process Towards REACH Registration - per Substance



157 registrations using LOA dossier and CSR
- 44 from LOA members
- 103 from SIEF members

Evaluation of Registrations

- **ECHA**
  - Review of individual dossier / testing proposals
  - Draft and Final Decision letters to Registrants
    - Prescribed response time and process
  - Revised Guidance
  - ECHA Campaigns
    - Substance Identification
    - Specific endpoints targeted

Evaluation of Registrations

- Community Rolling Action Plan
  - Member State Evaluations on their priorities
  - 2014 - 1,3-Butadiene, Germany,
  - Reporting to ECHA and Member States Q1 2015
  - Prior to review LOA updated dossier with current information
    - Human health - SBR model
    - Exposure updated
      - Use of CHESAR instead of spreadsheets tools used in 2010
      - Refinement of operational conditions based on industry standards
      - Description for use of Risk Management Measures implemented as standard for the type of substance
      - Removal of non-applicable Process Categories (PROCs)
      - Use of published environmental data for some exposure scenarios

Post Registration Activities

- **REACH Requirement to keep the dossier up to date**
  - New data that affects the risk characterisation or classification
  - Change in use
    - New exposure scenarios
  - Classification changes
- **Changing REACH scene**
  - Revised Guidance
  - Revised Tools
    - IUCLID, Chesar
  - Changes in REACH IT
    - Business and dossier Checking rules

Outlook

- **ECHA will continue focus on dossier evaluations and "improvements"**
  - **"… agency capacity for concluding evaluations has more than doubled each year since 2009."**

    ECHA Executive Director – Feb 2014
- **LOA dossier updating programme to ensure LOA dossiers remain current and meet current and future registrants needs**