



# Chromium Trioxide Authorization Consortium CTAC

Challenge of a uniform, europe-wide, supply chain intergrated dossier

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# Authorization relevance & experience

- **Number of pre-registered substances: 140.000**
- **Number of registered substances: 7663** (30.000 registrants, 19.07.2012)
- **SVHC Candidates: 84** (7 publications; <http://echa.europa.eu/web/guest/candidate-list-table>)
- **Prioritization: 37** (4 publications, 14 Cr(VI)-compounds)
- **Annex XIV: 14** (2 publications, 4 phthalates, 3 chromate pigments, arsenic oxides etc...)

ECHA homepage lists 800 comments on the proposal of prioritization of Chromium Trioxide

Chromium Trioxide cannot be considered Intermediate for the surface treatment despite an (electro-)chemical reaction will lead to its complete transformation, because the result is not a substance, but a treated article (out of scope).

# REACH requirements: Registration vs. Authorization



	Registration	Authorization
Manufacturer / Importer	must	can
Only Representative	must	can
Formulator / Dealer	can not	can
Downstream User	can not	can
Article User	can not	can not
Association	can not	can not
Substances	one per dossier	several per application
Applications	several	one (or extra fee)
Filing Fee ("other")	31.000 €	> 50.000 €
Response time ECHA	21 days (90 days)	18 month
Objective	Safe use	Substitution
Technical Evaluation	After Registration	Before Authorization
<b>Conclusion</b>	<b>Defined</b>	<b>Unpredictably Complex</b>

# Chromium trioxide manufacture, supply & application

- Manufacture of Chromium Trioxide is a two-step process starting from chromite ore, with sodium dichromate as an intermediate

- 0 Manufacturers within Europe
- 10 Importers, who manufacture outside of Europe
- 20 Formulators for “Surface Treatment” solutions
- > 2000 Downstream Users, that do “Surface Treatment”
- Millions of Articles that use chrome plated or passivated parts

— Registration

— Value Generation



# Content issues

## Cr(VI) in 14 of 37 prioritised Substances

- Focus on Cr(VI); disproportionate considering volumes, exposure and existing regulations

## Cr(VI) is an issue of workplace safety; consumer not exposed

- Annex XIV not effective, it is a tool for substances
- Use workplace safety laws to improve level of protection
- Use article focussed tools to safeguard consumer

## Tolerable / Acceptable Exposure Limits

- Definition in RAR 2005 did not stop discussions
- Requirements below today's detection limit would need new test systems & time for collecting data

## Safety for investments and legal compliance

- Commitment and compromise from all parties as tool to reduce complexity of several thousand potential applications
- Value creation of several hundred billion €

# Challenges

Application fees  
can only be  
optimized by  
vertical integration

- Model calculation, 1000 platers, 20 formulators, 10 importers
  - **Integrated:** 10 importers 50.000, 20 formulators 40.000, 200 platers (not covered by grouped dossier for whatever reason) 25.000/40.000 => **7.800.000 €**
  - **Horizontal:** 1000 small & medium platers, 25.000/40.000 each => **32.500.000 €**
- => Complete supply chain needs to be integrated for effective Authorization**

AoA technical  
input

- Confidential & sensitive know how
- => Service provider without conflict of interest**

SEA representative  
numbers

- Definition of applications / grouping
- => Service provider with technical background**

Timeline

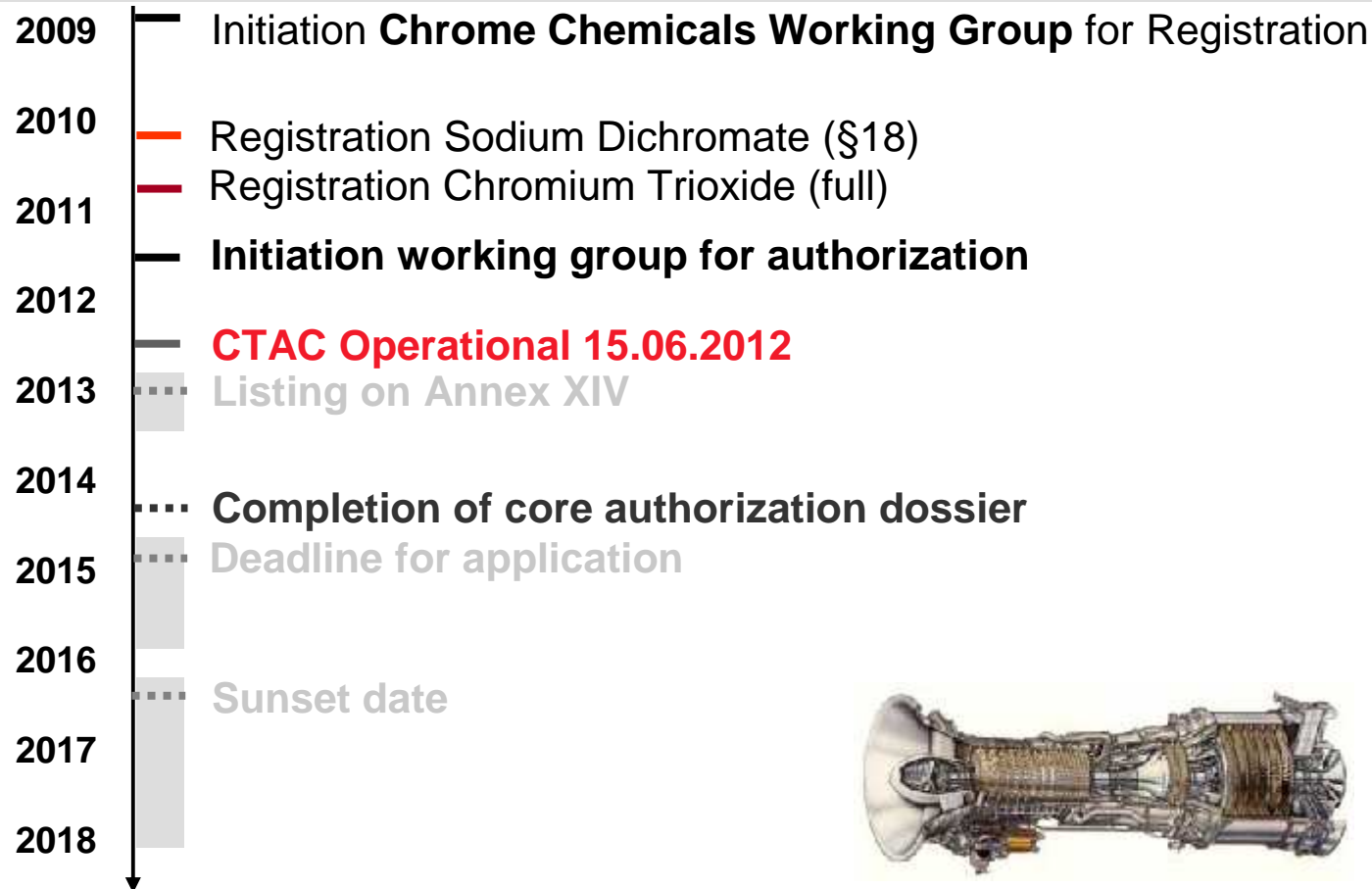
- Impossible task within minimum timeframe guaranteed by REACH
- => Accept financial risk to start preparation even before listing**



# Status of REACh process, industry actions

## Industry actions in registration and authorization

- **Two-Step process for creation of a consortium**
- **Pre-contract for feasibility study & to evaluate form and scope of cooperation; **completed****
- **Consortium contract published 15.01.2012; **signature period to 15.03. ; go-life 15.06. 2012****
- **Core Dossier to be completed six month before application deadline**



# Consortium framework

The Consortium will prepare authorization dossiers (for use by members) for to date the following six chromium trioxide uses:

- 1) Formulation of preparations
- 2) Functional chrome plating
- 3) Decorative plating
- 4) Other surface treatment **with** Chromium VI present on the end product (article)
- 5) Other surface treatment with **no** Chromium VI present at detection limit on the end product (article)
- 6) Small scale laboratory use



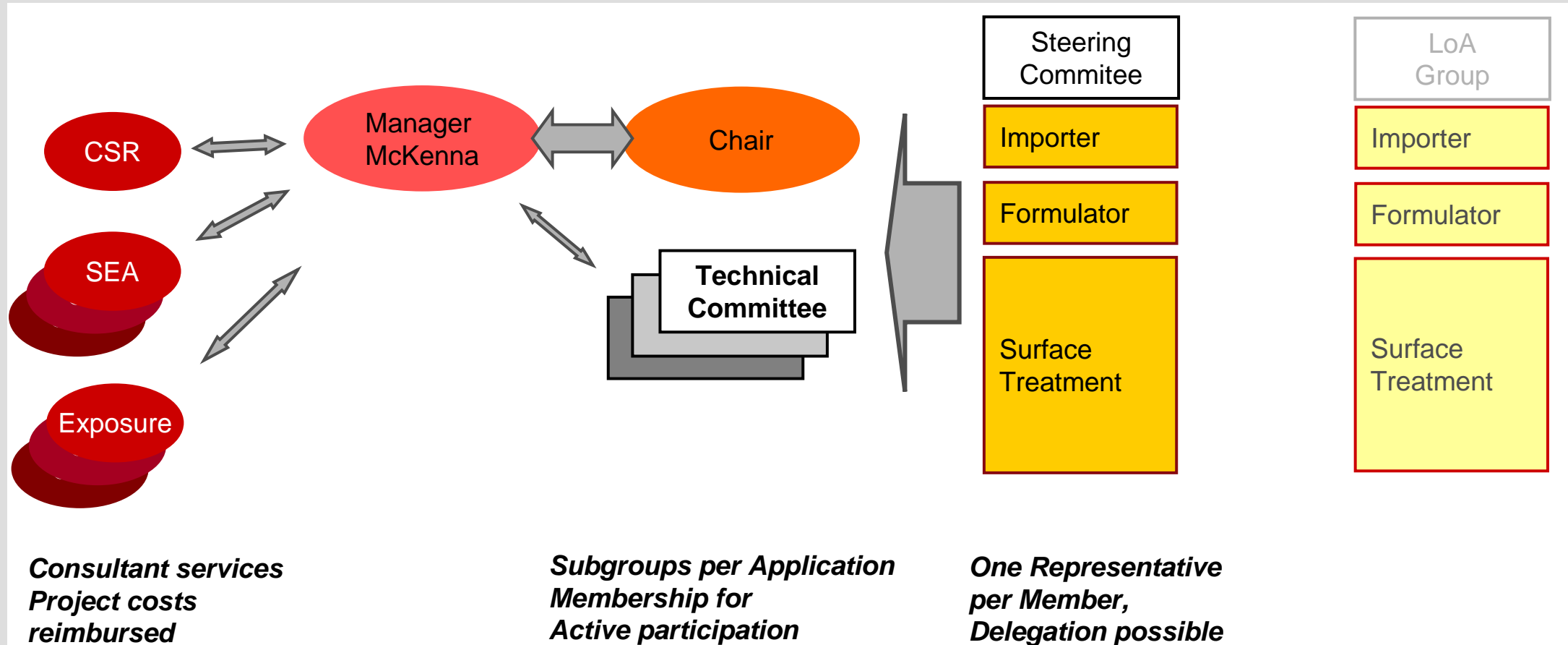
Consortium costs will be divided into common costs and costs per use. Larger companies will pay a higher share of costs than smaller companies

Any company that has not joined by June 15, 2012 may purchase a letter of access to their relevant dossier parts once the authorization dossier(s) will be ready (30 % additional charge)



# Consortium Structure

## Structure of the authorization consortium



# Conclusions

## Chromium Trioxide Authorization Consortium CTAC

- 154 active member companies
  - Representing Importers, Formulators and Downstream Users from all important European markets and sectors
- => Broad membership base guarantees representation and access to data**

## One Consortium

- One harmonized CSR
- One voice to ECHA, maximum representation & commitment

## Framework of Applications

- Reduction of complexity without loss of information quality
- Transferable to latecomers via LoA

## Dossier costs

- At 154 members estimated dossier costs reasonably diluted
- => Financial contribution transparent, fair, and bearable**



# Chrome Chemicals Working Group

Formed by chrome chemicals producers in 2008 to register high volume chrome chemicals;

Registrations submitted by 30.11.2010:

- Chromium trioxide
  - Sodium dichromate
  - Potassium dichromate
  - Basic chromium sulfate
  - Chromium(III) oxide
- } grouping, read-across approach for studies

Scope of registration is responsibility of each registrant (Intermediate / Uses)

4 working group members + 24 LoA for Cr(VI) Dossier

# Chromium trioxide prerequisites for safe use

**Workplace surveillance:**

**OEL 10  $\mu\text{g}/\text{m}^3$  Cr(VI)**

=> Proc 7 (industrial spraying) & Proc 11 (non-industrial spraying) not cleared

PPE to eliminate dermal contact;

No emission into the environment (waste air scrubber; water and solid waste reductive pre-treatment to Cr(III) + deposition)

No exposure of consumers via articles (No bio-available Cr(VI) in article)

=> **Uses advised against:** Any private use, professional use except for education / university

# Contract details

The Consortium is open to any legal identity that can apply for authorization: Manufacturer, Importer, Formulator, Dealer, Downstream User, Only Representative

- Membership includes all “affiliates”
- Initial signature Period 15.01. to 15.03.2012, indication of applications and company size
- Cool down-period to 15.06. 2012 => application decision can be revised \*
- Initial Payment period to 15.05. 2012
- Withdrawal clause: end of calendar year at 6 month notice, not before 31.12.2013
- Non payment can lead to expulsion
- Cost and Voting Key according to EU definition of Micro/Small/Medium/Large Company

\* *Kick-off meeting decision to re-open for latecomers until 15.06.2012*

# Financial details

Consortium costs will be divided into common costs and costs per use. Larger companies will pay a higher share of costs than smaller companies

- Cost / Vote Key (§ 11) => 1/2/3/4 shares for Micro/Small/Medium/Large enterprise
- Distribution Key (Annex 1 Part 2): Common costs, cost per application, individual
- Internal costs and costs for delegates will not be refunded
- Project work and existing data value can be refunded
- LoA Cost: (Dossier cost / number of founding members) + 30 %; refund only to founding members;

Budget estimate of **2,0 mio €** for preparation of one core and six application dossier.

*At 150 members, 50/50 common/application cost, even distribution between applications:*

=> **Micro-share <4.000 €; Large share 15.000 – 20.000 € spread over three years.**