Regulatory Requirements for Chemicals within a Global Market

Technical Committee of Petroleum Additive Manufacturers in Europe
For today no alarm planned.
Reminder: Anti-competition laws

As we have guests, which are direct competitors, we do not talk about:

• Any volumes
• Any prices
• Any strategic business decisions

Please limit your discussion to points related to Regulatory Requirements for Chemicals within a Global Market.
# Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>Welcome and Introduction</td>
<td>ATIEL and ATC</td>
</tr>
<tr>
<td>09:15</td>
<td>Regulatory Compliance for Chemicals on the Global Markets</td>
<td>ATIEL</td>
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<tr>
<td>10:00</td>
<td>OEM view and specific challenges</td>
<td>ACEA</td>
</tr>
<tr>
<td>10:45</td>
<td>Morning Coffee</td>
<td></td>
</tr>
<tr>
<td>11:00</td>
<td>Inventory compliance for existing chemicals and dual CAS issue</td>
<td>ATC</td>
</tr>
<tr>
<td>11:45</td>
<td>Inventory compliance for new chemistry</td>
<td>ATC</td>
</tr>
<tr>
<td>12:30</td>
<td>Lunch</td>
<td>ATC</td>
</tr>
<tr>
<td>13:30</td>
<td>Data communication in the supply chain, approaches of regulatory compliance for OEMs, tier 1 &amp; tier 2 suppliers</td>
<td>ATIEL</td>
</tr>
<tr>
<td>14:30</td>
<td>Afternoon Coffee</td>
<td></td>
</tr>
<tr>
<td>14:45</td>
<td>Qs &amp; As</td>
<td>All</td>
</tr>
<tr>
<td>15:45</td>
<td>Closing remarks</td>
<td></td>
</tr>
<tr>
<td>16:00</td>
<td>Close</td>
<td></td>
</tr>
</tbody>
</table>
Thanks for your attention!
Regulatory Compliance for Chemicals on the Global Markets

Sabine Hausmann
Head of Global EH&S, FUCHS Petrolub SE
Overview

(1) Welcome and Introduction
(2) From Substance to Lubricant
(3) The Regulatory Landscape
(4) Regulatory Compliance of Existing and New Chemicals
(5) Communication in the Supply Chain vs. Protection of CBI
(6) Outlook and Next Steps
Welcome & Introduction

- The volume of the lubricant market in 2018 reached nearly 30 Mio. Tons globally
- The Automotive Industry is the most important customer
- Global availability of the products is mandatory
- Global Regulatory Compliance is of vital importance

Source: UEIL
Welcome & Introduction

- Chemical Products are subject to numerous Regulatory Requirements
- The Regulatory Landscape for Chemicals is rapidly changing
- To ensure Global Regulatory Compliance for Chemicals Products has become quite complex
- Communication of regulatory information within the supply chain has become very important
Welcome & Introduction

We would like to improve the communication in our supply chain and the mutual understanding of the different requirements. Therefore we would like to invite you to an open discussion on

• what needs to be improved and
• how can we achieve it
From Substance to Lubricant
A finished lubricant is a formulation of various additive packages in a base fluid:
- Mineral Oil
- Synthetic Oil

Typical Additives are:
- Antioxidants
- Viscosity Modifiers
- Pourpoint Depressants
- Detergents / Dispersants
- Antiwear and Extreme Pressure Additives
- Friction Modifiers
- Corrosion Inhibitors

It can easily contain >3 different additives and >15 substances.
Chemical Inventories and Registration Schemes for Chemicals are Substance related.

In general, the Manufacturer of a Substance registers the substance in the relevant inventories.

To protect companies Intellectual Property, the complete composition of an Additive is typically not disclosed to the Formulator of a Lubricant.

In general, Lubricant Manufacturers collect regulatory information on Additive Level, in exceptional cases on substance level.
The Regulatory Landscape
Important Regulatory Requirements

- CWC: Chemical Weapon Convention
- PIC: Rotterdam Convention
- GHS: Globally Harmonized System
- DUAL –USE: Wassenaar Arrangement
- Embargo Regulations
- New Substance Registrations
- Chemical Inventories
- Restrictions & Prohibitions
- Biocidal Regulations
The Global Harmonized System (GHS)

- In 1992 the UN Conference on Environment and Development (UNCED) agreed upon the Agenda 21

- Chapter 19 is dealing with the Management of Toxic Chemicals and contains 6 Program Areas:
  
  (a) Expanding and accelerating international assessment of chemical risks;
  (b) Harmonization of classification and labelling of chemicals;
  (c) Information exchange on toxic chemicals and chemical risks;
  (d) Establishment of risk reduction programs;
  (e) Strengthening of national capabilities and capacities for management of chemicals;
  (f) Prevention of illegal international traffic in toxic and dangerous products

- This was the political mandate for the development of GHS
The Global Harmonized System (GHS)

- The GHS only is a recommendation
- Needs to be adopted into the national or regional legislation
- When adopting GHS, countries also often establish a Chemical Inventory
- Or existing Chemical Inventories are being revised
- That is the reason, why we see so many new Inventories and new legal requirements coming up
GHS and Inventories – current Status

- DSL / NDSL
- TSCA Reform
- EU REACH
- KKDİK (Turkey REACH)
- EAEU (GOST-Standards)
- IECSC
- KECl & K-REACH
- ENCS (METI) & ISHL
- TSCI
- PICCS
- VNECI
- AICS (NICNAS Reform)
- NZIoC

GHS Implemented | GHS in Progress | No info available
Regulatory Compliance of Existing and New Chemicals
Chemical Inventories

- The different Inventories were established at different times – some were established > 40 years ago
- The requirements / definitions of the different inventories are quite different
- It is possible that the same substance has been registered under different names / identifiers in the different inventories

<table>
<thead>
<tr>
<th>Chemical Inventory</th>
<th>Established Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>ENCS (Japan)</td>
<td>1973</td>
</tr>
<tr>
<td>TSCA (USA)</td>
<td>1976</td>
</tr>
<tr>
<td>EINECS (EU)</td>
<td>1981</td>
</tr>
<tr>
<td>ELINCS (EU)</td>
<td>1981</td>
</tr>
<tr>
<td>NLP (EU)</td>
<td>1993</td>
</tr>
<tr>
<td>NICNAS (Australia)</td>
<td>1990</td>
</tr>
<tr>
<td>DSL / NDSL (Canada)</td>
<td>1991</td>
</tr>
<tr>
<td>KECI (Korea)</td>
<td>1991</td>
</tr>
<tr>
<td>PICCS (Philippines)</td>
<td>1998</td>
</tr>
<tr>
<td>NZIoC (New Zealand)</td>
<td>2001</td>
</tr>
<tr>
<td>IECSC (China)</td>
<td>2012</td>
</tr>
<tr>
<td>TSCI (Taiwan)</td>
<td>2014</td>
</tr>
</tbody>
</table>
**Same Substance – different Identifiers**

- Under EU REACH many substances were registered under new identifiers
- In other Inventories the old CAS-No is still in use:

<table>
<thead>
<tr>
<th>Substance Type</th>
<th>Description</th>
<th>CAS-No</th>
<th>New CAS-No</th>
<th>Identification</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9-14 Aliphatics (2-25% aromatics)</td>
<td>Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)</td>
<td>927-344-2</td>
<td>64742-82-1</td>
<td>Naphtha (petroleum), hydrodesulfurized heavy</td>
</tr>
<tr>
<td>C9-14 Aliphatics (2-25% aromatics)</td>
<td>Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)</td>
<td>919-164-8</td>
<td>64742-82-1</td>
<td>Naphtha (petroleum), hydrodesulfurized heavy</td>
</tr>
<tr>
<td>C9-14 Aliphatics (2-25% aromatics)</td>
<td>Hydrocarbons, C8-12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)</td>
<td>928-136-4</td>
<td>64742-82-1</td>
<td>Naphtha (petroleum), hydrodesulfurized heavy; Low boiling point hydrogen treated naphtha</td>
</tr>
<tr>
<td>C9-14 Aliphatics (2-25% aromatics)</td>
<td>Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)</td>
<td>919-446-0</td>
<td>64742-82-1</td>
<td>Naphtha (petroleum), hydrodesulfurized heavy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>64742-88-7</td>
<td>Solvent naphtha (petroleum), medium aliphatic</td>
</tr>
</tbody>
</table>
Same Substance – different Identifiers
Example: Lithium 12-Hydroxystearate (Grease Thickener)

• Greases are oils, contained in a “chemical sponge”
• The “chemical sponge” is formed by a metal soap of fatty acid which acts as a dispersant (Grease Thickener)
• The Thickener is typically manufactured in-situ during the manufacturing process
Same Substance – different Identifiers
Example: Lithium 12-Hydroxystearate (Grease Thickener)

Starting Materials of the reaction:

- Li-Hydroxide
- Hydrogenated Castor Oil (HCO; CAS: 8001-78-3)
  Triglyceride – Ester of Glycerol with the saturated, hydroxylated 12-hydroxy, 9-octadecanoic acid, known as 12-Hydroxystearic acid

OR

- 12-Hydroxystearic acid (12-HSA; CAS: 106-14-9)
The Reaction Product can be described as:

- Lithium 12-Hydroxystearate (CAS: 7620-77-1)
- Castor Oil, hydrogenated, lithium salt (CAS: 64754-95-6)
- Fatty acids, castor-oil, hydrogenated, lithium salts (CAS: 68604-46-6)

Saponification Reaction:

$$3 \times \text{LiOH} + 1 \times \text{HCO} = 3 \times \text{Lithium-12-HS} + \text{Glycerol}$$

$$1 \times \text{LiOH} + 1 \times \text{12-HSA} = 1 \times \text{Lithium-12-HS} + \text{H}_2\text{O}$$

Water and Glycerol evaporate, due to high temperatures.

The Reaction Product can be described as:

- Lithium 12-Hydroxystearate (CAS: 7620-77-1)
- Castor Oil, hydrogenated, lithium salt (CAS: 64754-95-6)
- Fatty acids, castor-oil, hydrogenated, lithium salts (CAS: 68604-46-6)
New Substance Notifications

- Definitions of “New Substance” can be different from Inventory to Inventory
- Multiple ways to be compliant, beyond inventory listing
- Substance definitions are quite different; under EU REACH we know:
  - Mono-Constituent Substances
  - Multi-Constituent Substances
  - UVCB Substance
  - Polymers
- Multi-Constituents and UVCB Substances in some Inventories not defined
- Polymer requirements can vary
New Substance Notification – Example China

<table>
<thead>
<tr>
<th>Category</th>
<th>100kg/y</th>
<th>1t/y</th>
<th>10t/y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular New Substance</td>
<td>Simplified Notification – General Conditions</td>
<td>Regular Notification</td>
<td></td>
</tr>
<tr>
<td>Isolated Intermediate</td>
<td>Simplified Notification – Special Conditions</td>
<td>Regular Notification</td>
<td></td>
</tr>
<tr>
<td>Product and Process R&amp;D</td>
<td>Simplified Notification – Special Conditions (Valid for 2 years)</td>
<td>Regular Notification</td>
<td></td>
</tr>
<tr>
<td>Polymer of Low Concern</td>
<td>Simplified Notification – Special Conditions (No volume limit)</td>
<td>Regular Notification</td>
<td></td>
</tr>
<tr>
<td>Scientific Research or Testing</td>
<td>Scientific Research Record</td>
<td>Simplified Notification</td>
<td>Regular Notification</td>
</tr>
</tbody>
</table>

Differences in:
- Notification Requirements
- Notification Thresholds
- Data Requirements
- Testing requirements
New Substance Notifications

• In China and Japan a new substance is listed 5 year after notification
• During this time only the notifier is allowed to manufacture or import
• This right cannot be transferred in the supply chain

If the additive manufacturer holds a New Substance Notification, then

every importing legal entity needs to submit a secondary notification for the same substance!
Communication in the Supply Chain vs. Protection of CBI
Communication in the Supply Chain

- Communication within the supply chain is very important
- What is really needed, what is nice to have?
- Maintaining Confidential Business information (CBI) through-out the supply chain.
Outlook and Next Steps
Outlook and Next Steps

• This was just a short overview of the most important topics
• The following presentations will provide more details on the impacts
• Let’s discuss how we can get the regulatory “Monster” under control
• And have globally compliant products on the market!
Thank you very much for your attention!

Sabine Hausmann;
Head of Global EH&S
FUCHS Petrolub SE
Sabine.Hausmann@Fuchs.com
Global Chemical Compliance
Automotive industry view and specific challenges

ATIEL WORKSHOP „REGULATORY REQUIREMENTS FOR CHEMICALS WITHIN A GLOBAL MARKET“

FRANKFURT, 23.10.2019

Dr. Anita Hillmer
A chemical inventory or REACH like regulation keeps record of all chemicals manufactured, imported and/or used in the corresponding legal area.

- **Old mandatory chemical inventories:** USA, EU, China, Canada, Australia, Philippines, Japan, Korea, New Zealand
- **New inventories under development:** Turkey, Russia, Vietnam, Thailand, Brazil, Mexico, Argentina etc.
Download URL: https://www.acea.be/publications/article/reach-position-papers
Chemical substances that are not listed in a national chemical inventories will be regarded as new chemical substances under the specific chemical regulation.

No data no market principle: They shall be registered / notified to authorities prior to manufacture or placing on the market.
- This also applies for substances in articles (i.e. wiper fluid in vehicles) which are intended to be released.
- It also impacts several downstream regulations like notification of C & L (EU-CLP) or SNURs (US-TSCA).

Every chemical product which is foreseen for manufacture, import and/or use has to be known and checked - substance by substance:
- Validation of CAS# and substance name, especially for polymers (USA, CHINA, KOREA etc.)
- Validation of polymer status
- Check Third-Party Use permission (confidential entries)
- Validation of classification and labelling in the corresponding legal areas
- Safety Data Sheet preparation
The individual national chemical inventories are not harmonised (different entries & rules).

- All manufacturers/importers must take all differences into account and/or manage special notifications.

The Automotive Industry is globally using chemicals for production, operation and maintenance (e.g. after-sales materials, first-fill chemicals) and needs to know all relevant information to allow for compliance and market access.

- FULL (100%) knowledge about all relevant chemicals is required by the importer of the chemical = i.e. the vehicle importer.
- An increase of *incompliant chemical conformity declarations* provided by the chemical suppliers was noticed.
- Articles: One OEMs is already requesting full declarations in IMDS (confidential substance function) and starts to reject all MDSs with Jokers.
REASONS FOR INCOMPLIANT DECLARATIONS

▪ Lack of knowledge of the full chemical composition:
  – Full knowledge about the chemical composition of products provided to the automotive customer or place on the market is required but rarely existing.

▪ No common use of standard methods in the chemical supply chain:
  – Rules per legal area are often differently interpreted – no common guidance existing, e.g. for "multiple" CAS# or UVCB problem, exemptions etc.
  – Raw material compliance is often checked by only seeking confirmation from the supply chain without performing the required plausibility checks. Such confirmation (i.e. written supplier statements or Safety Data Sheets (SECTION 3 data)) are often incomplete or incorrect.

▪ Information sources:
  – The SDS SECTION 3 is often used as the only source for the full chemical declaration.
    ➔ this might be incomplete or incorrect (e.g. polymers or other non-hazardous substances are not subject of SDS SECTION 3).
  – CAS Online/CHEMLIST used only in minor cases.

▪ Misleading interpretation of exemptions (polymers, natural substances etc.)
Alternative “multiple” CAS No. per substance per legal area:

Different CAS No. are used to describe the same substance

This often results in the reporting of similar but not in any case identically chemicals without official confirmation by the responsible competent authorities

If “only” 2 CAS# are used = “dual” CAS#, but often much more CAS# necessary

<table>
<thead>
<tr>
<th>Region A</th>
<th>Chemical Product Trade Name XYZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance 1</td>
<td>CAS 1234</td>
</tr>
<tr>
<td>Substance 2</td>
<td>CAS 5678</td>
</tr>
<tr>
<td>Substance 3</td>
<td>CAS (3) 1238</td>
</tr>
<tr>
<td>Substance 4</td>
<td>CAS 5612</td>
</tr>
</tbody>
</table>

Case 1:

<table>
<thead>
<tr>
<th>Region B</th>
<th>Chemical Product Trade Name XYZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance 1</td>
<td>CAS 1234</td>
</tr>
<tr>
<td>Substance 2</td>
<td>CAS 5678</td>
</tr>
<tr>
<td>Substance 3</td>
<td>CAS (2) 2488</td>
</tr>
<tr>
<td>Substance 4</td>
<td>CAS 5612</td>
</tr>
</tbody>
</table>

→ All CAS No. are listed in the national inventory

→ Identical Chemical Product in Region A & B (Same trade name, properties, performance, SDS, Recipe No., ...) but...
→ Substance 3 with CAS No.(1) is not listed in the inventory of Region B
→ Replaced with CAS No.(2) (listed in Region B)
→ CAS No. (1) & (2) are describing the identical substance 3

Case 2:

<table>
<thead>
<tr>
<th>Region B</th>
<th>Chemical Product Trade Name XYZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Substance 1</td>
<td>CAS 1234</td>
</tr>
<tr>
<td>Substance 2</td>
<td>CAS 5678</td>
</tr>
<tr>
<td>Substance 3a</td>
<td>CAS (3) 2566</td>
</tr>
<tr>
<td>Substance 4</td>
<td>CAS 5612</td>
</tr>
</tbody>
</table>

→ Identical Chemical Product in Region A & B (Same trade name, properties, performance, SDS, Recipe No., ...) but...
→ Substance 3 with CAS No.(1) is not listed in the inventory of Region B
→ Substituted with substance 3a (listed in Region B)
→ CAS No.(1) & (3) are describing a different substance (3 & 3a)
Supplier often use for „rest-of-world“ a „dual CAS#“ which is – in this example – according to official TSCA experts not compliant due to the chain length and structure (branched vs. linear, odd versus equal chain length):

**EU-SDS**

<table>
<thead>
<tr>
<th>Gefährliche Inhaltsstoffe</th>
<th>Konzentration [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemische Bezeichnung</td>
<td>Einstufung (VERORDNUNG (EG) Nr. 1272/2008)</td>
</tr>
<tr>
<td>Acute Tox 4; H302</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td>Skin Irrit 2; H315</td>
<td></td>
</tr>
<tr>
<td>Eye Dam.1; H318</td>
<td></td>
</tr>
<tr>
<td>Aquatic Chronic2; H411</td>
<td></td>
</tr>
</tbody>
</table>

Den Volltext der in diesem Abschnitt aufgeführten Gefahrenhinweise finden Sie unter Abschnitt 16.

**US-SDS**

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Hazardous ingredients</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium dodecybenzene sulfonate</td>
<td>69227-09-4</td>
<td>&gt;= 1 - &lt; 2 %</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

In this case an official statement from EPA was requested by the OEM, but the supplier refused to ask the competent authorities.
Scenario 1 (Broader CAS# appropriate):
Product is a material of variable composition, with multiple carbon chain lengths in the product. Supplier uses a CAS# associated with a broader carbon chain length range in the US and a CAS# associated with a narrower chain length range in the EU. REACH regulations include a “10% rule,” under which identity profiles do not include chain lengths present at < 10%.

➔ The U.S. does not have a similar rule, thus the use of the CAS# associated with the broader chain length range is appropriate under TSCA.

Scenario 2 (Narrower CAS# appropriate):
Supplier uses a narrower CAS# in the U.S. and a more generic CASRN in the EU and the narrower CAS# is on TSCA.

➔ Assuming that the supplier has analytical data to confirm that the substance is accurately represented by the more specific structure and CAS#, the supplier’s use of the more specific CAS# in the US is appropriate for TSCA purposes. In this case maybe the REACH registration has to be re-evaluated?

Similar explanation required for the other legal areas too on a case-by-case decision.
Supplier statement:

- The CAS# XYZ is composed of 3 single substances.
- For the Australian inventory „AICS“ you have to split-off the into this individual components, which are all for its own listed.

Statement of the Australian authority:

- CAS# XYZ is an UVCB (Unknown, of Variable Composition, or of Biological Origin).
- The other CAS#, which are on AICS, refer to completely defined substances.
- CAS# of one single substance also refers to a series of monomers, which are components of its own mixture. From this it is ascertain which of the other CAS numbers listed will be present in the mixture, or if there may be other components in the mixture.

Considering all of this, we must treat CAS# XYZ (UVCB) as a separate chemical.
**POLYMER EXEMPTION PROBLEM**

<table>
<thead>
<tr>
<th>Name</th>
<th>EC / List no.</th>
<th>CAS no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatty acids, C16-18 and C18-unsatd., Me esters, sulfonated</td>
<td>269-913-1</td>
<td>68390-93-2</td>
</tr>
</tbody>
</table>

**OEM view:**

In order to make use of the polymer exemption under REACH, the \([3 + 1]\) rule and the 50% rule must be met. In OEM view, this fulfillment is very difficult for a polymer sulfide.

**Supplier statement:**

The fatty acids, C16 – C18 and C18 unsaturated Me-esters, sulfonated ingredient meets the EU REACH polymer definition.

**Statement of the German authority BAuA:**

..... the sulphurised fatty acid methyl esters mentioned here do not meet the above mentioned conditions under Article 3 (5) of the Regulation and accordingly should not be considered as polymers within the meaning of REACH. Rather, they are defined compounds listed as a substance. REACH registration is required if imported/manufactured > 1 tpa.
Reaction product with boric acids, fatty acid epoxide:

Confidential listed in TSCA, rest-of-world unclear or not-listed!

How can OEM / TIER 1 supplier check this easily in future without question back and without violating against trade secrets or revealing the supplychain?
PLATFOR M SOLUTION?

Additive manufacturers report their full recipes to a platform.

TIER 1 sends its recipe to a platform.

The OEM receives the complete recipe.
ATIEL Member Companies rely on their suppliers to make sure that their global inventory substance declarations are compliant and make sure to have agreements in place providing that the detailed information behind these declarations can be shared if this becomes necessary.
Manufacturer located in Asia
Additive not listed in CAS Online/CHEMLIST and in no other inventory except of EU!
TIER 1 + 2 suppliers relied on this statement!?
1. Include voluntary reliable statements in SDS, SECTION 15 (quick solution)

   Registration Name: Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics

   Identification Number: (EC #)920-107-4
   Registration Number: 01-2119453414-43-0001

   The national inventory listings are based on the CAS number or numbers listed below.

   | CAS     | 64742-47-8 |

   without disclaimer like e.g.
   “...information provided does not constitute a legally binding obligation...”.

2. Develop common criteria for difficult legal area exemptions, e.g. for:
   - UVCB substances/Reaction mass products
   - Hydrocarbons (EC 900# problem with new CAS#)
   - Salts of strong and weak acid/base reactions
   - Polymers, natural substances etc.)
3. Include valid "multiple" CAS# to CAS Online / CHEMLIST (example):

- **RN** 27859-58-1
- **CN** Butanedioic acid, 2-(tetrapropenyl)- (ISCA, Butanedioic acid, 2-(tetrapropenyl)- (IECSC, I Acide (tetrapropenyl)succinique (French) (DS Acido (tetrapropenyl) succinico (Spanish) (EI (Tetrapropenyl)butanedioic acid (ECL, AREC) (TETRAPROPENYL)BUTANEDIOIC ACID (PICCS)
- **FS** AUSTRALIA: AICS; CANADA: DSL; CHINA: IECSC KOREA: AREC, ECL; NEW ZEALAND: NZIoC; PHIL TCSI; USA: TSCA
- **CBI** Public
- **RLN** EC No.: 248-698-8 EINECS No.: 248-698-8 ECL Serial No.: KE-33664 AREC Serial No.: KE-33664
- **TNV** On TSCA Inventory

**Note 1:** it's not the official entry for an alternative CAS#!
TO-DO LIST

- Define criteria to provide reliable conformity statements.
- Define criteria for a transparent legally compliant solution that enables for use of the same substances globally without changing their customers internal production releases processes.
- Solve the “Multiple CAS No.” challenge:
  - Develop processes to enable companies reporting full chemical composition along the supply chain without violating the confidential business information (platform solution with trustee?)
  - If it seems necessary to use other CAS No. for single substances, the following criteria has to fulfilled:
    - CAS No. must be plausible and legally compliant.
    - Provide a scientific evidence on the correctness of the selected CAS No.
    - In case of doubts provide a written confirmation by the responsible competent authority.
- Make sure that modified chemical compositions always are approved by the automotive customer.
  - Assign for every chemical composition (“recipe”) a unique recipe identification No. which is mentioned on all relevant documents required to prove market access (i.e. SDS, full chemical declarations and registrations status confirmation)
- Start discussion at UN level aiming at globally harmonized chemical inventories or as alternative an agreement about mutual acceptance of the national chemical inventories.
“Experience is merely the name men gave to their mistakes.”
(Oscar Wilde, The Picture of Dorian Gray)
Thank you for your attention

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Global Chemical Regulatory Compliance: Existing Substances

Dr Mark Barratt
Dr Matteo Dalla Valle
Bastien Dufresne
Neal Smith
• History of Chemical Regulation
• Inventory Listing
• Risk Assessments for Existing Substances
• EU REACH (Registration-based)
• REACH-Like Regimes
• Substance Identity – REACH
• Substance Identity – Alt CAS RNs
• Summary – Current Challenges
• Confidential Business Information.
History of Chemical Regulation

- **Inventories came into force starting in the 1970s**
  - 1970s Japan ENCS, US EPA TSCA
  - 1980s EU EINECS
  - 1990s Canada DSL/NDSL, Philippines PICCS, Korea KECI

- **New chemical inventories are still being put in place**
  - Taiwan TSCI 2015
  - Vietnam VNECI Draft 2018

- **EU REACh came into force 2009**
  - Move from Inventory-based to registration-based.
  - Other countries are following suit (e.g. Turkey, Korea)
Inventory Listing

• **Chemical Inventory Listing**
  • List of substances in commerce at the time inventory comes into force
  • CAS RN and CAS Name listing.
  • KECI and EINECS gave separate identifiers
  • Japan lists by MITI number and MITI name – Broad categories
  • Flexibility of supply: Any company can import, manufacture or use an existing substance (unless restrictions have been imposed)

• **Limits of System**
  • Substances grandfathered in
  • No registration process
  • No risk assessment carried out before listing on original inventory
Most regulatory authorities are looking at risk assessments for existing substances. Testing requirements are in place for new substances, but how to gather data for substances that have been on the market for years? One approach is for the authority to identify priority substances and carry out risk assessment. This can be implemented through various initiatives such as OECD HPV, US EPA TSCA Work Plan, Environment Canada Substance Grouping Initiative. Industry is expected to submit existing data and use information, and certain uses may be restricted. Further testing may be required, and other countries are looking to introduce similar schemes.
EU REACh (Registration Based)

- Registration of all Existing substances over 1mt/a
  - No registration = no commercial sales, even for existing substances
  - Same data requirements as new substance registrations
  - Data requirements increase with tonnage
- Burden of data gathering and risk assessment falls on industry
- Inventory falls out of use
- Supply chain-specific and use-specific registrations
- REACh is a process: REGISTRATION, EVALUATION, AUTHORISATION and RESTRICTION of CHEMICALS.
  - Work does not end with registration – dossiers are updated regularly and registrants communicate with MSCAs carrying out evaluation.
  - Registrants constantly updating to maintain compliance
- Further testing can lead to new hazard classifications and new RMMs
• Other countries with chemical inventories are moving to a registration-based approach
• Inventory-based approach is slowly becoming a thing of the past
• REACH-like process will be repeated: Evaluations carried out by different authorities and may have different conclusions
• Data sharing needs to be negotiated for use outside the EU
• Registrants need to ensure consistency of approach e.g. for waiving and read-across
• Examples are Korea, Taiwan, Turkey
• ECHA is strict on substance identity
• Article 26 Enquiry Process
  • Companies have to provide very detailed analytical data
  • EC naming rules are different from CAS rules, which are different from IUPAC
  • ECHA may impose new names & identifiers, especially in the case of UVCBs
• ECHA has assigned new EC Identifiers to existing substances
  • e.g. petroleum distillates, hydrocarbons, Phenates
• Polymer Substance ID is complex
  • Polymers may or may not be registered in EU. CAS identifiers may cover a wide range of polymer structures.
• CAS RNs describing a substance in Rest of the World may not be accepted for REACh
• ECHA may also split a more generic substance name to two (or more) that are more specific (e.g. by narrowing the carbon range).
• Occasional mergers can also occur
• CAS Identifiers still apply in the rest of the world. Existing tox data will apply to the substance as manufactured as sold, therefore hazard classification information will apply to a product regardless of identifiers used in a particular region for inventory compliance.
• Inventories initially compiled based on what was in commerce
• Multiple CAS RNs can describe the same substance.
• Experts in the chemistry of a substance must determine if multiple CAS RNs apply
• Some CAS RNs can have a broader substance definition and some can be narrower, but can both describe the same industrially-manufactured substance
• The same substance can therefore be listed on different inventories under different CAS numbers.
• MITI numbers in Japan are based on different rules.
Summary – Current Challenges

• Inventory based systems are being replaced by registrations specific to supply chain
• Moving away from simple yes/no checklist for global compliance
• Existing substances are being assessed either as part of country work plans or REACh-like regulations.
• New testing results in new hazard classifications and RMMs
• For historical reasons or recent decisions by regulators, substance identifiers can change and differ from one country to another. Changing them may not be possible
• Communication is needed throughout the supply chain.
• Compliance landscape is always changing.
Confidential Business Information

• **Why is CBI important?**
  • Safeguards significant R&D and substance registration investment made by companies
  • Knowledge of product composition would potentially allow
    • Competitors to gain technological insight
    • Formulate similar products

• **When must compositional information be disclosed?**
  • SDS where applicable, i.e. section 3 in support of classification
  • Separately in support of specific regulatory requirements
How can companies protect compositional CBI?
- Full disclosure is not required on SDS
  - With limited exceptions, only hazardous substances above specified classification cut off must be shown in SDS
  - Companies following approval may keep low hazard substances confidential using a generic name
- Regulatory requirements frequently include systems to support maintenance of CBI
  - Recognizing importance of CBI
  - Aligning with international agreements under WTO TRIPS and UN GHS
  - Example Poison center UFI
- Registration/inventory notification
  - Substances may be notified to the confidential section of an inventory
  - Some information may be kept confidential as part of a registration
Where compositional information is disclosed outside the SDS, what steps should be taken to safeguard it?

- Disclosure under a formally signed Non-Disclosure Agreement between 2 companies
- Securely held
  - Limiting access to HSE and regulatory chemistry departments
  - Not on industry or company wide database
Regulatory Requirements within a Global Market

Inventory Compliance for New Chemistry

Mel Biring/Dave Cressey on behalf of ATC

23 October 2019
Topics for Today

- What are the drivers for new chemistry?
- The new molecule pipeline
- Notification considerations and processes
- Full notification and onward to inventory listing

Focus on ‘new’ substances

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Innovative companies seek to bring to market products that:

Meet customer technology needs
Have a better toxicological/safety profile
Lower environmental impact

This requires upfront investment in R&D to include compliance with regulations involving new chemicals

Meanwhile the number and the complexities of the regulations continues to increase this includes new substance notification schemes for industrial chemicals around the world.....
Customer Need
In our work with customers and OEMs we become aware of new materials, innovative hardware designs and fluid technology needs

Customer Commercialization
- Products are built from our knowledge to ensure timely and efficient product development
- The ultimate products we sell are tailored to specific customer / OEM needs
- Typically includes lab, Mechanical, field test data and OEM/industry approvals

Technology Development
- New testing capability
- New chemistry
- Structure-performance understanding
- Regulatory compliance testing
- Product notification – dossier submission etc..
- Intellectual property, CBI

Product Development
- Challenging performance targets including novel testing to anticipate customer / OEM needs
- Develop formulating knowledge and ultimately a core platform formulation based on new and existing chemistry
- Regulatory compliance
- CBI

Can be long development cycles
First considerations for new chemistries in a given country

Are there sufficient time/volume allowances to allow for initial R&D work by the company who wants to commercialise?
- R&D takes time and scale up, trial runs etc may require large volumes

What is the cost and timings for notification?
- If regulatory costs outweigh sales then new chemistries will not be notified
- Volume based requirements vs time to further build a market

Confidential Business Information – can others piggy back on my R&D and regulatory investment?
First considerations for new chemistries in a given country

Questions to ask before deciding a substance requires notification in any concerned jurisdiction:

1. Does the country have a new chemicals scheme for industrial chemicals?

2. Is the substance considered new and in-scope?

3. What about exemptions and exclusions?
Does the country have a new chemicals scheme for industrial chemicals?

- USA
- Canada
- EU
- Swiss
- South Korea (2)
- Japan (2)
- Taiwan (2)
- Australia
- Philippines
- China
- New Zealand

Thailand, Vietnam - active inventory building, others to follow....and revisions

EU-REACH, T-REACH, UK-REACH all non (pre)registered substances could be considered new
Is the substance actually „new“ and hence in-scope?

Each jurisdiction has an inventory of existing substances. If present on the inventory then usually no further new substance notification activity is necessary.

<table>
<thead>
<tr>
<th>Australia: AICS (AIIC)</th>
<th>Korea AREC and ISHA: KECI</th>
<th>Taiwan OSHA and TCSCA: TCSI</th>
<th>NZ: NZoIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan: ENCS &amp; ISHL</td>
<td>China: IECSC</td>
<td>Philippines: PICCS</td>
<td>USA: TSCA</td>
</tr>
<tr>
<td>Canada: DSL (NDSL)</td>
<td>EU: EINECS</td>
<td>CH: EINECS</td>
<td></td>
</tr>
</tbody>
</table>

KECI and EINECS are static and compliance is M/I/OR driven.

Inventory entries may be flagged or a listed substance may have further reporting/registration needs e.g. based on toxicity.

Confidentiality is possible within all except ENCS, ISHL, EINECS.
Is the substance actually „new“ and hence in-scope?

If a substance is on an inventory it is not necessarily readily visible:
A substance may have been added to a confidential chemical inventory
• Not visible via open search engines

A substance may have been allocated to a very generic inventory listing eg. the ENCS list:
– Eg if we try to find CAS 64742-54-7 (common base oil) on NITE-CHRIP

Other caveats mentioned earlier

Inability to find a substance on an inventory ≠ NEW
Inventories...What about the specific case of new polymers?

Each jurisdiction with inventory polymer listings has rules for polymers that can be considered to be inventory listed even if not specifically listed by CAS number. For example:

- Inventories containing polymers have a “2% monomer rule”
- PICCS has a top 2 monomer rule whereby if the top 2 monomer(s) by weight in your polymer are included in the definition of a PICCS listed polymer you can utilise that listing
- PICCS has a monomers on inventory rule whereby one can consider a polymer exempt if all monomers added at >2% are inventory listed. IECSC same but requires all monomers listed.
- Graft and block co-polymer rules exist in Japan and Korea
- ‘Onium salt rule’ in Japan, additionally there is a 1% monomer rule in Japan
- 2 sections of METI inventory dedicated to polymers, large number of entries generic
- In New Zealand if the polymer does not contribute to the hazard of the product it is not notifiable.
- In EU and CH a polymer’s ‘inventory status’ is dictated by that of its monomers
What about 'exemptions'?  

Exclusions from notification apply in jurisdictions for uses such as:

- Pesticide / biocide
- Pharmaceutical
- Food/feedstuff
- Veterinary
- Cosmetic
- Waste
- Radioactive material

Maybe able to completely exclude the substance from notification if it meets its definition of:

- Present within articles [from which there is no release]
- A byproduct
- Non-isolated
- Incidentally produced
- Naturally occurring
- In transit
- Etc, etc
Can we avoid full notification?

- R&D
- Low volume exemption
- Reduced/simplified/abbreviated notification
- Controlled use/exposure (intermediate) type categories
- Polymer notification (especially for PLCs)

THATS GREAT BUT...........

- Reporting needed in most cases and exemptions tend to be time limited
- Not always of use to help DUs who want 'global compliance' for a chemistry as many of these types of notification allow for the applicants use only.
If you exhaust all the possibilities for:

• Exclusion
• Exemption
• Existing listings
• Low volume / controlled or limited use

Full notification/registration is hence needed………. 
Full notification of substances

Typically required within volume bands with increased data requirements....

<table>
<thead>
<tr>
<th>Country</th>
<th>Notification Bands</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Korea - AREC</td>
<td>0.1 -1tpa (ISHA and AREC), 1-10tpa, 10-100tpa, 100-100tpa, &gt;1000tpa</td>
</tr>
<tr>
<td>USA</td>
<td>&gt;1tpa</td>
</tr>
<tr>
<td>Canada</td>
<td>0.1-1.0 tpa, 1-10 tpa, &gt;10tpa (NDSL dependence)</td>
</tr>
<tr>
<td>Japan</td>
<td>CSCL: &gt;10tpa, ISHL: &gt;100kg/pa</td>
</tr>
<tr>
<td>Taiwan</td>
<td>1-10tpa, 10-100tpa, 100-100tpa, &gt;1000tpa (CMRs more)</td>
</tr>
<tr>
<td>Australia</td>
<td>&gt;1tpa standard notification</td>
</tr>
<tr>
<td>China</td>
<td>1-10tpa, 10-100tpa, 100-100tpa, &gt;1000tpa</td>
</tr>
<tr>
<td>Philippines</td>
<td>&gt;1tpa</td>
</tr>
<tr>
<td>New Zealand</td>
<td>N/A</td>
</tr>
</tbody>
</table>
## Test data costs for full notification

<table>
<thead>
<tr>
<th>Registration type</th>
<th>Volume</th>
<th>Cost</th>
<th>Time for testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>global</td>
<td>1-10</td>
<td>up to $400,000</td>
<td>18-24 months</td>
</tr>
<tr>
<td>global</td>
<td>10-100</td>
<td>up to $600,000</td>
<td>2 years</td>
</tr>
<tr>
<td>EUREACH only</td>
<td>1-10</td>
<td>up to $100,000</td>
<td>18-24 months</td>
</tr>
<tr>
<td>EUREACH only</td>
<td>10-100</td>
<td>up to $500,000</td>
<td>2 years</td>
</tr>
</tbody>
</table>

---

- **Multi-year project!**
- **No adverse results**
- **AND THEN**
- notification compilation time
**Addition of new substances to inventories**

In practice different levels of notification then (eventually) lead to inventory listing

<table>
<thead>
<tr>
<th>Country</th>
<th>Inventory trigger</th>
<th>Time to listing</th>
<th>CBI?</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Korea - AREC</td>
<td>None</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Japan</td>
<td>CSCL: &gt;10tpa, ISHL: &gt;100kg/pa</td>
<td>CSCL 5 yrs, ISHL 1 yr</td>
<td>N</td>
</tr>
<tr>
<td>Taiwan</td>
<td>Any full notification / Level 4</td>
<td>5 yrs / immediate</td>
<td>Y</td>
</tr>
<tr>
<td>Australia</td>
<td>&gt;1tpa standard notification</td>
<td>Immediate or 5 yrs</td>
<td>N or Y</td>
</tr>
<tr>
<td>China</td>
<td>Any full notification</td>
<td>5 yrs for ‘general’</td>
<td>Y</td>
</tr>
<tr>
<td>Philippines</td>
<td>Abbreviated, or full</td>
<td>1 year after NOC…</td>
<td>Y</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Hazardous substances</td>
<td>Immediate</td>
<td>Y</td>
</tr>
<tr>
<td>USA</td>
<td>PMN + NOC</td>
<td>Immediate</td>
<td>Y</td>
</tr>
<tr>
<td>Canada</td>
<td>Highest relevant schedule + NOMI/NOEC</td>
<td>Ca. 4 months</td>
<td>Y</td>
</tr>
</tbody>
</table>

Until listing only the notifier can manufacture/import...positives and negatives

“I just spent $600,000 for global registration and I still have supply chain inflexibility!”
In practice different levels of notification (not just full) can lead to inventory listing. This may influence your notification strategy:

Full notification can lead to eventual inventory listing:
- Canada (Schedule 11)
- Australia (Synthetic, NAMW<1000, >1tpa, under STD*)
- Australia (Biopolymer, >1tpa notified under STD*)
- US (PMN)
- Japan CSCL (Full or PFS notification)
- Japan ISHL (Full notification)
- Philippines (Full notification)
- China (Full notification)

Limited notification can lead to eventual inventory listing:
- Australia (Synthetic, NAMW>1000, notified under LTD*)
- Australia (Synthetic, NAMW<1000, <1tpa, under LTD*)
- Australia (Biopolymer, <1tpa, notified under LTD*)
- Philippines (Abbreviated notification)
- Canada (Schedule 10 final)

PLC notification can lead to eventual inventory listing
- Canada (RRR)
- Australia (PLC*)
- USA (only possible pre-1995)

Test data requirements increase

Others:
- New Zealand – inventory listing can be requested on first import/manufacture of product
- EU – never applicable
- Switzerland – never applicable
TRADITIONALLY:
• If a substance is “new”, then it must be notified (<1% of substances)
• Then it must be added to the inventory *before* full flexibility import/manufacture
  – Exemptions from notifications do exist and depend on several factors, i.e. region, end use, hazards, volumes, etc.
• More of these schemes coming around the world

NOW AND THE FUTURE:
• Also need to factor in REACH-like schemes requiring registration of all “existing” substances….more of these coming around the world
• Inventory listing does not influence need to register, so *never* have full flexibility on who can import or manufacture

Notification numbers and complexity increasing, flexibility decreasing
Conclusions

• Investment in new products includes consideration of new chemical notification needs

• Notification work involves significant time and money

• The number and complexity of notification schemes is increasing:
  – The ability to give assurance a substance is ‘globally listed’ is becoming more onerous

• Increasing need for discussions within the supply chain on global compliance challenges
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Data communication in the supply chain, approaches of regulatory compliance for OEMs, tier 1 & tier 2 suppliers
Overview

(1) Basics, current ways of working
(2) Challenges
(3) Way forward, how can we improve?
Basics, current ways of working
Basics

- We all want to sell products through the supply chain.
- Legal regulatory requirements form the basis of what information should be shared along the supply chain to enable safe handling of products.
- Oil co and Add co have many teams in place to monitor regulations, manage classification and labelling and review inventory coverage.
- Product Stewards (from Add co’s and Oil co’s) are professional experts in their fields and can be trusted.
- Different levels of customer requirements.
- Some customers are asking for much more than legal minimum.
- Customers are repeating product stewardship review work completed by Oil co and Add co increasing time, cost & add complexity to the process.
- Working together can save time and cost.
Main Regulatory Requirements

- CWC: Chemical Weapon Convention
- PIC: Rotterdam Convention
- GHS: Globally Harmonized System
- Chemical Inventories
- Biocidal Regulations
- New Substance Registrations
- Restrictions & Prohibitions

Additional Regulations:
- DUAL –USE: Wassenaar Arrangement
- Embargo Regulations
Drivers for data communication, Compliance with two types of legislation

- Safety data sheets
- Product labels
- Classification of chemicals
- National worker protection legislation

Product Hazard Communication legislation (HazComm): Communication of the hazards within a country

Chemical Control legislation: Control of the manufacture, import and use of chemicals

- Chemical inventories (US, Canada, China, Philippines, Taiwan, Korea, Australia, Japan)
- Product/substance registers (EU REACH, Taiwan, Korea, Turkey, UK)
- Data requirements for compliance with chemical control legislation depend very much on the business model of the relevant company
Current ways of working

- Additive companies often work on a combination of raw material and substance level
- Oil companies often work at raw material level (ingredient/additive/component) not always at substance level
- OEM/Customers sometimes require substance level declarations for their own regulatory assessments & reportings as importer
- Trust within the supply chain is required
- Legislation dictates what must be shared (Hazardous substances above trigger levels), additional information sharing requires parties to work closely together, bringing confidentiality into play.
Challenges
Challenges

• Various levels of requirements and data sharing
• Non standardised comms, bespoke forms
• Different IT tools used by OEM’s/ customers
• Discussions about depth of data sharing, IP protection
• Management of non disclosure agreements (NDA’s)
• Growing regulatory landscape increases complexity
• If there is no trust in the supply chain and product stewardship work done by Add co & Oil co is repeated by OEM the process becomes very complex and challenging
Various levels of requirements and data sharing

Communication can be at a variety of levels:

• Inventory declaration/ company specific inventory letters
  a) high level, Yes/No
  b) detailed with CAS no. verification for each inventory
• Substance declaration – banned/prohibited list, present/not present
• Full formulation disclosure – substance, cas no. disclosure
  (Non Disclosure Agreements required)
Non standardised comms, bespoke forms

• OEM’s want declaration on bespoke forms – time consuming
  – This can mean 10 regional forms for one product to cover the globe, this increases time and resource required to deliver.

• More than one declaration – SDS, bespoke declarations and IMDS/COVISINT entries – need to ensure alignment of information at local and global levels
Different IT tools used by OEM’s/ customers

- Customer websites; Porsche, Bosch
- Industry websites; Covisint (US based), IMDS (Global), CAMDS (China)
- These are often quality and purchasing driven.
- Data inputter loses site of data distribution once released into system. Concern on confidentiality and IP. Add co. tend not to use.
Discussions about depth of data sharing

- **legal compliance**
  (HazComm & chemical control legislation)

- **customer (OEM) requirements**
  (internal standards, driven by business model)

- **IP protection**
  (communication of CBI, protection of Oil co’s & Add co’s IP)

**Conflict of interest**
Management of non disclosure agreements (NDA’s) (1)

• To protect intellectual property for oil companies and additive suppliers, NDA is required.
• Complex NDA covering Add co., Oil co. and customer/OEM can be required. Time consuming to set up and manage.
• Extremely difficult for Oil co’s to get NDA’s in place with lots of suppliers and to obtain 100% formulation disclosures.
• Despite NDA’s in place Add co’s do not always provide 100% formulation disclosures to Oil co’s.
• NDA can restrict where the data can be shared, additive co to oil co only – not able to share with customer.
• Agreements can prohibit what can be shared, ie do not share Add co. identity and raw material names to customer.
Management of on disclosure agreements (NDA’s) (2)

<table>
<thead>
<tr>
<th>What is shared</th>
<th>Add co. -&gt; Oil co.</th>
<th>Oil co. -&gt; OEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw material (RM) information: CAS, name, % range</td>
<td></td>
<td>Lubricants product formulation: CAS, name, % range</td>
</tr>
<tr>
<td>Reference to supplier identity as well as RM name is removed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required for</th>
<th>Add co. -&gt; Oil co.</th>
<th>Oil co. -&gt; OEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory assessment &amp; regulatory reportings</td>
<td></td>
<td>Regulatory assessments &amp; regulatory reportings</td>
</tr>
<tr>
<td>Regulatory disclosures &amp; notifications</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IP protection</th>
<th>Add co. -&gt; Oil co.</th>
<th>Oil co. -&gt; OEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protect IP of Add co. (RM compositional information)</td>
<td></td>
<td>Protect IP of Add co. &amp; Oil co.</td>
</tr>
<tr>
<td>Information only to be shared with Oil co’s HSE &amp; product stewardship functions</td>
<td></td>
<td>No link to supplier identity, no link to RM name</td>
</tr>
<tr>
<td>Only limited information is allowed to be shared with OEM’s/externals</td>
<td></td>
<td>Information only to be used for HSE &amp; product stewardship purposes</td>
</tr>
</tbody>
</table>
Growing regulatory landscape increases complexity

- GHS Implemented
- GHS in Progress
- No info available
Way forward, how can we improve?
How can we improve?

• Discussion
  Rather than designing new forms, discuss with supply chain what information is required and how it can be efficiently delivered.
• Is there certain trust in the supply chain? Has product stewardship review work to be repeated by customers/OEMS? If all product stewardship work is repeated by OEM the entire process becomes very complex and slow.
• Global vs. local business model – does this influence ways of working?
• Some OEM’s go to supplier directly if Oil company don’t give enough information – this is not ideal.
• Add co formulating directly for OEM, so Oil co on back foot.
Questions?
• BACK UP
Inventory Listings

Differences in Nomenclature
Nomenclature rules and what Competent Authorities accept as a chemical name for inventory listing has changed over time

- Nomenclature “rules” and naming conventions can vary from country to country
- Indeed CAS naming differs to ECHA naming

For example Hydrocarbon Solvents, >50 of these re-named for EUREACH:
  - CAS no 64742-95-6 = Solvent naphtha (petroleum), light aromatic
  - EU List No 918-668-5 = Hydrocarbons, C9, aromatics

It is not necessary to obtain a CAS number when applying to CAS IES for a CAS name
- So substances may appear on inventories without a CAS number

Considerable expertise needed to assess correct compliance status