



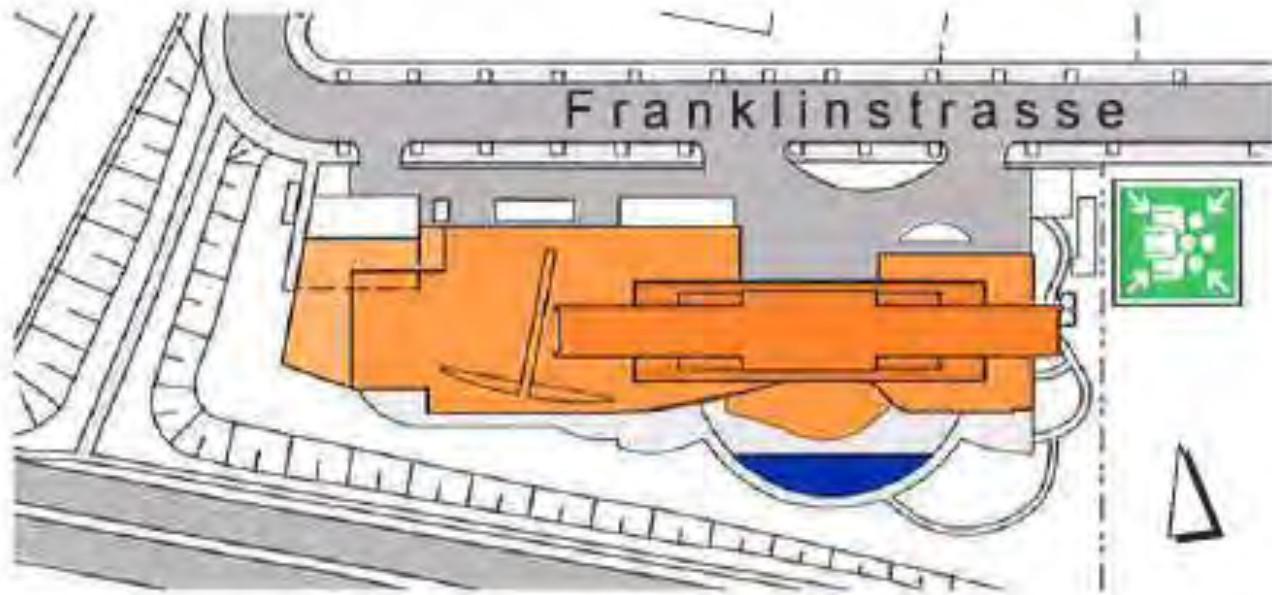
Regulatory Requirements for Chemicals within a Global Market



Technical Committee of Petroleum Additive Manufacturers in Europe



HSE



For today no alarm planned.

Reminder: Anti-competition laws

As we have guest, 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

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

Thanks for your attention!

Regulatory Compliance for Chemicals on the Global Markets

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

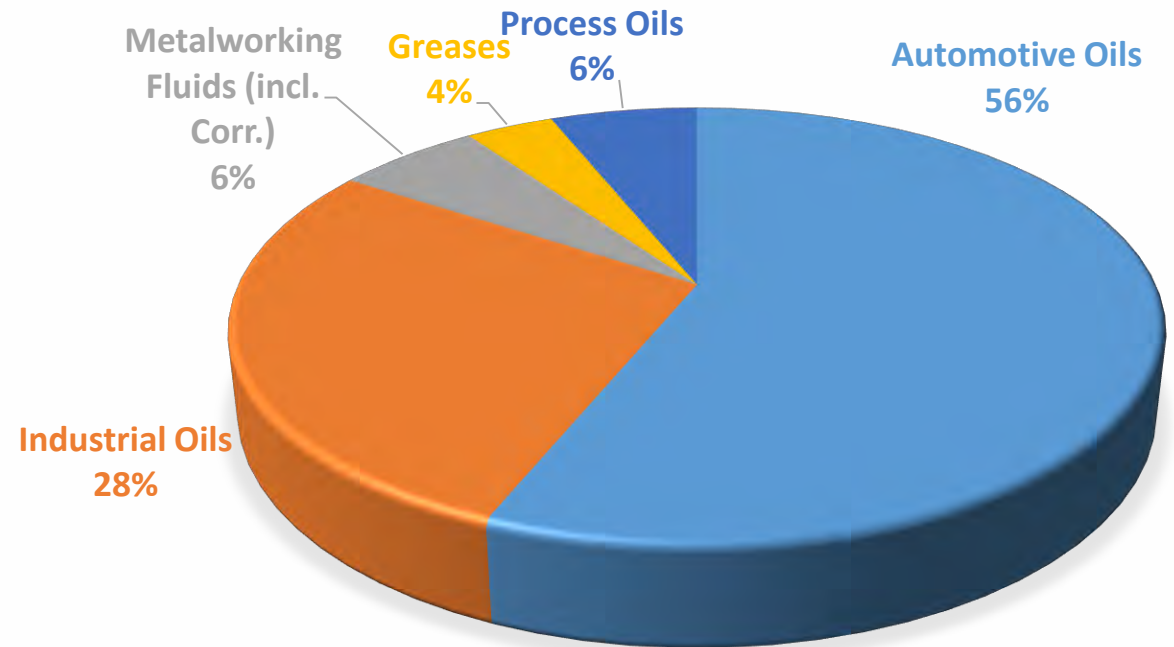
Overview

- (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.

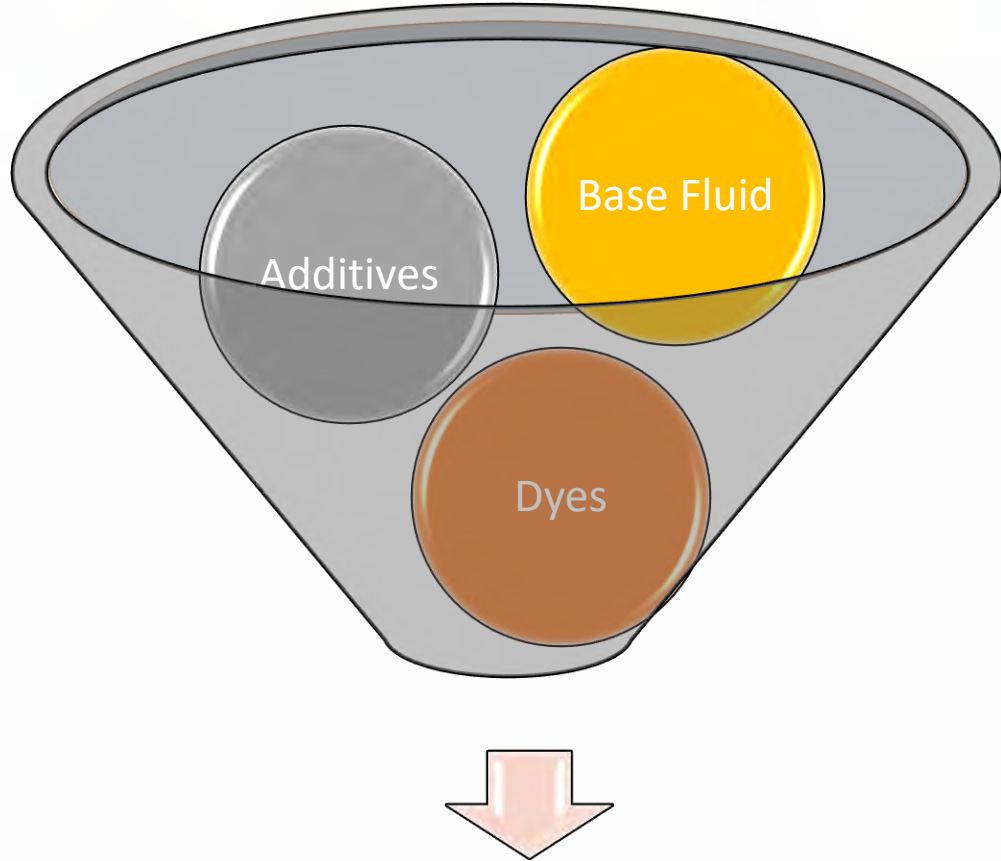
Therefore we would like to invite you to an open discussion on

- what needs to be improved and
- how can we achieve it



From Substance to Lubricant





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

Substance

Additive

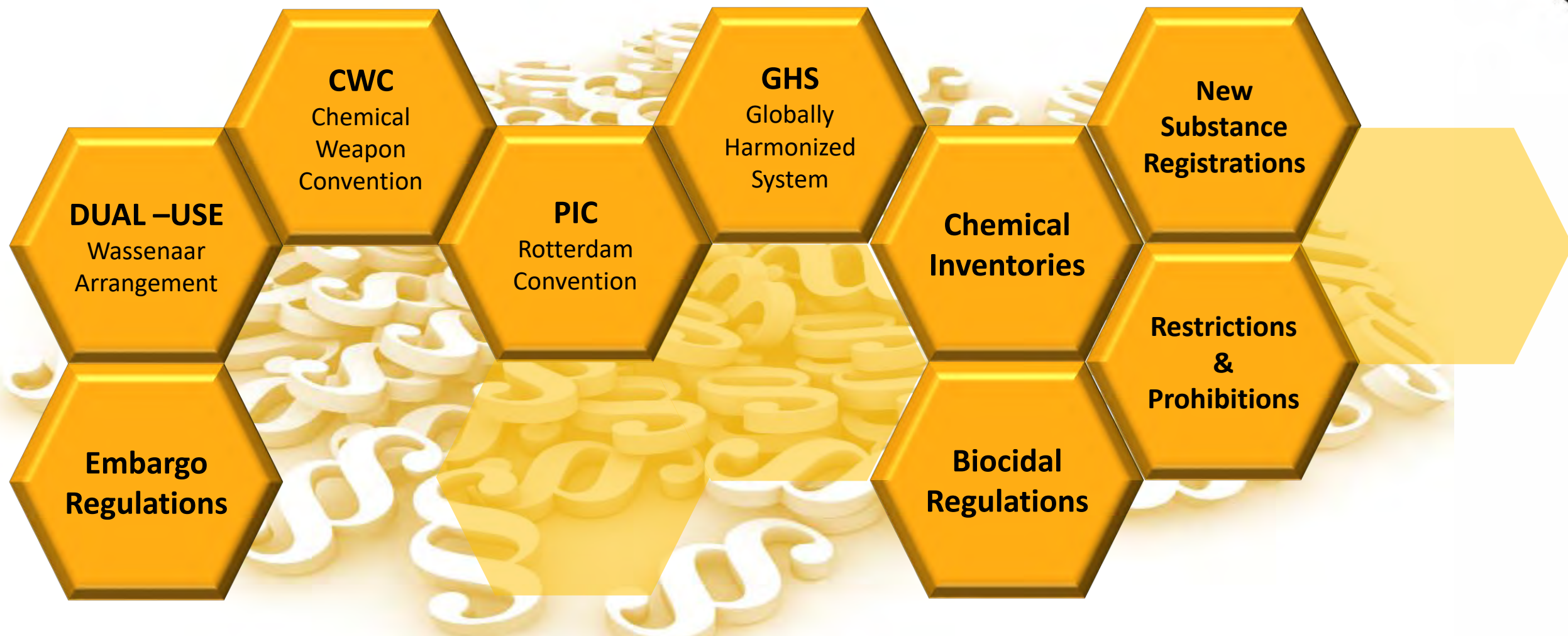
Lubricant

- 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

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The Regulatory Landscape

Important Regulatory Requirements



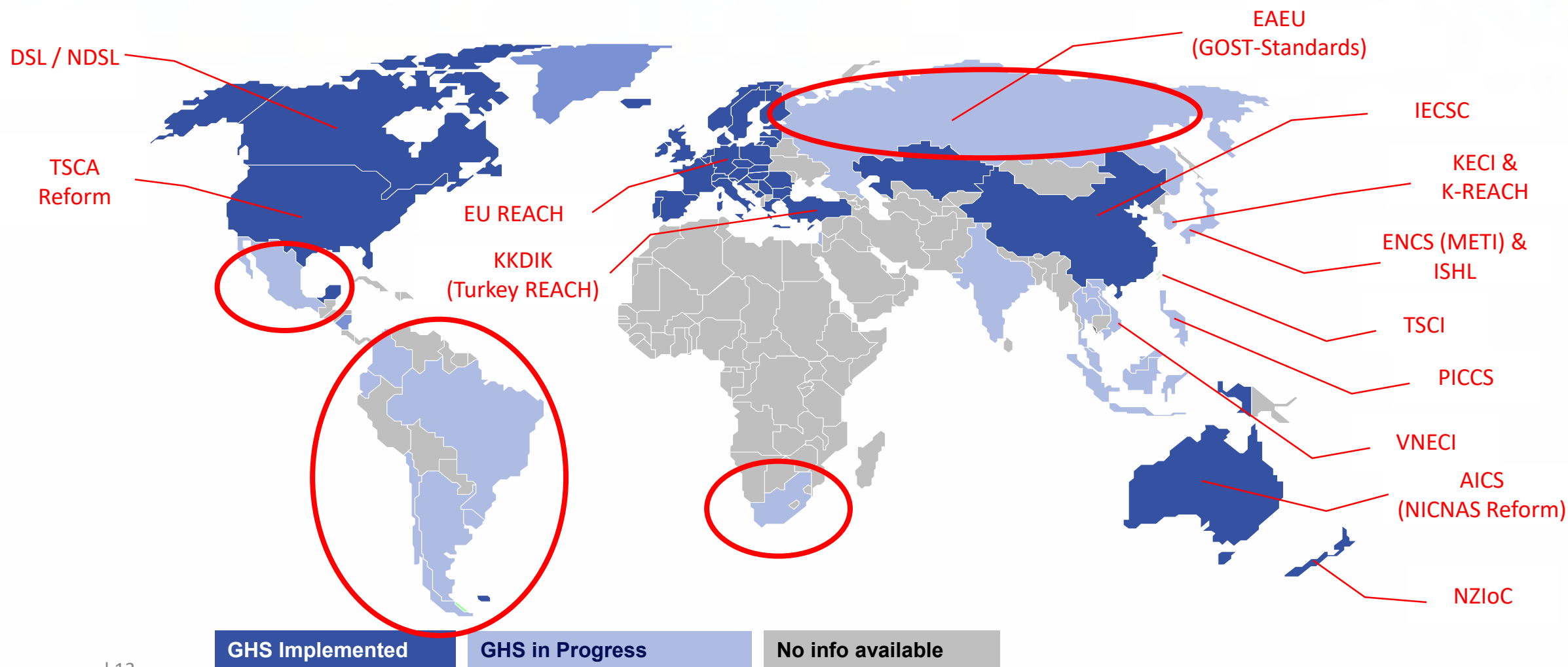
The Global Harmonized System (GHS)

- 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



The background of the slide is a composite image. The top portion shows abstract, glowing orange and yellow shapes. The bottom portion shows a close-up of a white plastic bottle pouring a yellowish liquid into a glass beaker, with the liquid creating a dynamic splash.

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

ENCS (Japan)	established in 1973
TSCA (USA)	established in 1976
EINECS (EU)	established in 1981
ELINCS (EU)	established in 1981
NLP (EU)	established in 1993
NICNAS (Australia)	established in 1990
DSL / NDSL (Canada)	established in 1991
KECI (Korea)	established in 1991
PICCS (Philippines)	established in 1998
NZIoC (New Zealand)	established in 2001
IECSC (China)	established in 2012
TSCI (Taiwan)	established in 2014

Same Substance – different Identifiers

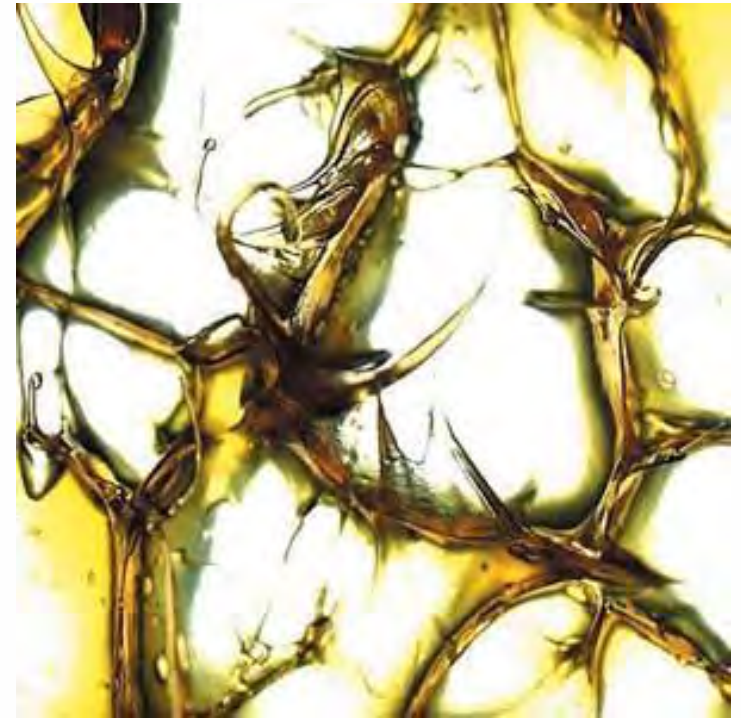
- Under EU REACH many substances were registered under new identifiers
- In other Inventories the old CAS-No is still in use:

C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	927-344-2	→	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy
C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	919-164-8	→	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy
C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C8-12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	928-136-4	→	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy; Low boiling point hydrogen treated naphtha
C9-14 Aliphatics (2-25% aromatics)	Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)	919-446-0	→	64742-82-1	Naphtha (petroleum), hydrodesulfurized heavy
			→	64742-88-7	Solvent naphtha (petroleum), medium aliphatic

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

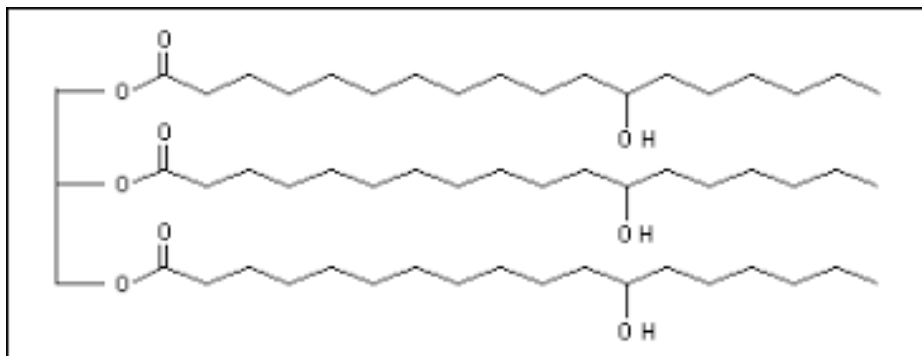


Same Substance – different Identifiers

Example: Lithium 12-Hydroxystearate (Grease Thickener)

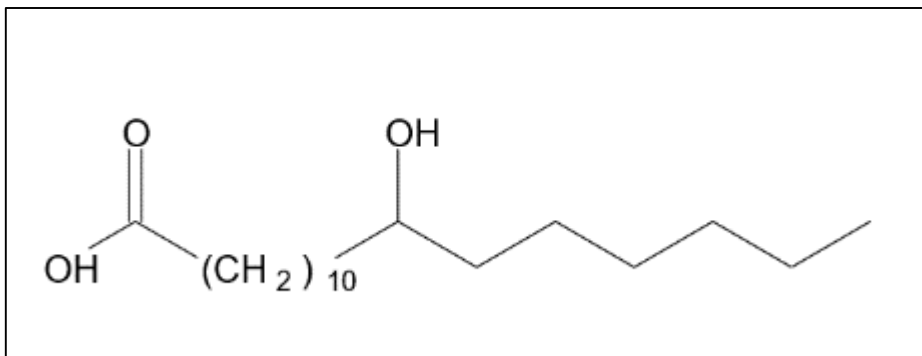
Starting Materials of the reaction:

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



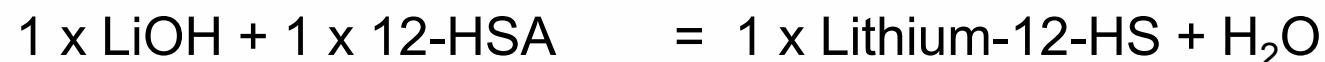
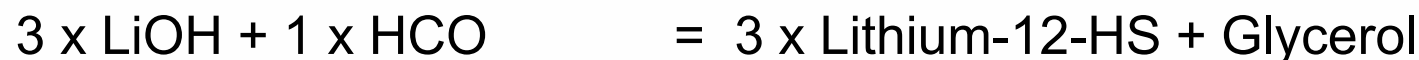
OR

**12-Hydroxystearic acid
(12-HSA; CAS: 106-14-9)**

Same Substance – different Identifiers

Example: Lithium 12-Hydroxystearate (Grease Thickener)

Saponification Reaction:



Water and Glycerol evaporate, due to high temperatures.

The Reaction Product can be described as:

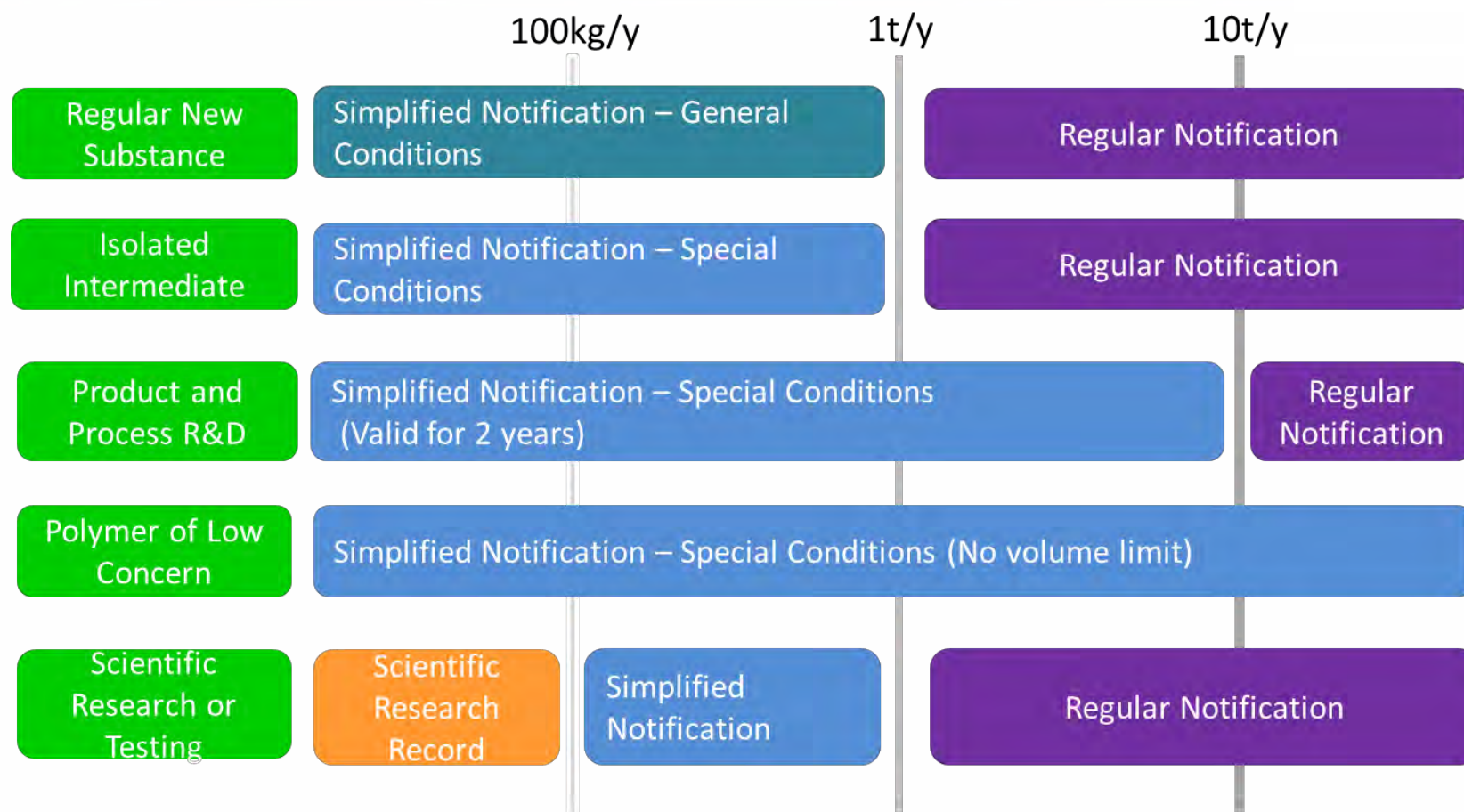
- Lithium 12-Hydroxystearate (CAS: 7620-77-1)
- Castor Oil, hydrogenated, lithium salt (CAS: 64754-95-6)
- Fatty acids, castor-oil, hydrogenated, lithium salts (CAS: 68604-46-6)

**YES, different CAS-Nos
can describe the same
substance!**

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



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!

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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.



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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

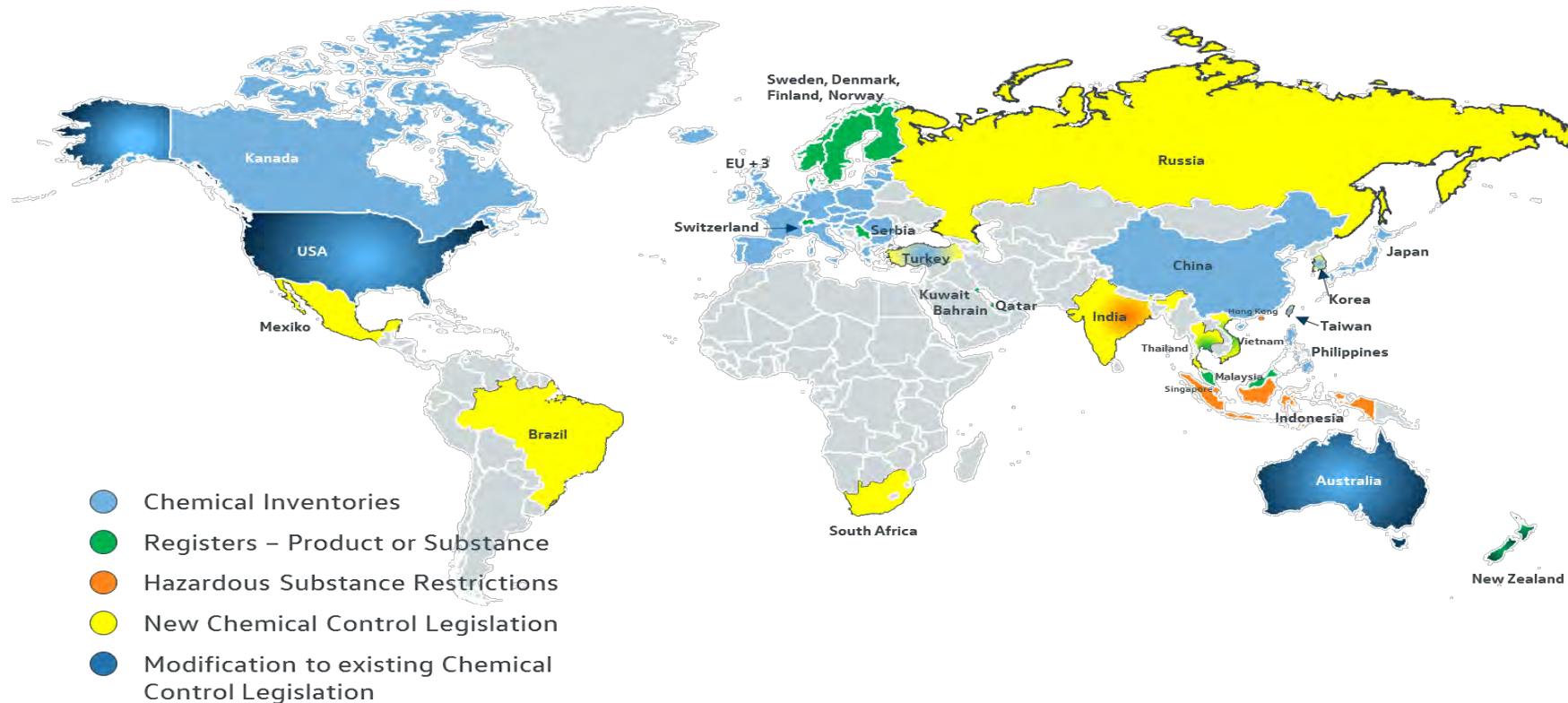
ATIEL WORKSHOP „REGULATORY REQUIREMENTS FOR CHEMICALS WITHIN A GLOBAL MARKET“

FRANKFURT, 23.10.2019

Dr. Anita Hillmer

CHEMICAL INVENTORIES

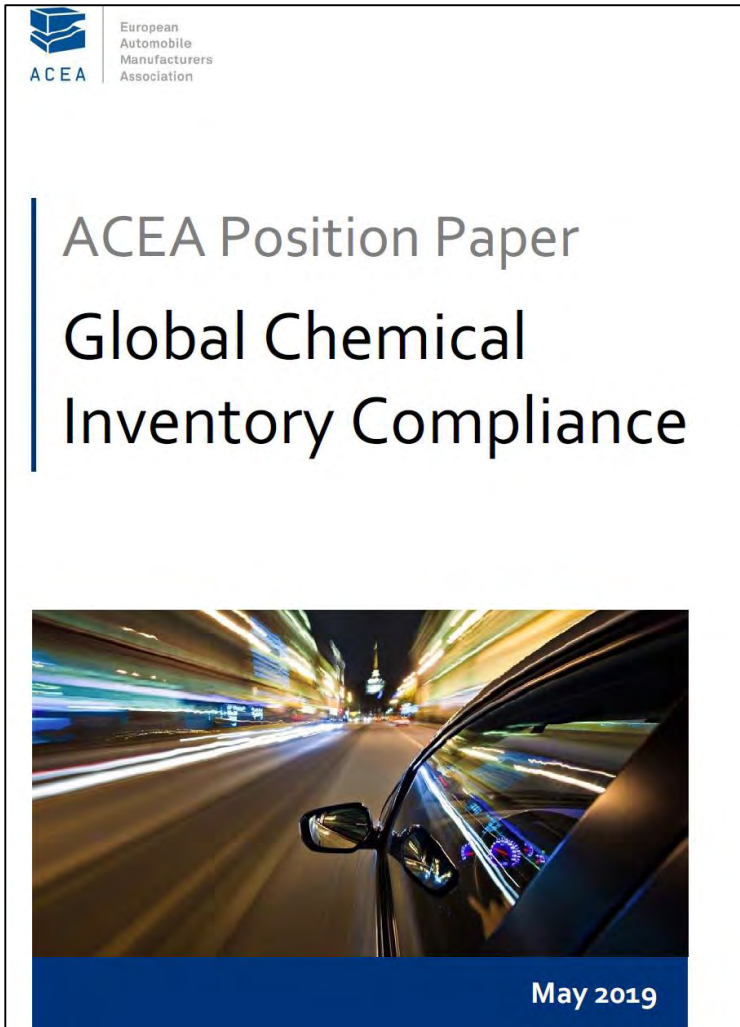
A chemical inventory or REACH like regulation keeps record of all chemicals manufactured, imported and/or used in the corresponding legal area



Source: Volkswagen AG

- 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.

ACEA POSITION PAPER



Download URL:
[https://www.acea.be/publications/
article/reach-position-papers](https://www.acea.be/publications/article/reach-position-papers)

CHEMICAL INVENTORY'S – OBLIGATIONS

- **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

CHEMICAL INVENTORY'S – CHALLENGES

- **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.)**

„MULTIPLE“ CAS# PROBLEM

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

Region A		Chemical Product	
		Trade Name XYZ	
Substance 1	Substance 2	Substance 3	Substance 4
CAS 1234	CAS 5678	CAS (1) 1278	CAS 5612

→ All CAS No. are listed in the national inventory

Case 1:

Region B		Chemical Product	
		Trade Name XYZ	
Substance 1	Substance 2	Substance 3	Substance 4
CAS 1234	CAS 5678	CAS (2) 2488	CAS 5612

- 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:

Region B		Chemical Product	
		Trade Name XYZ	
Substance 1	Substance 2	Substance 3a	Substance 4
CAS 1234	CAS 5678	CAS (3) 2566	CAS 5612

- 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)

„Dual“ CAS# EXAMPLE

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

ABSCHNITT 3: Zusammensetzung/Angaben zu Bestandteilen		
3.2 Gemische		
Gefährliche Inhaltsstoffe		
Chemische Bezeichnung CAS-Nr. EG-Nr. Registrierungsnummer	Einstufung (VERORDNUNG (EG) Nr. 1272/2008)	Konzentration [%]
Natriumtetrapropylbenzolsulfonat 11067-82-6 234-289-1	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 2; H411	>= 1 - < 2,5

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

US-SDS

3. Composition/information on ingredients		
Hazardous ingredients		
Chemical name	CAS-No.	Concentration (%)
sodium dodecylbenzene sulfonate	69227-09-4	>= 1 - < 2 %

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.

TSCA RULE EXPLANATION

- **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.

UVCB/REACTION MASS PROBLEM

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

Name 	EC / List no. 	CAS no. 
Fatty acids, C16-18 and C18-unsatd., Me esters, sulfurized	269-913-1	68390-93-2

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, sulfurized 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.

CONFIDENTIAL LISTING PROBLEM

Reaction product with boric acids, fatty acid epoxide:

```

L1  ANSWER 1 OF 1  REGISTRY  COPYRIGHT 2019 ACS on STN
RN  [REDACTED]  REGISTRY *
* Use of this CAS Registry Number alone as a search term in other STN files may
  result in incomplete search results. For additional information, enter HELP
  RN* at an online arrow prompt (=>).
ED  Entered STN: 11 Nov 2013
CN  [REDACTED]
MF  Unspecified
CI  MAN, CTS
SR  CAS Client Services
LC  STN Files:  CHEMLIST

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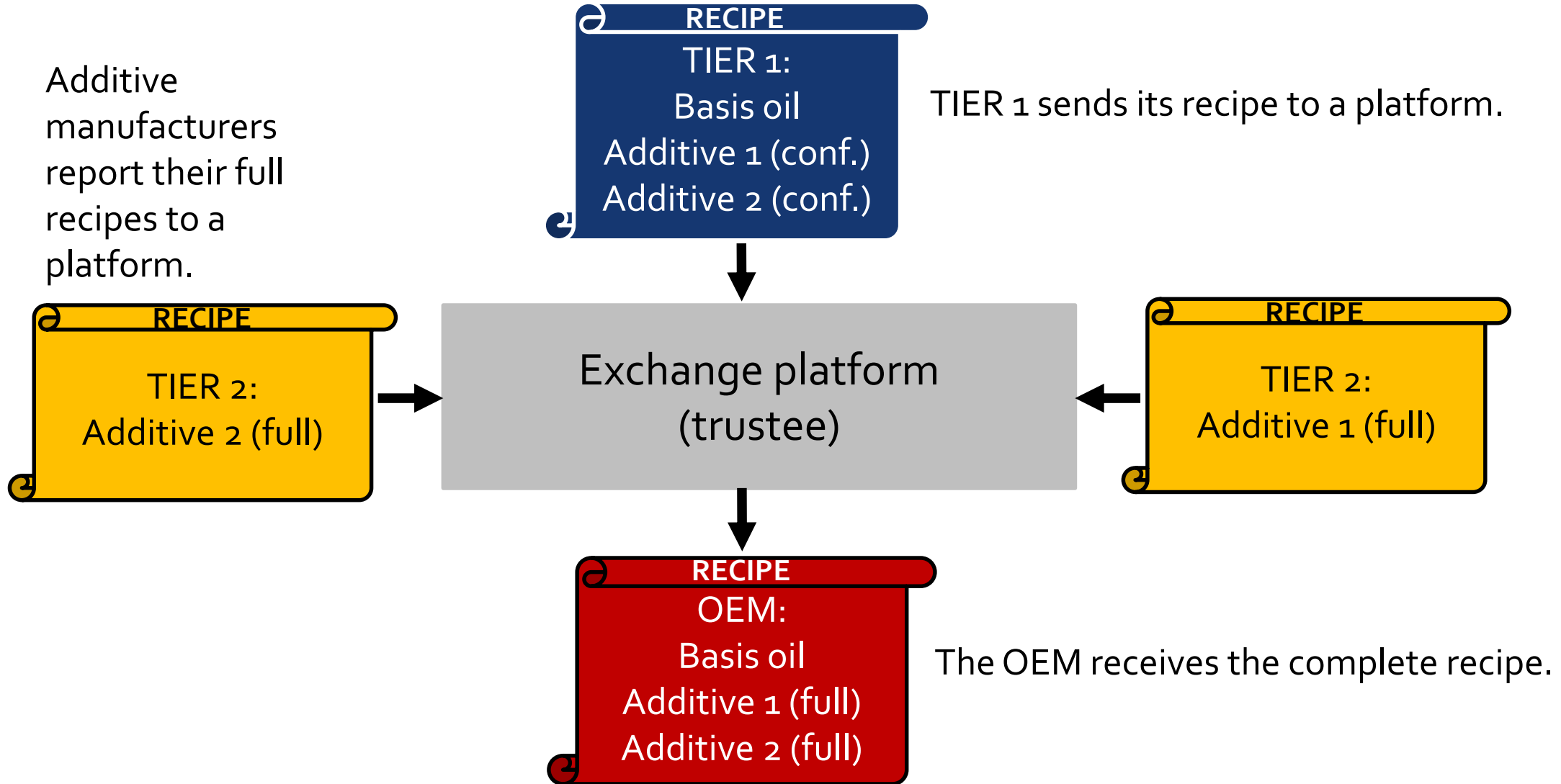
➔ ? no entry in CHEMLIST

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?

PLATFORM SOLUTION?

Additive manufacturers report their full recipes to a platform.



BASIC PRINCIPLE

Do not rely on supplier statements only!



Re: Global Inventory Statement

July 2019

Dear Customer,

ATIEL Member Companies work closely with their suppliers to ensure global inventory coverage for all substances used within ATIEL Member lubricants. In recent years new country inventories have become mandatory which has required existing substances to be registered or notified in compliance with the individual country requirements. Some countries have required tight identification of the substance before it can be registered or notified, and suppliers can use different CAS numbers for the same substance depending on how they define that molecule. This has resulted in different CAS numbers being registered on the new inventories, compared to existing inventories. Having different CAS numbers for the same substance in different regions and inventories does not mean that the substances are non-compliant.

Globally this means that multiple CAS numbers can be used to cover the global inventories for one given substance. This is a common situation within the lubricant industry. ATIEL Member Company suppliers give ATIEL Member Companies a declaration of their global inventory substance compliance.

ATIEL Member Companies rely on their suppliers to make sure that their global

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.

REALLY RELIABLE?

Chemical Inventory Status

Australia	(AICS)	Listed
Canada	(DSL)	Listed
China	(IECSC)	Listed
Japan	(ENCS)	Listed
Korea	(ECL)	Listed
New Zealand	(NZIoC)	Listed
Philippines	(PICCS)	Listed
USA	(TSCA)	Listed
EU	(EINECS)	Not listed

1	Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)	China	NO	1. Introduction of IECSC 2. Overview of MEP Decree No.7
2	Catalog of Hazardous Chemicals(2015)	China	NO	1. Introduction of Hazardous Chemical Management Regulations in China 2. Overview of China GHS
3	List of Toxic Chemicals Restricted to be Imported/Exported	China	NO	Overview of Toxic Chemicals Import & Export Environmental Administration Registration
4	Inventory of Prohibited Chemicals	China	NO	
5	List of Hazardous Chemicals for Priority Management- SAWS	China	NO	
6	Catalogue of Precursors and Chemicals used in Production of Narcotic Drugs and Psychotropic Substances	China	NO	Overview of Regulation on the Administration of Precursor Chemicals in China
7	Toxic Substances Control Act Inventory (TSCA)	U.S.A	NO	
8	New Zealand Inventory (NZIoC)	New Zealand	NO	Brief introduction of HSNO
9	Taiwan Chemical Substance Inventory (TCSI)	Taiwan	NO	Overview of Revised Toxic Chemical Substances Control Act (TCSCA)
10	Existing Chemicals List (KECI)	Korea	NO	Overview of the Act on the Registration and Evaluation of Chemicals (K-REACH)
11	Designated existing substances List (First Batch)	Korea	NO	Overview of the Act on the Registration and Evaluation of Chemicals (K-REACH)
12	K-REACH registration exemption substances list	South Korea	NO	

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!?

BASIC PROPOSALS (I)

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.)

BASIC PROPOSALS (II)

3. Include valid „multiple“ CAS# to CAS Online / CHEMLIST (example):

```

RN      27859-58-1
CN      Butanedioic acid, 2-(tetrapropenyl)- (TSCA,
        Butanedioic acid, (tetrapropenyl)- (IECSC, D
        Acide (tetrapropenyl)succinique (French) (DS
        (tetrapropenyl)succinic acid (REACH, EINECS)
        (Tetrapropenyl)bernsteinsaure (German) (EINE
        acido (tetrapropenil)succinico (Spanish) (EI
        (Tetrapropenyl)butanedioic acid (ECL, AREC)
        (TETRAPROPENYL)BUTANDIOIC ACID (PICCS)
        Succinic acid, (tetrapropenyl)-
FS      AUSTRALIA: AICS; CANADA: DSL; CHINA: IECSC
        KOREA: AREC, ECL; NEW ZEALAND: NZIoC; PHILIP
        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
        For VNECI see CAS Reg. No.: 455-95-8
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)



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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.**

- **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)

- **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 in place for new substances, but how to gather data for substances that have been on the market for years?**
- **One approach: Authority identifies priority substances and carries out risk assessment**
 - OECD HPV, US EPA TSCA Work Plan, Environment Canada Substance Grouping Initiative
 - Industry submits existing data and use information
 - Certain uses may be restricted
 - Further testing may be required
 - Other countries are looking to introduce similar schemes.

- **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.**

- **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



ATC

Regulatory Requirements within a Global Market

Inventory Compliance for New Chemistry

Mel Biring/Dave Cressey on behalf of ATC

23 October 2019

- ☐ 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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- **WHAT ARE THE DRIVERS FOR NEW CHEMISTRY?**

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

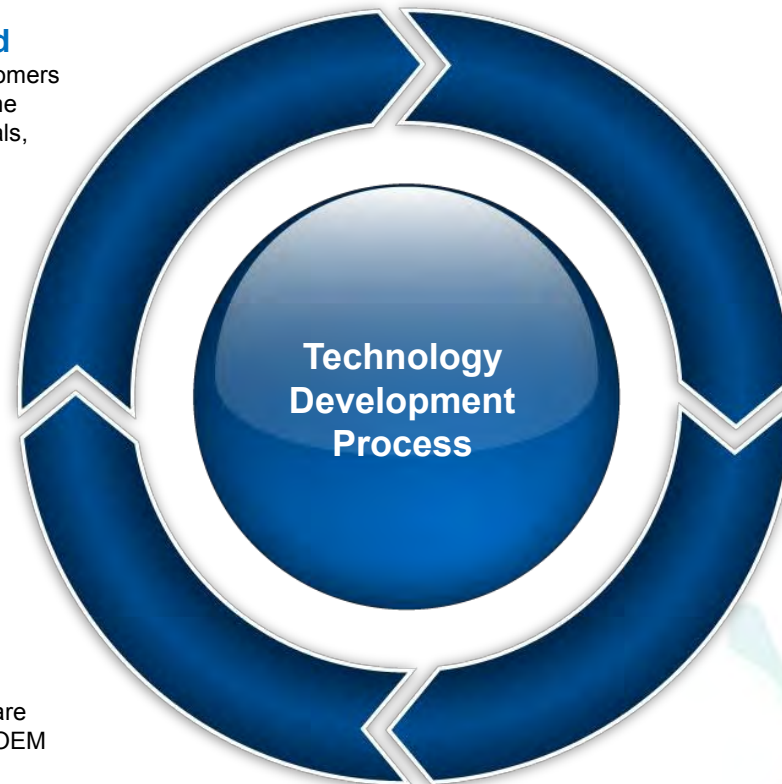
Meanwhile the number and the complexities of the regulations continues to increase this includes new substance notification schemes for industrial chemicals around the world.....

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

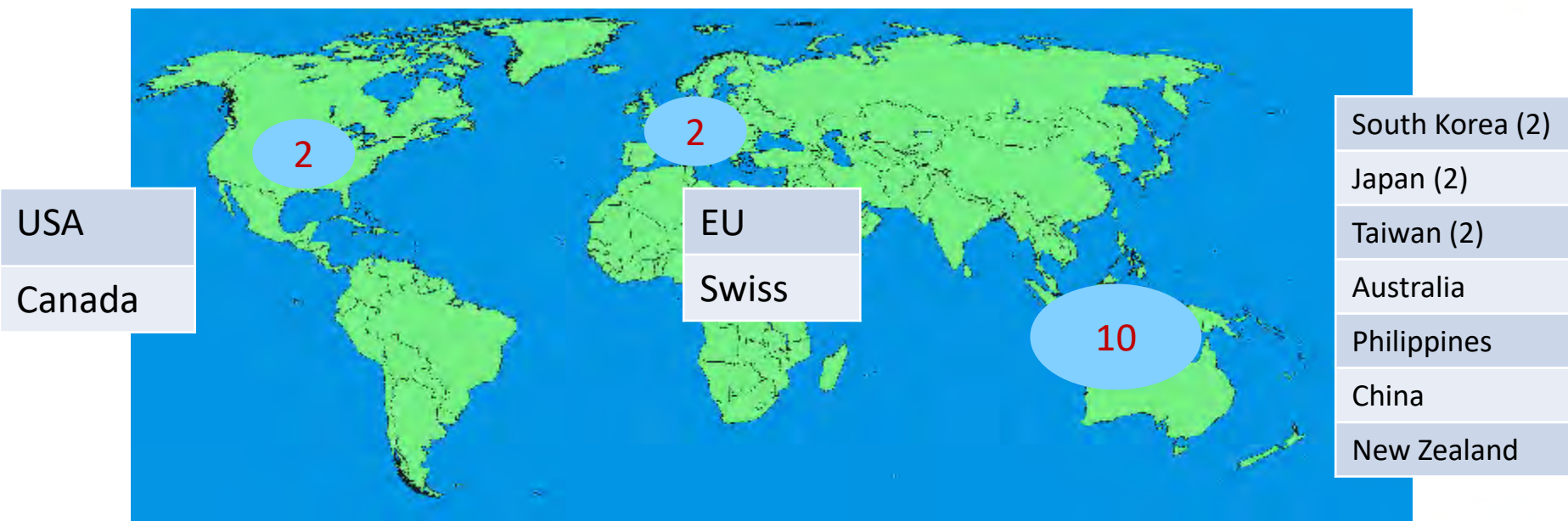
Questions to ask before deciding a substance requires notification in any concerned jurisdiction:

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?



Notification considerations and processes

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



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

Australia: AICS (AIIC)	Korea AREC and ISHA: KECI	Taiwan OSHA and TCSCA: TCSI	NZ: NZoIC
Japan: ENCS & ISHL	China: IECSC	Philippines: PICCS	USA: TSCA
Canada: DSL (NDSL)	EU: EINECS	CH: EINECS	

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 $\neq$ 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

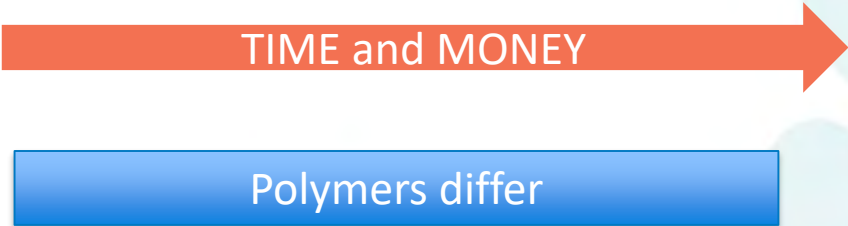
Full notification/registration is hence needed.....



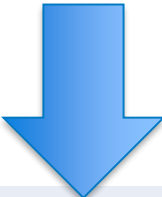
Full notification of substances

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

S. Korea - AREC	0.1 -1tpa (ISHA and AREC), 1-10tpa, 10-100tpa, 100-100tpa, >1000tpa
USA	>1tpa
Canada	0.1-1.0 tpa, 1-10 tpa, >10tpa (NDSL dependence)
Japan	CSSL: >10tpa, ISHL: >100kg/pa
Taiwan	1-10tpa, 10-100tpa, 100-100tpa, >1000tpa (CMRs more)
Australia	>1tpa standard notification
China	1-10tpa, 10-100tpa, 100-100tpa, >1000tpa
Philippines	>1tpa
New Zealand	N/A



Test data costs for full notification



Registration type	Volume	Cost	Time for testing
global	1-10	up to \$400,000	18-24 months
global	10-100	up to \$600,000	2 years
EUREACH only	1-10	up to \$100,000	18-24 months
EUREACH only	10-100	up to \$500,000	2 years



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

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

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)

Others:

- New Zealand – inventory listing can be requested on first import/manufacture of product
- EU – never applicable
- Switzerland – never applicable

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

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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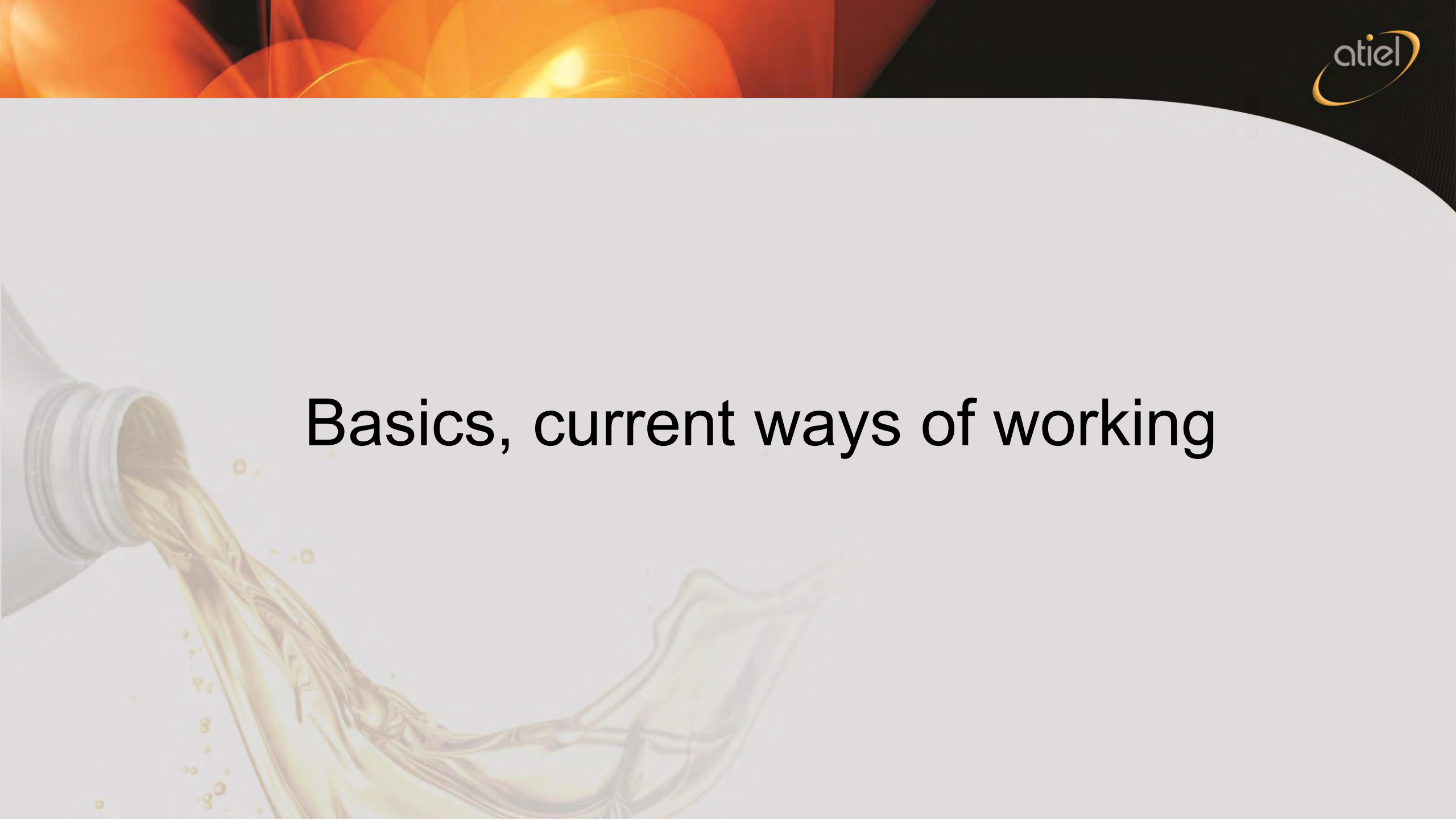
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Data communication in the supply chain,
approaches of regulatory compliance
for OEMs, tier 1 & tier 2 suppliers

Overview

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



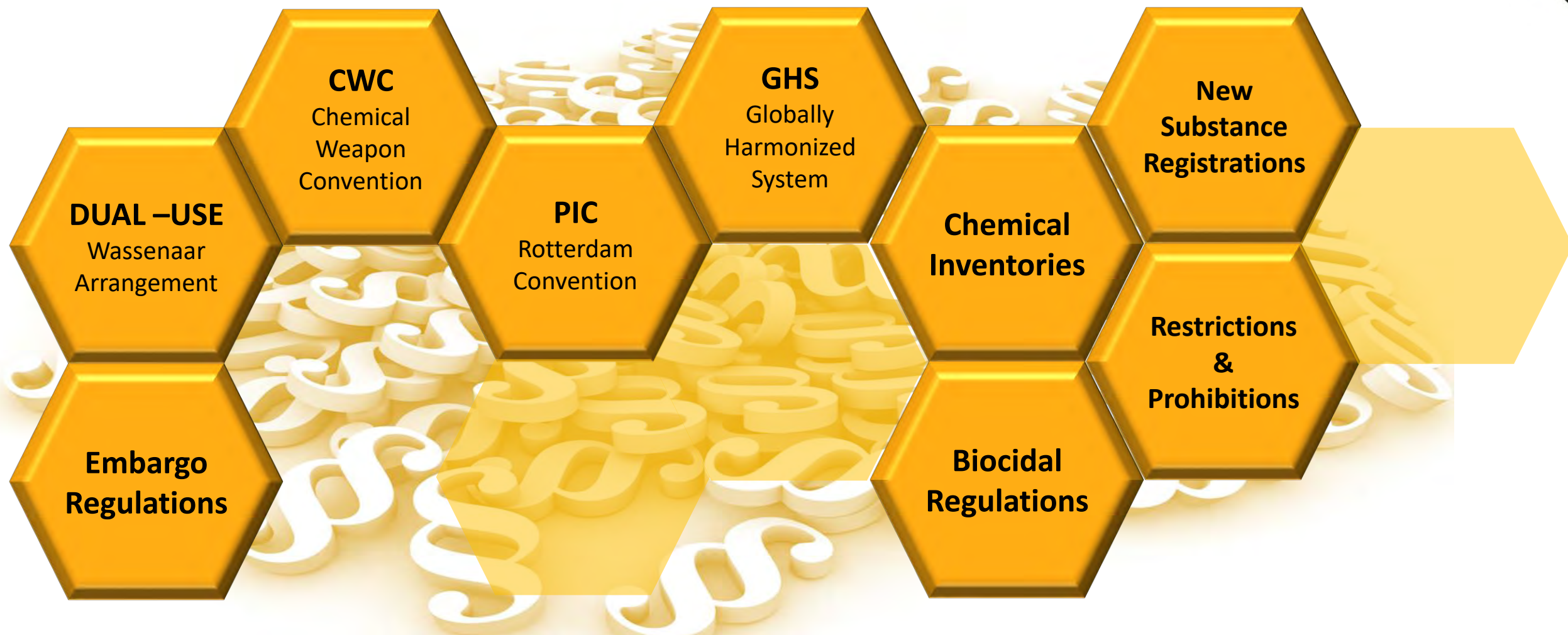
The background of the slide is a light gray with a large, curved white area on the right side. On the left side, there is a detailed illustration of a white plastic bottle pouring a golden liquid. The liquid is captured in motion, with a large splash and many small droplets trailing behind it. The top of the slide features a decorative orange and black abstract pattern.

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



Drivers for data communication, Compliance with two types of legislation



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

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

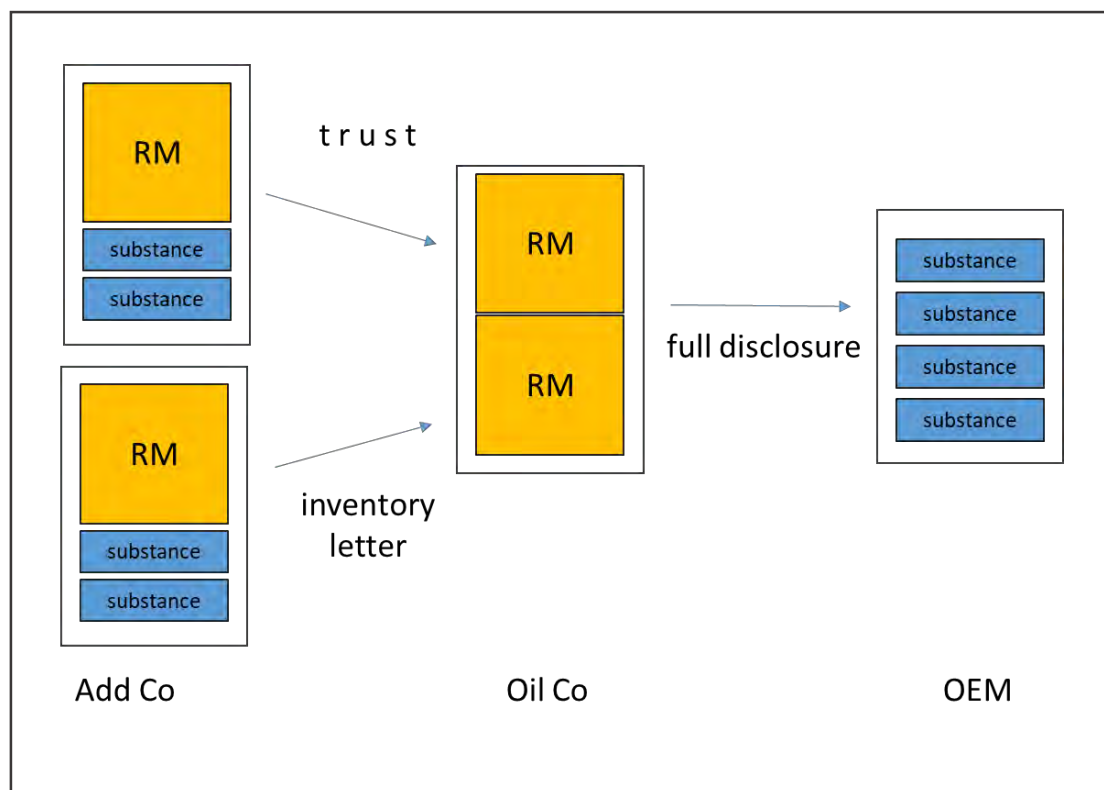


Chemical Control legislation:
Control of the manufacture,
import and use of chemicals



- 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.

A large, faint background image on the left side of the slide shows a white plastic bottle being poured. A stream of clear water is falling from the bottle's opening, creating a dynamic splash and ripples. The water is captured in a way that shows its movement and texture. The entire scene is set against a light, neutral background.

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

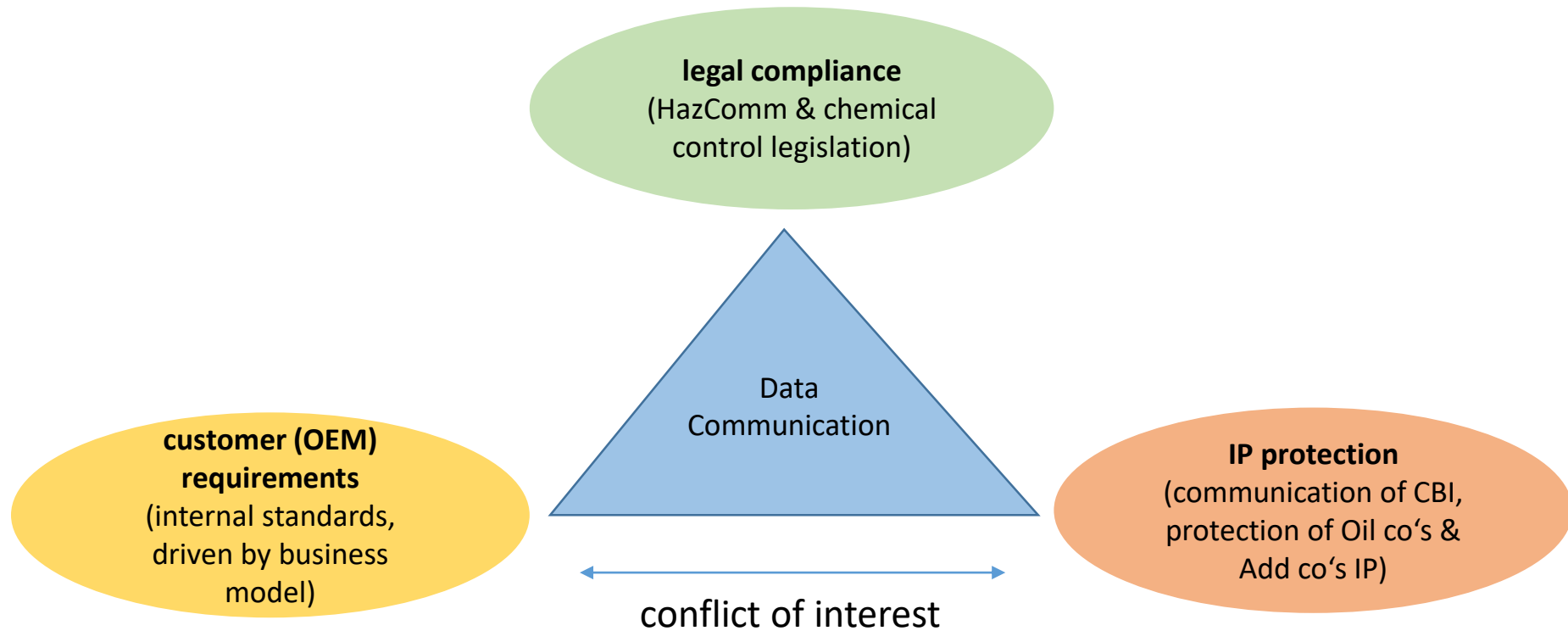
- OEM's want declaration on bespoke forms – time consuming
 - This can mean 10 regional forms for one product to cover the globe, this increases time and resource required to deliver.
- More than one declaration – SDS, bespoke declarations and IMDS/COVISINT entries – need to ensure alignment of information 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.



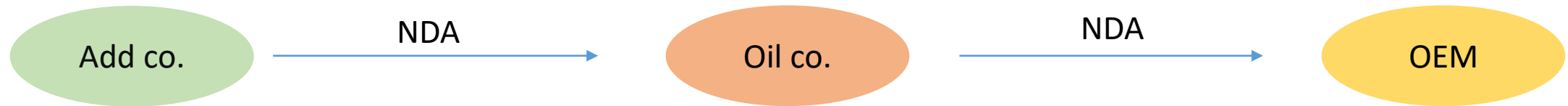
Discussions about depth of data sharing



Management of non disclosure agreements (NDA's) (1)

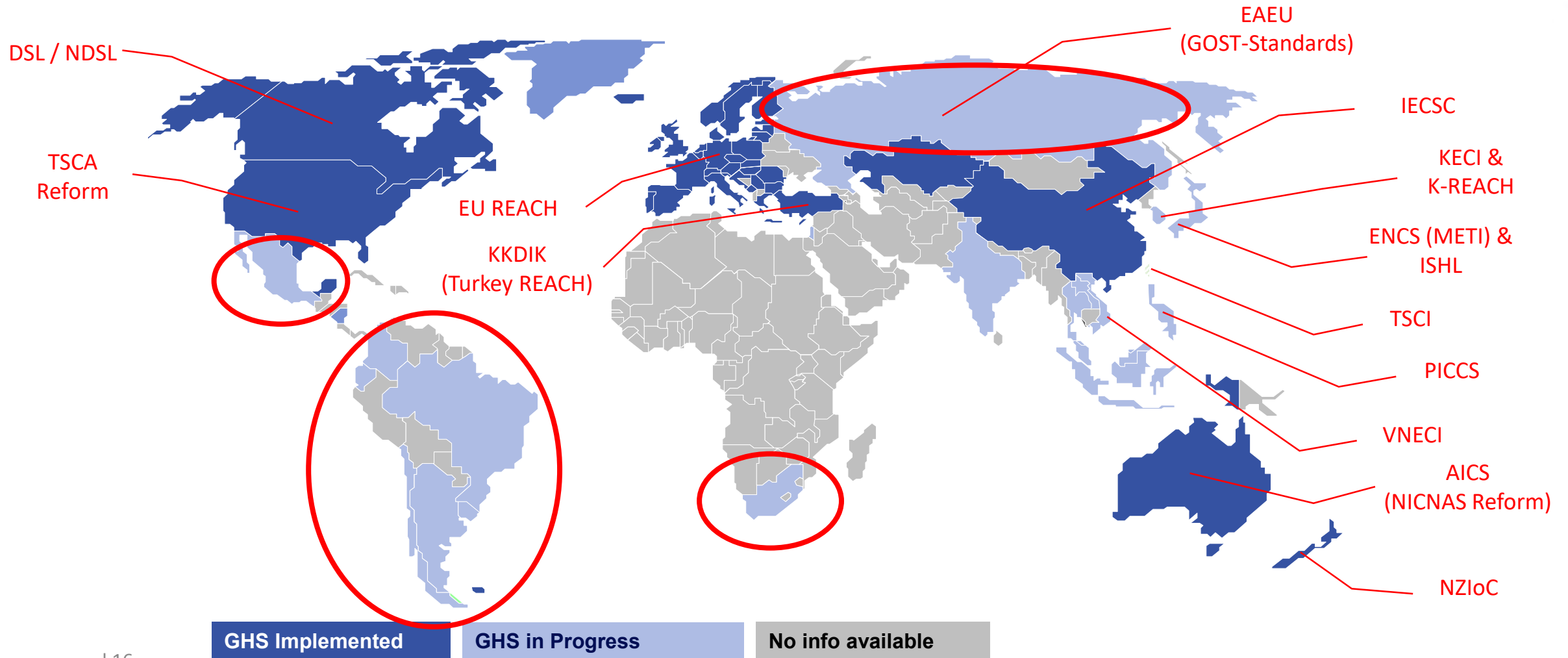
- To protect intellectual property for oil companies and additive suppliers, NDA is required.
- Complex NDA covering Add co., Oil co. and customer/OEM can be required. Time consuming to set up and manage.
- Extremely difficult for Oil co's to get NDA's in place with lots of suppliers and to obtain 100% 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)



	Add co. -> Oil co.	Oil co. -> OEM
What is shared	Raw material (RM) information: CAS, name, % range	- Lubricants product formulation: CAS, name, % range - Reference to supplier identity as well as RM name is removed
Required for	- Regulatory assessment & regulatory reportings - Regulatory disclosures & notifications	Regulatory assesments & regulatory reportings
IP protection	- Protect IP of Add co. (= RM compositional information) - Information only to be shared with Oil co's HSE & product stewardship functions - Only limited information is allowed to be shared with OEM's/ externals	- Protect IP od Add co. & Oil co. - No link to supplier identity, no link to RM name - Information only to be used for HSE & product stewardship purposes

Growing regulatory landscape increases complexity



A close-up, artistic photograph of water being poured from a white plastic bottle. The water is captured in mid-pour, creating a dynamic, flowing shape with visible ripples and splashes. The background is a soft, out-of-focus light grey.

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?



Thank

You

Claire Bailey
Senior Regulatory Chemist & Technology
Product Steward
Shell
claire.bailey@shell.com

Dr. Anette Schiller
Global Toxicology Manager,
Global Product Stewardship
BP
Anette.Schiller@de.bp.com

Peter Slijkhuis
Senior Specialist Global Trade Compliance,
REACH and Product Regulatory
Valvoline
pslijkhuis@valvoline.com

- BACK UP

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