

***REACH***

***&***

***Natural Complex  
Substances***

# How many are concerned ?

<b>Volume (T/an)</b>	<b>NCS</b>
> 1000	0
100-1000	11
10-100	47
1-10	90
<b>REACH Total</b>	<b>148</b>

**Available Information from ECHA**

# What is in REACH for NCS ?

- **Annex V** : Natural products are exempted !

Unfortunately the conditions to be fulfilled are not met

- **Récital 45** : The European Inventory of Existing Commercial Chemical Substances (EINECS) included certain complex substances in a single entry. UVCB (substances of unknown or variable composition, complex reaction products or biological materials) may be registered as a single substance under this Regulation, despite their variable composition, **provided that the hazardous properties do not differ significantly and warrant the same classification**

# What is in REACH for NCS ?

- **Annex XI section 1.5.** The Agency, after consultation with the actors concerned and other interested parties, will publish orientations as to the technically and scientifically appropriate methodology for the grouping of substances.

- **RIP 3 3-2. Draft Guidance on the Grouping of Chemicals.**

  - Paragraph 6.5.5 *Natural complex substances***

  - Inclusion in a chemical group is possible based on the constituents of the NCS where the major components can be clearly identified as the same as known chemicals.

## Natural Complex Substances (NCS)

All this is insufficient because the legislator has not taken the full measure of the specificity of E.O and extracts in relation to their complexity and variability.

As REACH stands now, we run the risk to be obliged to register several qualities of the same Essential Oil.

# Natural Complex Substances (NCS)

A sub-Group of EFFA, in liaison with EFEO and COLIPA, has prepared a “Guidance” document to help the registration of NCS under REACH

This document does not resolve all the issues but its main goal is to show that our industry strives to adapt to a legislation primarily conceived for synthetic chemicals

A meeting with DG Enterprise and DG Environment will be requested soon to present and discuss the content of this document.

# CORE of the PROPOSAL for SNC registration

The registration dossier of a NCS can be based upon:

- Data obtained with a **representative quality** of the NCS
- Data obtained on its significant constituents
- Data from Read-across with substances similar to its significant constituents

# CORE of the PROPOSAL for SNC registration

Classification and labelling will result from :

- Tests made with a representative quality of the substance

**OR**

- The classification of its dangerous constituents. One will utilise the DPD methodology (1999/45/EC and its future amendments resulting from the introduction of the GHS in Europe)

# NCS CATEGORIES

NCS can be divided into two categories:

- Type 1 → NCS Analytically characterised at 90% minimum.
- Type 2 → NCS Analytically characterised at less than 90%
- **The vast majority of the NCS to be declared are Type 1**

# REACH Article 10

**For a Type 1 NCS**, the dossier would consist of data obtained with a representative quality of the NCS itself **and/or** data from its significant constituents. For those constituents registered themselves under REACH, the dossier of the NCS would provide a reference to their dossier and their proposed classification

**For a Type 2 NCS**, Registration will have to be based upon tests conducted with a representative quality of the substance

# CHARACTERISATION of Type 1

## NCS

List all significant constituents ( $\geq 1\%$ ) and their median concentration (pourcentages obtained by surface normalisation of the peaks of the GC tracing)

Define their variability. It is proposed to take the 5<sup>th</sup> and 95<sup>th</sup> percentiles respectively for mini and maxi

In reference to RIP 3.10, list minor constituents classified for human health and/or environment down to a concentration of 0,1%

In order to insure **robust** statistics it is recommended that producers/importers regroup their analytical data within a consortium

# Example: Eucalyptus globulus E.O

## Significant constituents

Number of samples analysed → 149. Origin: China. Period: 2004 - 2007

	Median %	5 <sup>th</sup> Percentile %	95 <sup>th</sup> Percentile %
1,8 Cineol	80,3	79,6	81,7
Limonene	8,1	6,6	9,4
Terpinene gamma	3	1,5	4,3
Pinene alpha	2,7	1,4	4,8
Paracymene	2,3	1,4	3

# Example. Eucalyptus globulus E.O

## Minor constituents with classification

Beta Myrcene	0,65	0,3	1	Xn R65
Phellandrene alpha	0,55	0,15	0,8	Xn R65
Pinene beta	0,4	0,25	0,8	Xn R43-65 N R50/53
alpha Terpineol	0,35	0,1	0,85	Xi R38
Terpinene-1-ol-4	0,16	<0,1	0,35	Xn R22-38
Terpinolene	0,16	<0,1	0,3	Xn R65 N R51/53
Camphor	0,15	<0,1	0,35	Xn R20-68/22

**TOTAL → 98.2%**

# PROPOSITION to SELECT a REPRESENTATIVE SAMPLE

The tests required by REACH for classification are made to evaluate HAZARD and not RISK: as a consequence

- If **ONE** constituent of the NCS is recognised or suspected to be responsible of the hazard, select a sample containing this constituent at or near its maximum\*
- Otherwise, select a sample with a “typical” composition with full tracability

\* One will refer to the DPD rules for the authorised fluctuations in concentrations for the classification of a preparation

# REVIEW OF STANDARD REQUIREMENTS

A number of informations requested by Annex VII to IX are either not applicable or not technically feasible.

Adaptations are proposed where possible.

# Physico-chemical data

A number of endpoints are meant for chemically defined substances or appear to be irrelevant.

Melting point

Vapor pressure

Water solubility

Octanol/Water Partition Coefficient

Explosive Properties

Auto-inflammation Temperature

Oxidising Properties

Dissociation Constant

# Toxicological Data

The tests required are feasible with NCS

Data will be obtained with a representative quality of the NCS.

For Type 1 NCS one will have also the possibility to make use of data obtained on all its significant constituents and/or on substances with structures close from these constituents.

# Ecotoxicological Data

By contrast with the toxicological endpoint of REACH, we are facing here special difficulties.

- › Some tests will require adaptations.
- › Some are even **not feasible technically with NCS**

# ECOTOXICOLOGICAL requirements

TEST	Needs Adapt. ?	VII	VIII	IX
Acute Toxicity on Daphnia	Yes	X	X	X
Short term toxicity on fish	Yes		X	X
Long term toxicity on fish and on Daphnia	Yes			X
Simulation test on ultimate degradation in surface water	Not F.			X
Soil and Sediment simulation tests	Not F.			X
Hydrolysis as a function of pH	Yes		X	X
Adsorption/desorption screening study	Yes		X	X
Bioconcentration in fish	Not F.			X

# Long term Ecotoxicity of E.O

**ESSENTIAL OILS are Nature's daughters.**

Plants produce them and return them to the environment where they are physically and biologically degraded. No long term harmful effects in the Environment **has ever** been attributed to them.

In this perspective it appears inappropriate that REACH requests **long term** environmental effects and bio-accumulation in fish for them.

# In Conclusion

The main purpose of the document which will be presented to the Commission is to show that the Industry of Natural Aromatic Products strives to adapt REACH requirements to the specificity of its products.

It proposes a canvas to register our NCS and points out that adaptations of standard requirements of Annex VII to IX are a necessity.

After the discussion with the Commission, a final guidance document will be elaborated