



E.F.E.O.

European Federation of Essential oils

**EFEO REACH PROGRAM:
ROAD MAP
for REGISTRATION of
NATURAL COMPLEX SUBSTANCES**

*A Program to Facilitate
a Smooth Implementation of REACH
for the Supply and Downstream Use of NCSs*

November, 2008

ROAD MAP for REGISTRATION of NATURAL COMPLEX SUBSTANCES

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The EFEO REACH Road Map for the registration of NCSs is a living document, which is subject to changes while moving forward during the phase-in stages of REACH and while gaining experience with this new Regulation. The interests of all stakeholders of the NCS supply chain (producers, importers and downstream users) will be given due consideration as permitted by the REACH Regulation.

This Road Map does not replace or substitute in any way the REACH obligations of individual companies to preregister and register their substances and the identified uses. Companies can choose to adopt the recommendations of the EFEO REACH Road Map or decide to proceed as they prefer to assure a REACH compliant situation for their operations.

EFEO REACH PROGRAM: ROAD MAP for REGISTRATION of NATURAL COMPLEX SUBSTANCES

SUMMARY

EFEO aims to facilitate a smooth and timely registration of Natural Complex Substances (NCSs) under the REACH Regulation by companies who produce and import these substances. The program of this Road Map is designed to coordinate and help to accomplish timely such a REACH compliant situation for suppliers and downstream users. Alignment with the REACH program of EFFA for the registration of fragrance substances is regarded essential, as well as the cooperation with IFRA and its expert committees and with RIFM for the scientific aspects of the substance safety evaluation part.

The circa 150 NCSs of the portfolio for REACH registration has been divided over 20 Groups of NCSs. The NCSs of a Group have for a large degree the same or structurally similar constituents. For an NCS Group a Consortium will be formed, which consists of companies with an interest to register one or more NCSs of the Group. In the Consortium they shall jointly prepare the registration dossier by data collection and evaluation for their NCSs. Read-across of data between NCSs of the Group and data on the constituents shall be an important element in this process. Therefore a concept of *double grouping* is introduced by which:

1. the identified constituents of the NCSs are grouped by the characteristics of their chemical structure
2. the NCSs are grouped based on the chemical groups of their constituents

This *double grouping* will optimise the possibilities for read-across of data on constituents and NCSs. At the same time it will give a structure for the cooperation between consortia of NCS-Groups and EFFA's consortia, that deal with fragrance substances occurring as constituents in the NCSs.

NCSs that do not fit in a Group, which relates to fragrance substances, are assigned to a Group based on botanical origin or must be handled as Stand-Alone.

EFEO's schedule for the formation of NCS consortia follows from the *double grouping* concept and is prioritised by:

- a. the NCS of the Group with the highest volume band for registration and registration deadline
- b. the schedule of the Consortia of related fragrance substances, from whom data for read-across shall be obtained.

Only a few NCSs need registration by 2010, some more by 2013 and the majority by 2018, because of their lower volumes. The main constituents of the NCSs, which will play a key role for read-across purposes are fragrance substances in REACH volume bands with deadlines for registration of 2010 and 2013. Their data will become available for data sharing and read-across during the first half of the 10 years phase-in period, between 2009 and 2013. Accordingly the NCS consortia will be launched in 3 phases:

- *Phase 1: 2008-2010*
- *Phase 2: 2010-2012*
- *Phase 3: 2013-2015*

A separate excel file with details on the NCS-Groups belongs to this Road Map. The plan and group assignments will be updated as demanded while moving forward.

An efficient and cost effective registration program is expected as the result. Companies can plan the registration of their NCSs according to the schedule of this Road Map. EFEO will consider proposals to adjust the priorities of the presented schedule if the registrants for an NCS-Group request so with good reasons.

The EFEO REACH Committee:

Francis Thibaudeau	(EFEO President)
Jens-Achim Protzen	(EFEO Technical Committee)
Philippe Racine	(NCS Sub-Task Force)
Hans van Bergen	(REACH Consultant)

SIEFs (Substance Information Exchange Forum) and this Road Map

In January 2009 the SIEF process will start. SIEFs are formed for individual substances. SIEFs are NOT formed for groups of substances. SIEFs stay active at least until the end of the phase-in period of REACH (2018). Each SIEF will have a SIEF facilitator, most likely the company that will function as the Lead Registrant of the substance.

The aim of the EFEO REACH Road Map for the registration of NCS is to work in consortia per NCS-Group as it is in place for four of such consortia. These consortia shall assign a Lead Registrant for each of the NCSs of the Group. The company members shall jointly prepare the registration dossiers.

Companies may communicate the schedule of the EFEO Road Map to other SIEF members and explain the objectives of the plan to align the SIEF activities with the EFEO program.

EFEO REACH PROGRAM: ROAD MAP for REGISTRATION of NATURAL COMPLEX SUBSTANCES

I INTRODUCTION.

The REACH Regulation¹ by the European Union for the production, import and use of substances was published on December 30th, 2006 and entered in to force by June 1st, 2007. The 6 months period for pre-registration is open from June 1st to December 1st 2008, which will be followed by actual registration of the preregistered substances over a phase-in period of 11 years with deadlines by December 2010 for substances exceeding 1000 t/y and those of specific concerns, June 2013 for substances from 100 – 1000 t/y and June 2018 for substances from 1 – 100 t/y.

EFEO aims to facilitate a smooth and timely registration of Natural Complex Substances (NCSs) under the REACH Regulation and is committed to the program of this Road Map, which assists companies with the registration of the NCSs they produce and import in the European Union. The program is designed to coordinate and help accomplish a REACH compliant situation for suppliers and downstream users. Alignment with the REACH program of EFFA for the registration of fragrance substances is considered essential, as well as the cooperation with IFRA and its expert committees and with RIFM for the scientific aspects of the substance safety evaluation part.

The Road Map for the registration phase is an important next step in EFEO's ongoing REACH program. In symposia and with information letters company members were made aware of the upcoming obligations of the new Regulation. These obligations hold for producers and importers of NCSs as far as their products are used in non-food applications such as cosmetics, detergents, air fresheners and other fragranced products but also non-food flavour uses like oral care and tobacco.

It should be realised that EFEO will not take care of the actual registration. That duty resides with individual companies.

In this Road Map EFEO describes the process by which it intends to achieve the objectives. It includes a schedule which companies may follow for the registration of their NCSs, if exceeding 1 t/y produced or imported per legal entity and used downstream in applications, which are in the scope of REACH. EFEO conducted a survey, which gave about 150 NCSs for registration. Few NCSs need registration in excess of 100 t/y, while the majority falls in the two lower volume bands. In this context NCSs concern the diverse family of products of botanical origin such as essential oils, absolutes and extracts and fractions therefore.

The circa 150 NCSs of the portfolio for REACH are now divided over 20 NCS-Groups. The NCSs of a Group have to a large degree the same or structurally similar constituents. For an NCS Group a pre-consortium will be organised for the formation of a consortium, which consists of companies that intend to register one or more NCSs of the Group. In the Consortium² they shall jointly prepare the registration dossiers by data collection and evaluation for their NCSs. Scientifically justified read-across of data between NCSs of the

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. Off. J. of the European Union L396/1 of 30-12-2006 AND Corrigendum of May 29, 2007 in L 163/3 http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf

² Four such pre-consortia were initiated in March 2008 for 7 Citrus oils, 2 Mint oils, 2 Safrol containing oils and for Vetivert oil

Group and data on the constituents will be an important element in this process. Therefore the NCS-Consortia shall set up a cooperation with the related EFFA fragrance substances Consortia. An efficient and cost effective registration program is expected as the result.

Companies can plan the registration of their NCSs according to the schedule of this Road Map. EFEO will consider proposals to adjust the presented schedule if the registrants for an NCS-Group request so with good reasons. For such requests a timely alignment with the EFFA Consortia for the NCS-related fragrance substances will be given due consideration.

REACH registration extends over a period of eleven years after implementation of the Regulation by June 1st, 2007. It has a beginning and an end. The EFEO REACH Road Map is aligned with the phase-in structure of REACH. Phase-in substances are primarily those listed in EINECS, which is the case for the NCSs which are currently used. In order to benefit from the phase-in scheme companies shall have preregistered their substance(s) during the 6 months period for pre-registration starting June 1st and ending December 1st 2008. Data sharing in SIEFs (Substance Information Exchange Fora) between registrants of the same substance follows immediately thereafter. EFEO's NCS-Consortia are the formalised bodies for that purpose.

Actual registration by companies shall occur no later than by the deadlines of the three phase-in periods:

- for high volume substances (> 1000 t/y) and substances of concern > 1 t/y per legal entity by December 1st, 2010
- for substances with volumes of 100 –1000 t/y per legal entity by June 1st, 2013
- for substances with volumes of 1 – 100 t/y per legal entity by June 1st, 2018

Companies, who did not pre-register their substances, cannot make use of the phase-in scheme and must register the substance right away per December 1st 2008.

The EFEO REACH Road Map will be adjusted as needed, while moving forward and gaining experience with the new REACH Regulation. The success depends on the support given by all stakeholders and an enthusiastic participation of experts of companies!

II IDENTIFICATION OF NCSs FOR REGISTRATION

Phase-in substances for REACH registration are primarily those listed in EINECS. They are *legally* identified by their EINECS and CAS number combination and EINECS-description. Different types of NCSs of the same botanical source have under REACH the same identification numbers.

For the trade the same botanical species is often the source of several and quite different NCS products. They can differ by the part of the plant as the source and the methods used for production, giving essential oils, extracts, concretes, absolutes, resinoids, gums or distillation fractions. Such different qualities may contain different constituents and/or levels thereof, but are for REACH still the same phase-in substance. They must and can only be (pre)registered under their EINECS-CAS number combination and EINECS name. To assist pre-registration EFEO distributed with the information letter of September 2, 2008 on pre-registration an excel file with a cross-reference table for traded NCSs and their legal identifications under REACH.

The various types and qualities of NCSs originating from the same botanical source can be combined in one registration dossier. However their volumes will have to be taken together. If the NCS composition of the constituents differs to the extent that another hazard classification must be assigned then these NCS types and qualities shall be separately reported in one dossier. Therefore broad specification ranges per type and quality can be chosen as long as the hazard classification remains the same. Because one dossier covering all qualities is submitted, the registration fee must be paid also just once.

III PROTOCOL FOR REACH REGISTRATION OF NCSs

A joint Working Group of EFEO, EFFA and COLIPA has developed a protocol for "*The Registration for REACH of Natural Complex Substances used as Fragrance Ingredients*". The main principles of the protocol are a division in

- a. Type 1 "Well defined NCSs"
NCSs which are analytically characterised to at least 90 %
- b. Type 2 "Incompletely defined NCSs"
NCSs which are analytically characterised for less than 90 %

Appendix 6 of the NCS Protocol describes ways for the selection of appropriate samples of NCSs and how they should be characterised.

A REACH compliant registration for NCSs of types 1 and 2 shall be supported by:

- Data from tests conducted with a representative quality of the NCS as such
- Data directly obtained on the constituents
- Data indirectly obtained by read-across from data on substances related to the main constituents and other non-test methods.

The protocol gives further guidance on the adaptation of the standard data and test requirements. Several standard requirements will need an adaptation of the usual test protocols or the requirement may scientifically not be feasible and should be addressed in another way than testing the NCS or even be waived. The appendices in the protocol give the recommendations and justifications for each end point.

The protocol is a living document². New methods for data gathering on NCSs and their assessment will be evaluated and if validated the protocol will be updated.

IV. GROUPING OF NCSs

EFEO conducted in 2005 and 2006 among the members a survey for the NCSs, which they intend to register for REACH. A portfolio of circa 150 NCSs was the result. A subgroup of EFEO and EFFA collected from the potential registrants compositional information, which gave until now 122 NCS of Type 1, "Well defined NCSs" or which come close to the 90 % criterion for Type 1 characterization.

A minority remains as NCS Type 2 or is waiting further chemical characterisation.

The circa 150 NCSs of the REACH portfolio have been divided over

- 16 Groups of NCSs Type 1, which have the same or structurally related constituents (122 NCSs in total)
- 3 Groups of NCSs Type 2 based on botanical origin, i.e. benzoin, tree/oak moss (4 NCSs in total plus Vetivert)
- 12 NCSs positioned as Stand-Alone cases (counted as a group).
- Circa 25 NCSs, not yet included in any group pending constituent data and which may end up as stand-alone cases.

Among the company responses were 12 NCSs which are not further considered, because they are predominantly or exclusively used as flavours.

The grouping of the NCSs may get adjusted, if new data become available. Therefore it is added to the Road Map as a separate excel attachment.

Criteria for the grouping of NCSs

For the purpose of REACH registration a concept of double grouping is applied:

1. the identified constituents of the NCSs are grouped by the characteristics of their chemical structure
2. the NCSs are grouped based on the chemical groups of their constituents.

This *double grouping* will optimise the possibilities for read-across of data on constituents and NCSs. At the same time it will provide for the cooperation between consortia of NCS-Groups and consortia dealing with fragrance substances occurring as constituents in the NCSs.

In the first step the constituents present in a NCS in 1 % and above are taken into account for the group assignment³. The source for this information is the overview with the composition of the 121 Type 1 NCSs (July 21, 2008 and subsequent refinements), which has been prepared by an EFEO/EFFA working group lead by Ph. Racine. In total 260 constituents were chemically characterised. These constituents are all assigned to a chemical group used by EFFA for the grouping of the fragrance substances portfolio, for

² The June 25, 2008 version of the Protocol was discussed with ECHA, who recommended certain improvements and suggested to prepare some pilot dossiers of NCSs for their review. Followup actions have been initiated.

³ Constituents of less than 1 % shall be taken into account per NCS if relevant for the safety evaluation and hazard classification.

which EFFA took as the basis RIFM's chemical groups for the safety assessment of fragrance substances.

In the second step for the grouping of NCSs the identified constituents are consolidated for each NCS to a total percentage of the chemical groups represented in that NCS.

The above characterisation of NCSs in constituents and their chemical groups then leads to the grouping of the NCSs by applying the following criteria and naming convention:

1. Primary chemical group, the one chemical group of constituents which represents ≥ 50 % of the composition of the NCS, leads the NCS Group assignment
 - o Chemical groups represented in the NCS at levels ≥ 10 but < 50 % are in such cases secondary chemical groups
2. Secondary chemical groups become leading for NCS-grouping in the absence of a chemical group representing 50 % or more of the composition.
3. Tertiary chemical groups representing < 10 % of the composition are not considered leading for the grouping (except if it concerns certain substances of very high concern, e.g. safrol)
4. Names of the NCS Groups refer to the key constituent(s) of the primary chemical group or to the botanical source.

This approach results in the Groups of NCSs as presented in Table 1.

The NCSs and their group assignments is given in the separate excel file belonging to this Road Map. That file gives

- an overview of the NCS-Groups
- the primary chemical group for an NCS
- the secondary chemical groups relevant for an NCS
- the EINECS and CAS id-numbers
- the highest volume band for registration as reported in the EFEO surveys
- a sheet with names and numbers of the chemical groups as used by EFFA
- the Stand-Alones and NCSs (To Be Determined), those pending further analytical characterisation⁴
- two botanical groups (benzoin and moss)
- the NCSs considered as flavourings and therefore excluded from consortia formation

Details on the composition of NCSs will be made available in due course to the pre-consortia and their members.

⁴ Companies can submit analytical data of these NCSs to Ph. Racine (Philippe.Racine@Robertet.fr)

TABLE 1: GROUPS of NCSs for REACH Registration and Consortia Formation

NCS GROUP Name	NUMBER OF NCSs in GROUP	EFEО CONSORTIUM PRIORITY #	RELATED MAIN EFFA GROUP(S) @
BENZOIN *	2	C	N.A.
C10-15 ALYPHATIC ALCOHOLS / ESTERS	18	C	12, 39
CARVONE	7	C	109
CINEOL	6	B	92
CINNAMATES	3	D	20
CITRAL / CITRONELLAL	5	C	19
CITRUS	7	A	101
CITRUS / BERGAMOT *	1	C	101, 12
ESTRAGOL/ ANETHOLE	7	C	94
EUGENOL	7	C	122
MINT	2	B	13, 111
MOSS *	2	C	N.A.
PINE	7	B	101
SAFROL *	2	A	NA
SESQUITERPENES	17	C	102
TBD or STAND-ALONE *	12	C,D	N.A.
TERPENECYCLIC ALCOHOLS	6	C	13
TERPENE CYCLIC HYDROCARBONS	8	C	101
THUJONE	5	C	111
VETIVERT *	1	D	N.A.
TOTAL NCSs	125		

* Grouped by botanical origin, Stand-Alones and other specific cases.

The priority indicates the highest volume for REACH registration of one or more NCSs in the group: A = 1000 t/y, B = 100-1000 t/y, C = 10-100 t/y, D = 1-10 t/y,

@ The number relates to the EFFA chemical group, which characterises for the most part the constituents of the NCSs

V CONSORTIA FOR GROUPS OF NCSs

EFEО acts as the lead association for the organisation of NCS-Consortia formation and invites companies with an interest for registration for a kick-off meeting of a pre-consortium. It starts the process of cooperation between companies to prepare jointly the core data set of the registration dossiers and share data, while keeping in mind the provisions of the EU Competition Law.

In the kick-off meetings the potential registrants agree on the terms and conditions of their consortium and their respective roles. They agree also on the lead-company for the NCS-consortium and the lead-registrants per NCS of the group among the consortium members. In order to start these pre-consortia discussions a Memorandum of Understanding (MoU) must be signed by each candidate consortium member. This MoU sets the scene for further discussions regarding the actual consortium agreement. In addition EFEО provides a model agreement for a REACH Consortium which is identical to the agreement for EFFA's consortia but speaks of NCSs instead of fragrances substances.

A *modus operandi* for the Consortium is added as attachment 1.

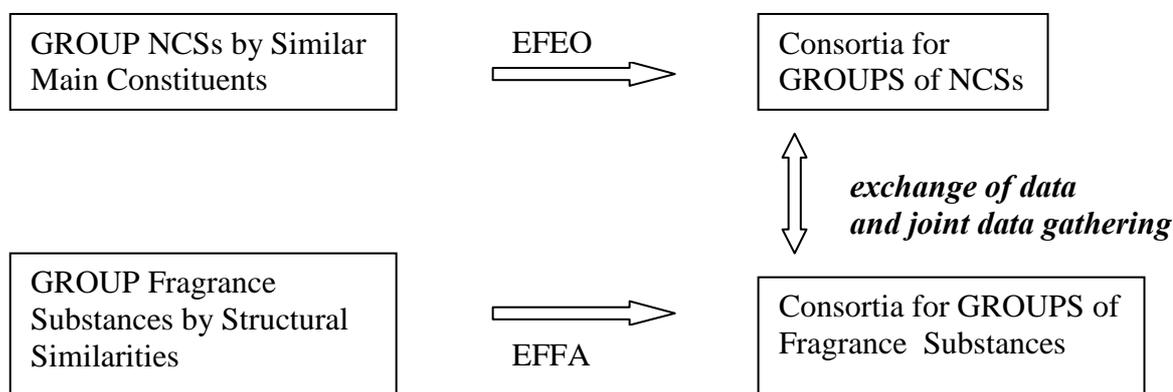
After the kick-off meeting EFEO will leave further work to the (pre-)consortia but remains available to provide guidance and stimulate consistency where needed.

VI SCHEME FOR CONSORTIA FORMATION FOR GROUPS OF NCSs

EFEO's planning for the formation of NCS consortia is driven by:

- the NCS in the Group with the highest volume band for registration and the corresponding registration deadline
- the schedule of the EFFA consortia of related fragrance substances, from which data for read-across shall be obtained.

If timewise both EFEO and EFFA consortia are aligned, then the *double grouping* concept will facilitate the intended cooperation and exchange of data between them and prevent duplication of work (see scheme).



Few NCSs need registration by 2010, some more by 2013 and the majority by 2018, The main constituents of the NCSs will play a key role for read-across purposes, Most of them are fragrance substances in REACH volume bands with deadlines for registration of 2010 and 2013. Their data will become available for data sharing and read-across during the first half of the 10 years phase-in period, between 2009 and 2013.

Accordingly the NCS consortia will be launched in 3 phases:

- Phase 1: 2008-2010
- Phase 2: 2010-2012
- Phase 3: 2013-2015

The table II presents the schedule for the formation of the NCS Consortia. The four consortia of the first phase (Citrus, Safrol-containing, Mint and Vetivert as a pilot Type2) were already launched in March 2008.

Column 2 of Table II gives the EFEO priority (A, B, C or D) for the NCS Group. Column 3 gives the EFFA priority (A, B, C or D) for the related fragrance substances groups. The columns 3 and 4 which refer to the EFFA grouping indicate the primary (presence >50 %) and secondary (presence 10 – 50 %) chemical groups of the NCS constituents, which are separated by the / symbol.

The roll-out of an NCS Group for consortium formation can be advanced based on requests of the registrants. Such requests will be given due consideration.

TABLE II. PLANNING FOR THE FORMATION OF CONSORTIA

Initiation of Consortia: phase 1:2008-2010 phase 2:2011-2012 phase 3:2013-2015	EFEQ CONSORTIUM PRIORITY *	EFFA PRIORITY * for RELATED CONSORTIA >= 50 % / 10-<50%	RELATED EFFA CHEM.GROUPS Primary / Secondary	NCS Group Name	NUMBER OF NCSs in GROUP
phase 1	A	A / 0	101	CITRUS	7
phase 1	B	0 / A,A	0 / 13, 111	MINT	2
phase 1	A	A,B / B	101, 122 / 94	SAFROL	2
phase 1	D			VETIVERT (pilot Type 2)	1
TOTAL in PHASE 1					12
phase 2	C	A / A,A,B,B	12, 39/ 101, 118 (64, 122)	C10-15 ALYPHATIC ALCOHOLS / ESTERS	18
phase 2	C	A / A	109 / 101, 111	CARVONE	7
phase 2	D	A / B	20 / 55	CINNAMATES	3
phase 2	C	A / A, A, B,A	19 / 12,13,94,101	CITRAL / CITRONELLAL	5
phase 2	C	A / A,A	101 / 12,39	CITRUS / BERGAMOT	1
phase 2	B	A / B	101 / 40	PINE	7
phase 2	C	A / B,B,A,A	13 / 6, 94,101,102	TERPENE CYCLIC ALCOHOLS	6
phase 2	C	A / B,B	111/ 40,92	THUJONE	5
phase 2	B	C / A,B,A	92 / 13,40,101	CINEOL	6
TOTAL in PHASE 2					58
phase 3	C			BENZOIN	2
phase 3	C	B,A / B,A	94, 101 / 99,111	ESTRAGOL / ANETHOLE	7
phase 3	C	B / B,B	122 / 99,102	EUGENOL	7
phase 3	C			MOSS	2
phase 3	C	B/ A,B,B,B,B	102 / 13,36,43,99,107	SESQUITERPENES	17
phase 3	C,D	VARIOUS	VARIOUS	TBD or STAND-ALONE	12
phase 3	C	A / A,B,B,B	101 / 13,92,99,102	TERPENE CYCLIC HYDROCARBONS	8
TOTAL in PHASE 2					55

The priority indicates the highest volume for REACH registration of one or more NCSs in the group.: A = 1000 t/y, B = 100-1000 t/y, C = 10-100 t/y, D = 1-10 t/y,

VII IDENTIFIED USES, EXPOSURE SCENARIOS AND SAFETY ASSESSMENTS

Identified Uses

Essential for REACH registration are the identified uses of substances. The registrants shall describe the identified uses in the dossier. If the volume is 10 t/y or more and the substance classifies as hazardous the registrant must conduct a risk assessment for human and environmental exposure and include a Chemical Safety Report (CSR) with appropriate risk management measures. The key aspects of the CSR with the measures for safe handling during production and use shall be communicated to downstream users in the extended Safety Data Sheet.

The NCSs of this portfolio are used to perfume a multitude of consumer and industrial products. The most common uses are in

- cosmetics⁵
- cleaning products
- air fresheners

Minor usages shall also be reported.. For instance articles other than air fresheners with an intended release like candles, toys, cloths, etc. can be fragranced and may contain NCSs.

A sub-section of the NCS portfolio is also used in flavours for non-food products, i.e. uses in toothpaste and other oral care products are cosmetics and are under the scope of REACH⁶.

Uses can be described in broad categories if the exposure scenarios are similar. The EFFA REACH TF will give guidance on the use descriptions of fragrance substances, which also apply to NCSs.

The safety of their use in consumer products shall as always be controlled by the levels of the standards of the IFRA Code of Practice and prescribed by the EU's regulations or as the REACH risk assessments may demand.

Exposure scenarios

The characteristics of the operations in the fragrance supply chain and the common use of the NCSs and fragrance substances in products lends itself well for a generic description and assessment of the handling and exposure situations in the workplace and emissions to the environment. These scenarios are developed by the EFFA REACH TF in cooperation with downstream user organisations. The NCS Consortia are advised to adopt these scenarios for the risk assessments of their NCSs.

Companies who produce NCSs will have to review individually their production operations and assess their workplace exposure and environmental emissions. For this assessment they can use generally adopted models for a first tier assessment, which may well demonstrate a sufficient level of safety. Otherwise an iteration of the assessment should follow by collecting more accurate data.

The outcome of the exposure and risk assessments shall give the conditions of safe use, which shall be described in the CSR part of the registration dossier. They must be communicated to downstream users by means of the extended safety data sheet.

VIII COORDINATION, TOOLS AND RECORD KEEPING

IUCLID 5 will be the tool to prepare the registration dossiers. Members of NCS Consortia should become familiar with this software (www.iuclid.eu). Registration dossiers must be submitted to ECHA via REACH-IT (<https://reach-it.echa.europa.eu/reach/public/welcome.faces>). EFEO coordinates the organisation of training courses for lead and other registrants.

TEAM-space has been identified as excellent vehicle to post and share information between consortium members. It allows for different levels of authorization to maintain, consult or post documentation. EFEO can contract and organise this facility for the NCS-Consortia. The costs will be charged to the consortia.

⁵ According to REACH art. 14.5 b human safety of substances in cosmetics is outside the scope of REACH.

⁶ Oral care applications are cosmetics under Dir. 76/768/EEC, for which the safety assessment of consumer exposure is outside the scope of REACH.

A Gatekeeper Team with experts of EFEO, EFFA, IFRA and RIFM is formed especially to review the data evaluations and gap analyses and proposals for additional data gathering and testing and to provide expert advise to the NCS consortia.

The EFEO office will serve as the official depository of the signed MoUs and Consortium Agreements. Each NCS-Group Leader will hold a duplicate copy of this file.

EFEO is the central point to maintain the NCS-Groups. Changes that may follow and information of general interest to the NCS-Consortia will timely be communicated. EFEO will stay in contact with the Consortia to provide coordination, stimulate consistency and monitor progress. Regularly the Consortia and EFEO will exchange updates of the list of Consortium participants, their contact points and the NCS lead registrants.

MODUS OPERANDI OF NCS-CONSORTIA.

EFEO facilitates the formation of REACH consortia for groups of NCSs (Natural Complex Substances) and their uses, which are in the scope of REACH such as in fragranced products and in flavours for cosmetics. A Model Agreement for the structure and organization of these consortia has been prepared by EFFA, which is also adopted by EFEO for the NCS Consortia. This paper describes a *modus operandi* for the consortia, which follows from the Model Agreement. The organization is similar to the consortia for fragrance substances.

In this program the formation of a REACH NCS-Consortium is preceded by a pre-consortium, in which the organization and the roles and responsibilities of the members is defined. The consortia will operate with

- A Steering Committee
- A Group Leader (a member company)
- A Coordinator
- A Technical Committee
- A Lead Registrant per NCS of the Group

1. ORGANIZATION, ROLES AND RESPONSIBILITIES.

1.A Steering Committee.

The NCS-Consortium will operate through a Steering Committee, which will exercise overall direction and control over the consortium. All company members of the consortium have a seat in the Steering Committee. They have equal voting rights.

Associate members of the NCS-Consortium may attend on invitation the meetings of the Steering Committee, but have no voting rights.

1.B NCS-Consortium Group Leader

The Steering Committee appoints one of the company members as NCS-Consortium Group Leader. A representative of this member company is appointed as chair person.

The position of Group Leader is best fulfilled by a company with one or more NCSs in the highest tonnage band for registration, because it has an interest to prepare one of the most extensive registration dossiers. One can deviate from this preference, if a company of a substance of a lower volume band volunteers and its candidacy is supported by the Steering Committee.

If more than one company have an interest in NCSs in the highest volume band, the company that has not yet taken the role of Group Leader in other consortia is the preferred candidate. If these companies already fulfill this role in several consortia, their existing workload as Group Leader should be considered to fairly share this task.

EFEO will maintain an overview of NCS-Consortia and their Group Leaders.

1.C Coordinator

The Coordinator of the consortium is appointed by the Steering Committee and is preferably an expert of the company that functions as the Group Leader or a person representing that company.

Consortia can deviate from this recommendation and e.g. appoint someone from another member company or an independent person, if such a person is identified.

EFEO will maintain an overview of the Coordinators of the NCS-Consortia.

1.D Technical Committee.

The Technical Committee (TC) will be composed of company experts. All companies functioning as lead registrant for a substance should assign a technical person for the TC work. The TC appoints a chair person. The Coordinator assists the chair person with the organization. The role of secretary can be fulfilled by a representative of any consortium member.

The TC can create sub-groups for e.g.

- NCS naming and characterization
- Physico-chemical data
- Human toxicity
- Eco-toxicity

It is recommended that the TC adopts the identified uses as agreed by the EFFA REACH-TF and also apply for risk assessment purposes the exposure scenarios and assessment tools as approved for fragrance application by the EFFA REACH-TF.

1.E Lead Registrants

Consortia will have to agree, which company will function as Lead Registrant for each of the NCSs.

As a general rule NCS-Consortia shall agree to assign this responsibility to a company who will register the NCS in the highest volume band among registrants. In that way the core data set of the Lead Registrant covers all data requirements for the concerned NCS. The frequency for consortium members to fulfill this role should be divided in a fair manner.

EFEO will maintain an overview of the Lead Registrants for the NCSs.

2. TASKS FOR REGISTRATION

2.1 Naming, Characterization and Identification

The first task of a NCS-Consortium is to complete the “sameness” check. This check will determine if members and registrants have indeed the same NCS to register. If so, they will use the same identification parameters for their (pre-)registration as described in RIP 3.10, such as the registration name(s) and the CAS and EINECS identification numbers.

For the “sameness” check of NCSs consortium members shall – if applicable – determine that the qualities of their NCSs are:

- of the same botanical source and the same part of the plant
- produced in the same manner (cold pressed, distillation, extraction)
- comparable in composition and have the same hazard classification (ref. recital 45 of REACH)

If these criteria are fulfilled, it merits a registration of the NCS under the same common name and identification numbers by submitting one lead dossier with the core data set. Different

qualities of the same botanical origin can be combined in one dossier. However their volumes will have to be taken together.

Part of the sameness check is the chemical characterization and identification of the constituents. It will show, if the NCS is a Type 1 “Well defined NCSs” or Type 2 “Incompletely defined NCSs”, which influences the data collection and evaluation.

2.2 Data Summarization and Gap Analysis

The Lead Registrants are responsible for the summarization of the existing data on the NCS for which they will submit the core dossier. They share the data in the consortium and will ask other members to complete the overview with anything they may hold. The consortium can decide to seek external support for this task.

The task for data summary per NCS shall include a search for existing data on the NCS required for the highest volume band and other relevant data that may be of value for the NCSs of the Group. The Lead Registrants shall also investigate for which end point the NCS shall be treated as a Type 1 case for read-across to data of the constituents. The consortium will negotiate with the consortia for fragrance substances to obtain access to the data overviews for their NCS constituents. Adaptation of the standard requirements for the characteristics of the NCSs is part of this task, for which justifications will have to be provided.

The result is a summary for each of the NCSs consisting of:

- data obtained for a representative quality of the NCS as such
- data available for the constituents and suitable for read-across
- a quality rating of the above data using the Klimisch system
- a gap analysis for the NCS and the volume band for registration.

The data summaries are submitted to the TC for review and a consistency check.

2.3 Intelligent Test Plan

The TC of the Group develops an intelligent test plan to obtain data for the gaps. The plan takes into account the testing initiated by the consortia for the fragrance substances relevant as constituents to the NCSs. For animal tests of Annex IX and X the plan is presented as a test proposal, which is included in the registration dossier. For gaps not involving animal testing the missing data will have to be generated and be included in the dossier either by testing the NCS or by further investigation of read-across options.

The data summary and the intelligent test plan are submitted to the Steering Committee of the NCS-consortium for approval and then sent to the Gatekeeper Team for consultation.

2.5 Preparation of the CSA / CSR

A CSA will have to be completed for all NCSs of the Group. The CSA gives a hazard classification and if classified as hazardous a CSR shall be prepared in case the registration volume exceeds 10 t/y for a legal entity. For substances exceeding 10 t/y per legal entity REACH requires also a PBT/vPvB assessment as part of the dossier. The protocol for the REACH registration of NCSs and the EFEO and EFFA programs shall give further guidance on this aspect.

It is expected that registrants of NCSs may be able to use parts of the CSRs of the related fragrance substances, because the type of uses of NCSs and fragrance substances in

products is the same and the exposure scenarios for NCSs and substances apply *mutatis mutandis*. This will avoid duplication of work and assures consistency in the approach.

The Lead Registrants of substances are expected to complete the CSA and CSR for their NCSs.

2.6 Preparation of the Dossier in IUCLID 5

The overall objective of the consortium is the completion of the registration dossiers for the NCSs of the Group.

Robust study summaries and proper referencing to studies of the constituents is a task for the Lead Registrant of the NCS. Proof for access to the data for registration purposes will have to be obtained from the data owners. The Lead Registrant shall prepare the dossier in IUCLID 5 and share the core data set with other registrants and the consortium members for review and consistency check.

If the Lead Registrant can not prepare the dossier for what ever reason, assistance from inside the NCS-consortium can be requested or external sources can be contracted by the NCS-consortium or the Lead Registrant to complete the task. The cost sharing rules of the consortium agreement will apply.

The TC shall agree on the core data set of the registration dossiers for all the NCSs of the Group and submit the proposal for approval to the Steering Committee.

The EFEO/EFFA/IFRA/RIFM Gatekeepers are available to advise.

Lead Registrants of a substance will in their dossier mention the identity of companies who participated and subscribe to the completion of the core data set in the dossier of the Lead Registrant. The supporting companies shall prepare their REACH (mini)dossier, in which they refer to the Lead Registrant.

3. ROLES & RESPONSIBILITIES OF GROUP LEADER AND COORDINATOR

The Group Leader and the Coordinator play a vital role in the NCS-Consortium. Their responsibilities are here described in more detail.

An ideal situation exists if the roles of Chair of the Steering Committee and Coordinator are fulfilled by representatives of the company functioning as Group Leader.

GROUP LEADER

The Group Leader provides the chair person of the Steering Committee for the NCS-Consortium, who

- Has ultimate responsible for the coordination of the activities of the NCS-Consortium and for the representation towards outside parties, including other REACH-consortia, authorities at the European level and at the national level.
- Supervises the minutes of each SC meeting drawn up by the Coordinator and sign the final minutes so that actions and decisions can enter into force.
- Proposes to invite Associate Members to participate to the meetings to the SC.
- Ensures the correct functioning of the SC. The SC's main function is to take financial and political decisions.

Technical issues will be proposed by the TC and the SC will approve or disapprove them or propose adjustments. The Group Leader will therefore ensure (with the assistance of the Coordinator) that the following tasks of the SC are handled in a smooth and efficient way:

- Setting the general policy of the Group Consortium;
- Approving the planning and co-ordination of activities;
- Approving the scientific and financial evaluations of data proposed by the TC and fixing the financial compensations;
- Approving the testing proposals to generate New Data as proposed by the TC;
- Appointing the Lead Registrant for each NCS of the Group as proposed by the TC;
- Approving the budget and the financial accounts;
- Deciding upon any modification of the consortium agreement;
- Deciding on the acceptance of late joining members and the expulsion of a Member
- Deciding on the acceptance and expulsion of Associate Members
- Making any other decisions in the interest of the objectives and the cooperation under the Consortium Agreement.

COORDINATOR

The Coordinator of the consortium is the focal point (the spider in the web), who's role includes the following:

- Is in charge of the day-to-day management of the NCS-consortium, including a proper administration of the activities;
- Assists the Chairman of the SC;
- Ensures that the NCS-consortium is functioning properly by:
 - Supervising the progress and managing the timeline / road map as agreed
 - Assisting the Group Leader, the SC and TC
 - Writing the minutes of the SC
 - Organizing meetings of SC and TC.
 - Functioning as the point of contact for consortium members
 - Deal with membership matters, including the financial part
 - Execute decisions by SC and TC
 - Collect data summaries of the NCSs of the Group

The Coordinator may delegate part of his tasks to a technical consultant, with the approval of the SC, reports on a regular basis to the SC and informs it of the progress.

In performing these duties, the Coordinator shall report to the SC Chairman.

LIST OF ACRONYMS

CAS	Chemical Abstracts Services
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DU	Downstream User
EFEO	European Federation of Essential Oils
EFFA	European Flavour & Fragrance Association
EINECS	European Inventory of Existing Commercial chemical Substances
ESDS	Extended Safety Data Sheet
EU	European Union
IUCLID	International Uniform Chemical Information Database
IFRA	International Fragrance Association
NCS	Natural Complex Substances
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIP	REACH Implementation Project
RIFM	Research Institute for Fragrance Materials
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
UVCB	Substances of Unknown or Variable composition, Complex reaction products or of Biological origin