



E.F.E.O.
European Federation of Essential oils

E.F.E.O. AGM - JUNE 14, 2011 IN PARIS

LEGISLATION DEVELOPMENTS

LUTZ DUESHOP -SECRETARY E.F.E.O.

- „ SEVESO-II-“ Directive 96/82/EC
- EU REACH Regulation No 1907/2006 - MSDS
- EU CLP Regulation No 1272 /2008
- EU Flavouring Regulation No 1334/2008
- EU Cosmetic Regulation 1223/2009
- EU Pesticide Regulation Developments
- EU Contaminant Regulation No 1881/2006



E.F.E.O. AGM - JUNE 14, 2011 IN PARIS
- „SEVESO-II-“ DIRECTIVE 96/82/EC

Objective :

-Control of major accident hazards involving dangerous substances

Operator obligations :

- General obligations to prevent accidents
- subject of inspections by authorities
- Notification obligations
- „MAPP“ major accident prevention policy
- Safety report and safety management system
- Internal emergency plans
- Public information obligations

Current status :

- Revision in EU Parliament (background : CLP)
- ENVI report : Oct 2011, Plenary Session Dec 2011
- entry into force June 2015



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Quantities / thresholds

ANNEX I
List of dangerous substances

PART 1
Categories of substances and mixtures

Annex I Part 1 covers all substances and mixtures falling under the hazard categories listed in Column 1:

Column 1	Column 2	Column 3
Categories of dangerous substances and mixtures	Qualifying quantity (tonnes) of substances as referred to in Article 3(9) for the application of	
	Lower-tier requirements	Upper-tier requirements
Section 'H' – HEALTH HAZARDS		
H1 ACUTE TOXIC Category 1, all exposure routes	5	20

H2 ACUTE TOXIC Category 2, all exposure routes		
P5a FLAMMABLE LIQUIDS - Flammable liquids, Category 1, or - Flammable liquids Category 2 or 3 maintained at a temperature above their boiling point, or - Other liquids with a flash point ≤ 60°C, maintained at a temperature above their boiling point (see note 12)	10	50
P5b FLAMMABLE LIQUIDS - Flammable liquids Category 2 or 3 where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards, or - Other liquids with a flash point ≤ 60°C where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards (see note 12)	50	200

Section 'E' – ENVIRONMENTAL HAZARDS		
E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1	100	200
E2 Hazardous to the Aquatic Environment in Category Chronic 2	200	500



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Prodarome initiative : exemptions for essential oils

PART 2

Named substances

Where a substance or group of substances listed in Part 2 also falls within a category of Part 1, the qualifying quantities set out in Part 2 must be used.

Column 1	CAS number ¹⁶	Column 2	Column 3
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Dangerous substances

Amendment

Annex I List of dangerous substances Part 2 Named Substances

To add:

Dangerous substances	CAS number	Qualifying quantity (tonnes) for the application of	
		Lower tier requirements	Upper-tier requirements

Essential oils and similar substances covered by ISO Standard 9235 Aromatic natural raw materials-Vocabulary, with the exception of those classified under Acute toxic Cat 1, all exposure routes, Acute toxic Cat 2 all exposure routes, Acute toxic Cat 3 dermal and inhalation route (see note 7), STOT specific target organ toxicity-single exposure Cat 1.		5000	50 000
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E.F.E.O. AGM - JUNE 14, 2011 IN PARIS **- „ SEVESO-II-“ DIRECTIVE 96/82/EC**



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13th May 2011

To the Members of the ENVI-
Committee on Environment,
Public Health and Food Safety
in the European Parliament

E.F.E.O. Position on a proposed amendment of the « Seveso -II -Directive »

Currently, the ENVI is dealing with a **revision of Directive 96/82/EC** on the control of major accident hazards involving dangerous substances, document COM (2010)781 final/ 2010/0377(COD).

E.F.E.O. is the Branch Association of producers and importers of **essential oils** used as raw materials for the fragrance and flavour industries in the EU, most of the companies qualifying as SMEs. E.F.E.O. supports all measures aiming at a **high level of protection** against hazards to health and environment, and thus appreciates that categories of dangerous substances and thresholds for the application of lower- tier and upper- tier requirements are set out in Annex 1 part 1 and 2 of the a.m. Directive.

Nevertheless E.F.E.O. is convinced that the Directive under revision **does not adequately reflect the situation of natural products** such as **essential oils** as these products - when stored under proper conditions and adequate safety controls in particular industrial sites - **do not** present a major accident hazard.

Thus, E.F.E.O. appreciates the initiative started by the National Association of Fragrance Manufacturers in Grasse/France (Prodarom) which targets at the inclusion of essential oils and similar substances (except those which bear a particular risk) in **annex I part 2** of the Directive, setting specific lower - and upper tier requirements for this product group.

The **amendment proposal** and a detailed justification are enclosed to this E.F.E.O. position. E.F.E.O. **appeals to the Members of the European Parliament to support this approach** and to opt for the proposed amendment which is regarded a pragmatic solution under adequate consideration of the actual risk.

E.F.E.O. support to the PRODAROM initiative

- **Support letter 13th May 2011**

- **target:**

- **Exemption of several essential
oils from „ Seveso II“**

-**Exemption from certain
requirements**




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E.F.E.O. AGM - JUNE 14, 2011 IN PARIS REACH REGULATION 1907/2006 - MSDS

EU Regulation No 453/ 2010 - New MSDS format since December 2010 also for essential oils



 **E.F.E.O.**
European Federation of Essential oils

New SDS format under REACH :
Do your Safety Data Sheets comply with the new rules ?

This E.F.E.O. information summary is to briefly inform our members and their suppliers about the new SDS requirements for substances (= Essential oils) as of 01st December 2010.

Legislation text : Regulation (EC) No 453/2010 annex (*) amending REACH Regulation (EC) No 1907/2006 annex II, is available in all Community languages under:
<http://eur-lex.europa.eu/JOH.html.do?uri=OJ%3A%3A2010%3A133%3ASOM%3AEN%3AHTML>

Information requirements / structure : See Regulation (EC) No 453/2010 annex I part B (attached here for information: language versions EN, FR, IT, ES). All headings (16) and subheadings (49) must appear in the SDS; all applicable/available information must be provided in these sections/subsections, do not leave a subsection blank.

Important items to consider:

- Until 01st June 2015, the **classification** information under new CLP Regulation 1272/2008 and under Directive 67/548/EEC ("DSD") must be provided
- **Labelling** information must comply with new CLP, i.e. hazard pictograms, signal words, hazard statements, precautionary statements
- Section 3 on **composition**: The chemical identity of the **main constituent**, and the chemical identity of **any other constituent** must be presented if itself **classified** and contributing to the classification of the substance
- all CLP information must be in line with the notification information to be submitted to the ECHA ("CSL inventory")
- REACH **registration number** required under section 1.1 "product identifier" if already issued by ECHA

Extended eSDS/ annex to be attached: Exposure scenarios from Chemical Safety Report / CSR (in case of individual production / import volume above 10 tons p.a.), not yet applicable to companies registering under REACH by 2013 or 2018 as CSR is not yet due.

Transitional periods: The new format applies to all substances placed on the market on/ after 01st December 2010. In case of substances already placed on the market before this date, the new format does not need to be made available until 01st December 2012.

Example SDS: It might be helpful to consult a commented example SDS, see under http://reach.bdi.info/Standardisatzkatalog/ANNEX_New_GHS_SDS_EN_20092010.pdf

* as per 1st June 2015, the SDS format version II of Regulation No 453/2010 applies.

- Information in line with CLP notification
- Classification under DSD and CLP
- Section 3: Main constituent and classified constituents
- Section 1.1. : REACH Registration No.
- eSDS / exposure scenarios > 10 t
- Language of EU target country
- Transitional periods
 - 01 st December 2012
 - 01 st June 2015

info

New ECHA Guidance on the compilation of safety data sheets , May 2011 (draft version 3)



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CLP REGULATION 1272 /2008



➔ **New classification and labelling**

- if placed on the market on/after 01st Dec. 2010
- if placed on the market before 01st Dec. 2010
transitional period (01st Dec. 2012)

➔ **CLP notification by 03rd January 2011**

➔ **Recent amendments by EU Reg.No 286/2011(01st Dec. 2012)**

- new sub categories for respiratory and skin sensitizers
- amended label elements/hazardous to the aquatic environment
- changed design of pictograms GHS 07,09
- minimum label and pictogram dimensions



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CLP REGULATION 1272 /2008

➔ New minimum label and pictogram dimensions

Table 1.3

Minimum dimensions of labels and pictograms

Capacity of the package	Dimensions of the label (in millimetres) for the information required by Article 17	Dimensions of each pictogram (in millimetres)
Not exceeding 3 litres:	If possible, at least 52 × 74	Not smaller than 10 × 10 If possible, at least 16 × 16
Greater than 3 litres but not exceeding 50 litres:	At least 74 × 105	At least 23 × 23
Greater than 50 litres but not exceeding 500 litres:	At least 105 × 148	At least 32 × 32
Greater than 500 litres:	At least 148 × 210	At least 46 × 46'



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CLP REGULATION 1272 /2008

New ECHA information source : terminology database

The screenshot shows the ECHA term database search results for the term "Causes serious eye damage". The search results are listed in a scrollable area, with the selected term highlighted in blue. The search interface includes a language dropdown set to "EN - English" and a "Hazard statement" dropdown. The search results list various hazard statements, with "Causes serious eye damage" being the selected one. The search results also include a "Term Note" and a "Term Ref" section.

The screenshot shows the ECHA term database search results for the term "Causes serious eye damage" in French. The search results are listed in a scrollable area, with the selected term highlighted in blue. The search interface includes a language dropdown set to "EN - English" and a "Hazard statement" dropdown. The search results list various hazard statements, with "Provoque des lésions oculaires graves" being the selected one. The search results also include a "Term Note" and a "Term Ref" section.

Domain	Chemical legislation, CLP
Code	H318
FR Hazard statement	Provoque des lésions oculaires graves.
Reliability	*****
Term Ref	Règlement (CE) n° 1272/2008 du Parlement européen et du Conseil du 16 décembre 2008 relatif à la classification, à l'étiquetage et à l'emballage des substances et des mélanges, modifiant et abrogeant les directives 67/548/CEE et 1999/45/CE et modifiant le règlement (CE) n° 1907/2006, 32008R1272:FR
Term Note	Mention de danger: Lésions oculaires graves/irritation oculaire, catégorie de danger 1
EN Hazard statement	Causes serious eye damage.
Reliability	*****
Term Ref	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, 32008R1272:EN
Term Note	Hazard statement: Serious eye damage/eye irritation, Hazard Category 1



E.F.E.O. AGM - JUNE 14, 2011 IN PARIS

EU FLAVOURING REGULATION NO 1334/2008

- **Applies since 20th January 2011**
- **Flavouring preparations are:**
 - **essential oils**
 - **extracts**
 - **oleoresins**
- **no evaluation /approval required for flavourings**
 - **from food source material**
 - **from non-food material if hitherto used for flavourings**
- **new requirements for the use of the term „ natural“**
- **restrictions : maximum levels in the final food product**
 - **substances present in essential oils by nature**
 - **e.g. estragol, safrole, menthofuran, methyleugenol, coumarin,pulegone**




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EU FLAVOURING REGULATION NO 1334/2008

- Information sources



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E.F.E.O. Information
New EU Flavouring Regulation & Essential Oils
for Use In Food

Status 23rd November 2009

The EU Flavourings Regulation No 1334 /2008 (replacing EU Directive 88/388/EEC) was published in the Official Journal of the EU No L 354 of 31 December 2008, entered into force on 20th January 2009 and will be applicable as per 20th January 2011.

The following information might be of use for E.F.E.O. members as suppliers to the food industries and is meant as an aid to prepare for the application of the new Regulation particularly with a view to the correct labelling and the use of the term "natural", as well - as to respond to questions from industrial customers on usability, safety concerns and correct marking of the final product. This information is mainly focussed on essential oils as a flavouring preparation; with a view to flavouring substances and other flavour categories specific information may be found in the EFFA Guidance, see below section 6.

1. How are Essential Oils regulated under Reg. No. 1334/ 2008?


The Regulation covers **flavourings**, not intended to be consumed as such but added to food in order to impart or modify its odour/taste. The term "flavouring" covers six different **categories**, i.a. "**flavouring preparations**" (Art.3 (2) lit. d; I, ii), which also includes **essential oils, extracts, oleoresins, tinctures** derived from food and non-food sources produced by methods listed in annex II (List of traditional food preparation processes, like distillation, rectification, extraction, pressing).

"Flavouring preparations" should not be confused with the category of "flavouring substances" which are **chemically defined substances** (Art.3 (2) lit. b), and "natural flavouring substances" (Art.3 (2) lit. c) which are chemically defined flavouring substances corresponding to substances naturally present and identified in nature (e.g. limonene as such which also appears in citrus oils by nature).

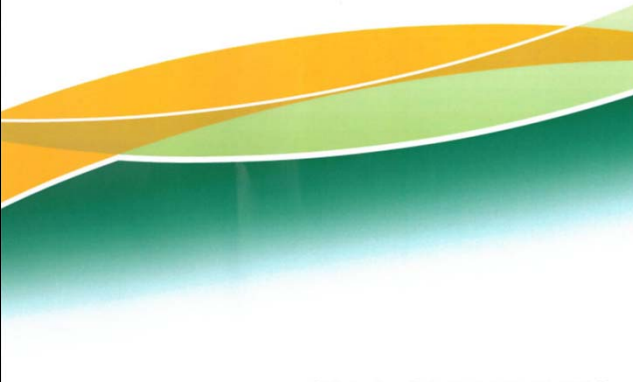
Flavourings (including flavouring preparations) may only be used for food if, on the basis of scientific evidence available, **they do not pose a safety risk to health** and their use does not mislead the consumer (Art.4).

Flavouring preparations **do not need to undergo a (safety) evaluation / approval** if obtained from **food source material** (Art. 6(1) lit. a), provided that there is no doubt about the safety. If derived from **non-food material**, an **evaluation, approval and inclusion** in the so-called **Community list** (Art. 9 and 10, future **annex I**, based on the "flavouring list" established under Regulation EC 2232/96 by December 31st, 2010) would be required before placing on the market/use in food. **Please note:** Many essential oils may be derived from sources not regarded as food, but this does **not** automatically lead to an evaluation requirement, see Art.3 (3), and particularly recital No 16 of the Regulation:

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CIAA
Confédération des industries agro-alimentaires de l'UE
Confederation of the food and drink industries of the EU.



CIAA GUIDELINES
on Regulation (EC) No. 1334/2008
on Flavourings and Certain Food Ingredients
with Flavouring Properties for Use in and on Foods



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EU COSMETIC REGULATION NO 1223/2009

New Rules on Cosmetic products replacing Directive 76/768/EEC

- in force since 11th January 2010**
- application as per 11th July 2013**
- particularly important:**
 - annex II list of substances banned in cosmetic products**
 - annex III list of substances with restricted use in cosmetic products**
- already now in force:**
 - Art. 15 : ban of substances classified as „CMR“**



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EU PESTICIDE REGULATION DEVELOPMENTS

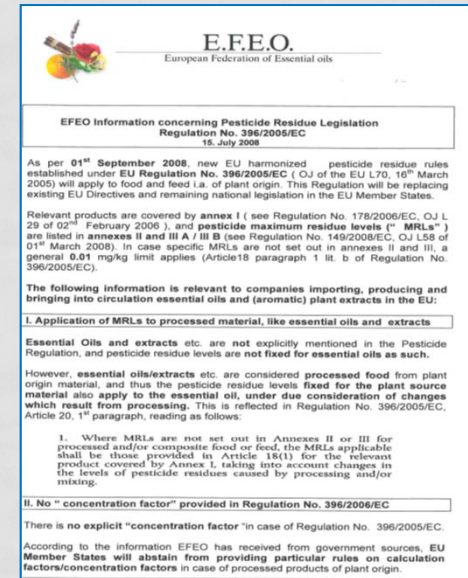
- EU Regulation No 396 /2005 /EC and annexes
- applicable also to essential oils !
- carefully observe recent amendments to the annexes, e.g.

EU Reg. No. 310 /2011, 28th March 2011; **citrus fruit**

- bromopropylate 2,0 mg/kg to 0,01 mg/kg
- methidation 5,0 mg/kg to 0,02 mg/kg
- effective 21. Oct. 2011

EU Reg. No 524 /2011, 26 th May 2011; **spices (nutmeg, mace)**

- Biphenyl 0,01 mg/kg to 0,05 mg/kg (analytical limit)
- Biphenyl in future (draft SANCO , EFSA report) **1,0 mg/kg**





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EU CONTAMINANT REGULATION NO.1881/2006

- contaminants = mycotoxins, heavy metals, etc
- application to **essential oils?**
- essential oils not explicitly mentioned in the Regulation!
- contaminant limits for **listed source materials** also apply to the essential oil /processed product!
- application of a concentration factor

- consequence for essential oils:

⇒ aflatoxin and ochratoxin A limits apply to essential oils derived from listed spices (capsicum,pepper, nutmeg, tumeric)

⇒ Other contaminants (e.g. lead, cadmium): **no application to essential oils**