AGM Paris, France, 4th June, 2019
E.F.E.O. European Federation of Essential Oils

Legislation update 2018/2019

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Attorney at law
Secretary General to E.F.E.O

BREXIT in 2019 ????....

BREXIT 31st October, 2019?
What about....
import from UK
export to UK
REACH substances from/to UK ....?
TRADE WAR and Essential Oils ....

already installed last year:

EU additional customs duties on goods from US - possible reaction:

<table>
<thead>
<tr>
<th>1st step: 20th June 2018</th>
<th>up to 25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1106 10 80</td>
<td>25 %</td>
</tr>
<tr>
<td>1004 28 80</td>
<td>25 %</td>
</tr>
<tr>
<td>1004 29 80</td>
<td>25 %</td>
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<table>
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<tr>
<th>2nd step: 23rd March 2021</th>
<th>up to 10%</th>
</tr>
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<tr>
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<tr>
<td>1109 54 10</td>
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<td>1109 66 10</td>
<td>10 %</td>
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<td>1109 65 10</td>
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<td>1109 64 10</td>
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<td>1109 63 10</td>
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<td>1109 60 10</td>
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<td>1109 57 10</td>
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<td>1109 56 10</td>
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<td>1109 57 00</td>
<td>10 %</td>
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<tr>
<td>1109 56 00</td>
<td>10 %</td>
</tr>
</tbody>
</table>

annex I
Cosmetic beauty products/preparations

annex II
Orange oil, not deteperned Lemon oil, not deteperned Other (terpenic by-products, extracted oleoresins)

TRADE WAR and Essential Oils ....

New challenges in 2019:

Additional US import duties on essential oils from EU announced on 8th April, 2019

Additional EU import duties on essential oils from US announced on 17th April, 2019
TRADE WAR and Essential Oils ....

New challenges in 2019:
Additional US import duties on essential oils from EU

“3301.12.00 Essential oils of orange;
3301.13.00 Essential oils of lemon;
3301.19.10 Essential oils of grapefruit;
3301.19.51 Essential oils of citrus fruit, other, nepisoi (= not elsewhere specified or included);
3301.24.00 Essential oils of peppermint (Mentha piperita);
3301.25.00 Essential oils of mints, other than peppermint;
3301.29.10 Essential oils of eucalyptus;
3301.29.20 Essential oils of oregano;
3301.29.51 Essential oils other than those of citrus fruit, other, nepisoi;
3301.30.00 Resinsoids;
3301.90.10 Extracted oleoresins consisting essentially of nonvolatile components of the natural raw plant; 3301.90.50 Concentrates of essential oils; terpenic by-product of the deterpenation of essential oils; aqueous distillates & solutions of essential oils.”

TRADE WAR and Essential Oils ....

New challenges in 2019:
Additional EU import duties on essential oils from US

3301210 terpenic oils of sweet and bitter orange, incl. concretions and absolutes (excl. orange flower oil)
3301310 terpenic essential oils of lemon, incl. concretions and absolutes
3301720 terpenic essential oils of citrus fruit, incl. concretions and absolutes (excl. those of sweet and bitter orange)
3302250 terpenic oils of mints, incl. concretions and absolutes (excl. those of peppermint “Mentha piperita”)
3302290 terpenic oils of clove, mace and ylang-ylang, incl. concretions and absolutes
3302320 terpenic oils of clove, mace and ylang-ylang, incl. concretions and absolutes
3302941 essential oils, not deteriorated, incl. concretions and absolutes (except of citrus fruit, mint, clove, mace and ylang-ylang)
3302971 terpenic oils of geraniol, jasminum and verbena, incl. concretions and absolutes
3302997 terpenic oils of lavandula or of lavender, incl. concretions and absolutes
3302991 terpenic essential oils, incl. concretions and absolutes (excl. of citrus fruit, geraniol, jasminum, lavandula, menthol, verbena, clove, mace and ylang-ylang)
TRADE WAR and Essential Oils ....

New challenges in 2019:
Additional EU import duties on essential oils from US

- List 3 - CN 3301 1300 lemon oil
- List 4 - 3301.12.00 orange, 3301.19.10 grapefruit, 3301.19.51 citrus fruit (other), 3301.24.00 peppermint (Mentha piperita), 3301.25.00 mints other than peppermint, 3301.29.10 eucalyptus, 3301.29.20 orris, 3301.29.51 oils other than those of citrus fruit, etc.

TRADE WAR and Essential Oils ....

Trade relations USA-China

A. Additional US import duties on essential oils from China 25%

List 3 - CN 3301 1300 lemon oil

List 4 - 3301.12.00 orange, 3301.19.10 grapefruit, 3301.19.51 citrus fruit (other), 3301.24.00 peppermint (Mentha piperita), 3301.25.00 mints other than peppermint, 3301.29.10 eucalyptus, 3301.29.20 orris, 3301.29.51 oils other than those of citrus fruit, etc.

B. Additional Chinese import duties on essential oils from US 25%, intended

| 489 | 33012940 | 桂油（包括浸膏及净油） |
| 490 | 33013010 | 苦尾凝脂 |
New situation since 1st June, 2018:

What happens if no registration dossier has been submitted for pre-registered substances?

- No EU imports of essential oils for cosmetic purposes
- No use of such essential oils by customer
- Imports suspended until registration dossier has been submitted
- Goods on stocks may be sold as they are regarded imported (= physically introduced into EU customs territory)

Substances under REACH: Brief summary on legal provisions

- Import
- Export
- Transit
- Contract terms
Authorities: Actions announced

ECHA News Letter release No 2/17th May, 2018:

• SME Status will be checked
• At least 5% of the dossiers will be checked for compliance
• Substance evaluation: further information requests from ECHA
• EU-wide enforcement project on REACH registration in 2019

In 2019, there will be an EU-wide enforcement project on registration. Inspectors and customs authorities will check that companies have fulfilled their registration obligations and that the conditions are in place for registering a substance as an intermediate under strictly controlled conditions.

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4. Compliance with REACH registration obligations

In their press notice ECHA NR/17(01), the European Chemicals Agency have officially announced REACH inspection activities continuing throughout 2019, involving the inspection authorities and customs authorities of the EU and EEA Member States. The checks will cover imported and manufactured substances in all tonnage bands, mainly focusing on quantities of 1-100 tons p.a.

The checks/inspections will also aim at parts of the registration dossier and will be updated as necessary. The checks are based on the EU-wide REACH enforcement project (REF-7) which had been finally prepared by the end of 2018.
REACH challenges in 2019

“Post-registration”-period: ECHA recommendations

Companies need to keep their registration dossiers updated - ECHA REACH Roadmap 2018 phase 7

- Make a plan for keeping your registration up to date. Keep track of new data, potential new uses for your substance, and volumes produced or imported.
- Make sure you have access to your REACH-IT account, as we use this channel to communicate with you.
- Have a platform to collaborate with your other co-registrants to deal with new registrants and requests for more information from authorities.
- Submit an inquiry for each new substance you place on the market in quantities over one tonne per year.
- Follow the authorities’ work. Check your portfolio for substances that are subject to regulatory action and see whether safer alternatives are available.

Further effects of REACH:

ECHA “Candidate list” of substances of concern (currently 197 entries)

Possible consequences:

- Regulation (EC)1907/2006, annex XIV - list of substances subject to authorization
- Regulation (EC) 1907 2006, annex XVII -list of restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles
REACH Challenges in 2019

- Regulation (EC) 1907/2006, annex XIV - list of (>30) substances subject to authorization

<table>
<thead>
<tr>
<th>Substance</th>
<th>ROSIN</th>
<th>Decision date (2)</th>
<th>Decision date (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-alkyl-1-alkene-1-ol</td>
<td>01-01-2011</td>
<td>01-01-2011</td>
<td></td>
</tr>
<tr>
<td>EC No: 203-029-4</td>
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</tbody>
</table>

- Regulation (EC) 1907/2006, annex XVII - list of restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (>67 entries)

64. 1,4-dichlorobenzene
CAS No: 106-46-7
EC No: 203-000-5

CLP Regulation

- CLP Regulation (EC) No 1272/2008 on classification, labelling, packaging
- Application: 1st December, 2010 (substances) and 1st June, 2015 (mixtures)
- Pictograms, Hazard statements, Precautionary statements
CLP Regulation amendments

Amendments by Regulation (EU)2017/542 as of 1st Jan. 2020

- New annex VIII parts A, B, C (information on mixtures)
  Purpose: Information to be provided to poison centers and appointed bodies in the EU MS.
- Applies to importers and downstream users (not addressed: producers)
- Annex VIII part C: submission format
  – identification of the mixture and of the submitter; classification of the mixture, label elements and toxicology; product identifiers of the mixture components.
- Application depending on end users: 2020 (fin. consumer) / 2021 (commercial use) / 2024 (industrial use in sites)

CLP Regulation amendments

- ECHA Guidance Paper

1.3 Aim of this guidance

The aim of this guidance is to clarify and assist companies, appointed bodies and poison centres in the implementation of the new tasks and requirements outlined in Annex VIII to the CLP Regulation.

This guidance provides information on:

- the scope of Annex VIII to CLP, i.e. for which type of mixtures the required information has to be submitted;
- who should submit information in accordance with Annex VIII to CLP and by when;
- issues to consider when preparing for a submission of information;
- the use of the "Unique Formula Identifier" (UFI);
- the use of the harmonised European Product Categorisation System (EuPCS);
- details of the information required to be submitted;
- the use of the common XML harmonised reporting format;
- which changes or new information trigger the need for an update.
Cosmetics Regulation 1223/2009 since 2013

**SURVEY ON THE ANNEXES:**

- Annex I: Cosmetic Safety Report set up by the responsible person prior to marketing (page 79)
- Annex II: Substances prohibited in cosmetic products, more than 1300 reference numbers (page 83)
- Annex III: List of substances with restricted use in cosmetic products (page 128)
- Annex IV to VI: Lists of colorants, preservatives, UV filters (pages 176, 192, 201)
- Annex VII: Symbols to be used on packaging/containers (page 203)

**COMPANIES ADDRESSED / AFFECTED BY THE REGULATION:**

Regulation No. 1223/2009 applies to the “cosmetic product”, i.e. by definition: “any substance or mixture intended to be placed in contact with ... the external parts of the human body ... or with the teeth and the mucous membranes of the oral cavity with a view ... to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”.

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Cosmetics Regulation 1223/2009

**Still pending: fragrance allergens**

- Background: SCCS opinion on fragrance allergens, June 2012
- Public consultation on a DG Sanco draft proposal - comments by 14th May 2014
- In addition to 26 allergens listed in annex III, labelling:
  - > 1.0 % laurel oil and > 0.2 % tree-off (floral) products

annex II - essential oils concerned: I.e. camphor, cloves, Ylang Ylang oil, cedar oil, pine oil, lavender oil, cinnamon oil, several citrus oils, fennel oil, clove oil, jasmine oil, juniper oil, lavender oil, peppermint oil, geranium oil, narcissus oil, rose flower oil, sandalwood oil

- Transitional period: three years

annex II - HICC, atranol and chLOORotanol banned

**Last major change: Regulation (EU) 2017/1410: Ban on HICC, Atranol and Chloroatranol ex oak tree moss as from 23rd August 2019**
Cosmetics Regulation 1223/2009

Recent change: Regulation (EU)2019/831 amending annexes II,III,V as from 12th June 2019 – CMR substances annex II new entries 1385- 1611

Flavouring Regulation 1334/2008

- Several changes on the Community list annex I: Chemically defined flavouring substances, following EFSA Flavouring group evaluations

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Name</th>
<th>Description</th>
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<tbody>
<tr>
<td>Ethanol</td>
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<td>Acetaldehyde</td>
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<td>Propionaldehyde</td>
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<td>107-13-1</td>
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<td>Valeraldehyde</td>
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<tr>
<td>Caprovaldehyde</td>
<td>111-27-9</td>
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<td>Caprovaldehyde</td>
<td>Caprovaldehyde</td>
</tr>
</tbody>
</table>

Most recent amendment: Deletion of Furan -2(5h) Entry into force 21th May 2019
Essential oils used for medicinal purposes

- Essential oils from field distillation: GACP
- No document required: Countries with "equivalent protection level"
  Australia, Brazil, Israel, Japan, Switzerland, USA, Republic of Korea

Essential oils as feed additives

(Released date 22.05.2019)
Edition 5/2019 (271)
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Directorate E - Food and feed safety, innovation
Unit E5 – Animal nutrition, veterinary medicines

- Buchu leaves oil
- Amyris oil
- Lime oil
- Neroli bigarade oil
- Petitgrain bigarade oil
- Mandarin oil
- Cardamom oil
- Ginger oil
- Turmeric oil
- Geranium rose oil
- Eucalyptus oil
- Clove oil
- Broom tea tree oil
- Tea tree oil
- Melaleuca cajuputi oil
- Niaouli oil
- Alsophe oil
- Bay oil
- Citronella oil
- Lemongrass oil
- Vetiver oil
Pesticides and Contaminants

Pesticides and contaminants in the plant source material

MOSH/ MOAH

Heavy metals

PAH

Anticholinesterase

PA, TA, TA

Mycotoxins

Chlorinated and Perchlorated

DEET

Pesticides and Contaminants

Glyphosate

Dioxin

Pesticides Regulation No 396/2005

MRL (Maximum Residue Limits)

- MRLs refer to the listed plant source material
- MRL applicable to essential oils from the source material!
- Compliance of the source material = compliance of the E.O.
- Calculation: concentration factor based on experience
- General Rule: 0.01 mg/kg for non-listed pesticides!
- Frequent updates: appr. 130 Regulations since 2006
- Public awareness (authorities, customers, consumers)
Pesticides & concentration factor

- No processing factors/concentration factors determined by Regulation 396/2005:
  - Art. 20 (1) - changes caused by processing to be taken into account
  - Art. 20 (2) and annex VI – no specific factors set.
- Current considerations on EFSA level:
  - Calculation of processing factors
  - Context: authorization procedure for plant protection substances
  - Not designed as factors under Regulation 396/2005!

Contaminants – „PA“

A never ending challenge since 2013:
- “PA”-pyrrolizidine alkaloids from weeds
- affected: different herbal infusion materials
- PA also be present in essential oils extracted from plant source material?
- Draft EU maximum limits

<table>
<thead>
<tr>
<th>Contaminants - PA</th>
<th>µg/kg limit</th>
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<tbody>
<tr>
<td>Herbal infusions - Roses, Neroli, Lavender, Camomile, Peppermint, Lemon verbena (solid or dried product)</td>
<td>400</td>
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<tr>
<td>Other herbal infusions (solid or dried product)</td>
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<tr>
<td>Tea Camellia leaves and flowered tea (solid or dried product)</td>
<td>100</td>
</tr>
<tr>
<td>Tea and herbal infusions for infants and young children (solid or dried products)</td>
<td>75</td>
</tr>
<tr>
<td>Tea and herbal infusions for infants and young children (liquid)</td>
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<tr>
<td>Food supplements containing herbal ingredients excluding oils</td>
<td>400</td>
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<tr>
<td>Pollen-based bee supplements</td>
<td>500</td>
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<tr>
<td>Pollen and pollen products</td>
<td>400</td>
</tr>
<tr>
<td>Herbs (fresh, frozen and dried)</td>
<td>1000</td>
</tr>
<tr>
<td>Borage, sunflower, marigolds and oregano (fresh, frozen and dried)</td>
<td>400</td>
</tr>
<tr>
<td>Curry seeds (seed spices)</td>
<td>400</td>
</tr>
</tbody>
</table>
MANY THANKS FOR YOUR ATTENTION!