IFRA Guidance to "Green" Fragrance terminology Final – October 15, 2010

Definition: Green	.2
Definition: Green Chemistry	
Definition: Natural	
Definition: Organic Ingredients	.5
Definition: LCA	.6
Definition: Biodegradation	.6
Environmental Hazard Labeling of Natural Complex Substances ("NCS")	.8
Green labels	.9

Introduction

Global warming, mass pollution, a possible mistrust of new technologies and various other threats impacting the environment have led our society to be increasingly committed to the protection of nature. Over and above short term marketing choices, citizens consider this change in their daily behavior as a necessity based on the long term prospects for their and the planet's future. In this context, the industry would like to be recognized as participating in the development of this society view, and also as giving the consumer, the possibility to live according to the new 'environmental' deal, which impacts all aspects of the aware citizen's life, based on their beliefs and values. Consequently, the present document provides a common understanding of the basic concepts and terminology used in this field.

Many of the terms defined in this document and the motivation for acting on these topics are linked to the much more comprehensive topic of sustainability. Although a broad coverage of sustainability would go beyond the scope of this document, this concept has an important impact on green terminology and its definition acts as a touch stone since sustainability is implicit within all the green definitions. According to the Bruntland report, of the World Commission on the Environment and Development convened by the United Nations in 1983, sustainability is defined as 'the development that meets the needs of the present without compromising the ability of future generations to meet their own needs'. According to US EPA, sustainability is defined¹ as the act of balancing a growing economy, protection for the environment and social responsibility², so that together they lead to an improved quality of life for the current and future generations.

- · Forced labor and exploitative child labor are not allowed
- Buyers and producers trade under direct long-term relationships
- · Producers have access to financial and technical assistance
- Sustainable production techniques are encouraged
- Working conditions are healthy and safe
- Fair trade principles prohibit the use of Genetically Modified Organisms
- Equal pay for women and men
- Fair Trade provides access to pre-financing of up to 60% from the buyers.

¹ <u>http://www.epa.gov/greenacres/landuse.html</u>

² The social responsibility notably involves the Fair Trade concept which consists of a trading partnership, based on dialogue, transparency and respect that seeks greater equity in international trade. Fair Trade principles include:

From another angle, certification bodies, dedicated to assess products and manufacturing processes with regard to green terminology, increasingly appear on the market and have more and more importance for consumers. This has contributed to multiple definitions for the various green concepts (such as what is an organic ingredient and what do fair trade or sustainable mean) and sometimes these definitions prove to be nebulous, confusing or even contradictory.

The document intends to provide a common understanding of the different concepts/terminology used and to make the fragrance industry association point of view clearer. However, this 'Green' definition document does not aim to create an additional green label and, in any case, IFRA does not have the intention to be considered as a certification body.

Definition: Green

The term 'green' is a concept related to environmental friendliness and is an overlapping term with the concept of 'sustainability'. Moreover, 'green' can have many meanings and therefore this term is rarely used as a marketing claim itself, but it can stand for a concept behind a brand/product line.

Green labels are supposed to help consumers to spot products that are formulated according to special rules that are claimed to make the products less harmful to the environment. It thus becomes more and more common to see such logos on products.

Fragrance manufacturers and others can make their own claims about products, or may participate in one of the many voluntary labeling schemes designed to highlight some special feature of a product.

No legal definition of Green fragrance ingredient exists as ever more finished products are marketed under the banner of organic, ecological and natural properties. For consumers and manufacturers alike, the situation is becoming increasingly confusing.

Also in the communication between final consumers, consumer product manufacturers and suppliers, when talking about 'green', a broad spectrum of concepts comes to mind, that is not necessarily congruent in the understanding of the partners in dialogue and therefore can lead to some confusion. Some might think of 'natural' or 'organic' fragrances, others focus on biodegradability and still others include 'nature identical'³ under the 'green' marketing umbrella.

Of course, due to the currently limited supply of Fair Trade ingredients, this option may not be actionable for a lot of products. Shipping Fair Trade materials from far away markets would substantially increase their carbon footprint and would offset their environmental benefits. Therefore this concept within the fragrance industry should be managed very carefully and in a balanced fashion.

³ Nature identical fragrance ingredients are, by definition, molecules known to exist in natural scents / plants but that are of synthetic origin.

[•] An example of Fair Trade certification body is Max Havelaar

All Fair Trade is labeled by a certification system designed to allow consumers to identify goods which meet agreed standards. Regular audits are done.

There is further a great variability between countries and regions, with some being more advanced regarding the support of 'green type' claims, e.g. via private or semi official certification bodies.

The objective of this document is to help clarify what is meant by a number of terms linked to the 'green' concept within the fragrance industry and to ensure (as far as possible) that sound science is used for criteria substantiating 'green' product claims. Another goal would be to make the fragrance industry's clients aware of the main challenges possible presented by NGO's attention to 'green' claims.

On the following pages there are a number of definitions of terms provided by IFRA to which the fragrance manufacturer, consumer or product manufacturer may be confronted with.

It is recommended to always keep in mind that the terms 'natural' or 'organic' mean nothing with respect to hazard or allergenic properties of a material. A 'natural' or 'organic' material is not per se safe, like a synthetic material is not per se safe or dangerous. An organic material could be a sensitizer or environmentally unfriendly as could a synthetic material.

As almost none of the terms used in context with green labels are officially regulated, it is essential to align the expectations of consumers and customers with the capabilities of fragrance manufacturers based on a close dialogue.

Definition: Green Chemistry

Green Chemistry requires chemical producers to choose processes and products that reduce waste, energy, water consumption, emissions, and the use and production of undesirable substances.

In practice, Green Chemistry refers to environmentally friendly chemicals and processes. Even though there are no official norms that define Green Chemistry, an indicative charter with 12 principles to be followed by Green Chemists exists, as published by Anastas, P. T.; Warner, J. C. Green Chemistry: Theory and Practice, Oxford University Press: New York, 1998, p.30. Oxford University Press) and approved by the US Environmental Protection Agency.

Those principles are:

1. Prevention - it is better to prevent waste than to treat or clean up waste after it has been created

2. Atom Economy - Synthetic methods should be designed to maximize the incorporation of all materials used in the process into the final product.

3. Less Hazardous Chemical Synthesis - Wherever practicable, synthetic methods should be designed to use and generate substances that possess little or no toxicity to human health and the environment.

4. Designing Safer Chemicals - Chemical products should be designed to effect their desired function while minimizing their toxicity.

5. Safer Solvents and Auxiliaries - The use of auxiliary substances (e.g., solvents, separation agents, etc.) should be made unnecessary wherever possible and innocuous when used.

6. Design for Energy Efficiency - Energy requirements of chemical processes should be recognized for their environmental and economic impacts and should be minimized. If possible, synthetic methods should be conducted at ambient temperature and pressure.

7. Use of Renewable Feedstocks - A raw material or feedstock should be renewable rather than depleting whenever technically and economically practicable.

8. Reduce Derivatives - Unnecessary derivatization (use of blocking groups, protection / deprotection, temporary modification of physical/chemical processes) should be minimized or avoided if possible, because such steps require additional reagents and can generate waste.

9. Catalysis – Catalytic reagents (as selective as possible) are superior to stoichiometric reagents.

10. Design for Degradation - Chemical products should be designed so that at the end of their function they break down into innocuous degradation products and do not persist in the environment.

11. Real-Time analysis for Pollution Prevention - Analytical methodologies need to be further developed to allow for real-time, in-process monitoring and control prior to the formation of hazardous substances.

12. Inherently Safer Chemistry for Accident Prevention - Substances and the form of a substance used in a chemical process should be chosen to minimize the potential for chemical accidents, including releases, explosions, and fires.

In order to anticipate increasing State Regulations as well as NGO, consumers and customers demand IFRA Members increasingly invest into Green Chemistry.

Definition: Natural

Natural means existing in, or produced by nature.

There is no official regulatory definition for the term "natural" for the fragrance industry.

However IFRA (International Fragrance Association), as outlined in IFRA IL 737, considers fragrance ingredients to be natural when these pre-exist in natural source materials from which they are isolated exclusively by physical means. IL 737 largely refers to what is described in ISO-Norm 9235⁴.

The IFRA position allows the presence of traces of synthetic solvents, antioxidants, etc. provided their presence is declared.

The "100%" natural approach is very restrictive for the fragrance industry. However, there remains the possibility to claim the presence of a certain percentage of natural ingredients or alternatively a few well-identified natural ingredients present in the fragrance compound.

A natural product is not necessarily organic, as it can be grown with chemical fertilizers, pesticides etc. Inversely, an organic product is always natural.

⁴ Definition of 'Natural raw material' according to the ISO norm 9235: Raw material of vegetable, animal or microbiological origin, including the products derived from this material by enzymatic processes or by traditional procedures of preparation (e.g. drying, torrefaction or fermentation).

Moreover, a natural product is not automatically sustainable (nor is synthetic equal to non-sustainable activities).

The ISO norm 9235, on which IFRA's natural definition is mainly based, does not define the term 'Natural Origin', which is more and more used by the industry. Although the natural origin concept is basically related to feedstock, there is no unanimously approved and clear definition in the industry. IFRA stresses that it does not make a distinction between a substance termed "natural" and of "natural origin" as long as it respects the criteria of ISO norm 9235.

Definition: Organic Ingredients

Natural organic raw materials are (manufactured with) natural raw materials that are "guaranteed organic", meaning that they are grown without the use of conventional pesticides and artificial fertilizers.

The use of the word "organic" is controlled by law and can be used on raw materials only if they are produced according to rules certified by an approved certification body. Excepted in the State of California⁵, there is no specific organic regulation that applies to consumer products. However, and by default, the consumer goods manufacturing industry applies essentially the standards dedicated to food.

Organic agriculture and food are labeled Organic by certification bodies whose standards are set by governmental authorities or professional associations approved by the appropriate authorities (e.g. Organic Food Federation (US), ACOS (UK)). For cosmetics and other industries, private certification bodies with different standards are involved, such as BDIH, QAI, Oasis...

Organic raw materials can serve the production of finished products of various 'green' or 'natural' levels.

Most private certification bodies allow an organic logo for products made of raw materials which are not 100% organic.

However specific requirements are common to all certification bodies such as:

- Extraction solvent recognized by the Certification Agency
- An extraction method with a specific process (essential oils, CO2 extracts, absolutes, ...)
- Packaging and labeling according to specific criteria...
- No origin of genetically modified organisms (GMO)

When a product is labeled 'Organic' it provides the assurance that the product, and/or its ingredients and the manufacturer have gone through a thorough investigation.

Because of the limited supply of 'organic' fragrance ingredients, this option may not be actionable for a lot of products. Shipping 'organic' ingredients from far away markets would substantially increase

⁵ California Organic Products Act of 2003 specifically covers food and cosmetics. A product needs to be 70% certified organic (30% no restrictions) to claim "certified organic" or "made with organic ingredients".

their carbon footprint and would offset their environmental benefits. Therefore this concept within the fragrance industry should be managed very carefully and in a balanced fashion.

Definition: LCA

Life Cycle Analysis (LCA) can cover the assessment of the environmental, human and social impact of a given product or service throughout its lifespan.

LCA involves making detailed measurements during the manufacture of the product, from the sourcing of the raw materials used in its production and distribution, through to its use, possible recycling, and its eventual disposal and the fate of the waste (is there degradation etc.).

LCAs enable a manufacturer to quantify how much energy and raw materials are used, and how much solid, liquid and gaseous waste is generated, at each stage of the product's life.

The total amount of carbon dioxide (CO_2) emitted over the full LCA of a product or service gives you the carbon foot print of a product.

There are other "footprints" for total greenhouse gases, freshwater usage, wildlife habitat destruction etc.

The life cycle assessments are carried out with dedicated software packages and by expert judgment.

The purpose of measuring the environmental performance of products and services is to give metrics for progressive improvements and to provide the client with a precise indication of a product's environmental impact.

Definition: Biodegradation

Biodegradation is the process by which carbon based substances are broken down by living organisms, ultimately to inorganic end products (like e.g. water or carbon dioxide) and biomass. It can proceed in the presence (aerobic biodegradation) or absence (anaerobic biodegradation) of oxygen.

Biodegradation tests are made by laboratories according to internationally accepted OECD, ISO and OPPTS guidelines. (for a detailed list see appendix 7.9-1 in the ECHA guidelines (<u>http://guidance.echa.europa.eu/docs/guidance document/information requirements r7b en.pdf</u>). The same standards are therefore applied to all chemicals substances.

These tests can be relatively simple screening tests (e.g. the OECD 301 ready biodegradability and OECD 302 inherent biodegradability tests) or complex higher tiered simulation types of tests (e.g. OECD 303A, sewage treatment simulation test). It is important to recognise that the guidelines are

not applicable to all substances. For example, for substances that are poorly soluble in water, volatile or adsorbing the OECD concluded that only a subset of the ready biodegradability test guidelines were applicable (ECHA Guidance on information requirements and chemical safety assessment Chapter R.7b: Endpoint specific guidance, <u>http://guidance.echa.europa.eu/docs/guidance document/information requirements r7b en.pdf</u>. For volatile substances (e.g. most fragrance ingredients) these are the OECD 301C, 301D, 301F and 310 test.

The criteria for biodegradability that are accepted by some of the eco-label groups and for other types of biodegradable substances (e.g. detergents in the EU) are that they should pass the criteria for "ready" or "inherent biodegradability" (i.e. 60-70% biodegradation in the OECD 301 series, OECD 310 or OECD 302 series)

There is no regulatory definition on which to base claims of biodegradability to be made on cosmetics.

It needs to be elucidated within the fragrance industry in conjunction with its customers, whether it is feasible to agree to a common position as to what is regarded as a "biodegradable fragrance". As outlined below, this needs to be based on the biodegradability of the individual constituents of a fragrance mixture. However, it needs to be clarified whether

- a) the constituents need to be readily biodegradable in line with OECD guideline 301 or whether less stringent criteria might apply, such as if a test failed only the 10-day window criterion.
- b) Whether inherently biodegradable ingredients are equally considered
- c) Whether the results need to be based on an OECD-, GLP-compliant study or even QSAR modeling applies
- d) To what percentage (mass or molar) the criteria need to apply for the mixture, e.g. to 60%, 70%, 90% or even 100% of the ingredients, before the whole fragrance mixture is considered "biodegradable"

Standard biodegradation tests have been developed for single substances and measure ultimate biodegradation as a function of either the CO₂ evolved or O₂ consumed. Thus for mixtures, such as a formulated fragrance, they do not provide information on the biodegradability of individual constituents. It should also be noted that these tests, which give pass/fail results on the basis of a certain percentage of measured degradation could give a false "desired" result for a mixture containing a high level of a specially chosen biodegradable diluent. Biodegradation testing of mixtures is also very difficult from a technical perspective. Different water solubilities and vapor pressures result in different biological availabilities. This might make different test designs necessary. Furthermore, following degradation by analytical means becomes inaccurate if not impossible. For these reasons the **testing of formulated fragrances for biodegradability should NOT be an option**. Instead the biodegradability of a formulated fragrance may be assessed based on data on the individual ingredients and by summing the percentages (by weight) of ingredients which are biodegradable according to, but not limited to, the criteria outlined below. The biodegradability and environmental acceptability of fragrance materials is further discussed in IFRA IL 620 and the associated annex 1.

The biodegradability of a fragrance composition must be determined on the basis of data relating to each ingredient,

Test	OECD / ISO	Parameter
READY TESTS		·
DOC Die away	301A / ISO 7827	DOC elimination
CO ₂ evolution	301B / ISO 9439 / OPPTS 835.3120	CO ₂ production
Modified MITI	301C	Oxygen consumption
Closed bottle	301D / ISO 10707	Oxygen consumption
Modified OECD	301E / ISO 7827	DOC elimination
Screening		
Manometric test	301F / ISO 9408	Oxygen consumption
Headspace test	310 / ISO 14593	CO ₂ production
INHERENT TESTS		·
BODIS-Test	ISO 10708	Oxygen consumption
Modified MITI II	302 C	Oxygen consumption
Zahn-Wellens Test	302 B / ISO CD9888 / OPPTS	DOC elimination
	835.3200	
S.C.A.S Test	302 A / OPPTS 835.3210	DOC elimination
		CO ₂ production in sealed vessels

Differing Criteria of Ready and Inherent Biodegradation Test*

*Less stringent 28-day test. Higher inoculum (bacteria) levels.

Biodegradation test data on essential oils and natural extracts is scarce. This is because many are complex mixtures and standard biodegradation test have been developed for single substances. An assessment of the biodegradability of a natural complex substance (NCS) may be made on a case by case basis depending on the relative composition and degradability of underlying constituents. Tests may be conducted on NCSs that consist of structurally related constituents which are expected to have similar degradation potential (e.g. Vetivert oil, all constituents have sesquiterpene structures). If the NCS passes the biodegradation test criterion it can be concluded that the underlying constituents comprising the complex substance are not expected to be persistent (OECD, 2001).

Environmental Hazard Labeling of Natural Complex Substances ("NCS")

A Natural Complex Substance may be classified on the basis of the data obtained by testing this material if the test results are considered reliable. For grades of NCSs and for endpoints for which reliable test data are not available hazard classification of complex substances should be evaluated on the basis of levels of their known chemical constituents in line with rules for mixture classifications such as the Dangerous Preparations Directive in Europe ("conventional method").

A huge number of natural materials do need to carry environmental hazard classification, which one will find in the guidance document established by the fragrance and flavor industry (IFRA-IOFI Labeling Manual, EFFA Code of Practice), together with information on the potential health hazards of the material.

Green labels

The proliferation of Green labels is the consequence of the lack of standard international certification bodies that can impose their own definition and criteria. Each country and each producer can therefore propose its own standards. Few examples of this competition for the most relevant Green labels are summarized in Annex I.

Annex I: examples of green labels



<u>NASAA</u> is the official Australian and International Organic Certifier. In addition to certifying operations within Australia,

NASAA certifies production and processing operations worldwide (in Nepal, Brazil, Indonesia, Samoa...) comprising over 10,000 small farmers.



<u>AIAB</u> is the Italian Association for Biological Agriculture. It is a non profit organization active in Italy only through regional associations that aim at controlling and certifying the use of biological techniques with strict standards in order to promote a biological agriculture.



<u>COSMEBIO</u> and <u>BDIH</u> are the French and German professional associations of the ecological and organic cosmetics.

Both associations established a charter with strict standards to guarantee certified cosmetic products containing natural and organic ingredients. They have developed lists identifying certified organic cosmetic products and provide transparency on the type of ingredients and the manufacturing procedures used.

No specific logo

<u>COSMOS-Standard</u> is an International Association conjointly founded by BDIH (professional association), COSMEBIO (professional association), ECOCERT Greenlife (certification body), ICEA (certification body) and SOIL Association (consumer association) to develop a harmonized and internationally recognized standard for organic and natural cosmetics.



<u>ECOCERT</u> is a French independent controlling and certification body. Ecocert controls agricultural companies (installations, buildings, ingredients, methods...) in order to ensure that they meet the required criteria for biological agriculture.



<u>NaTrue</u> is an International Interest Grouping of Natural & Organic Cosmetics, manufacturers who claim that they aim to safeguard the highest possible standards for natural cosmetics and their ingredients. NaTrue believes that a definition of Natural & Organic Cosmetics must be solely intended to meet consumers' expectations in terms of highly natural formulations and skin compatibility.



The <u>SOIL Association</u> is the UK's leading environmental charity promoting sustainable, organic farming and championing human health. It is an independent charity with high standard particularly on animal welfare (for example pigs and poultry) and the use of pesticides.



The United States Department of Agriculture has an organic program (NOP) that develops, implements, and administers national production, handling, and labeling of the USDA standards for organic agricultural products. NOP accredits100 certifying agents nationwide.