

## **IASC Position on Aloe Vera & REACH Registration**

### **Finished Product Marketers of Aloe vera Leaf & Inner Leaf Juice**

Manufacturers of finished products in the form of food, feedingstuffs, supplements, or medical devices have no requirement to register under REACH as such products are regulated by other legislation. Cosmetics products may be subject to registration requirements – please refer to the [IASC Draft Guidance: Understanding the REACH Regulations](#), for more details.

Under REACH, substances that are covered by the human food or animal feedstuff regulations (i.e., those intended for consumption by humans or animals, such as drinks products, food and food additives) are exempt from the provisions of Titles II (Registration), V (Downstream users), VI (Evaluation) and VII (Authorisation)<sup>1</sup>. This means, for example, that the aloe vera juice used in drink products would not require registration under REACH. Any finished food products are exempt from the provisions of Title IV of REACH (Information in the supply chain), but food ingredients supplied to food processors may require a Safety Data Sheet.

### **Raw Material Suppliers**

#### **Aloe vera Inner Leaf Juice – Raw Materials**

It is the opinion of the IASC that aloe vera inner leaf juice raw materials suppliers, including powders and concentrates thereof, being sold or imported into the EU should have no requirements to register under REACH. However, as noted above, food ingredients supplied to food processors may require a Safety Data Sheet.

This opinion is primarily due to the fact that aloe vera inner leaf juice is a substance which occurs in nature and is primarily processed only via manual or mechanical means (cut, sliced, crushed, screen filtered, etc.), with no chemical modification.<sup>2</sup> Clearly, this opinion may not apply in cases where any additional chemical processing is conducted, and such processors would need to assess their need for registration on an individual basis.

#### **Aloe vera Leaf Juice – Raw Materials**

It is the opinion of the IASC that, in the case of aloe vera raw materials where the entire leaf is used as the starting ingredient to make aloe vera leaf juice, including powders and concentrates thereof, being sold or imported in to the EU, should have no requirements to register under REACH (unless being used for a purpose other than in food, feedingstuffs,

or medical devices). However, as noted above, food ingredients supplied to food processors may require a Safety Data Sheet.

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<sup>1</sup> See Article 2(5)(b) of the REACH regulations for details

<sup>2</sup> Guidance for Annex V, Exemptions from the obligation to register, Version: 1, March 2010 - [http://guidance.echa.europa.eu/docs/guidance\\_document/annex\\_v\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/annex_v_en.pdf)



According to Article 3(40), a '**not chemically modified substance**' means '*a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities*'.

Cellulase is often applied in the processing of aloe vera leaf raw material to reduce overall viscosity. The cellulase reduces viscosity by shortening the naturally occurring polysaccharide-chain constituents contained within the juice by separating them into smaller parts. This change in length does not "chemically modify" the constituents of aloe vera juice, as the constituents are still present in their original chemical structure, beyond being separated into smaller pieces.

## Background

The material found below is an excerpt from the IASC draft guidance: *Understanding the REACH Regulations*. The complete draft guidance can be found [HERE](#).

## What is REACH?

REACH is the acronym for the European Union (EU) regulation **Registration, Evaluation, Authorization and Restriction of Chemicals**. The law took effect on June 1, 2007 and will be phased in over an 11 year period. It was developed and implemented to replace about 40 other legislative controls in an effort to streamline and improve the former legislative framework on chemicals marketed in the EU. REACH places greater responsibility on industry to manage the risks that chemicals may pose to consumer health and the environment.

## How does REACH impact herbal products such as dietary supplements and foods?

Manufacturers of the following will have NO REQUIREMENT to register under REACH:

- Products manufactured and marketed as dietary supplements<sup>3</sup>, or;
- Products manufactured and marketed as a food or feedingstuffs<sup>4</sup>, or;
- Products manufactured and marketed as a medical device<sup>5</sup>

These products are regulated by other, pre-existing regulations and are not subject to REACH<sup>6</sup>.

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<sup>3</sup>Regulated by Directive 2001/83/EC, relating to medicinal products for human use.

<sup>4</sup>Regulated by the Food Safety Regulation 178/2002/EC. Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree within the Community before 15 May 1997. Regulation EC 258/97 of 27 January 1997 of the European Parliament and the Council lays out detailed rules for the authorization of novel foods and novel food ingredients. Foods commercialized in at least one Member State before the entry into force of the Regulation on Novel Foods on 15 May 1997, are on the EU market under the "principle of mutual recognition". ([http://ec.europa.eu/food/food/biotechnology/novelfood/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm))

<sup>5</sup>Regulated by either 726/2004/EC or 2001/82/EC

<sup>6</sup>See Article 2, Sec. 6 for a complete list

## How does REACH apply to Raw Materials/Ingredients?

Raw materials/ingredients, particularly those with substances defined as naturally occurring, may not need to be registered under the regulations. The following information will help suppliers of raw materials/ingredients and manufacturers further understand their requirements.

According to Article 2, Section 7 of the regulations:

7. The following shall be exempted from Titles II, V and VI:
  - (b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;

Annex V lists the following information (please note emphasis added to #8, in bold):

### ANNEX V

#### EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.
2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.
3. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.
4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
  - (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
  - (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
5. By-products, unless they are imported or placed on the market themselves.
6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
7. The following substances which occur in nature, if they are not chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.
8. **Substances occurring in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC.**
9. Basic elemental substances for which hazards and risks are already well known:



The following information is taken from Section 3/39, definitions – Substances which occur in nature:

39. Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

Therefore, a raw materials supplier providing ingredients that are processed in accordance with the above definition, or are not processed in any way that chemically modifies the raw material/ingredient, the material is exempt from registration.