

LOW REGULATORY CONCERN CHEMICALS (LRCC)

Discussion Paper No. 5

REVIEW OF DEFINITIONS NATURALLY OCCURRING CHEMICALS AND ESSENTIAL OILS

1. PURPOSE

This discussion paper reviews the definitions for naturally occurring chemicals and essential oils that are available nationally and internationally. Recommendations are also made regarding the amendment of the NICNAS definition of naturally occurring chemicals, adoption of the International Organization for Standardization (ISO) definition of essential oils, and NICNAS guidance materials for naturally occurring chemicals and essential oils.

2. BACKGROUND

Among the LRCC reform initiatives requiring further work was a review of the definition of naturally occurring chemicals. Recommendation 9.3 of the LRCC Final Report recommends that

“NICNAS review of the definition of naturally occurring chemicals, particularly in relation to steam distillation extraction of essential oil”.

NICNAS has a number of exemptions from new chemicals notification in the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act). NICNAS does not require the notification of naturally occurring chemicals as these are taken to be on the Australian Inventory of Chemical Substances (AICS). Naturally occurring chemicals are not considered industrial chemicals for the purposes of NICNAS Registration. While a definition of the naturally occurring substance is included in the Act, no guidance on the application of this definition is currently available, e.g. in the NICNAS Handbook of Notifiers.

It has been noted that the current definition of naturally occurring does not provide certainty to the essential oils industry when making a decision if notification to NICNAS is required. This requires NICNAS to make case-by-case decisions on whether an essential oil is naturally occurring or not based on examination of the extraction processes. This lack of certainty is further compounded by fact the Act does not contain a definition of an essential oil. Internationally definitions for both essential oil and naturally occurring substances exist.

3. NATURALLY OCCURRING CHEMICALS

3.1 Australia’s definition of naturally occurring.

A naturally occurring chemical is defined in s5 of the Act as:

“(a) An unprocessed chemical occurring in a natural environment,

- or
- (b) a chemical occurring in a natural environment, being a substance that is extracted by:
- (i) manual, mechanical, or gravitational means, or
 - (ii) dissolution in water; or
 - (iii) flotation; or
 - (iv) a process of heating for the sole purpose of removing uncombined water, without a chemical change in the substance”.

The physical processes that are included in the definition are restricted to those processes, where minimal chemical change to the chemical is likely to occur during its extraction.

NICNAS considers the following factors when determining whether or not a chemical meets the definition of naturally occurring under the Act:

- (1) origin of the chemical, particularly if manufactured;
- (2) physical and chemical changes that occur during any processing, especially in the case of steam distillation;
- (3) consideration of how any heat is applied in any processing; and
- (4) variability of chemical composition from batch to batch.

3.2 International Definitions of Naturally Occurring

European Union

The European Union defines naturally occurring substances as “occurring in nature as such, unprocessed, or processed only by manual mechanical or gravitational means; by dissolution in water or flotation or by heating solely to remove water, or which are extracted from air by any means”. There is no requirement in the EU to report these chemicals individually in ELINCS; they are reported in ELINCS under the collective name “naturally occurring”. However, substances (as such or as part of mixtures) that are produced by chemical modification of naturally occurring products or are separated from them by physical processing can be reported (European Chemicals Bureau, 2005).

This definition of a naturally occurring substance is expected to change in the EU under the proposed Registration, Evaluation, Authorisation of CHEMicals (REACH) legislation. Under draft REACH legislation published in late 2005, the definition was amended to include steam distillation as an acceptable means of extraction. Therefore naturally occurring substances will be defined as substances which occur in nature means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical, or gravitational means; 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. The scientific rationale for the inclusion of steam distillation as an acceptable means of extraction has not been published.

US EPA

Advice has been received from the US EPA on definition of naturally occurring substances in *Toxic Substances Control Act 1976* (TSCA). Under TSCA any chemical substance which is naturally occurring and (1) which is (i) unprocessed or (ii) processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or (2) which is extracted from air by any means, shall automatically be included in the inventory under the category 'Naturally Occurring

Substances'. Substances that are derived from natural products and are processed by methods other than those above are subject to reporting and would fall within the unknown or variable composition, complex reaction products, and biological material (UVCB) category for inventory listing purposes. Biological substances extracted with solvents other than water or extracted using steam also would not be considered to be naturally occurring and would this be subject to inventory reporting; many of these substances also fall into the UVCB category.

Canada

Under the *Canadian Environmental Protection Act 1999*, a naturally occurring substance is defined as a substance which occurs in nature as such, which is chemically unprocessed or which is extracted from air by any means, or physically processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, or by heating solely to remove water.

“Substances occurring in nature as such, unprocessed or processed only by manual mechanical, or gravitational means, by dissolution in water, by flotation, or by heating solely to remove water, or which are extracted from air by any means”, are not reported individually. These substances are covered on the Canadian Domestic Substances List (DSL) by the entry “naturally occurring substances” (Environment Canada, 1989).

Canada provides the following guidance information on substances occurring in nature - “Methods which are considered not to alter the chemical identity of substances occurring in nature include: filtration, milling, cutting, pressing, any gravitational separation (decantation, centrifugal methods) processing by electrostatic means, extraction with water (not with other solvents). Isolated substances, or those which are part of mixtures produced by chemical modification of naturally occurring products or are separated from them by physical processing, are reported. Physical processing includes such methods as: distillation, steam distillation, crystallisation, sublimation, heating for reason other than to remove water, salting out and ion exchange (product obtained by)” (Environment Canada, 1989).

3.3 Organisation of Economic Cooperation and Development (OECD)

The current OECD definition for naturally occurring substances is “substances occurring in nature that are unprocessed, processed only by manual, gravitational, or mechanical means or by dissolution in water, or by flotation, or by heating solely to remove water, or are extracted from air by any means without chemical change in the substance” (OECD, 2005). The Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals of the OECD has agreed that this working definition should be tested, i.e. open for public comment, during 2005-2006 in the context of the work on New Chemicals and Existing Chemicals.

Comparison with NICNAS

The definitions of naturally occurring substances currently used by most international regulatory agencies do not differ significantly from the NICNAS definition. Clearly, the inclusion of steam distillation in the EU definition means that it now differs significantly from the NICNAS definition. The lack of information on the scientific rationale for the inclusion of steam distillation has restricted detailed discussion on the difference.

4. ESSENTIAL OILS

4.1 Essential Oils in Australia

The use of essential oils is widespread in Australia. Essential oils are used either in pure form or compounded with other ingredients. Many of the compounded oils and fragrance oils are a mixture of the synthetic and natural essential oils. Pure essential oils and preparation of essential oils are widely used, including in aromatherapy, therapeutic preparation, as repellents, in food flavouring, in domestic cleansers, and environmental fragrances.

AICS lists a large number of essential oils. To accurately search AICS for an essential oil, the full chemical name, CAS Number, botanical name and extraction method are required.

Many of the essential oils that were in use in Australia at the time of creating AICS were not grandfathered on AICS as the industry at the time assumed they fell under naturally occurring chemicals (which did not need notification as they are assumed to be an existing chemical, on the inventory whether listed or not). One of the concerns expressed by the essential oil industry is that all the essential oils not grandfathered on AICS would need to be notified before they can be added to AICS. This matter is dependent on the definitions of both naturally occurring and essential oils.

4.2 Definition of Essential Oils

International Organization of Standardization (ISO)

ISO defines essential oil as “products obtained from natural raw materials by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process or by dry distillation. The essential oil is subsequently separated from the aqueous phase by physical means”. Synthetic or “nature identical” oil are not included in the ISO definition.

Australia

Essential oils are not defined in the Act. The National Drugs and Poisons Scheduling Committee (NDPSC) has adopted the ISO definition of essential oils and this definition is included in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP). The SUSDP is the decisions of the NDPSC regarding the classification of drugs and poisons into Schedules for inclusion in the relevant legislation of the Australian states and territories. It also includes model provisions about containers and labels, and recommendations about other controls on drugs and poisons (NDSPC, 2005).

European Union

In EINECS plant extracts are defined as “extractives and their physically modified derivatives such as tinctures, concretes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues etc. obtained from (Genus species, family name). No definition of “essential oil” could be found in the EU legislation. However, the terms of “oil” and “oils, expressed” have been defined for the inventory of ingredients employed in cosmetic products. The term “oil” is used for all types of essential oils, obtained either by dry distillation or by steam distillation, flash pasteurisation etc. The term ‘oils,

expressed” is used for the essential oils obtained by mechanical processes mainly for the cold-pressed essential oils obtained from the epicarp of citrus fruits.

USA EPA

Essential oils are listed on the inventory by names, CAS number, and definitions. TSCA definitions generally contain the phrase “extractives and their physically modified derivatives” followed by the genus and species of the biological source. The definition may also include a list of the primary components of the oil (US EPA, 2006).

It is noted that critical to the definition to essential oil and naturally occurring is the process of distillation.

4.3 Toxicity of Essential Oils

The toxic mechanisms of essential oils can be divided into two categories: specific and non - specific toxicity. In specific toxicity, there is a clear biochemical explanation for the observed effect, such as inhibition of a vital enzyme activity or the blockage of a receptor molecule. Non-specific toxicity is used to describe situations where the only demonstrable interaction is a non-specific, reversible, hydrophobic combination between the cellular or organelle membrane components and the chemical. It generally accepted that when the single acute toxic dose is in excess of one gram/kilogram (g/kg), the non-specific toxicity is most likely to be the mechanism of toxic effects. It should be noted some essential oils clearly have both specific and non-specific toxic activity, these are mainly the compounds with an acute toxic dose below one g/kg (NDPSC, 1998).

Metabolites of essential oils have been shown to lead to hepatotoxicity, lung toxicity, or nephrotoxicity, sensitisation, mutagenicity, and carcinogenicity. Most essential oils have been shown to cause contact sensitisation in some individuals. Furthermore, some essential oils which contain methoxypsoralens can cause primary photosensitisation in all exposed individuals following local application or ingestion (NDPSC, 1998).

In its opinion concerning “Essential Oils” in June 2003, the European Union’s Scientific Committee on Cosmetic Products and Non Food Products Intended for Consumer (SCCNFP) stated “there is no demonstration in the peer review scientific literature that fragrances compounds of natural origin are “safer” than synthetics”.

An essential oil can be regulated by number of agencies in Australia, depending on its use. NICNAS regulates essential oils when these are used in aromatherapy, as environmental fragrance, and for household cleaning purposes. The Therapeutic Goods Administration will regulate essential oils used for therapeutic purpose. While, the Australian Pesticides and Veterinary Medicines Authority and Food Standards Australia and New Zealand regulate essential oils that are used as a repellent and as flavouring in foods, respectively.

Essential oils that are likely to be hazardous to the public may be referred to NDPSC for consideration. The NDPSC when scheduling the essential oil will consider its toxicity, purpose of use, potential for abuse, safety in use, and the need for the essential oil.

5. STEAM DISTILLATION

5.1 Essential oil extraction

There are three main methods used to concentrate plant flavour and fragrance substances:

1. Distillation;
2. Mechanical separation; and
3. Solvent extraction.

The method used will determine the quantitative and qualitative composition and hence the organoleptic properties of product (Ullmann's Encyclopaedia of Industrial Chemistry, 2005).

Essential oils are usually liquids isolated from plant parts. The majority of constituents of the commercial viable essential oils are terpenes eg hydrocarbons, alcohols, aldehydes, ketones, acids and esters. Essential oils are either distilled or expressed. Distillation of essential oils can be by water, steam, water-steam, or dry with steam distillation being the most common form of distillation. High-pressure steam distillation is used to extract the essential oil when botanical material and the essential oils are sufficiently heat resistant or non - hydrolysable. A number of essential oils require the enzymatic release of the volatile component before steam distillation (Smith et al 2005).

In addition, the distillation of essential oils at elevated temperatures results in the transformation of thermolabile substances and some typical components are only released from their precursor in the plant under distillation conditions (Ullmann's Encyclopaedia of Industrial Chemistry, 2005).

5.2 Steam Distillation and Naturally Occurring Chemicals

It is NICNAS's opinion that steam distillation is a physical process that falls outside the current definition of naturally occurring chemicals. In addition, NICNAS recognises some chemical changes may occur during steam distillation, particularly if high-pressure steam is used. While others have noted that distillation of essential oil at elevated temperature is known to result in the transformation of some thermolabile substances (Ullmann Encyclopaedia of Industrial Chemistry, 2005).

6. PROPOSAL

Recommendations

Recommendation 1: That the definition of naturally occurring chemicals in s5 of the Act is to remain unchanged as:

Naturally-occurring chemicals means:

1. an unprocessed chemical occurring in a natural environment
or
2. a chemical occurring in natural environment, being a substance that is extracted by:
 - i. manual, mechanical or gravitational means;
or
 - ii. dissolution in water; or
 - iii. flotation; or

- iv. a processing of heating for the sole purpose of removing uncombined water.

The NICNAS definition will thus continue to be consistent with the current OECD, US and Canadian definitions of naturally occurring substances. This definition will be reviewed again when the OECD public comment period for the working definition ends. This process will consider the arrangement in REACH.

Recommendation 2: That NICNAS adopts the ISO definition of essential oil, this would be consistent with the current definition used in SUSDP.

Recommendation 3: That NICNAS develop and publish the guidance on naturally occurring substances. Any guidance information will include steam distillation as an acceptable extraction method provided there is sufficient scientific evidence that the distillation conditions used do not result in chemical transformation of the components. This will allow a level of consistency with EU REACH legislation until there is sufficient scientific rationale for the inclusion of steam distillation (unqualified) in the definition.

Recommendation 4: Develop guidance on essential oils in relation to their definition and interpretation as naturally occurring.

Recommendation 5: Establish an expert essential oils working group to work with NICNAS on this guidance material.

References:

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