NATURALLY-OCCURRING CHEMICALS

Guidance Document

1. Background

In the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), an industrial chemical which meets the definition of 'a naturally-occurring chemical' is taken to be on the Australian Inventory of Chemical Substances (AICS), whether listed or not, and therefore does not require notification as a new chemical prior to manufacture or importation into Australia.

Similarly, an industrial chemical which meets the definition of 'a naturally-occurring chemical' is not within the definition of a 'relevant industrial chemical' in the Act and is therefore not considered when working out the value of introduced chemicals each year when applying for NICNAS registration.

2. Definition of a naturally-occurring chemical

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".

Guidance on these processes is included below.

It is noted that the definition of a naturally-occurring chemical is consistent with equivalent definitions in other notification and assessment schemes.

2.1 (a) Unprocessed chemicals occurring in a natural environment

The first part of the definition of a naturally occurring chemical (part (a)) applies to chemicals which can be obtained from, for example, plants, micro-organisms or animals without any processing at all, e.g. blood and milk from animals. The definition also applies to certain inorganic matter such as minerals, ores, crude oil, coal and natural gas which can be, for example, obtained from the earth or sea without any processing.

2.2 (b) Chemicals extracted without a chemical change

The second part of the definition of a naturally-occurring chemical (part (b)) applies to chemicals which occur in nature but which have been processed by certain means without any change in the chemical composition of the chemical. A description of these processes, with examples, is set out below.

2.3 (b)(i) Extraction by manual, mechanical or gravitational means

The simplest method of separation is when a naturally-occurring chemical is removed from its matrix or another chemical by hand or machine without any change in the chemical composition. Processes which may be applicable include:

- Filtration, where the solid and liquid phases of a mixture are mechanically separated by passing the mixture through a porous medium;
- Centrifugation, where the liquid phases or solid and liquid phases of a mixture are separated by mechanical/gravitational means;
- Sedimentation, where the solid and liquid phases of a mixture are gravitationally separated by enabling the settling of solids in liquids;
- Cold pressing, where the liquid of a liquid-solid mixture is separated by squeezing the matrix to obtain the liquid
- Sieving, where the solids in a mixture can be separated on the basis of particle size.

2.4 (b)(ii) Extraction by dissolution in water

In this separation method (for water-soluble chemicals), the only solvent which can be used to extract the chemical from other components in a mixture is water. The dissolution by any other solvent or mixture of solvents or mixture of water with other solvents disqualifies the chemical from being naturally-occurring.

Examples of this process include the extraction of sugar from sugar beets using water, the leaching of soluble tea from tea leaves and the extraction of a water-soluble chemical from a mineral ore.

2.5 (b)(iii) Extraction by flotation

Flotation is a physicochemical property-based separation process widely used in mineral processing to separate minerals from waste rock or solids. Flotation is based on the use of wettability differences of solid particles, where mineral ore is pulverised and mixed with water and special chemicals that cause preferential wetting of the solid particles. The unwetted particles are carried to the surface by air bubbles to obtain a mineral concentrate, eg lead, zinc and copper concentrates.

2.6 (b)(iv) Extraction by a process of heating for the sole purpose of removing uncombined water

Heat can be used to purify or concentrate chemical compounds by removing uncombined water. For the purposes of meeting the NICNAS definition of a naturally-occurring chemical, the heat applied is not to serve any other purpose, e.g. heat necessary for steam distillation. An example of this extraction process would be the drying of a wet clay or mineral, where moisture is not chemically-bound to the substrate.

3. Application of the definition

In determining whether a chemical meets the definition of a naturally-occurring chemical, a number of factors need to be considered, including:

- How was the substance obtained?
- Has the substance been obtained after some form of processing?
- If so, what type of processing?
- Was heat used in the processing?
- Was there any likelihood of chemical change during processing?

The physical processes that are included in the definition are restricted to those processes where no change in the composition of the chemical during extraction will occur.

If the chemical or mixture containing the chemical has been imported, e.g. in a product, documentation may be required from the supplier to assist in determining whether the substance meets the definition of a naturally occurring chemical.

4. Steam distillation

Distillation is the separation process based on the difference in composition between a liquid mixture and the vapour formed from it. The difference in composition is due to the different effective vapour pressures of the components in the liquid mixture. The vapour is then condensed to a liquid (the distillate). In steam distillation, steam is used to lower the distillation temperatures of high boiling organic compounds that are immiscible with water. In the process, steam is charged to the matrix to volatilise the hydrophobic liquid and carry it across to a chilled condenser for subsequent liquefaction and separation from water. Variations in temperature, pressure and distillation time are used to control the process.

Steam distillation is commonly used to extract chemicals from plant material, e.g. the extraction of essential oils from leaves, bark or other plant materials. In the steam distillation of essential oils, the hot steam helps to release the aromatic molecules from the plant material as the steam forces open the pockets in which the oils are kept in the plant material. The temperature and pressure of the steam need to be carefully controlled to prevent burning of the plant material or the essential oil. Also, the distillation must be allowed to continue for such time to sufficiently extract the oil's components from the plant as some components are released more quickly than others.

Under the current NICNAS definition of a naturally-occurring chemical, steam distillation is not regarded as an allowable process as it does not meet the extraction requirements of part (b) of the definition, in particular, the use of heat for a process other than the removal of combined water. In addition, there is uncertainty regarding the potential for chemical change during steam distillation. The scientific literature cites reports of chemical change during steam distillation, including the thermal degradation of heat-sensitive compounds and the hydrolysis of other compounds.

5. Extraction of essential oils

An essential oil is the volatile oil derived from some part of a plant, e.g. leaf, stem, flower or peel, and usually carries the odour or flavour of the plant. Essential oils are usually lipophilic compounds and therefore usually not miscible with water. Some essential oils are nearly pure single compounds, e.g. oil of wintergreen, however, most are mixtures of many chemicals.

Essential oils are generally extracted by distillation, including steam distillation. Other processes include cold pressing, e.g. for citrus peel oils, solvent extraction, supercritical fluid extraction (with CO_2) and hydro distillation. In some cases, extracted essential oils are further processed to remove undesirable components, e.g. rectification of peppermint oil to remove dimethyl sulfide.

Therefore, for the purposes of new chemicals notification and NICNAS registration, introducers of essential oils need to determine whether their oil meets the NICNAS definition of a naturally-occurring chemical. Most importantly, the process used for extraction needs to be compared with the allowable processes in the definition of a naturally-occurring chemical, and any likelihood of change in chemical composition during the extractive process needs to be examined. The use of heat during extraction, e.g. by steam distillation, or chemical change during the extraction process will disqualify the oil from being regarded as a naturally-occurring chemical. Numerous studies have indicated differences in chemical composition between the natural plant oil and the commercial oil. Also, the scientific literature contains numerous studies citing the variations in chemical composition between oils extracted by different means.

As a guide, non-invasive processes carried out at room temperature may fulfil the definition of a naturally-occurring chemical, e.g. cold pressing, however, processes requiring the application of heat during extraction, unless to remove water, are subject to uncertainty regarding chemical change during the extraction process. Also, some oils may have water-soluble components which are hydrolysed in treatment with water or steam.

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