



REBECA Workshop: Review of potential risks of botanicals and semiochemicals

Current regulation systems and data requirements in Australia

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Biological Agricultural Product

Definition:

...the active constituent comprises or is derived from a living organism (...) with or without modification...



Biological Agricultural Product

Exemption:

biologically derived chemical that has **direct toxicity** to the target species

purification and full **identification** possible

Examples:

nicotine, strychnine, rotenone and ivermectin.



Biological Agricultural Products

Group 1: **Semiochemicals**

low exposure:

- **very low application rates**
- **high volatility**
- **application in bait, trap or encapsulated formulation**

Potential for low toxicity



Biological Agricultural Products

Group 2: **Plant extracts**

unpurified or purified

**incomplete purification and composition
not fully characterised**

Examples:

- **“Pyrethrum”, consisting of a mixture of related pyrethrins**
- **Neem oil, Neem extract, consisting of a mixture of characterised and uncharacterised components**



Data requirements

Biological properties of active constituent

- natural occurrence and distribution in Australia of the source organism
- natural occurrence of the chemical or relationship to the form occurring in an organism
- mode of action and specificity
- likely biological effects arising from use



Data requirements

Chemistry and manufacture (contaminants)

Toxicology and Occupational Health and Exposure

Residue studies normally not required

Environmental fate

Ecotoxicity

Efficacy