

26-Feb-2002

Natural Healthcare Products

Proposed management of risk

Level of risk	Risk management options	Example
Risk associated with OTS* availability unacceptable	Prohibition or professional guidance and supervision only	Vitamin B6 (All options) > 500 mg
Defined risk for defined sub-groups, or ingredient levels	Warning statements and/or ingredient limits and/or special GMP requirements	* 250-500 mg
Risk ill defined but acceptable	Voluntary caution statements & education	** 100-250 mg
Negligible risk	Ingredient listing on label	<=100 mg

Note: Unlike foods, all Natural Healthcare Products have ingredients listed on label.
 Therefore, this is a default Risk Management Option on all product.

* Off The Shelf
26-Feb-2002

* **Warning:** Vitamin B6 has been reported to affect nerve function at high levels. If you experience tingling of the fingers or similar symptoms, stop using this product.
 ** **Caution:** If you experience tingling of the fingers, stop using this product.

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Level of risk	Risk management options	Example
Risk associated with OTS* availability unacceptable	Prohibition or professional guidance and supervision only	Royal Jelly * (Warning statement)
Defined risk for defined sub-groups, or ingredient levels	Warning statements and/or ingredient limits	"Royal jelly may cause serious allergic reactions. Most reports have been in asthma sufferers."
Risk ill defined but acceptable	Voluntary caution statements & education	
Negligible risk	Ingredient listing on label Note: Unlike foods, all Natural Healthcare Products have ingredients listed on label. Therefore, this is a default Risk Management Option on all product.	

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* Report To Minister of Health On The Findings Of The Bee Product Warning Scientific Review Working Group
•Associate Professor Lynn Ferguson (Chair)
•16/17 August 1999

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Level of risk	Risk management options	Example
Risk associated with OTS* availability unacceptable	Prohibition or professional guidance and supervision only	Bee Pollen * (Ingredient listing)
Defined risk for defined sub-groups, or ingredient levels	Warning statements and/or ingredient limits	
Risk ill defined but acceptable	Voluntary caution statements & education	
Negligible risk	Ingredient listing on label Note: Unlike foods, all Natural Healthcare Products have ingredients listed on label. Therefore, this is a default Risk Management Option on all product.	

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Risk associated with OTS* availability unacceptable	Prohibition or professional guidance and supervision only	Propolis* (Ingredient listing)
Defined risk for defined sub-groups, or ingredient levels	Warning statements and/or ingredient limits	
Risk ill defined but acceptable	Voluntary caution statements & education	
Negligible risk	Ingredient listing on label Note: Unlike foods, all Natural Healthcare Products have ingredients listed on label. Therefore, this is a default Risk Management Option on all product.	

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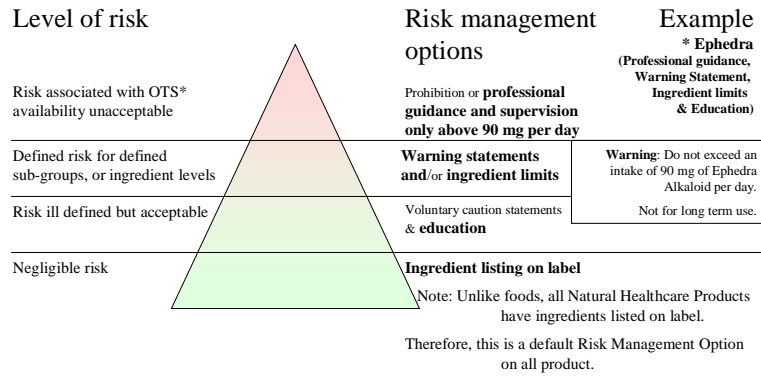
Level of risk	Risk management options	Example
Risk associated with OTS* availability unacceptable	Prohibition or professional guidance and supervision only	St John's wort (Caution Statements & Education)
Defined risk for defined sub-groups, or ingredient levels	Warning statements and/or ingredient limits	St John's wort can interfere with the way some medicines work. If you are taking a prescription medicine consult a healthcare professional before use.
Risk ill defined but acceptable	Voluntary caution statements & education	
Negligible risk	Ingredient listing on label Note: Unlike foods, all Natural Healthcare Products have ingredients listed on label. Therefore, this is a default Risk Management Option on all product.	

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* Cantox Health Sciences International Risk analysis:
Safety Assessment And Determination of a Tolerable Upper Limit For Ephedra, Dec 2000