Botanical Safety Assessment Guiding Document

An Introduction

Presented by the

ASEAN COSMETIC ASSOCIATION

9 June, 2010

Botanical Safety Assessment Guidelines

Presentation content:

- **What it is / what it is not;**
- **How was it created?**
- **The key guiding principles;**
- **The future;**

WHAT IT IS/ WHAT IT IS NOT

- It is a "guidance" document;
- It is a set of scientific recommendations for gathering data/ information;
- It is a compilation of various modern principles of toxicology to help describe the safety profile of a botanical;
- It is about "continuous improvement";
- It is an effort to help ASEAN transition to a higher level of competitive advantage;

What it is

- It is an approach based on the principles of risk assessment:
  - Hazard identification;
  - Dose/Response considerations;
  - Exposure assessment;
  - Risk characterization;

WHAT IT IS NOT

- It is not a mandatory /rigid set of scientific rules;
- It is not a pointer to any current potentially unsafe situation or process;
- It is not a recommendation supporting anecdotal evidence alone;
- It is not a “second class” compilation of non-validated set of “work instructions”;
- It is not a hurdle to business or an unrealistic demand for an overnight change;

HOW WAS IT CREATED ?

- Involvement of practicing toxicologists & academic researchers (regional & global);
- A thorough evaluation of current practices and of use of botanicals in cosmetics;
- Adequately scoping the current guidelines to focus on cosmetics and their usage patterns;
- Thorough “research” of published *peer-reviewed* models of toxicity evaluations;
- Blending the same with use of “traditional wisdom / knowledge”;

THE KEY GUIDING PRINCIPLES

- History of safe use;
- Comparative approach or the similarity approach;
- Threshold of toxicity concern;
- Classical toxicology;

HISTORY OF SAFE USE

Available online at www.sciencedirect.com
ScienceDirect
Food and Chemical Toxicology 45 (2007) 2513–2525
www.elsevier.com/locate/foodchemtox

History of safe use as applied to the safety assessment of novel foods and foods derived from genetically modified organisms

A. Constable [a], D. Jonas [b], A. Cockburn [c], A. Davi [d], G. Edwards [e], P. Hepburn [f], C. Herouet-Guicheney [g], M. Knowles [h], B. Moseley [i], R. Oberdörfer [j], F. Samuels [k,*]

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History of Safe Use

- Body of knowledge accumulated from the use and experience of that ingredient within its cultural context and conditions of use;
- A description of its safety profile;
- A good description of History of Safe Use can be used:
  - As a STARTING point in safety assessment;
  - Used for reference material;
  - Highlight knowledge;

History of Safe Use

Caution:

- May require intensive research/generation of data;
- Must consider the botanical ingredient as consumed: quality and quantity;

Comparative Approach

Pergamon

Food and Chemical Toxicology 34 (1996) 931–940

The Safety Assessment of Novel Foods

GUIDELINES PREPARED BY ILSI EUROPE NOVEL FOOD TASK FORCE

D. A. JONAS[a], E. ANTIGNAC[b], J.-M. ANTOINE[c], H.-G. CLASSEN[d], A. HUGGETT[e], I. KNUDSEN[f], J. MAHLER[g], T. OCKHUIZEN[h], M. SMITH[i], M. TEUBER[j], R. WALKER[k] and P. DE VOGEL[l]

PERGAMON

Food and Chemical Toxicology 41 (2003) 1625–1649

www.elsevier.com/locate/foodchemtox

Guidance for the safety assessment of botanicals and botanical preparations for use in food and food supplements

B. Schilter[a], C. Andersson[b], R. Anton[c], A. Constable[a], J. Kleiner[d,*], J. O'Brien[e], A.G. Renwick[f], O. Korver[g], F. Smit[h], R. Walker[i]

Comparative Approach

- Determine what (if any) existing materials should be used as a comparison;
- If there is no comparison, the novel material is not necessarily unsafe, but an extensive safety assessment maybe required;
- Once a comparison(s) is identified, the assessment might be performed on the basis of botanical and phytochemical characterization, methods of processing, previous human exposure and intended exposure;
- Approach designed to highlight equivalence, similarity or differences between the new material and its traditional counterparts;

The Threshold of Toxicological Concern

The Threshold of Toxicological Concern

- **Threshold:** a dose at, or below which, a toxicologically significant response is not seen;
- *The Threshold of Toxicological Concern (TTC)* is the level of exposure to chemicals below which no significant risk to human health is expected to exist;
- Used by various regulatory bodies (FDA, JECFA, EU) for safety evaluation of low-level chemicals even in the absence of toxicological data;

Fd Cosmet. Toxicol. Vol. 16, pp. 255–276. Pergamon Press 1978. Printed in Great Britain

Review Section

ESTIMATION OF TOXIC HAZARD—A DECISION TREE APPROACH

G. M. CRAMER and R. A. FORD

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and

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ELSEVIER

Food and Chemical Toxicology 42 (2004) 65–83

www.elsevier.com/locate/foodchemtox

Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet

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Classical toxicology / Clinical Safety

Classical toxicology / Clinical Safety

- Actual testing may be needed to assure the safety of a botanical;
- ACA does not recommend testing the raw materials or products on animals;
- ACA supports the use of validated non-animal tests, and / or clinical safety testing if supported ethically;
- Mutagenicity; Skin / Eye Irritation ; Sensitization ; UV absorption ;

QUESTIONS / SUGGESTIONS