Botanical Safety Assessment Guiding Document
An Introduction

Presented by the
ASEAN COSMETIC ASSOCIATION

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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:  

- 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
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,*

a Nestlé Research Centre, Vers-Chez-les-blanc, 1000, Lausanne 26, Switzerland
b Independent Consultant, Mill House, Ciliau Aeron, Lampeter SA48 8DD, UK
c Independent Consultant, Toxico-Logical Consulting Ltd, Gravesend Farm, Albury, Ware, Herts SG11 2LW, UK
d Groupe Danone, Rue Helder 15, 75439 Paris Cedex 09, France
e Independent Consultant, 63 Woodlands Road, Sonning Common, Reading RG4 9TD, UK
f Unilever, Safety and Environmental Assurance Centre, Colworth Park, Sharnbrook, Bedfordshire MK44 1LQ, UK
g Bayer CropScience, Regulatory Toxicology, Bioscience, 355 Rue Dostoievski, Sophia-Antipolis 06903, France
h Coca-Cola European Union Group, 1424 Chaussée de Mons, 1070 Brussels, Belgium
i Independent Consultant, Blandford House, Reading, Berkshire, RG1 3RD, UK
j Bayer CropScience AG, BioScience, MBAS, Industriepark Hoechst, K607, 65926 Frankfurter Main, Deutschland, Germany
k International Life Sciences Institute (ILSI) Europe, Av. E. Mounier 83,Box 6, B-1200 Brussels, Belgium

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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
The Safety Assessment of Novel Foods

GUIDELINES PREPARED BY ILSI EUROPE NOVEL FOOD TASK FORCE

D. A. Jonas*, E. Antignac†, J.-M. Antoine†, H.-G. Classen*, A. Huggett†,
I. Knudsen*, J. Mahler†, T. Ockhuizen*, M. Smith*, M. Teuber†, R. Walker†
and P. De Vogel‡

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

B. Schilter*, C. Andersson†, R. Anton‡, A. Constable*, J. Kleiner™, J. O'Brien‡,
A.G. Renwick†, O. Korver‡, F. Smith*, R. Walker†
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 be 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
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- **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;
Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet

R. Kroes\textsuperscript{a}, A.G. Renwick\textsuperscript{b}, M. Cheeseman\textsuperscript{c}, J. Kleiner\textsuperscript{d,*}, I. Mangelsdorf\textsuperscript{e}, A. Piersma\textsuperscript{a}, B. Schilte\textsuperscript{d}, J. Schlatter\textsuperscript{b}, F. van Schothorst\textsuperscript{e}, J.G. Vos\textsuperscript{f}, G Würtzen\textsuperscript{g}

\textsuperscript{a}Utrecht University, Institute for Risk Assessment Sciences, Faculty of Veterinary Medicine, Yakoblaan 2, P.O. Box 80176, NL-3508 TD Utrecht, The Netherlands
\textsuperscript{b}University of Southampton, Clinical Pharmacology Group, School of Medicine, Biomedical Sciences Building, Bassett Crescent East, Southampton S016 7PX, UK
\textsuperscript{c}Food and Drug Administration, Food Contact Division, HFS-175, 200 C Street SW, Washington DC 20204, USA
\textsuperscript{d}LIST Europe, Avenue E. Mounier 85, Box 8, B-1200 Brussels, Belgium
\textsuperscript{e}Professor Institute of Technology and Aerosol Research, Department of Chemical Risk Assessment, Niklaas Reastraat 11, D-28625 Hanover, Germany
\textsuperscript{f}National Institute of Public Health and the Environment, Antonie Van Leeuwenhoeklaan 9, P.O. Box 1, NL-3720 BA Bilthoven, The Netherlands
\textsuperscript{g}Novo Research Centre, Via-chez-la-BLAN, P.O. Box 94, CH-3000 Lausanne 26, Switzerland

\textsuperscript{h}Swiss Federal Office of Public Health, Food Toxicology Section, Sträffelschneise 101, CH-3004 Zürich, Switzerland

\textsuperscript{f}Coca-Cola Nordic and Baltic Division, Strandvejen 60, DK-2000, Hellerup, Denmark
Classical toxicology / Clinical Safety
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- 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;