4. Revision of ISO/IEC Guide 51

COPOLCO has submitted the attached proposal (annex 5) to revise Guide 51 Safety aspects -- Guidelines for their inclusion in standards***,*** *noting that the current edition dates from 1999. The TMB is consequently invited to approve the proposal and to decide on an appropriate structure to carry out the work. As this is a joint ISO/IEC Guide,The TMB will need to invite the IEC/SMB to concur.*

TECHNICAL MANAGEMENT BOARD ACTION *The TMB is invited to*

a) *note/comment on the above;*

b) *approve the proposal to revise Guide 51;*

c) *decide on the structure to carry out the work;*

d) *invite the IEC/SMB to concur.*

ANNEX 5 to TMB 12/2009 (Rev. 1)

ANNEX 1 to COPOLCO 13/2008 (Rev. 2)

NEW WORK ITEM PROPOSAL FOR ISO

Revision of ISO/IEC Guide 51: 1999

November 2008

New Work Item Proposed by COPOLCO: Revision of ISO/IEC Guide 51, *Safety Aspects – Guidelines for their inclusion in standards*

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1 Title of proposal

Revision of ISO/IEC Guide 51, *Safety aspects – Guidelines for their inclusion in Standards,* 2nd edition,1999.

2 Scope

This proposal considers the revision of ISO/IEC Guide 51, *Safety aspects – Guidelines for their inclusion in Standards*,1999.

The recommendation includes maintenance of the approach aimed at reducing the risk arising from the use of products, processes, technologies or services together with possible improvements and inclusions to the Guide.

3 Purpose

ISO/IEC Guide 51 provides standards writers with guidelines for the inclusion of safety aspects when developing and discussing standards. It is applicable to any safety aspect related to people, property or the environment, or a combination of one or more of these. This Guide adopts an approach aimed at reducing the risk arising from the use of products, processes or services. The complete life cycle of a product, process or service, including both the intended use and the reasonably foreseeable misuse, is considered.

4 Justification

At the plenary meeting of COPOLCO in May 2006, the Working Group on Consumer Product Safety was asked to examine the need to revise ISO/IEC Guide 51 (COPOLCO Resolution 14/2006). The last revision of this Guide took place in 1999. In accordance with ISO's Systematic Review Procedure requiring regular revision every five years of all International Standards and Guides, a review and possible revision of the Guide is considerably behind the due date.

There is a defined need for revising ISO/IEC Guide 51, especially in a world that advances risk evaluation as a vital component of safety analysis. This is a modern concept that needs re-evaluation and expansion within the Guide. Risk management must be recognized and restated, while working in accordance with ISO 31000 and within the definitions of ISO Guide 73. To create a safer consumer environment there is a need to make more efficient use of Guides, Standards and conformity assessment resources. In addition, it is necessary to identify gaps that have now become apparent and strengthen existing Guides to satisfy new needs.

Furthermore, the development of new ISO Risk Management Standards and guidelines (such as the ISO 31000 on Risk Management) are being written to be generic and to cover a broad spectrum of sectors. These Standards typically reference documents such as ISO/IEC Guide 51 with respect to definitions and guidance on safety specific topics. It, therefore, becomes increasingly important for Guide 51 to be up to date and to reflect the relationship with other new and existing ISO documents.

The guide highlights product safety issues that are of specific concern to consumers, and therefore it is proposed to focus a revision of the guide on consumer product safety. This will reduce the likelihood of conflict with other ISO projects such as ISO/IEC Guide 73 and ISO 31000 which have been published since 1999.

Recent statements and discussion among those responsible for consumer product safety such as Meglena Kuneva, Commissioner for Consumer Protection in the European Union, have identified the need for the "enforcement of higher consumer product safety standards."

Furthermore, an APEC declaration of the 15th Economic Leaders' Meeting in September 2007 declared "there is a perceived need to enhance product safety. There is a need to develop a more robust approach to strengthening food and consumer product safety standards….without creating unnecessary impediments to trade. Additional capacity building in this area is a priority."

5 Potential benefits

For ISO:

A revision of Guide 51, followed by promotion, may highlight and encourage the use of ISO/IEC Guides. Following the COPOLCO survey, interested Standards makers contacted the team with recommendations for improvements and stated that an updated and revised document would be extremely useful on which to base new Standards and revisions of current Standards.

For standards writers:

ISO/IEC Guide 51 should adequately cover safety aspects for Standards development committees. Risk assessment and safety are of prime importance when writing today's Standards. Standards, international and national, for consumer product safety, technology and other related areas are increasingly risk or performance based. Most, if not all, of these Standards require the users to develop and maintain risk assessments for demonstrating safety conformance, as opposed to prescriptive requirements. Standards writers will benefit from an updated version of the Guide 51 that can be referenced for all safety, risk assessment specific guidance and definitions. This will allow for Standards users to apply standardized and consistent definitions and frameworks for risk assessment for all safety related Standards.

For consumers:

Safety is of prime importance to consumers. 2007 has seen major recalls on the basis of defective or unsafe products. Consumers need and deserve an efficient safety regime in the development, manufacturing, sale and performance of products. An updated ISO/IEC Guide 51 will enhance safety aspects by being useful reference material.

For business and for standards users:

Standards are a key source of information and guidance for manufacturers and other suppliers. A Standard that has been drafted with reference to a revised ISO/IEC Guide 51 should inherently be mindful of modern safety aspects and requirements. Moreover, product designers will benefit from considering the safety concepts included in the Guide.

For government:

Regulatory agencies in safety sectors develop safety specifications or adopt Standards and guidelines published by organizations such as the ISO for regulatory purposes. ISO/IEC Guide 51 has provided the necessary guidance to these agencies to make standardized, informed decisions.

Specifically definitions for terms such as “safety”, “hazard”, “foreseeable misuse” and frameworks for risk analysis etc. allow regulatory agencies to provide guidelines to the regulated sectors on acceptable methods for compliance.

Increasingly, as codes and Standards become risk or performance based, the importance of ISO/IEC Guide 51 will significantly increase to help regulators address subjectivity in decision-making especially as it pertains to making decisions on safety and risk assessments. The maintenance of an updated version of Guide 51 becomes extremely important as a result.

It will be for easier for governments to reference Standards in regulations that have considered Safety guidelines. A revised Guide 51 will provide governments with increased confidence if safety concerns were specifically discussed and integrated into the Standard development process.

For legal purposes:

Standards that have used ISO Guides during their development would be considered as a minimal acceptable approach to risk assessment and would demonstrate a minimum due diligence required to manufacture a safer product.

For international harmonization:

A revised edition of ISO/IEC Guide 51 will foster global harmonization of Standards worldwide by providing general safety guidelines for reference for the international community to decrease technical barriers to free trade. Safety rationales could be applied in a cross-frontier manner to yield consistent and reliable safety standards.

6 Survey of COPOLCO members and interested persons

It was decided to survey all COPOLCO member nations, especially highlighting the Product Safety Working Group members. Government regulators and Consumer Protection and Safety groups also added valuable input. Consumers International, ANEC, the European Risk Assessment Group, Canadian Safety experts and CPSC (USA) were further invited to respond.

The goal of the consultation was explained to members as a determination on whether there was a need to revise ISO/IEC Guide 51 second edition 1999 and what changes, if any, COPOLCO members believed needed to be made to the document.

A short questionnaire, attached as Annex 1, was circulated in order to solicit views, and supporting documentation in reference to comments was requested.

7 Results of survey and comments

Responses to the survey were initially received from COPOLCO members from 11 countries. Further responses were subsequently forwarded from other countries.

All responses are included in Annex 2.

Comments are detailed from COPOLCO members and stakeholders - CHOICE (Australia), Competition and Consumer Commission (Australia), Standards Department and Government Relations Office (Canada), DS (Denmark), Consumer Council in DIN (Germany), MSZT (Hungary), JISC (Japan), KATS (Korea), Malaysian Association of Standards Users (Malaysia), Office for Risk Assessment (Netherlands), SN (Norway), DGSM (Oman), ASRO (Romania), SIS (Sweden), TISI (Thailand), Intertek (USA) and ANSI (USA).

There was one abstention, from NEN (Netherlands). The findings confirmed that that there was a definite need for revision of ISO/IEC Guide 51.

8. Recommendation

Following a survey of its members and other interested parties, COPOLCO recommends that ISO considers the revision of ISO/IEC Guide 51.

Furthermore, COPOLCO has included possible editorial changes for consideration.

Annex 1

QUESTIONNAIRE

Revision of ISO/IEC Guide 51 – Safety Aspects – Guidelines for their inclusion in Standards

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ISO/IEC Guide 51 provides standards writers with guidelines for the inclusion of safety aspects in standards. It is applicable to any safety aspect which impacts people, property or the environment, or a combination of one or more of these (e.g. people only; people and property; people, property and the environment).

This Guide adopts an approach aimed at reducing the potential risks arising from the use of products, processes or services.

The complete life cycle of a product, process or service, including both the intended use and the reasonably foreseeable misuse, is considered.

In accordance with ISO's Systematic Review procedure , which sets out their regular revision cycle for all International Standards and Guides, the goal of this short questionnaire is to determine if there is a need to revise ISO/IEC Guide 51, 2nd edition, 1999. The results of the questionnaire will be used to provide supporting documentation for the development of a detailed proposal for COPOLCO members to consider, and if agreed, to present to ISO to address this issue.

ISO/IEC Guide 51, 2nd edition,1999 (pdf) is attached at Annex 2 for reference. Please note that it is strictly for consultation and not for further reproduction or distribution.

Name : .....

Organization: .....

Contact details: .....
.....
.....

E-mail address: .....

1) In your country, do you refer to or use ISO/IEC Guide 51 -

Yes ❒ No ❒ Don't know ❒

2) In your country, have any comments on the suitability of Guide 51 been received from -

Public authorities	Yes ❒	No ❒	Don't know ❒
Standards organizations	Yes ❒	No ❒	Don't know ❒
Consumer groups	Yes ❒	No ❒	Don't know ❒

3) If yes, what comments have been made?

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4a) The COPOLCO Product Safety Group has already proposed/received some suggestions for consideration of incorporating into a revised version of the standard. These suggestions are provided below as a guide to the feedback we require from this survey. Please indicate whether you agree with the suggested alteration by marking Yes or No.

1) ISO/IEC Guide 71 was not included in the normative references (pg 1, 7), thereby ignoring reference to the disabled and elderly. Yes ❒ No ❒

2) 'Safe' (pg 3) should be highlighted throughout the document, Yes ❒ No ❒

3) A rationale should be included (pg 6), labelling should be itemised as a safety aspect (pg 7) separate from information Yes ❒ No ❒

4) The size of the information should be considered (pg 8, 9) as well as attachment to the product at point of sale (pg 9) Yes ❒ No ❒

5) The bibliography needs checking and updating (pg 10.) Yes ❒ No ❒

6) Suggest changing the phrase 'reasonably foreseeable misuse' in the Guide due to possible interpretation of this phrase as meaning "misuse" might be "reasonable". One option for the change is to refer to the GPSD where it is suggested to consider product risk as 'intended for or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them'. This would have the additional benefit of harmonizing Guide and GPSD terminology.
Yes ❒ No ❒

7) Under section 3.3, suggest making the definition of "harm" more general by dropping the word 'physical'. Yes ❒ No ❒

8) Sections 3.10 and 3.12 present the definitions of 'risk analysis' and 'risk assessment', respectively. However, now there seems to be common agreement that risk analysis has three essential components -- risk assessment, risk management, and risk communication, where risk assessment is typically conducted through hazard characterization and exposure assessment.
(A few examples include but are not limited to *Quantitative Risk Analysis* by David Vose, *OMB Proposed Risk Assessment Bulletin*, and *First Report on the Harmonisation of Risk Assessment Procedures* by the European Commission.) Suggest redefining the definitions for risk analysis and risk assessment in the Guide based upon the above-mentioned aspects.
Yes ❒ No ❒

9) Figure 1 'Iterative process of risk assessment and risk reduction' is the cornerstone for illustrating how risk assessment should be carried out. Risk has two distinct components -- hazard and exposure. The process represented by Figure 1 seems to indicate that by defining intended use and misuse, hazard identification can be achieved which then can lead to risk estimation.
The other key component - exposure assessment was left out. Suggest a different framework (please refer to the website raguide.ram.com) Yes ❒ No ❒

10) Figure 2 addresses risk reduction. The 'organization' under the 'Use' table is not defined in the Guide and can be ambiguous to readers. Suggest either defining or dropping it.

Yes ❒ No ❒

4b) If 'No' was marked for any of the above suggestions, please give a reason or an alternative -

Number	Comment

4c) Would you suggest further alterations or is the Guide deficient in some aspect?

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5) Do you have any other comments? Yes ❒ No ❒

6) If yes, please elaborate.

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Please complete and return the questionnaire to the attention of **Ms. Dana Kissinger-Matray, Secretary of ISO COPOLCO , Fax : + 41 22 733 34 30 , E-mail: copolco@iso.org** by **10 March 2007**

We thank you in advance for your assistance.

****

Annex 2

RESULTS OF THE QUESTIONNAIRE ON THE REVISION OF ISO/IEC GUIDE 51 – *SAFETY ASPECTS – GUIDELINES FOR THEIR INCLUSION IN STANDARDS*

Answers were received from COPOLCO members in 11 countries: ANSI (Intertek - USA) ASRO (Romania), DGSM (Oman), DIN (DIN Consumer Council - Germany) DS (Denmark), JISC (Japan), KATS (Korea), MSZT (Hungary), SIS (Sweden), SN (Norway), and TISI (Thailand)*.

There was one abstention from NEN (Netherlands).

1) In your country, do you refer to or use ISO/IEC Guide 51?

– 9 countries answered "yes"

– 2 countries answered "no"

– 1 country did not know

2) In your country, have any comments on the suitability of Guide 51 been received from

- **Public authorities:** 1 country answered "yes", 8 countries answered "no" and 1 country did not know

- **Standards organizations:** 1 country answered "yes", 8 countries answered "no" and 1 country did not know

- **Consumer groups:** 1 country answered "yes", 9 countries answered "no" and 1 country did not know

3) If yes, what comments have been made?

JISC (Japan) made some comments

Country	***Comments***
JISC (Japan)	*The descriptions of "safety" and "risk management" should be reviewed and clarified in order that standards users can understand their concepts and use the standards, because the concepts of safe design and risk management are unclear in the current guide.* *If safe design and risk management are properly understood and applied, they can be used effectively in preventive action.* *In addition, this guide can be used effectively to promote understanding of the causes of accidents, whether or not the cause of the accident is related to the design.*

* A follow-up survey in 2008 (Annex 2 to COPOLCO 13) indicated further support from BIS (India), BOBS (Botswana), CNI (Czech Standards Institute), ICONTEC (Colombia), SABS (South Africa), and SCC (Canada).

Question 4a)

4a) The COPOLCO Product Safety Group has already proposed/received some suggestions for consideration of incorporating into a revised version of the standard. These suggestions are provided below as a guide to the feedback we require from this survey. Please indicate whether you agree with the suggested alteration by marking Yes or No.

1) ISO/IEC Guide 71 was not included in the normative references (pg 1, 7), thereby ignoring reference to the disabled and elderly.***)*** Yes □ No □

   9 countries answered "yes" and 1 country answered "no"

2) 'Safe' (pg 3) should be highlighted throughout the document, Yes □ No □

   10 countries answered "yes" and 1 country answered "no"

3) A rationale should be included (pg 6), labelling should be itemised as a safety aspect (pg 7) separate from information Yes □ No □

   10 countries answered "yes" and 1 country answered "no"

4) The size of the information should be considered (pg 8, 9) as well as attachment to the product at point of sale (pg 9) Yes □ No □

   10 countries answered "yes" and 1 country answered "no"

5) The bibliography needs checking and updating (pg 10.) Yes □ No □

   11 countries answered "yes"

6) Suggest changing the phrase 'reasonably foreseeable misuse' in the Guide due to possible interpretation of this phrase as meaning "misuse" might be "reasonable". One option for the change is to refer to the GPSD where it is suggested to consider product risk as 'intended for or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them'. This would have the additional benefit of harmonizing Guide and GPSD terminology. Yes □ No □

   10 countries answered "yes"

7) Under section 3.3, suggest making the definition of "harm" more general by dropping the word 'physical'. Yes □ No □

   11 countries answered "yes"

8) Sections 3.10 and 3.12 present the definitions of 'risk analysis' and 'risk assessment', respectively. However, now there seems to be common agreement that risk analysis has three essential components -- risk assessment, risk management, and risk communication, where risk assessment is typically conducted through hazard characterization and exposure assessment. (A few examples include but are not limited to *Quantitative Risk Analysis* by David Vose, *OMB Proposed Risk Assessment Bulletin*, and *First Report on the Harmonisation of Risk Assessment Procedures* by the European Commission.) Suggest redefining the definitions for risk analysis and risk assessment in the Guide based upon the above-mentioned aspects. Yes □ No□

9 countries answered "yes"

9) Figure 1 'Iterative process of risk assessment and risk reduction' is the cornerstone for illustrating how risk assessment should be carried out. Risk has two distinct components -- hazard and exposure. The process represented by Figure 1 seems to indicate that by defining intended use and misuse, hazard identification can be achieved which then can lead to risk estimation.

The other key component - exposure assessment was left out. Suggest a different framework (please refer to the website raguide.ram.com) Yes □ No□

9 countries answered "yes" and 1 country answered "no"

10) Figure 2 addresses risk reduction. The 'organization' under the 'Use' table is not defined in the Guide and can be ambiguous to readers. Suggest either defining or dropping it.

Yes □ No □

9 countries answered "yes" and 1 country answered "no"

4b) If 'No' was marked for any of the above suggestions, please give a reason or an alternative

Comments from	Point	*Comments*
ANSI - (USA Intertek)	2	*Even though "safe" is a key concept for the Guide, there are other terms (e.g., safety, risk) that probably deserve equal attention. Prefer to reserve the highlight for the phrases defined by the Guide.*
SN (Norway)	1	*Why mention these group specific*
	3	*Labelling is part of the information and there is no need to mention it separately*
	4	*Difficult to define general size. Specifications of elements following the product should rather be included in ISO 31000 (under development)*
	8	*Risk communication is not part of a risk analysis, but use of it. Risk assessment includes evaluation. See ISO 31000 and ISO/IEC Guide 73.*
	9	*"Hazard" and "Exposure" is only a part of how to describe a risk, and is not a risk analysis in total.*
	10	*Organization is OK and describes "more than one person", but perhaps it could be described more specific.*
TISI (Thailand)	**7**	*The meaning of injury is the physical harm then by dropping the word "physical" could not make the definition of harm more general.*

4c) Would you suggest further alterations or is the Guide deficient in some aspect?

Two countries answered "no".

Countries	***Comments***
DGSM (Sultanate of Oman)	*The requirements for the "Safety Labelling" may also be suitably included.*
DS (Denmark)	*1) We suggest that issues of global relevance be included in the Guide – e.g. safety aspects relevant for developing countries or stakeholder groups with special needs. It should be mentioned in the guide that in some cases the standards should make room for alternative technical solutions that the most advanced one on the market – an example could be the development of standards for sterile hypodermic syringes for single use which is mostly aimed at covering the needs of the developing countries.* *2) Updating of normative references* *Adding ISO/IEC Guide 74:2005 – Graphical symbols –Technical guidelines for the consideration of consumers' needs to the guide.*

5) Do you have any other comments? Yes □ No □

Three countries answered "yes" and seven countries answered "no".

6) If yes, please elaborate.

Countries	***Comments***
Intertek (USA)	*For point number 9, the alternative framework for Figure 1 of the Guide was not included in this draft survey. We hereby enclose it in the response (e-mail) for your reference.*
SN (Norway)	*A revision of Guide 51 should be harmonized with the development of ISO 31000 and the revision of ISO/IEC Guide 73 "Risk management – vocabulary – guidelines for use in standards". The revision of Guide 51 is, in our opinion, not urgent.*
TISI (Thailand)	*Clause 3.2* *The statement should be "combination of the probability and frequency of occurrence".* *Figure 1* *"Maintenance" and "disposed" should also be defined in 3rd block for hazard identification.*

Additional Comments from other stakeholders

1. Gail O'Bryen
Director, Product Safety Compliance
Australian Competition and Consumer Commission

I think this review provides an opportunity to augment the document to give a more practical guidance on writing safety standards. It will be able to complement the Guidance standard: Consumer product safety: Practical guidance for suppliers that is hopefully to be developed.

Risk management is a well-established discipline. Identifying risks involves asking what, why, where, when and how danger could arise. Approaches used to identify risks may include checklists, judgements based on experience and records, flow charts, brainstorming and scenario analysis.

The specific comments are:

- Section 6, Achieving tolerable risk, needs to be improved to better explain, emphasize and graphically illustrate the value of designing hazards out of products over other risk reduction options. 6 f) currently lists risk reduction means in order of priority, but fails to demonstrate the relative advantages of design over the other means. I think a graphic depiction of the relative value would be very helpful in this regard.

- I think the guide should include a note about the importance of rationales. This could go into section 7.4.1.

2. Antonio Bonacruz
CHOICE, Australia

I am always interested with matters on product safety. I find it appalling that regulatory bodies in Australia are not so serious on their concern for product safety and I feel that they are almost acting irresponsibly. The availability of guides in the absence of specific Standards is better than having no Guides at all and I am pleased that they are going to be updated. I also support the adoption and harmonization of particular safety aspects into specific ISO/IEC Standards.

3. Dirk van Aken, Scientific Officer, Food and Consumer Product Safety Authority, Office for Risk Assessment, Den Haag, Netherlands

I can say that I would support the revision of ISO/IEC Guide 51. Recently, you sent some suggestions that you had already received; I agree with most of them and in particular I think that it would be worthwhile to harmonise the terminology in this Guide with that in other areas, e.g. chemical safety and food safety. This implies introducing terms like hazard characterization and exposure assessment. The EuroSafe WG on risk assessment will probably also adopt such a terminology.

4. Xiao Chen and Gene Rider, ANSI
Risk Assessment & Management

Please see the following comments with regard to the revision of Guide 51.

- Suggest changing the phrase 'reasonably foreseeable misuse' in the Guide due to possible interpretation of this phrase as meaning "misuse" might be "reasonable". One option for the change is to refer to the General Product Safety Directive (European Directive) where it is suggested to consider product risk as 'intended for or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them'. This would have the additional benefit of harmonizing Guide and GPSD terminology.

- Under section 3.3, suggest making the definition of "harm" more general by dropping the word 'physical'.

- Sections 3.10 and 3.12 present the definitions of 'risk analysis' and 'risk assessment', respectively. However, now there seems to be common agreement that risk analysis has three essential components -- risk assessment, risk management, and risk communication, where risk assessment is typically conducted through hazard characterization and exposure assessment. (A few examples include but are not limited to *Quantitative Risk Analysis* by David Vose, *OMB Proposed Risk Assessment Bulletin*, and *First Report on the Harmonisation of Risk Assessment Procedures* by the European Commission.) Suggest redefining the definitions for risk analysis and risk assessment in the Guide based upon the above-mentioned aspects.

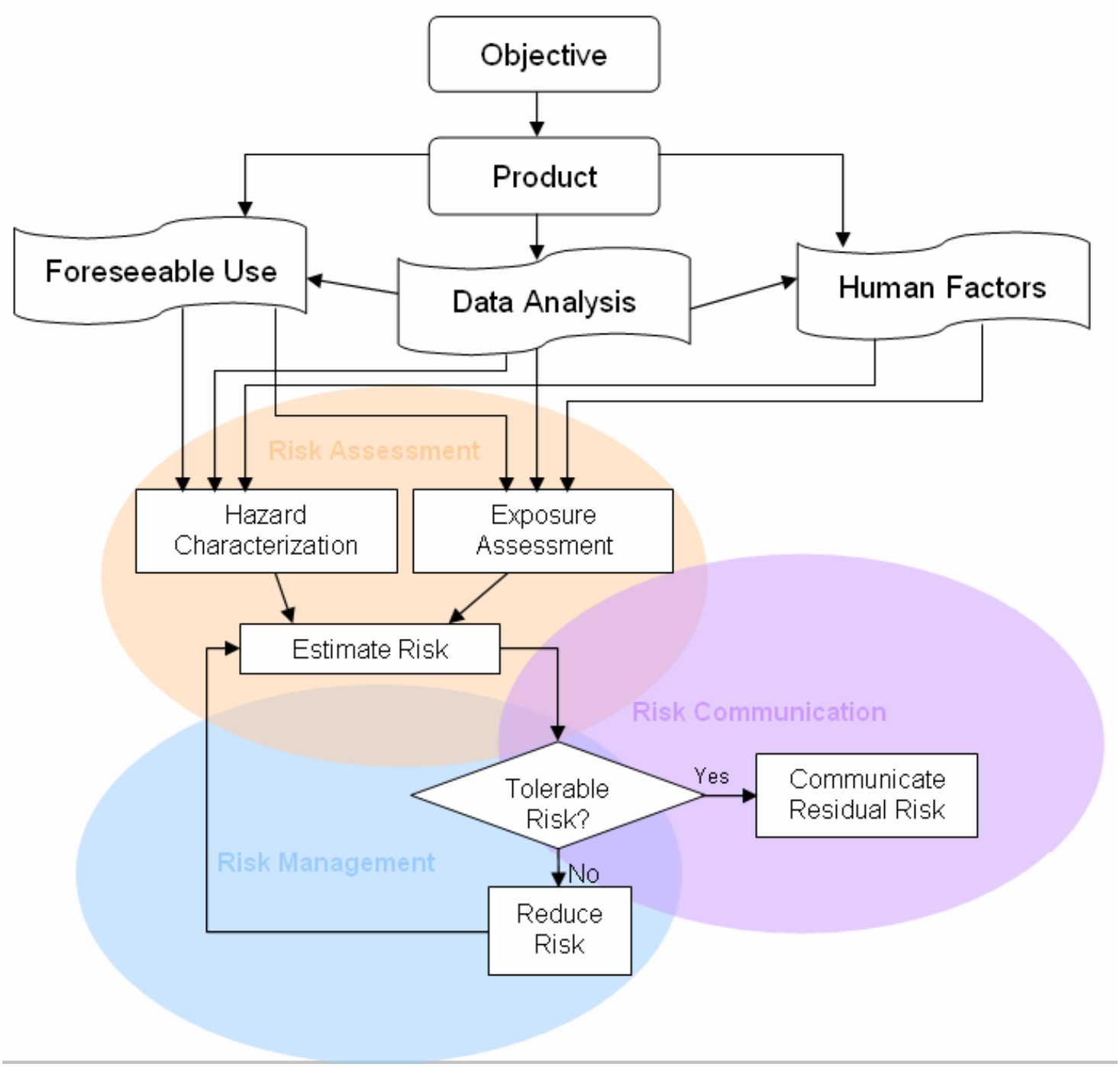
- Figure 1 'Iterative process of risk assessment and risk reduction' is the cornerstone for illustrating how risk assessment should be carried out.

- Risk has two distinct components -- hazard and exposure. The process represented by Figure 1 seems to indicate that by defining intended use and misuse, hazard identification can be achieved which then can lead to risk estimation. The other key component -- exposure assessment was left out. We would like to suggest a different framework (please see attachments). As you know, we are also working with the EuroSafe WGRA. Please feel free to refer to the website raguide.ram.com.

- Figure 2 addresses risk reduction. The 'organization' under the 'Use' table is not defined in the Guide and can be ambiguous to readers. Suggest either defining or dropping it.

Consider using a **RISK ANALYSIS CHART FOR CONSUMER PRODUCTS**

RISK ANALYSIS CHART FOR CONSUMER PRODUCTS



RISK GUIDELINE CHART

START

Objective

- What is the main purpose of doing risk assessment?
- What is the scope of the risk assessment?

Product

- What is the distribution amount of the product? Annual?
- What is the product lifespan/duration/deterioration?

Is there any appropriate warning for the assembly,

- use and/or disposal of the product?
- What are the product hazards?
- Is the hazard inherent to defective products only?
- Is the hazard linked to a special state of the product?
- Is the product hazard dependent on any external factor?

Demographics

- Demographics of consumers (e.g., age, gender)
- What is the vulnerability of the exposed consumer?

Data Analysis

- How many incidents were reported, and what is the corresponding time period and geographic coverage?
- What product is the direct cause of incident?
- What product is involved in the incident?
- Where did the incident occur?
- How did the incident happen?
- How many people are likely to be injured in each incident?
- Is there any product failure or malfunction?
- What is the cause / mechanism of incident?
- What is the nature of incident?
- Which body part(s) was affected?
- What is the intent of incident?
- What is the disposition / severity of incident?

Foreseeable Use

- Who uses the product?
- What are the users' perceptions on the potential hazard (obvious vs. hidden)?
- What is users' (perceived) controllability of risk?
- Are there any warnings recognizable and comprehensible to the consumer?

- What is the product intended for (by the designer)?

- How attractive is the product to the intended user, and unintended user?

- What is the use that a consumer may see for the product, taking into account any noticeable aspects or features?
- What is the frequency and duration of use?

- What kind of task or action needs to take place for the product hazard to manifest itself?

- What could happen, potentially go wrong?

Human Factors

- Does repeated exposure increase sensitivity, and/or are there cumulative factors that increase risk?

- What is the nature and/or type of the incident?

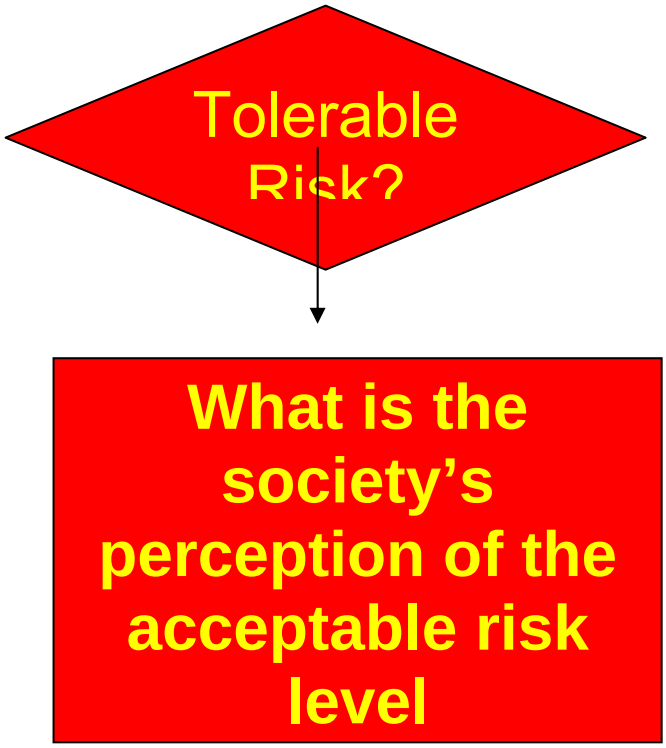
- Which body part(s) is affected by the injury?

- What is the worst-case scenario for incident outcome?

- Is the effect acute or chronic?

Risk Characterization

- What is the overall conclusion on risk assessment result based upon probability of occurrence and severity of adverse events?



Decision Making

What is the uncertainty level of the decision?

Who should be informed?

What action needs to be taken?

What is the plan/schedule for update?

5. G. Rae Dulmage, Director, Standards Department and Government Relations Office, Underwriters' Laboratories of Canada, Ottawa, Ontario

Revise the Scope to reflect that Risk may be created or generated during the manufacturing or production process. There is a need to apply the Guide concepts to them. Highlight that the consideration of safety aspects in a product (including a service) needs to begin at the point of conception, continue through the design phase, on through the prototype or trial work and the production stages to the end user and the product life cycle. User concerns can in totally be separated from the concept, design and production functions with respect to safety.

There is a need for a performance or outcomes based approach. Inherent in this is the consideration of those who will use the standards developed. Often the consideration of the different languages and the application of the riipple test are not applied. English, though a very fascinating language, can create problems when the safety concepts in a standard are translated and the nuances are lost. At ULC for example we try in our standards work to think of how those who will apply the standard. We have to think beyond the members of the committee. Whatever safety aspects a standard covers they must be understood by the suppliers, designers, consultants, technicians, factory workers and subcontractors too. The proposal should highlight the need to give guidance on a clear language performance/outcomes based approach to safety aspects in standards development.

6. Ratna Devi Nadarajan
Malaysian Association of Standards Users

Page 2 ;

3.3
harm
physical injury or damage to the health of people, or damage to property or the environment

3.4
harmful event
occurrence in which a **hazardous situation** results in **harm**

3.5
hazard
potential source of **harm**
NOTE The term **hazard** can be qualified in order to define its origin or the nature of the expected **harm** (e.g. electric shock hazard, crushing hazard, cutting hazard, toxic hazard, fire hazard, drowning hazard).

3.6
hazardous situation
circumstance in which people, property or the environment are exposed to one or more **hazards**

Comments:

Based on the definition for hazardous situation (clause 3.4) in the context of the Guide, ***we perceive*** it would mean the following:

Occurrence in which ***circumstance in which people, property or the environment are exposed to one or more (****3.6 hazardous situation)* ***potential source of harm*** *(3.5 hazard) results in* ***physical injury or damage to the health of people,*** *or* ***damage to property or the environment (****3.3 harm****).*

It is rather confusing to comprehend in that sense.

We need to replace the words in the text with the definition and see if our intended message / concept is preserved.

Clause 5.3

We propose that the diagram be consistent with the established concept or model for risk assessment / management – which was suggested already in earlier communications.

Clause 6.0

The content of this clause will be modified to suit the clause 5.3 (if this is changed)

Clause 7.0

We suggest that there should be some kind of advise to standard writers that for example there should be a review of tolerable limits etc as and when technology changes, environment conditions warrants it etc.

Clause 7.1

We suggest that there are examples for each type of safety standards given under this clause.

Clause 7.4.2.2

7.4.2.2 Instructions
Instructions and information provided shall cover safe conditions for operating the product, process or service.
In the case of products, the instructions shall cover **the use, cleaning**, maintenance, dismantling and destruction/disposal, as appropriate.

In this context, see ISO/IEC Guide 14 and ISO/IEC Guide 37.

Suggest to reword:
In the case of products, the instructions shall cover the use, **its impact to the environment,** cleaning, maintenance, dismantling and destruction/disposal, as appropriate.

7.4.4
Safety during testing
Standards specifying test methods may prescribe procedures and/or the use of substances or equipment which could create a **risk**, for example to the laboratory staff. Where relevant, the standard shall include warning statements, as follows:

- A general warning statement appearing at the beginning of the standard;

- Specific warning statement(s), as appropriate, preceding the relevant text within the standard.

Suggest to add another bullet:
- any specific environmental aspect or impact

Others:
2 Normative references
The following normative documents contain provisions which, through reference in this text, constitute provisions of this Guide. **For dated references, subsequent amendments to, or revisions of, any of these publications do not apply.** However, parties to agreements based on this Guide are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

Further Comments:
Do not quite understand the second line.(amendments should apply shouldn't it……?) Are we referring to the contents which were relevant at the time of drafting of the Guide 51?

Useful References :

CODEX ALIMENTARIUS COMMISSION REPORT OF THE TWENTY-SIXTH SESSION Rome, 30 June - 7 July 2003

Appendix IV. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius

1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

2) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.

3) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

http://www.fao.org/docrep/006/y4800e/y4800e0o.htm

HAZARD IDENTIFICATION AND RISK ASSESSMENT – OECD Principles

http://www2.oecd.org/guidingprinciples/document/pg038.asp

Risk assessment, in this context, is a tool used in risk management to help understand risks and inform the selection and prioritization of prevention and control strategies. With risk assessment, risks can be ranked on a relative scale and technical/organizational/ policy options can be evaluated, so that results can be maximised in terms of increased safety. This helps in the choice of options.

Risk assessment also provides information to policymakers to help them develop risk acceptability or tolerability criteria against which different objectives or programmes can be assessed.

Risk assessment is a process that consists of a number of sequential steps, i.e.: hazard identification; event scenario assessment; consequence assessment; likelihood assessment; and risk integration and comparison.

The Australian Models of Risk Assessment

http://www.health.gov.au/internet/wcms/publishing.nsf/Content/ohp-ehra-2004.htm~ohp-ehra-2004-background.htm

There are a variety of models used for risk assessment in Australia by government agencies and consultants (Appendix 5). This document uses a model of risk assessment that involves five stages. The model follows a review of various models and is based largely on the National Academy of Sciences model (1983) with the addition of a preliminary step, 'Issue Identification':

- issue identification;
- hazard identification;
- dose–response assessment;
- exposure assessment for the relevant population; and
- risk characterization.

These five stages are closely linked and highly dependent on the preceding stages. The model is illustrated in Figure 1, below. The terminology is similar to terminologies used by other major models (See Figure 1, Appendix 6).

1.6.1 Issue identification

Issue Identification identifies issues amenable to risk assessment and assists in establishing a context for the risk assessment by a process of identifying the problems that the risk assessment needs to address. It includes identifying:

- what is the concern;
- what is causing the identified concern;

- why is the concern an issue;
- how the concern was initially identified;
- how the concerns were raised;
- whether the issue is amenable to risk assessment; and
- whether risk assessment is appropriate.

1.6.2 Hazards vs. issues

'Hazards' need to be distinguished from 'issues'. The determination of the issues is necessary to establish a context for the risk assessment and assists the process of risk management. Issues have dimensions related to perceptions, science, economics and social factors. Examples of issues are: community concerns over emissions from a smelter; community outrage over the proposed development of a communications tower; assessment of a new water treatment chemical; and changes to a microbiological food standard.

'Hazards' relate to the capacity of a specific agent to produce a particular type of adverse health or environmental effect. Examples of hazards are: the capacity of benzene to cause leukemia; the capacity of solar radiation to cause skin cancer; the capacity of *Salmonella* to cause vomiting and diarrhoea.

1.6.3 Hazard assessment

'Hazard Assessment' is comprised of 'Hazard Identification' and 'Dose–Response Assessment'.

1.6.4 Hazard identification

Hazard identification involves determining:

- what types of (adverse) health effects might be caused by the agent; and
- how quickly the adverse health effects might be experienced and their duration (Health Canada, 1999).

The data for hazard identification will come from a range of toxicological, epidemiological, *in vitro* and mechanistic studies. Not only the agent may need to be assessed but, in the case of chemicals, the breakdown products e.g. acrolein as well as butadiene when doing environmental monitoring; the four metabolites of atrazine (desethylatrazine, desisopropylatrazine, diamonochlorotriazine and hydroxyatrazine) when monitoring atrazine contamination of water catchments.

1.6.5 Dose–response assessment

Dose–response assessment considers both qualitative and quantitative toxicity information to determine 'the incidence of adverse effects occurring in humans at different exposure levels' (US EPA, 1989, p. 1.6). Where available, human and animal evidence will be assessed as part of this process. Risk assessment cannot be done without good dose–response information. Whereas constant doses can be used in animal studies, long term human exposures may be variable. This may be a significant source of uncertainty and there is a need to develop an integrated estimate of long-term exposure.

1.6.6 Exposure assessment

Exposure assessment involves the determination of the frequency, extent duration and character of exposures in the past, currently, and in the future. There is also the identification of exposed populations and particularly sensitive sub populations, and potential exposure pathways. Environmental monitoring and predictive models can be used to determine the levels of exposure at particular points on the exposure pathways. The contaminant intakes from the various pathways under a range of scenarios can then be estimated (US EPA, 1989).

Where the risk assessment is being done as part of a protective and pro-active risk assessment, exposure assessment data may not be available and may have to be estimated. Modelled data may also be used where the data package is limited.

1.6.7 Risk characterization

Risk characterization provides a qualitative and/or quantitative estimate, including attendant uncertainties, of the nature, severity and potential incidence of effects in a given population based on the hazard identification, dose–response and exposure assessments.

1.6.8 Follow up

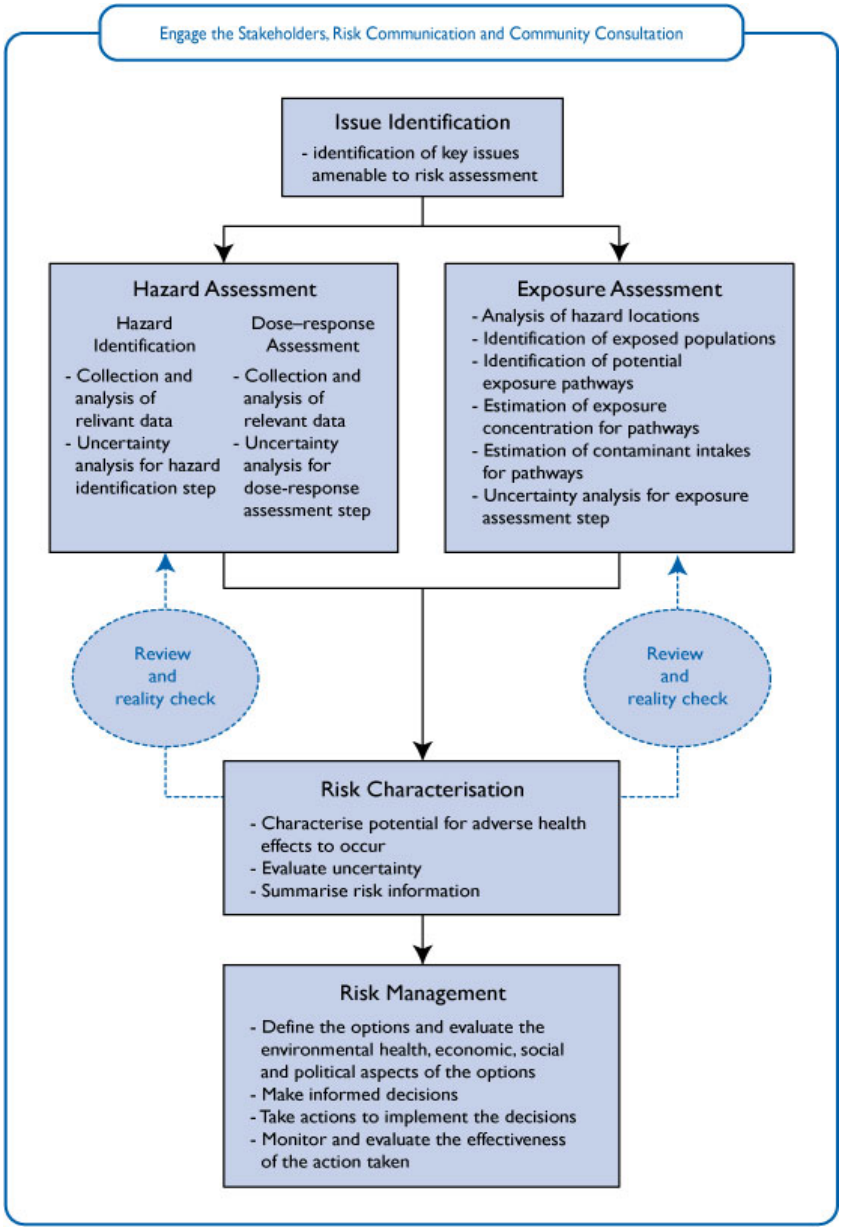
Risk assessment is an iterative process that will be reviewed as the risk assessment progresses. After risk assessment is completed there may be a need to review the situation from time-to-time as new information becomes available or circumstances change to ensure that the risk assessment is still relevant and protective.

1.6.9 Aims of the health risk assessment method

The method is intended to assist risk assessment practitioners and those evaluating risk assessments. The aims of the method are:

- to identify information needed to make decisions;
- to make the decision-making process more explicit by identifying the specific elements affecting risk so that more objective and scientific decisions can be made;
- to make the decision process more transparent to promote confidence by the community, industry and scientists about decisions and actions taken;
- to increase consistency in risk assessment so that different people assessing similar problems will come to comparable conclusions;
- to have the ability to account for the range of risks that are present or could arise as the result of actions;
- to refine the assessment and management of risk so that better decisions are made and more rigorous risk assessment and management occurs;
- to enable the adoption of future improvements to risk assessment; and
- to enable risk-benefit analysis and the evaluation of the outcomes of risk management decisions about current and possible future risks (ACDP, 1996).

Risk assessment model follows -



Risk assessment model