Appendix III Guidelne for Use of the Health Risk Assessment Model



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Introduction

The Health Risk Assessment Model is a tool which may be used by the inspector/auditor as guidance when evaluating the health risk of a product.

The model uses Severity of Consequences (horizontal axis) and Likelihood of Occurrence (vertical axis) to determine the rating for deficiencies which impact on health and safety.

The Severity of Consequences for an identified hazard is set based on the health outcome. (Subclinical = low, temporary disability = medium, permanent disability/death = high). As well, severity of consequences is based on the worst case scenario as it relates to the health of the end user eg., microbiological pathogens will always be categorized as high whereas physical hazards will usually be categorized as low or medium.

The Likelihood of Occurrence is the vertical axis which relates strictly to the **hazard** likelihood that it will appear in the product (i.e. likelihood that the end user will be exposed to the hazard identified). This will be influenced by items such as in-plant process controls, type and use of product, target group, regulatory requirements, complaint file, plant history and other relevant information eg., a metal hazard due to defective equipment prior to a metal detector will be categorized as low, whereas without a metal detector it will be categorized as high.

The following definitions apply to the model:

- A) **Satisfactory** (Sa) No deficiencies noted which would result in a health risk or risk of contamination or adulteration.
- B) **Nonsatisfactory** If deficiencies are noted which would result in a health risk of contamination or adulteration, they are to be assessed using the following criteria:
 - Minor Deficiency (Mi) Deficiencies which could result in a low health risk or

a low to moderate risk of contamination or

adulteration.

Major Deficiency (Ma) - Deficiencies which could result in a moderate health

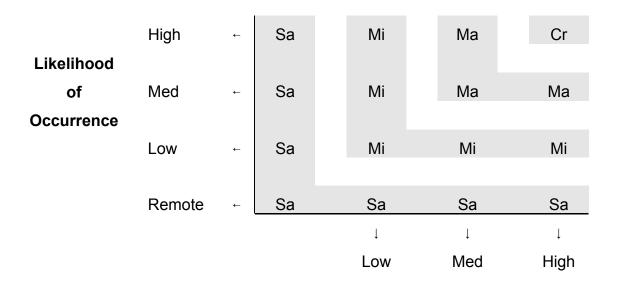
risk or a high risk of contamination or adulteration.

Critical Deficiency (Cr) - Deficiencies (including contamination) which could

result in a high health risk.

FIGURE I

Health Risk Assessment Model



Severity of Consequences

Likelihood of Occurrence

Based on:

- •control at the subitem
- •frequency of deficiency
- controls at other sub items
- other relevant information

Severity of Consequences

Based on;

- type of hazard involved
- health outcome (low = subclinical, medium = temporary disability, high = permanent disability or death

Exception - Population at risk is considered for sensitive populations such as infants, immunocompromised, or individuals using products as a sole source of nutrition are involved.