FSA Meeting on the Microbiological safety of powdered infant formula
London, UK, January 18th, 2007

WHO initiatives for the control of *Enterobacter sakazakii*

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E.Sakazakii in Powdered Infant formula

- WHO activities on *E. Sakazakii*
- WHO/FAO risk assessments
- Work of Codex/CCFH
- Development of guidelines

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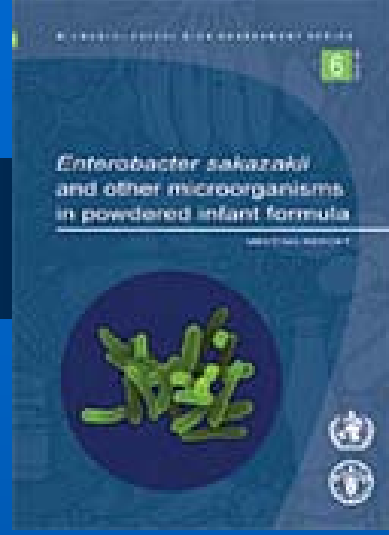

- 2004 Scientific assessment of *E.sakazakii*
- 2004 CCFH initiate revision of the Code of Practice for infant formula
- 2005 World Health Assembly Resolution
- 2006 FAO/WHO Risk Assessment on *E.sakazakii*
- 2006 WHO guidelines on preparation, storage and use of powdered infant formula
- 2006 CCFH advance on code of practice, sampling plans and micro criteria.
- 2006-7 FAO/WHO web based user friendly risk assessment model

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Traditional areas of risk assessment

Chemical

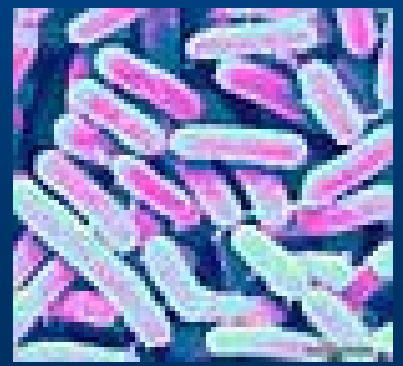
- Food additives
- Flavouring agents
- Residues of veterinary drugs
- Pesticide residues
- Contaminants
- Naturally occurring toxicants

Microbiological

- Well known pathogens
  - *Salmonella*
  - *Listeria monocytogenes*
  - *Campylobacter*

Reasons for a risk assessment

- **Powdered infant formula (PIF) meeting the existing international/Codex standards implicated in cases of illness**
- **Codex revising code of hygienic practice for foods for infants**
- **Requests to address *E. sakazakii* in revised code**
- **How?**
  - **micro criteria?**
  - **guidance for manufacturers?**
  - **guidance for users?**



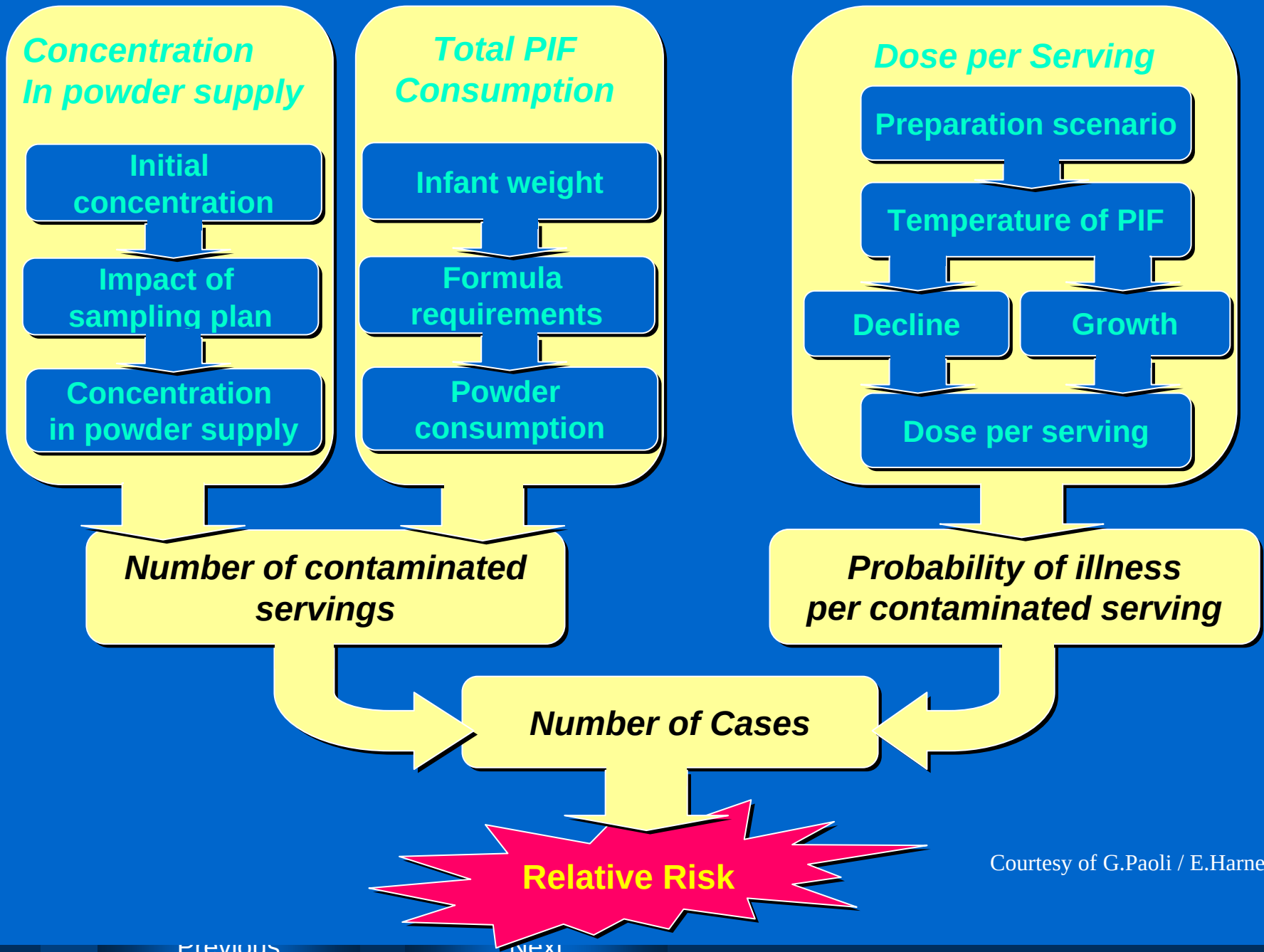
→ **FAO/WHO risk assessment**

What was different?

- **Urgency**
  - **High mortality in infants**
  - **World health assembly requested rapid action**
  - **Request from risk manager was better defined**
- **Very specific product**
- **Product in international trade – Centralised production goes often to many different countries**

New user friendly focus

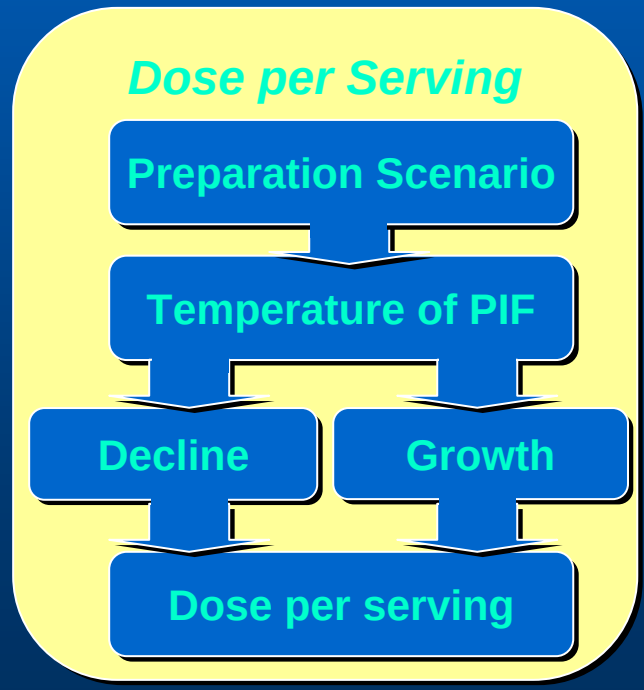
- **Numerous inputs left to the decision of the user with real time response to risk managers questions (within reason / capability of model)**
- **Focus is on relative risk - comparison of intervention measures and associated risk reductions**
- **Model estimates the dose of *E. sakazakii* in prepared PIF at consumption**



Courtesy of G.Paoli / E.Harnett

A Closer Look at Preparation and Handling

- **The model is scenario based**
- **Specification of specific scenarios underpins the prediction of the dose in prepared formula at consumption**



Scenarios

- **Scenarios includes preparation, cooling/holding, re-warming and feeding**
- **Scenarios consider:**
  - **Temperature of re-hydration liquid**
  - **Preparation scenario (single bottle, 1litre container..)**
  - **Temperature for cooling/holding**
  - **Room temperature for feeding**
  - **Duration of each preparation stage**
- **Model predicts the temperature of the formula over entire time from re-hydration to feeding**

Basic Scenarios

- Eight basic scenarios were investigated
- Conditions were specified for cool, warm and very warm room temperatures
- Scenarios covered the combinations of:
  - Cooling by refrigeration (4°C) or holding at room temperature
  - Inclusion or exclusion of an explicit re-warming action
  - Short or long feeding periods
- Each of these scenarios was run at a series of different reconstitution temperatures
  - 10, 20, 30, 40, 50, 60 and 70°C
  - Resulting in the comparison of 168 different preparation scenarios

Example Output: Basic Scenarios

Table. 11. Relative risk of different preparation, storage and handling practices for formula prepared and used at a warm ambient room temperature (Room temperature = 30°C) (+ X means an increase in risk of X fold, - X means a decrease in risk of X fold)

Preparation, storage and feeding scenarios	**Relative increase or decrease in risk compared to the baseline scenario of 1 at different temperatures of rehydration of PIF**						
	10 °C	20 °C	30 °C	40 °C	50 °C	60 °C	70 °C
Refrigeration, re-warming, extended feeding period	**+ 2**	**+ 34**	**+ 8**	**+ 27**	**+ 83**	**+ 1.8**	> - 100,000
Refrigeration, re-warming, short feeding period	1	1	1	1	**+ 2.6**	- 1.3	> - 100,000
Refrigerated storage, no re-warming, extended feeding period	1	1	1	1	**+ 2.7**	- 1.3	> - 100,000
Refrigeration, no re-warming, short feeding period	1	1	1	1	1	- 1.3	> - 100,000
No refrigeration, re-warming, extended feeding period	**+ 3**	**+ 6**	**+ 15**	**+ 55**	**+ 161**	1	> - 100,000
No refrigeration, re-warming, short feeding period	1	1	1	**+ 1.7**	**+ 5**	- 1.3	> - 100,000
No refrigeration, no re-warming, extended feeding period	1	1	**+ 2.8**	**+ 22**	**+ 97**	- 1.3	> - 100,000
No refrigeration, no re-warming, short feeding period	1	1	1 (Base line)	1	**+ 3**	- 1.3	> - 100,000

Ex. Of Outputs

- ↑ holding times at room temperature result in large increases in risk
- Same holding-time under refrigeration - very small risk increase (1.3 fold)
- In general
  - Scenarios that involve periods of holding at room temperatures are associated with greatest risk
  - Rehydration with liquid of 70C is an effective risk mitigation strategy for all scenarios investigated

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Codex use of the risk assessment

- The RA is flexible - many scenarios considered
- User-friendly - user can provide certain inputs relevant to a specific country or situation
- Real-time application
- Next step - interaction with Codex risk managers - utility of tool will be in some way measured by speed of revision of Codex code of practice
- Use of RA to validate/guide on going revision of the Code.
- Draft Revised Code is out for comments
- Next meeting of Codex CCFH in Dec 2006

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WHO Guidelines for preparation of PIF

- Some of the current instructions on PIF product labels, and those recommended by health authorities, may lead to increased risk of *E. sakazakii* illnesses. These should be reviewed in light of the risk assessment results
- The RA experts and WHA : consider labeling of PIF as not sterile product.
- The RA is used by FAO/WHO to develop guidance, as requested by the World Health Assembly (WHA) in 2005
  - **“the preparation, use, handling, and storage of infant formula so as to minimize risks where infants cannot be or are not fed breast milk”**
- The Guidelines includes home-based and health care-based situations
- Developed in collaboration with FSAI and FAO

How safe is our food?

Food safety initiative
World Health Organization

For further information :

Internet :

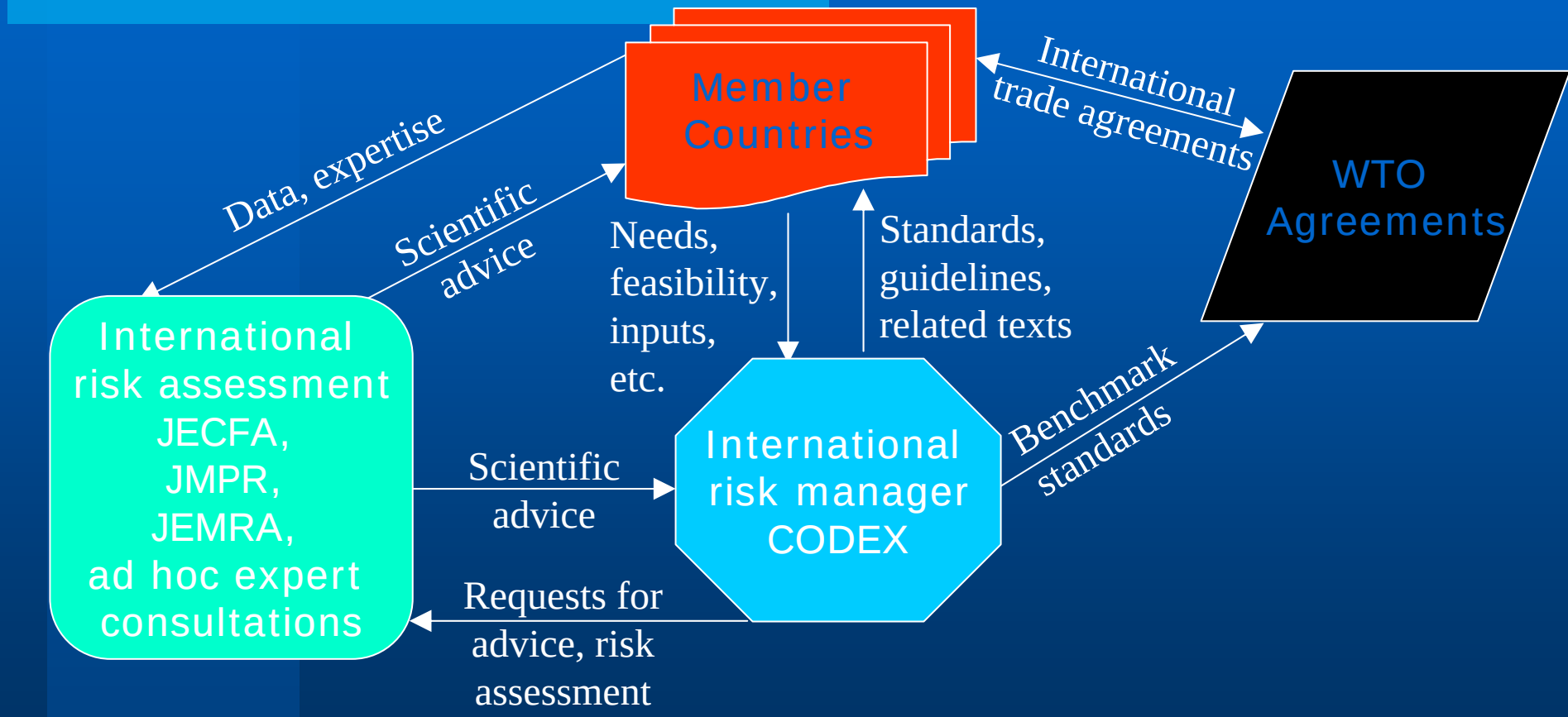
http://www.who.int/foodsafety

E.mail:

bishopj@who.int

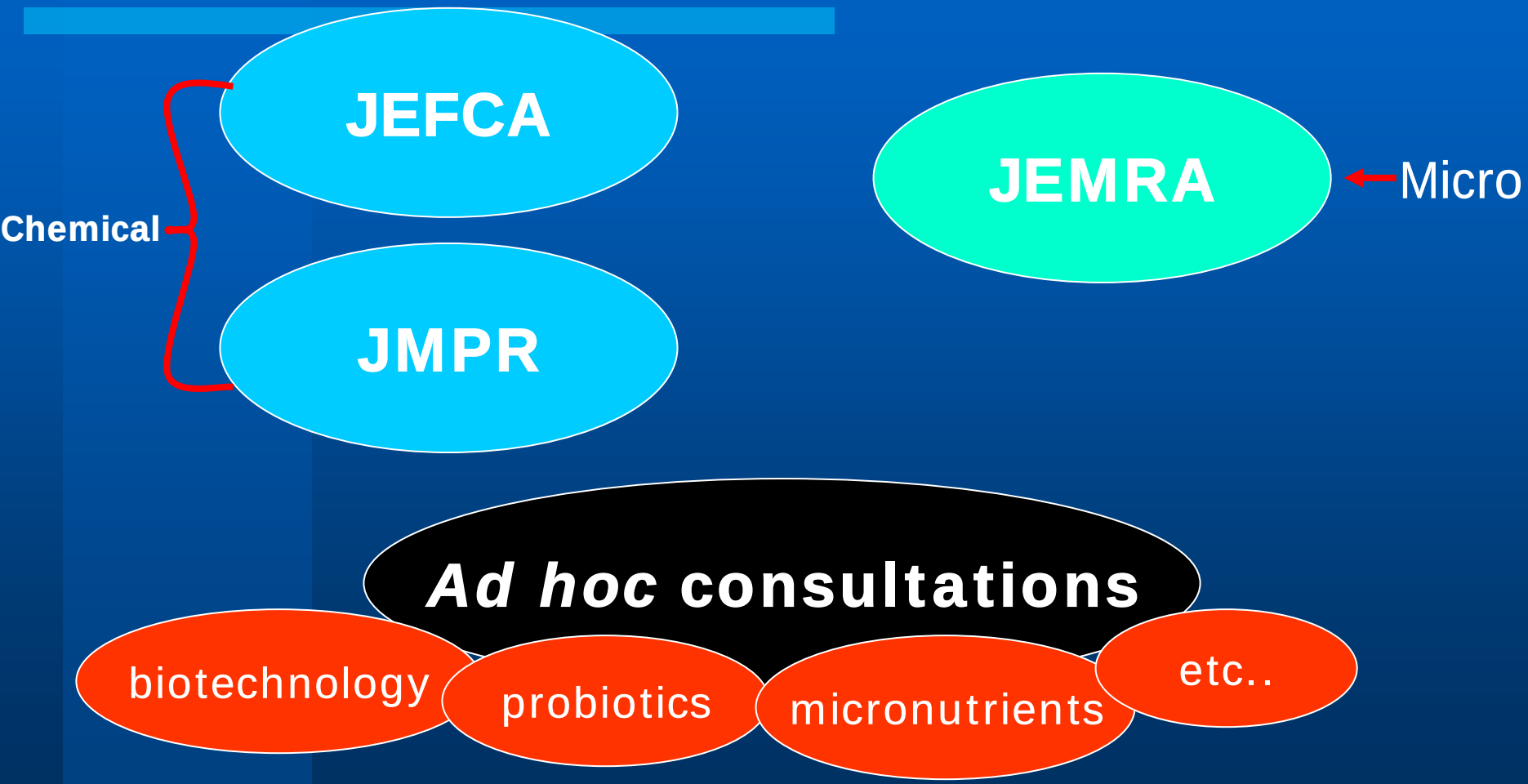
benembarekp@who.int

FAO/WHO risk assessment programme



Courtesy Dr. s Cahill, FAO

Risk assessment groups



Courtesy Dr. s Cahill, FAO

Addressing new and emerging hazards

- ***Enterobacter sakazakii*** **in powdered infant formula**

- **Requests for assessment came from relevant Codex Committees and Member Countries**
  - **new area of work within the last 2 years includes scientific evaluation and risk assessment**
  - **topical issue requiring risk management decisions**