



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Additives Forum Pilot

Towards a shared understanding of additives permitted
for use in foods

Melanie Fisher
General Manager,
Food Standards (Canberra)

Tuesday, 12 December 2006

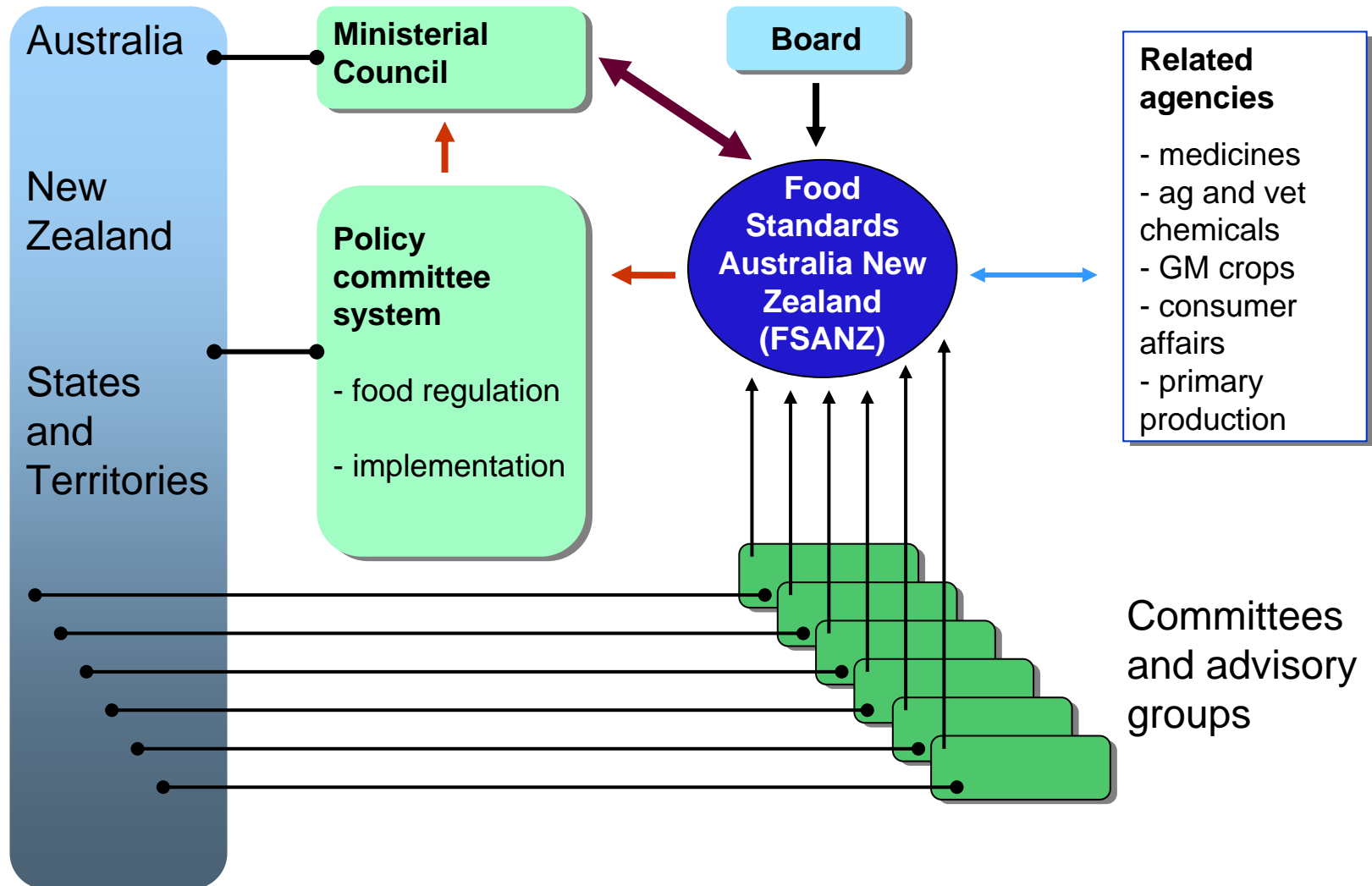
Ann Naco – Co-ordinator



Overview

- Opening remarks
- Assessing food additives
- Dietary exposure assessments
- Current Applications & Proposals relating to food additives
- P298-Review of benzoates & sulphite permissions
- Discussion & evaluation

Food Regulatory System

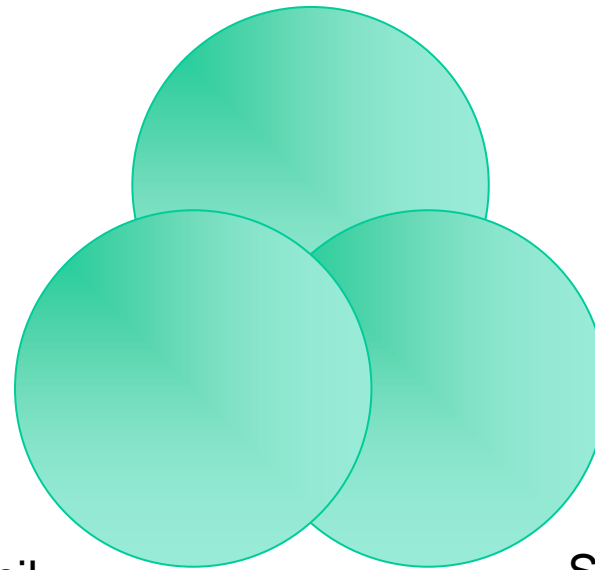




Who does what?

Standard setting
FSANZ (consistent with Codex)

Food regulatory system depends on effective collaboration.

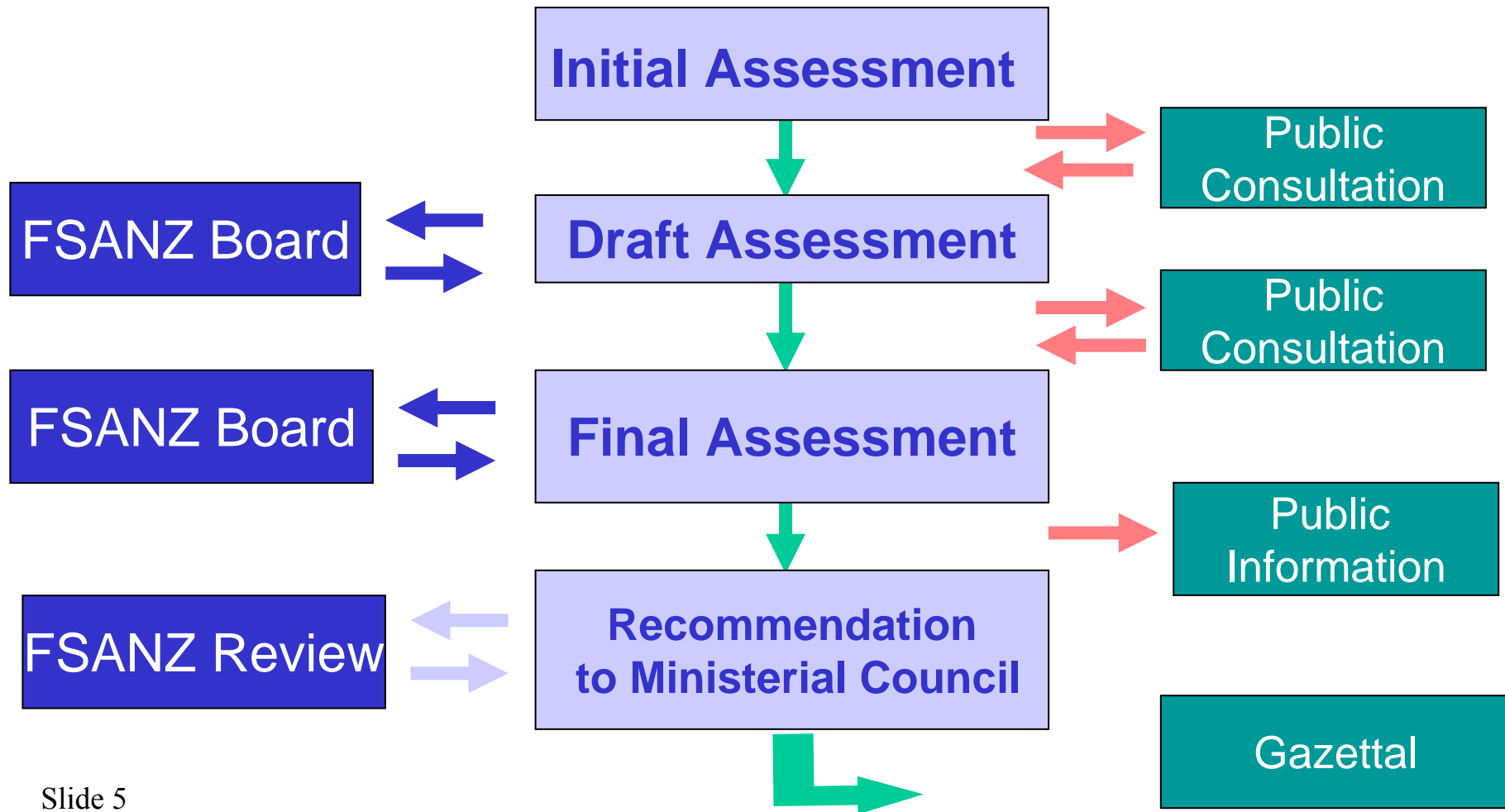


Policy
Ministerial Council
(States/Territories/Aust/NZ)
(health/agriculture portfolios)
FSANZ Act

Enforcement
States/Territories/ISC
FSANZ (monitoring)
AQIS (imported foods)
Local government



Amending the Code





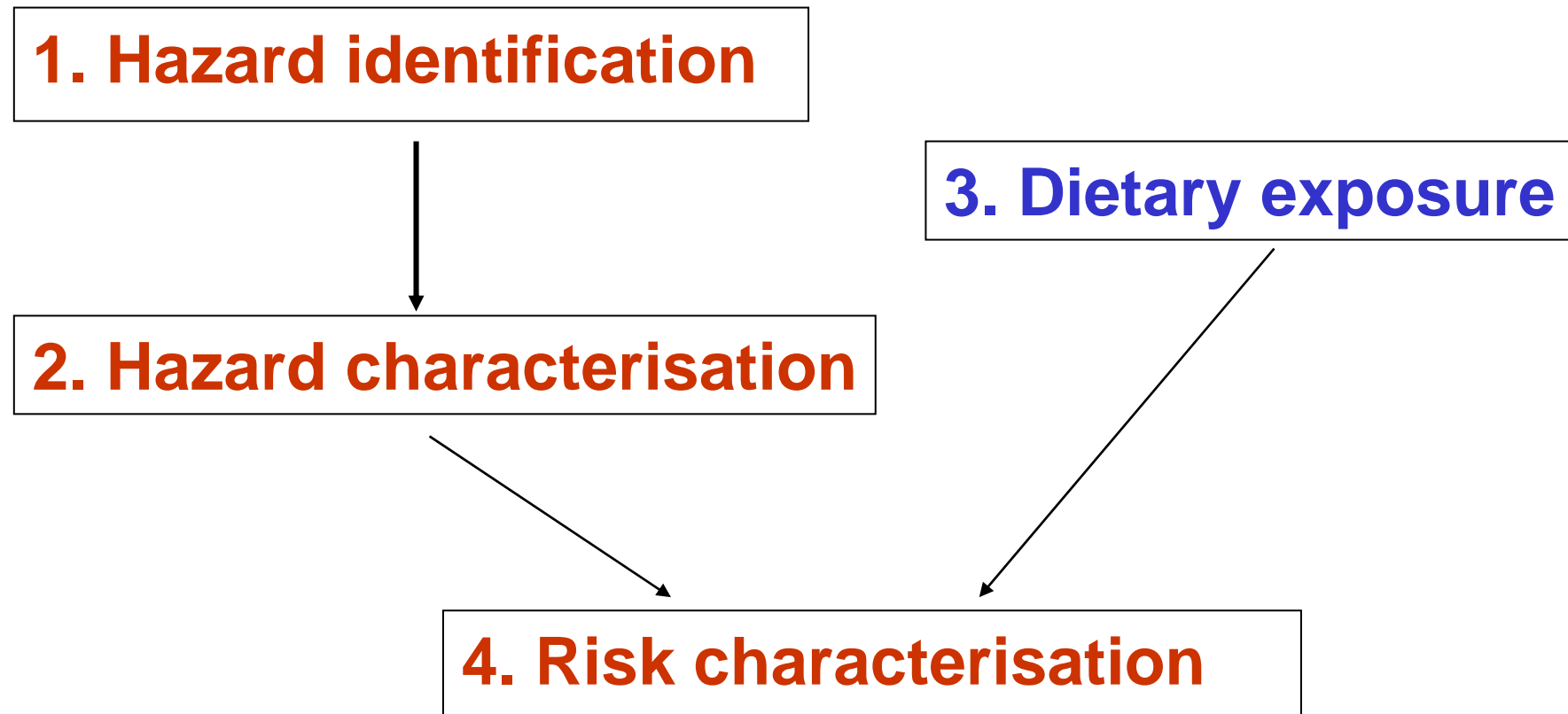
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Assessing Food Additives: Dr Glenn Stanley

Dr Glenn Stanley
Senior
Toxicologist/Risk
Manager



Risk Assessment Framework





RISK ASSESSMENT QUESTIONS

What is the short- and long-term toxicity of the chemical (additive)?

What is the level of exposure to the chemical?

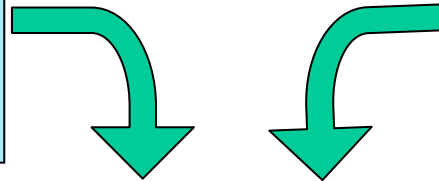
Is there a potential public health problem?



Hazard Assessment

Epidemiological data

- less precise
- highly relevant



Animal toxicity data

- more precise
- less relevant

OUTCOMES

- Some understanding of kinetic and metabolism
- Identify target organs
- Possible mechanism of action
- Dose-response relationship
- Evidence of a threshold/NOEL

NOEL: No Observed Effect Level

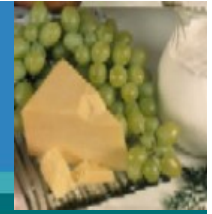


Risk Characterisation

An estimation of the probability of occurrence and severity of an adverse effect(s) in a given population under defined exposure conditions.

In other words:

What is the likely health risk?



Risk Management Questions Food Additives

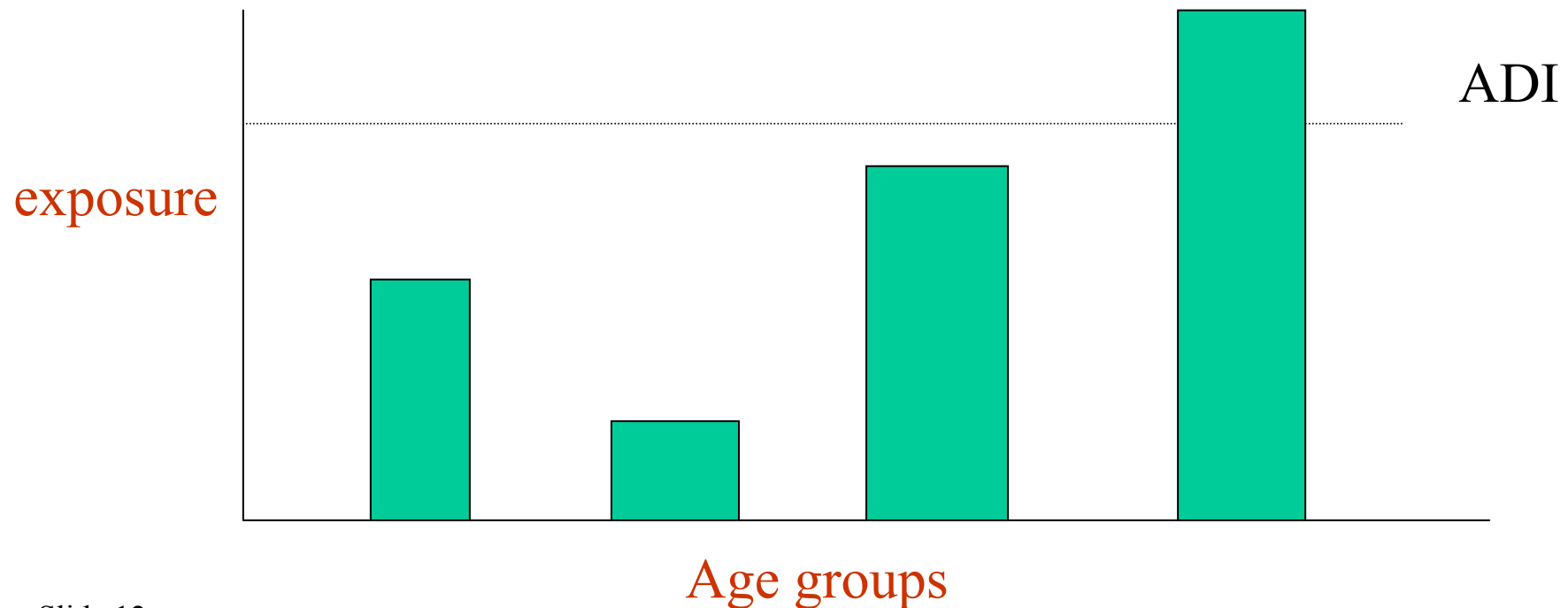
Q1. Can an ADI be established?

Q2. Will it allow the food additive to be used in a narrow range or broad range of foods?



Chemicals with an ADI

A comparison can be made between the ADI and the anticipated (or known) level of exposure from all foods for each population group.





Neotame

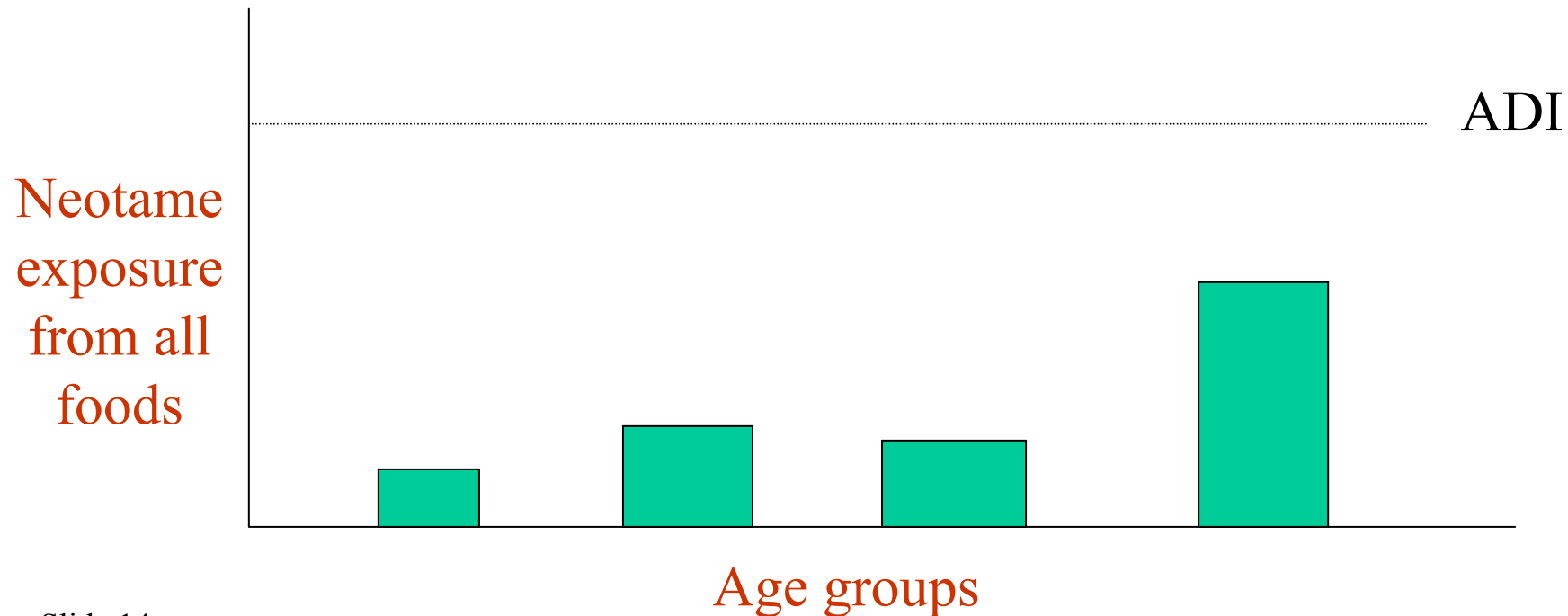
(new intense sweetener)

- ADI: 2 mg/kg bw per day
- Wide proposed use in food
- Total estimated dietary exposure: less than ADI
- Use level in food: GMP in all foods



Neotame Exposure

The total anticipated level of dietary exposure to neotame from all foods is below the ADI





Sulphites

- ADI: 7 mg/kg per day (JECFA)
- Short and long-term studies in rats and pigs
- Irritation and inflammation in stomach
- Total level of dietary exposure for specific age groups exceed the ADI



Risk Management Questions Food Additives

Q3. What is the health risk of exceeding the ADI for a short period?



Exceeding the ADI for a Short Period for a Food Additive

- ADI for almost all food additives is derived from long-term animal studies
- ADI is based on a NOEL from animal studies using a safety factor (usually 100)
- The NOEL is based on the most sensitive adverse effect (eg, enzyme induction, bodyweight changes, clinical pathology parameters)

Brief exposure over the ADI for most food additives is not a health concern



Risk Management Questions Food Additives

Q4. Are there any individuals for which there are specific risks not accounted for by the ADI?



Individual Reactions to Food Additives

1. Individuals with genetically-based metabolic disorders (eg aspartame)
2. Individuals with a particular sensitivity / intolerance to certain food additives (eg MSG)



Summary –Risk Assessment

- To identify the potential hazard associated with exposure to a food additive
- To determine at what dose the hazard may occur
- To establish NOEL and set an ADI from long-term studies



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Dietary exposure assessments for food additives

Janis Baines
Section Manager (acting)
Modelling, Evaluation and Surveillance Section

Food Additive Forum
12 December 2006

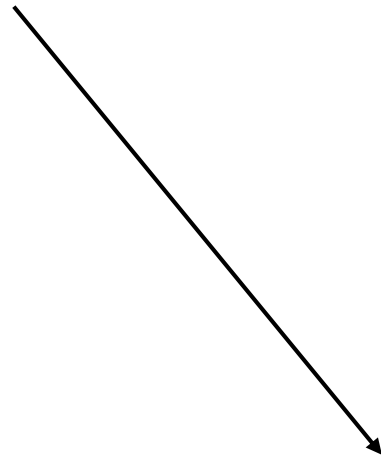


Risk Assessment Process

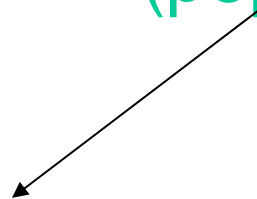
1. Hazard identification (adverse effects)



2. Hazard characterisation (dose response relationship)



3. Exposure Assessment
(population exposure)



4. Risk characterisation (comparison of exposure to reference health standards)



What is a dietary exposure estimate?

A dietary exposure estimate is where food consumption data and food chemical data are combined to estimate dietary exposure to food chemical(s).

$$\text{Dietary Exposure} = \sum \text{Food consumption} \times \text{Food chemical concentration}$$

Summed for all foods

Can be adjusted for body weight



Dietary exposure assessments

How do we choose data and method?

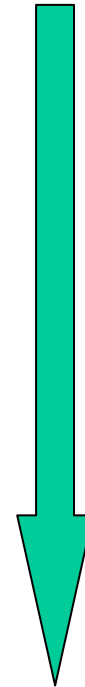
- Depends on
 - purpose of assessment
 - nature of hazard (time period for development of adverse effects, sensitive populations)
 - data available (quantity, quality)
 - time and resources available
 - statistical capability
 - existence and type of reference health standards
 - skills and experience of modeller



Chemical concentration data

- Maximum levels (eg Codex or FSANZ Code permissions)
- Reported use levels (from food labels or manufacturers)
- Monitored levels (raw food or commodities)
- Levels in foods as consumed (total diet study)

First estimate



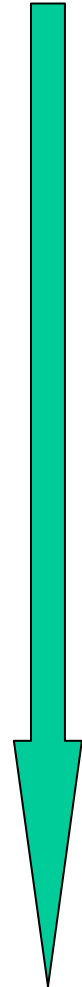
Best estimate



Food consumption data

simple

Per capita data (apparent consumption or food supply data, WHO regional diets)	One data point for whole population No individual data
Model diets (constructed for age/gender groups, eg NZ TDS)	One data point for each group No individual data
Household diets (Household Expenditure Survey)	Data for each household No individual data
National nutrition survey (DIAMOND, Australian TDS)	Individual data Distributions of data
National survey by brand and flavour (intense sweetener survey)	Individual data Distributions of data



complex



Sulphites

- Tiered approach
- DIAMOND and ATDS methods
- Different types of chemical concentration data used at different stages.



Sulphites – Step 1:

- Assessment based on maximum permitted levels (MPLs) in the Food Standards Code.
 - Mean exposure for Australian population = 350% ADI
 - Conclusion: refinements required (even though there is an MPL, manufacturers may not use sulphites up to that level)



Sulphites – Step 2

- Refinement using manufacturers' use data – collected via meetings and correspondence.
- Mean exposure for Australian population = 230% ADI.
(Was 350% based on MPLs)



Sulphites – Step 2

- Conclusion: further refinements needed.
- Sulphites degrade over time, as they do their job as a preservative.
- The amount that manufacturers add may not be in the food when it is purchased by the consumer, therefore analytical concentration data required.



Sulphites – Step 3

- Analytical data from enforcement agencies from compliance testing (samples were collected from supermarkets and analysed).
- Mean exposure estimated based on retail level analytical samples = 180% ADI.
(Was 230% ADI based on manufacturers data)



Sulphites – Step 3

- Conclusions – further refinement required.
- Sulphites degrade during storage & cooking.
- Analytical data required for foods in their prepared form i.e. in the form that people would eat it (e.g. meat is generally eaten cooked).
- Include sulphites in the next Total Diet Study.



Sulphites – Step 4

- Analytical data collected via the 21st Australian Total Diet Study (foods prepared to a ‘ready to eat’ state).
- Mean exposure estimated = 35-30 % ADI for 2 years & above.
- 95th percentile = 130% ADI 2 years & above.

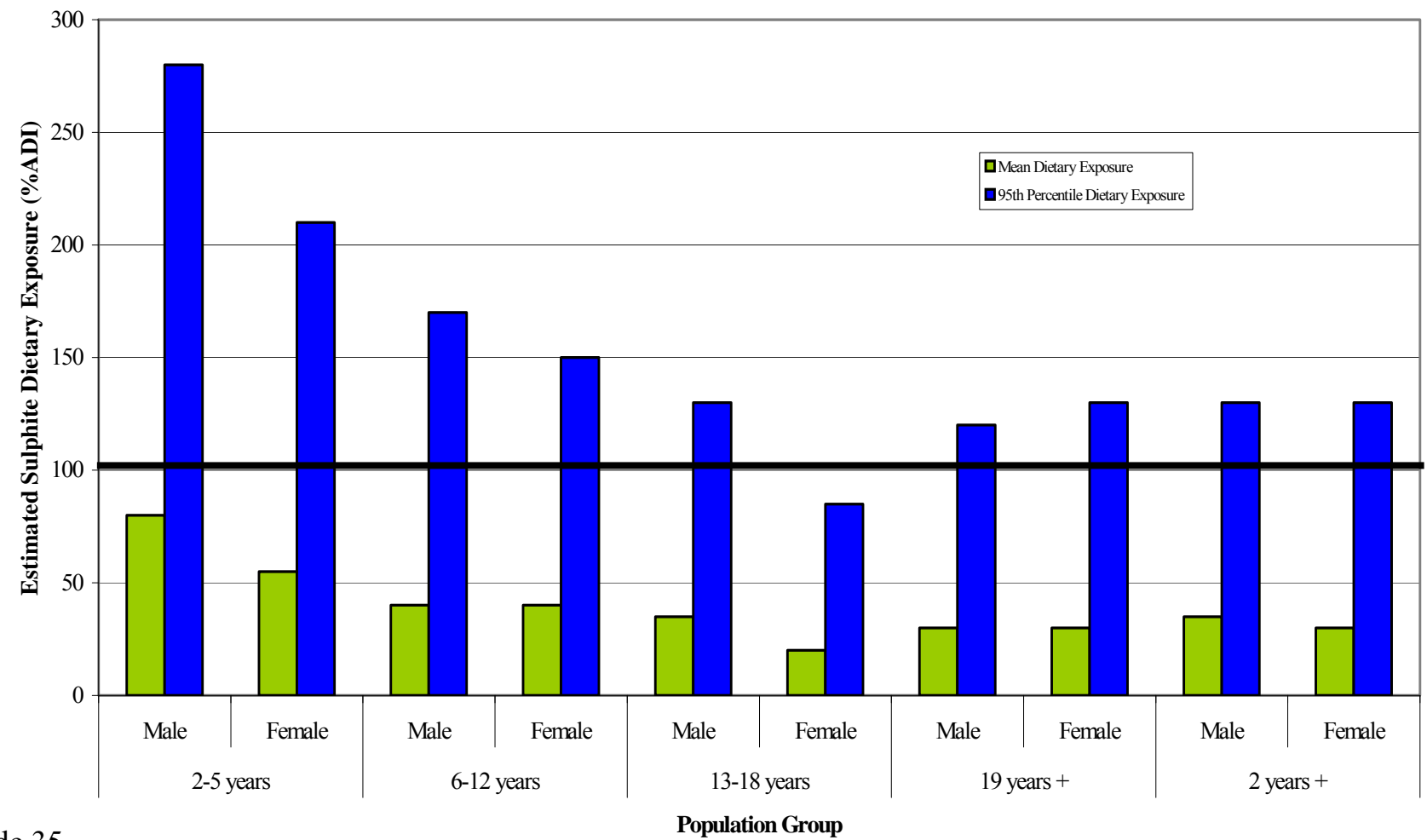
(Was 180% ADI based on non-prepared foods)



Sulphites – Step 4

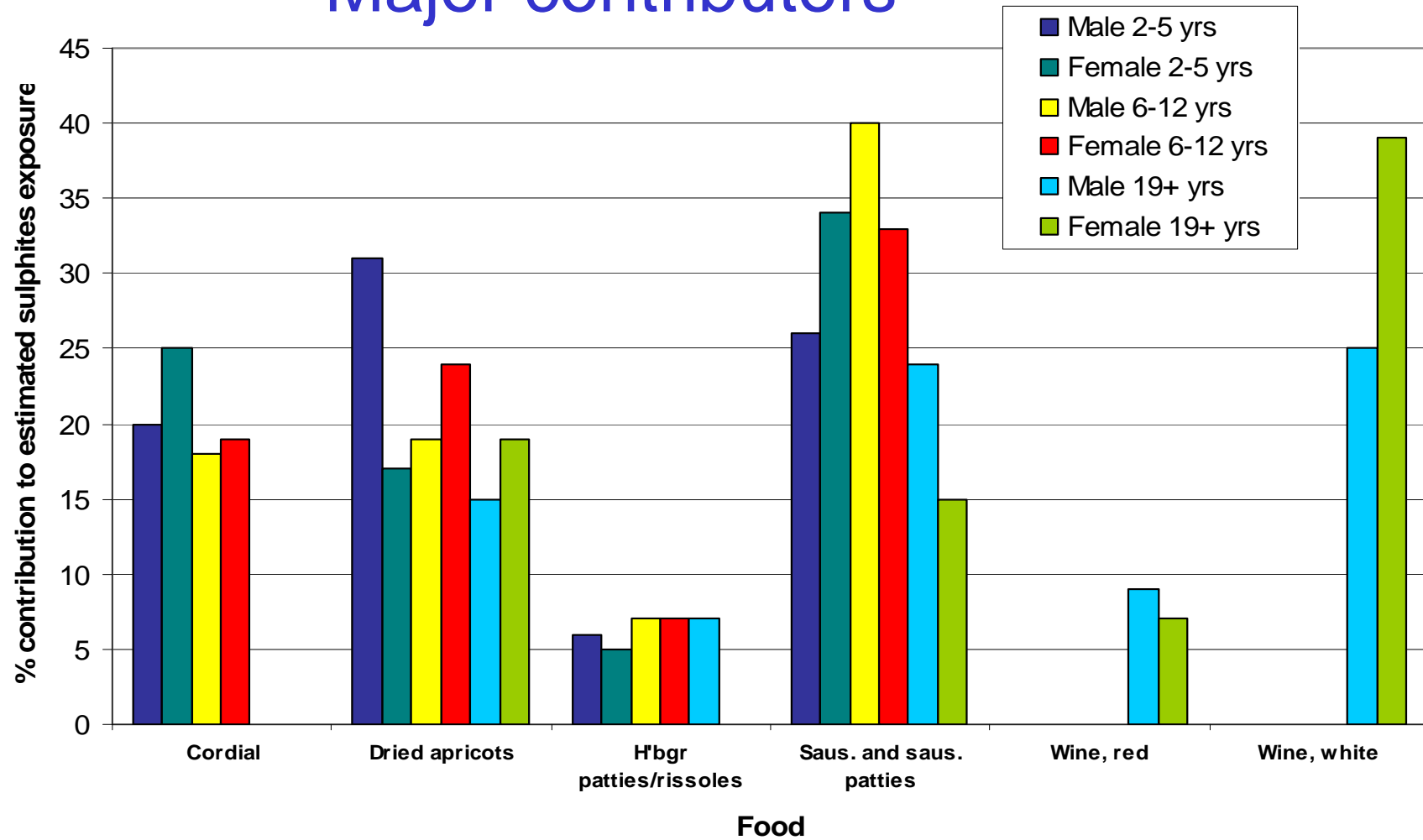
- Children 2-5 years: mean exposure 80% ADI, 95th percentile 280% ADI.

Estimated dietary exposure to sulphites





Major contributors





Sulphites – Step 4

- Conclusion: raise a Proposal to assess risk management options.

Currently being considered under P298.



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Current Applications & Proposals* relating to Food Additives

Dr Leanne Laajoki

*publicly available on the FSANZ web site:

<http://www.foodstandards.gov.au/standardsdevelopment/standardsworkplan.cfm>



Applications

- **A540 – Steviol glycosides as intense sweeteners**
to approve the use of extracts from the herb *Stevia rebaudiana* in various foods
- **A542 – Natamycin, extension of use as FA**
as a preservative against fungus growing in fruit & veg preparations, breads, bakery products, dairy & fat based desserts, dips, snacks, sauces & toppings
- **A555 – Declaration of Antioxidants in fats & oils**
to require declaration of any antioxidant present in food on the label whether or not it is performing a technological function



Applications - Cont

- **A565 – Nisin, extension of use as FA**
as antimicrobial agent/preservative on whole cuts, pieces & processed meat, poultry & game products
- **A585 – Dimethyl dicarbonate (DMDC) as a processing aid**
DMDC is currently approved as a food additive. This application seeks its re-classification as a processing aid.



Proposals

- **P279 – Review of schedule 1, Std 1.3.1-Food Additives**
to address anomalies and to clarify the presentation of food additive permissions
- **P287 – Review of cyclamate permissions**
to review cyclamate permissions in all foods
- **P298 – Benzoate & sulphite permissions in food**
to review permissions so as to reduce the levels of benzoates & sulphites to consumers of concern



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Risk Management In Practice

Proposal P298 – Sulphite and benzoate permissions in foods

Christel Leemhuis
Senior Risk Manager
12 December 2006



Proposals

- FSANZ can raise Proposals to consider changes to the Australia New Zealand Food Standards Code (the Code).
- Proposals are progressed in a similar way to Applications and consist of an Initial, Draft and Final Assessment Reports and there are 2 rounds of public consultation.
- Proposals are not subject to statutory timeframes which allows FSANZ time to consult widely and generate data.

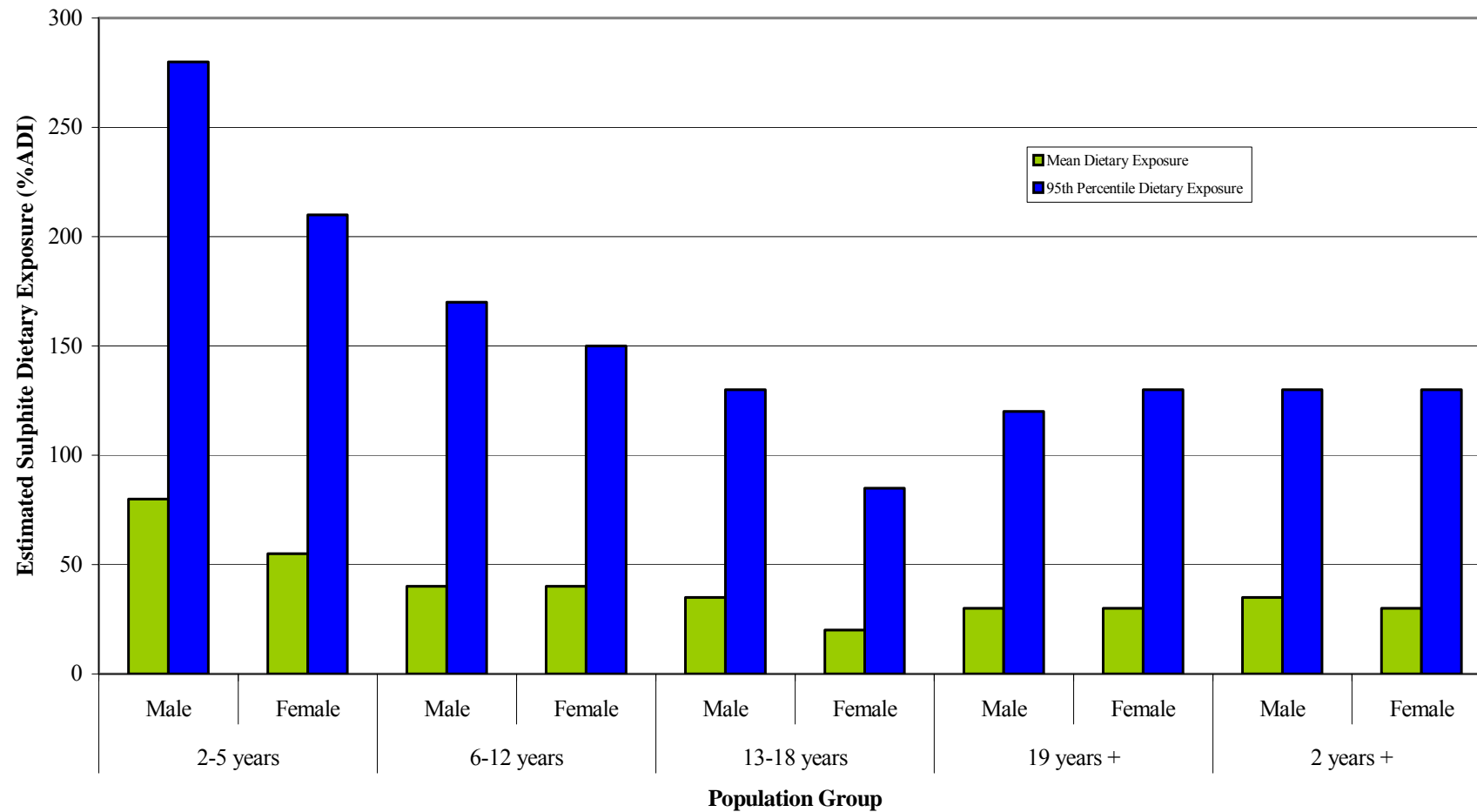


Background P298

- The 21st Australian Total Diet Study (ATDS) looked at the preservatives sorbates, benzoates and sulphites in a range of foods with current permitted levels in the Code.
- The 21st ATDS showed some consumers were above the ADI for sulphites and benzoates for some population groups.
- Consumers above the ADI were identified only for 95th percentile (high) level.
- Proposal P298 - sulphites and benzoates in foods was raised as a result of the 21st ATDS.

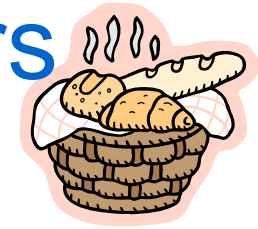


Australian Dietary Exposures



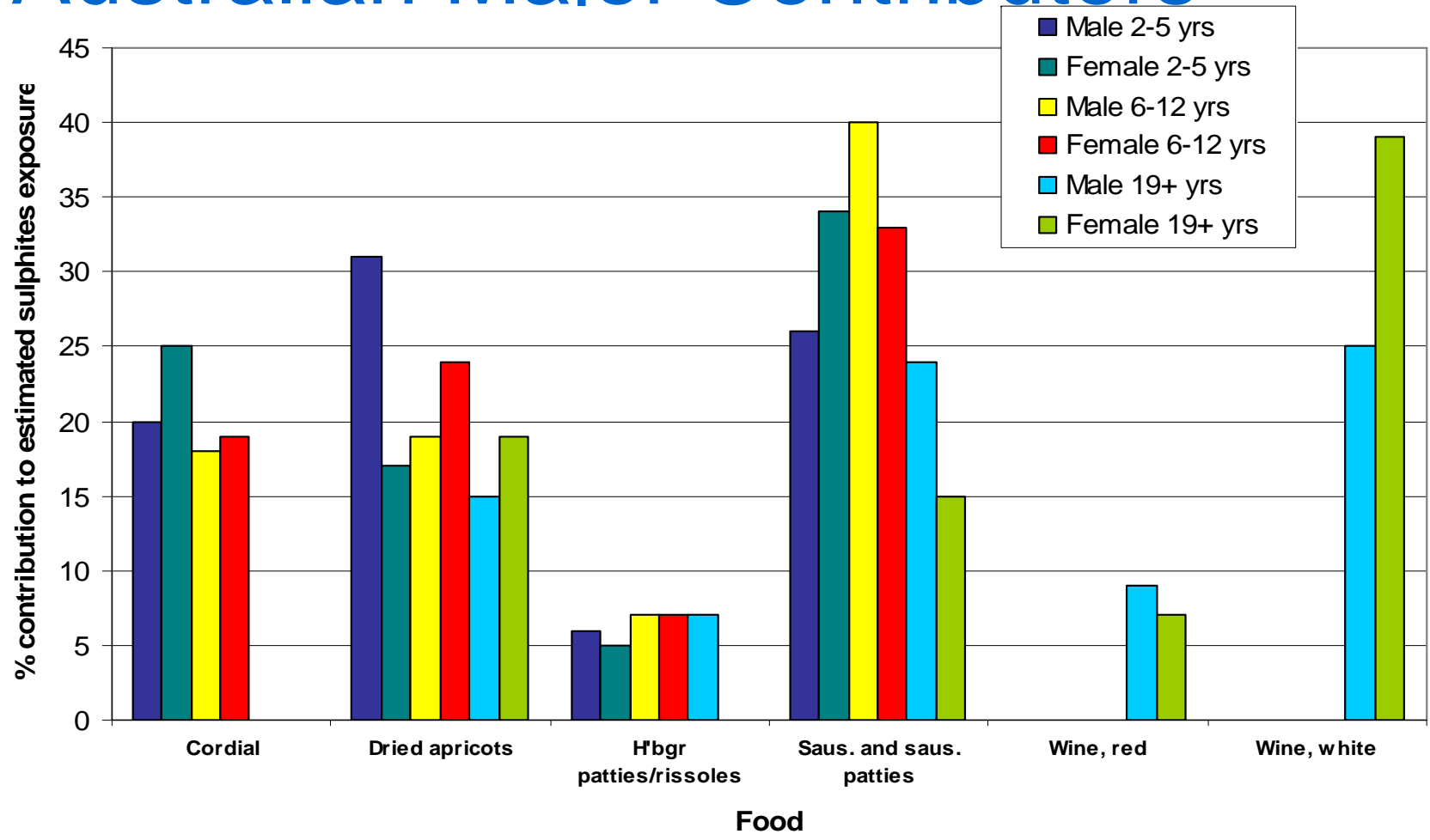


Australian Major Contributors



- Foods identified as contributing to benzoate exposure include cordials, orange juice and soft drinks.
- Foods identified as contributing to sulphite exposure include dried apricots, sausages, cordials and wine (19+ years).

Australian Major Contributors

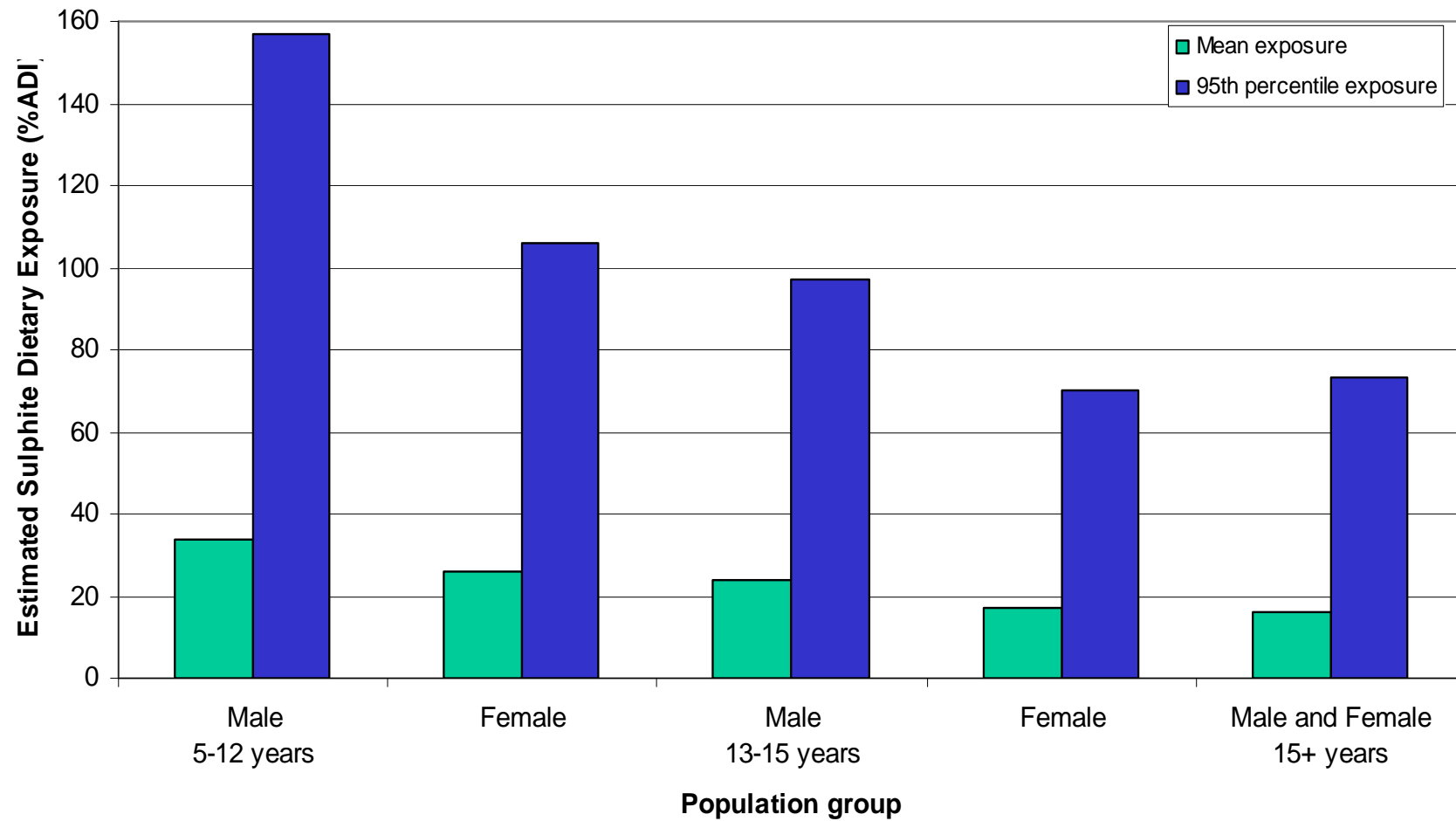




New Zealand Dietary Exposures

- New Zealand did a similar study to the ATDS for the preservatives.
- New Zealand have now completed the dietary exposure assessments for adults and children.
- New Zealand also identified some exceedances of the ADI for some 95th percentile (high) consumer groups.

New Zealand Dietary Exposures

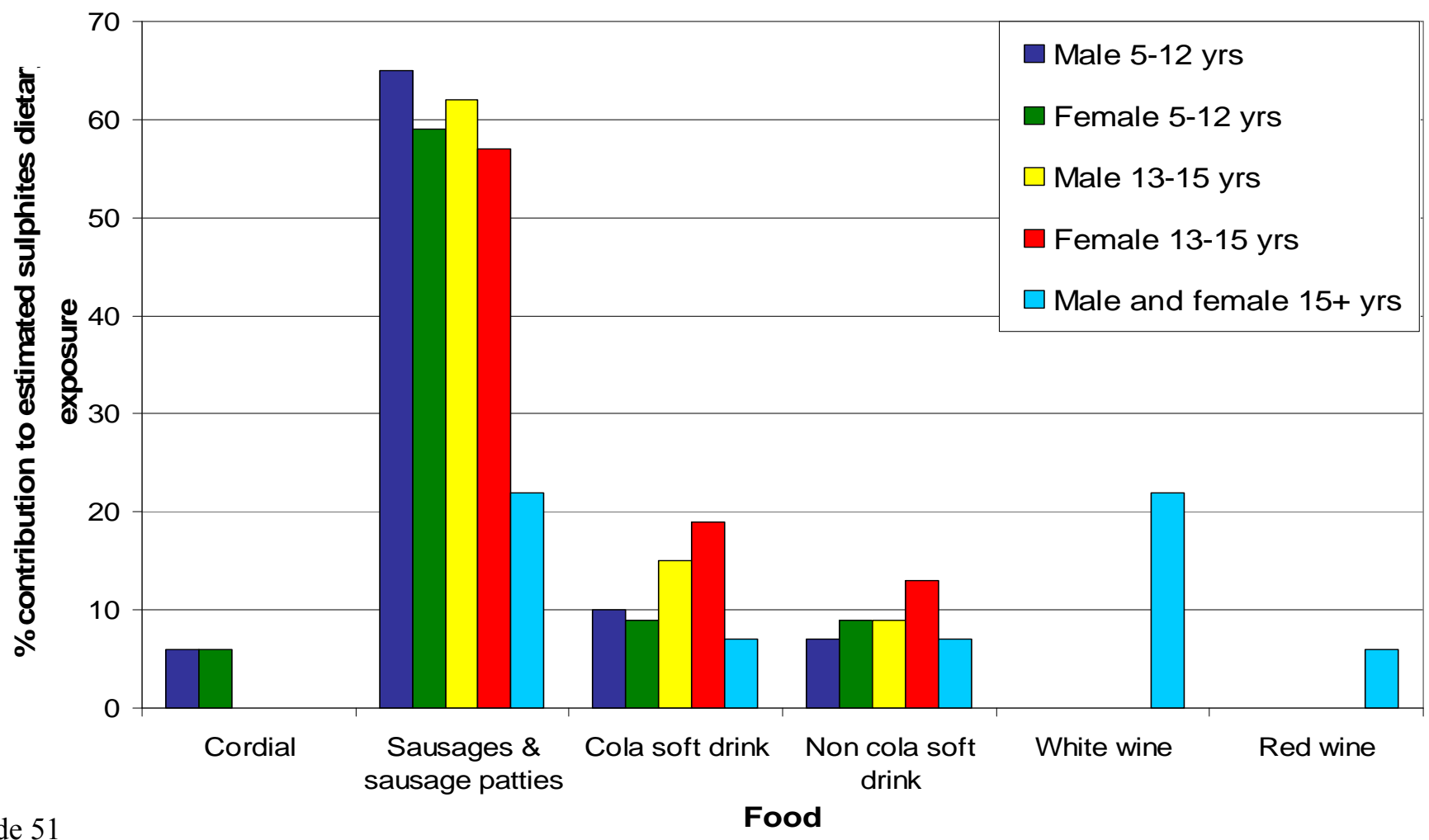




New Zealand Major Contributors

- New Zealand major contributors were sausages, soft drinks (cola and non-cola), cordial and wine (adults only).

New Zealand Major Contributors





The Story So Far



Initial Assessment Report (IAR)

- FSANZ prepared an IAR for P298.
- The IAR considered the issues identified in the 21st ATDS and presented potential ways forward for this Proposal.
- The IAR was released for public comment in October 2005.



Options Presented in the IAR

- Option 1.** Maintain the *status quo* by not altering permissions for sulphites.
- Option 2.** Review and reduce permissions for benzoates and/or sulphites for certain foods.
- Option 3.** Review and partially replace the use of benzoates and/or sulphites with alternative preservatives, or consideration of altering the methods of preventing microbial spoilage.
- Option 4.** Encourage consumers to eat a balanced diet and not over-consume foods with high levels of sulphites.



Identification of Major Stakeholders

- FSANZ received 24 submissions in relation to P298 and views were very polarised.
- Examples
 - Any changes in preservative levels would make it difficult to prevent food spoilage.
 - Reduction of allowable limits and alternatives should be pursued.
 - Changes to sulphite permissions are likely to have a significant cost impact which may be passed on to consumers.



Consultation with Stakeholders

- Consumer groups/consumers
 - Are being consulted via the Food Additive Forum and the Consumer Liaison Committee.
- Jurisdictions
 - Jurisdictions are being consulted via the Jurisdictional Forum which has representatives from Australian States and Territories and New Zealand.
- Industry
 - Are being consulted with, via advisory groups and ad hoc meetings.



Moving forward



Issues for FSANZ to Consider in its Assessment

- Are there any additional data to affirm or contradict FSANZ results from the ATDS?
- In which foods can we reduce preservative levels?
- Are there alternatives to these preservatives that can be used in some foods?



Additional data to affirm or contradict FSANZ results?

- Additional data can assist FSANZ in estimating dietary exposure more accurately.
- FSANZ has requested and received additional data on levels of preservatives used by manufacturers which was considered in the modelling.



Reduction in levels?

- FSANZ and industry have identified foods where reductions in the amount of preservative used can be made including:
 - Cordials
 - Wines
 - Some processed meats



Alternatives?

Why do we use preservatives?



Preservatives:

- Combat Microbiological Contamination
- Increase Shelf Life
- Maintain Colour and Texture



Are there Alternatives for these preservatives?

- FSANZ is working closely with various industries to determine any alternatives that may be used instead of these preservatives.
- Alternatives identified must be safe for use and maintain product integrity and overall safety of the food product.



Next Steps



Draft Assessment Report (DAR)

- FSANZ is currently considering P298 at Draft Assessment.
- The DAR will need to contain a full safety assessment (including toxicological, dietary modelling and microbiological assessments) as well as a proposed actions including draft regulatory measures.



Considerations

- Time – data generation, consultation etc.
- Standards – the Food Additive Standard applies to both Australia and New Zealand so FSANZ needs to consider impacts in both countries.
- Complexity – diverse industries involved, wide variety of views, and no obvious alternatives.

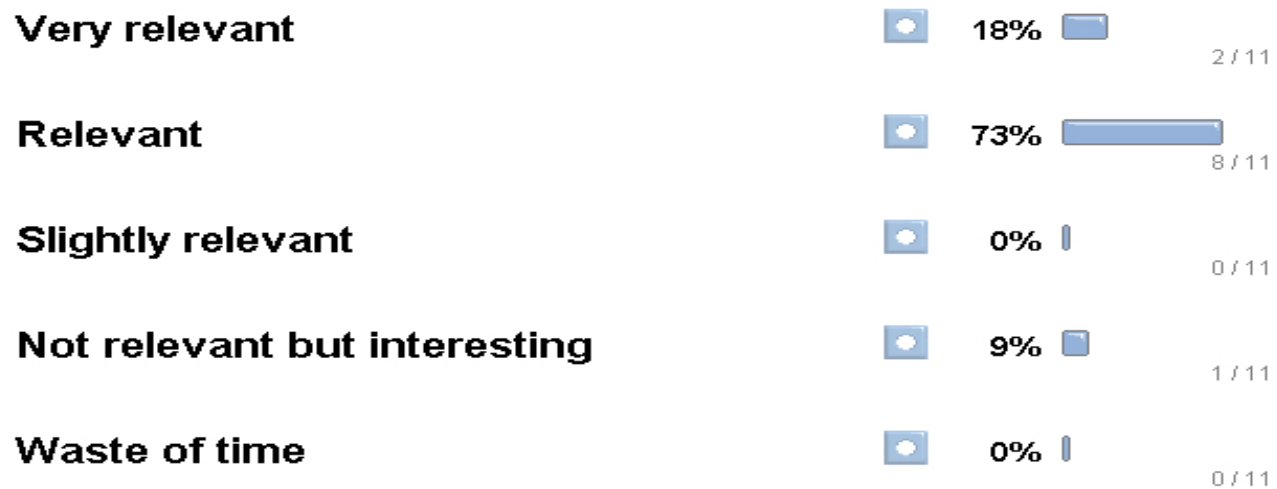


General Discussion

After the general discussion please spend a few moments to evaluate this presentation.

(Only one answer allowed)

Please rate the relevance of the information provided today



(Only one answer allowed)

Please rate how user friendly you found the technological aspects of this forum



(Only one answer allowed)

Please rate the overall usefulness of today's seminar



(Only one answer allowed)

Do you think we should run seminars like this in the future?

Yes



No





Thank you

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