Overview of the comments received during the public consultation

Luisa Ramos Bordajandi
Scientific officer - BIOCONTAM Unit

Follow-up meeting of the public consultation
10 December 2014, Brussels

OUTLINE

- Number and contributors
- Overview of the comments submitted
  - on the overall structure and scope of the draft opinion
  - on the draft assessment of the exposure
  - on the draft assessment of human health risks

NUMBER OF ENTRIES SUBMITTED

Number of entries received 193

- Illegible entries -70
- Empty entries -1
- Entries also submitted by email and corresponding to one same comment -5

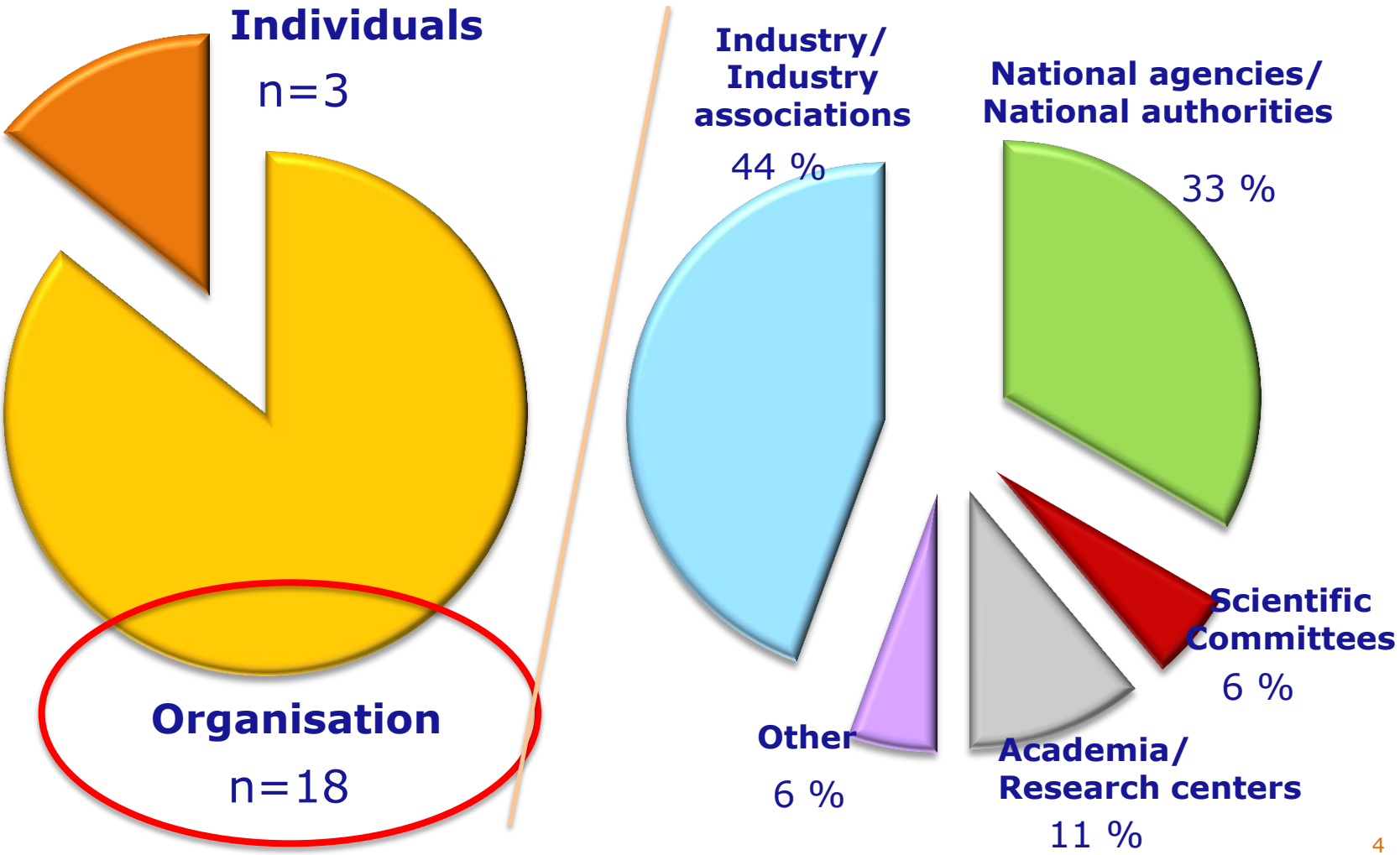
Duplicate entries

- Same entry in a particular section submitted twice by the same organisation -4
- Same entry in different sections submitted twice by the same or different organisation(s) -22

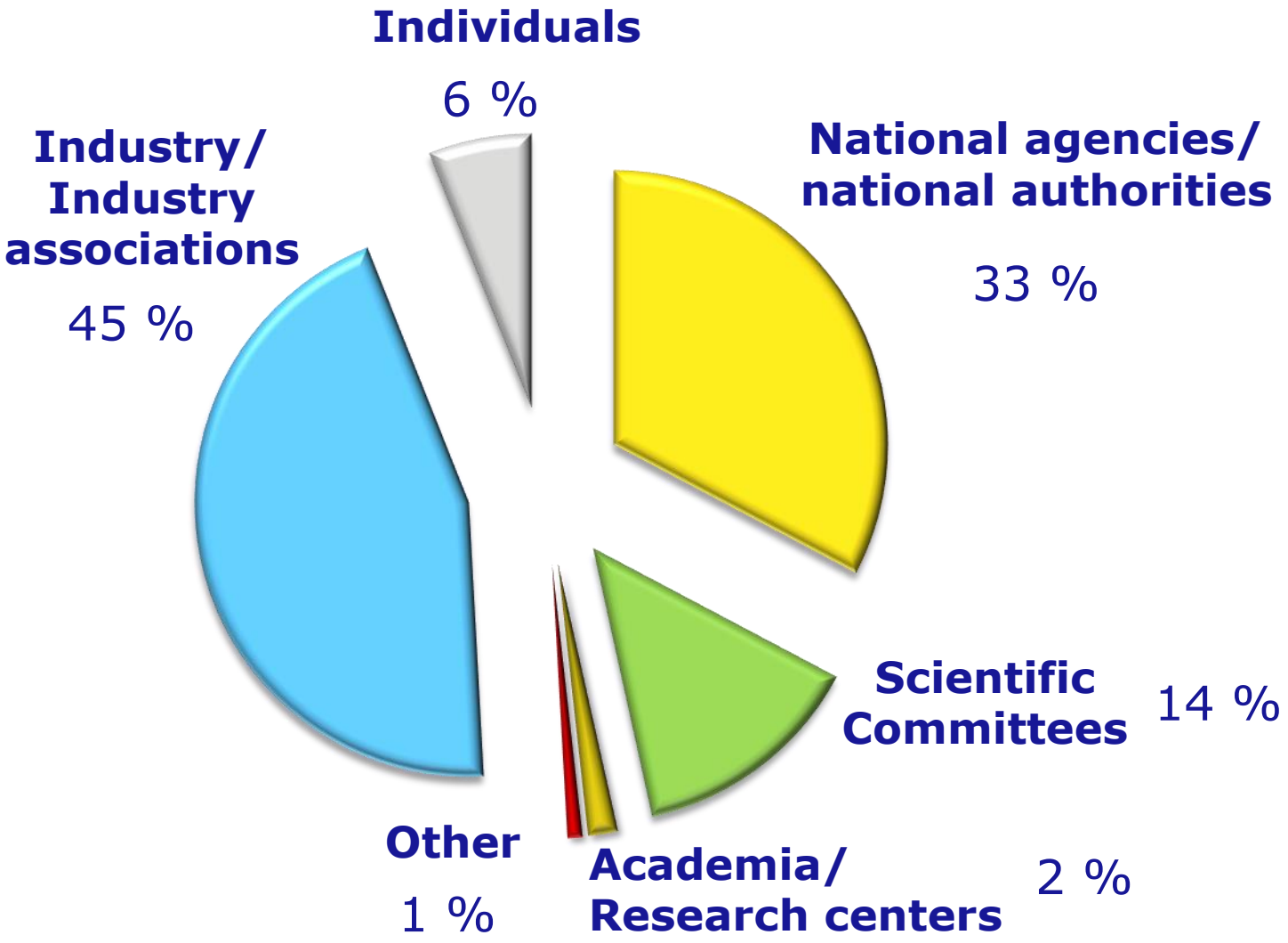
Number of entries 91

TYPE OF CONTRIBUTOR

Entries were received from 21 interested parties



ENTRIES PER TYPE OF CONTRIBUTOR



CONTRIBUTORS TO THE PUBLIC CONSULTATION

Comments submitted on behalf of an organisation

- **National agencies/national authorities**
  - Austrian Agency for Health and Food Safety (AGES)
  - French Agency for Food, Environmental and Occupational Health Safety (ANSES)
  - National Food Administration of Sweden (NFA Sweden)
  - Istituto Superiore di Sanità (ISS)
  - Kantonales Labor Zürich
  - Chilean Food Quality and Safety Agency (ACHIPIA)

CONTRIBUTORS TO THE PUBLIC CONSULTATION

Comments submitted on behalf of an organisation

- **Scientific committees**
  - UK Committee on Toxicity (COT)/Committee on Carcinogenicity (COC)
- **Academia/research centres**
  - Spanish National Research Council (CSIC)
  - Technical University of Denmark (DTU)
- **Others**
  - LTD H-Group

CONTRIBUTORS TO THE PUBLIC CONSULTATION

Comments submitted on behalf of an organisation

- **Industry / Industry federations**

  - FoodDrinkEurope (FDE)
  - European Potato Processors' Association (EUPPA)
  - European Coffee Federation (ECF)
  - Association of the German Confectionary Industry (BDSI)
  - Novozymes A/S

  - Frozen Potato Products Institute (*USA based*)
  - National Coffee Association (*USA based*)
  - Renaissance BioScience Corp. (*Canada based*)

CONTRIBUTORS TO THE PUBLIC CONSULTATION

Comments submitted on personal capacity

- 3 individuals submitted comments on their personal capacity (not on behalf of an organisation)

OVERVIEW OF COMMENTS

- On the overall structure and clarity
- On the scope of the draft risk assessment
- On the formation in food and mitigation measures
- On the occurrence data/food grouping/exposure assessment
- On the draft assessment of human health risks
- On the recommendations

… on the overall structure and clarity

"(...) **high quality and comprehensive nature** of the scientific opinion and were broadly in agreement with the evaluation and conclusions reached"

"(...) the opinion is **overall sound and thoughtful,** and it surely represents a step forward with regard to the protection of consumers from exposure to process contaminants"

"The opinion is very **thorough and comprehensive**"

"We **welcome the recognition and inclusion of the occurrence data that was submitted by industry,** comprising data from various sectors"

… on the overall structure and clarity

"I recommend to **clearly separate the older studies (i.e., those performed before JECFA 2005) from the more recent studies,** which should be discussed and described in more detail"

"(...) the Panel's conclusions and discussions frequently appear within the body text rather than as a distinct numbered subsection. (...) **in some instances, difficult to read and digest the information that is being presented**"

"(...) **the report lists all cancers observed in epidemiological studies one after the other.** While this approach has the advantage of systematically analysing lines of evidence in response to a specific issue, **it can cause the corpus of data and publications to become over-fragmented,** ultimately meaning that there is **not sufficient perspective to judge a set of arguments that may be a part of a continuum of similar effects**"

… on the scope of the draft assessment

"(...) the most useful work of EFSA would be the **evaluation of options for mitigation and estimation of their effect on exposure for the concerned groups of consumers**"

"(...) finding **appropriate (mitigation) measures and estimating their potential of improvement** is a key subject and should be tackled by EFSA, advising the risk managers"

… on the formation in food and mitigation measures

"Elimination is neglected in the draft opinion "

"Section 4.5 on mitigation **should be completed by successful measures which underline that improvements are feasible** (…)

"It is important that **risk-benefit tradeoffs be considered when considering specific mitigation strategies**"

… Information on studies aimed to measure the impact of raw material, storage and processing on the levels of AA

… Information on specific mitigation measures (e.g. enzymes, yeasts)

… on the occurrence data/food grouping/ exposure assessment

Related to …

… the way of reporting the occurrence and exposure data

… the terminology

… the comparison of levels between food groups

… the assumptions made for the exposure assessment

… the description of the exposure assessment methodology

… the category coffee beverages

… the non-dietary exposure

… on the occurrence data/food grouping/ exposure assessment

… the way of reporting the occurrence and exposure data

Due to the very different levels,

"to **split the 'coffee and coffee substitutes' into the two sub-categories**"

When comparing to other food groups,

"to refer to acrylamide levels in coffee and in coffee substitutes **as consumed**"

Comments on the occurrence data /draft food grouping / exposure assessment

… the terminology

"The **term 'coffee Americano' is not a common term across Europe.** We would propose to replace it with 'drip filter coffee'"

"clear and consistent differentiation between **'French fries'** and **'potato crisps'**"

Regarding Brand loyalty,

"(…) the title of this section needs to more closely reflect the calculations that have been undertaken e.g. **Loyalty to particular product sub-type or category**"

Comments on the occurrence data /draft food grouping / exposure assessment

… the assumptions made for the exposure assessment

"reconsider whether 5% is the proper **cut-off for assuming the potato was fried in consumer surveys**"

"The **dilution factor** used to recalculate from coffee substitutes (solids) to coffee substitutes (beverage) (…) is not in accordance with actual market practice and advices for product preparation"

Comments on the occurrence data /draft food grouping / exposure assessment

… the description of the exposure assessment methodology

"According to AA-exposure, only the Lower Bound - and the Upper Bound-approach are used. **Why not the Medium Bound (MB)?**"

"(…) In the present draft the **modelling approach is not even addressed,** even though important additional conclusions could be drawn – in particular **it must be assumed that for some consumers exposure is markedly higher than now assessed**"

"(…) The use of the scenario modelling is appropriate but the **base-line scenario is not sufficiently explained**"

Comments on the occurrence data /draft food grouping / exposure assessment

… the category coffee beverages

"It would be interesting to have more **details on the data for 'Unspecified coffee (Beverage)'** since this covers a significant number of samples"

… the non-dietary exposure

"include **quantitative data on other sources wherever possible** (or note when this is not possible) which would allow for a better understanding of the contribution of dietary exposure and would aid in interpreting the epidemiological studies and risk characterisation"

… on the draft assessment on human health risks

Related to …

… the toxicokinetics

… the consideration of adverse effects and identification of NOAELs

… the use of Harderian gland as critical end-point

… the epidemiological studies and their limitations

… on the draft assessment on human health risks

… toxicokinetics

"it is not clear the **correspondence between the GA dose level and the AA intake that may produce that internal GA exposure**"

"**detailed analysis of kinetic differences between the inhalation and oral routes** (…) to investigate further the differences in susceptibility to tumours between species and following different routes of exposure"

… on the draft assessment on human health risks

… the consideration of adverse effects and identification of NOAELs

"It is surprisingly that dose-related degeneration of the **testicular germinal epithelium is questioned as adverse effect,** as it is a pathologic alteration"

"consider to establish a NOAEL (or BMD10) for the endpoint **'histopathological alterations of the male reproductive tissues'**"

"consider to establish a NOAEL for the endpoint **'persistent structural changes in the developing brain'**"

… on the draft assessment on human health risks

… use of Harderian gland as critical end-point

"(…) the relevance of using this endpoint to translate carcinogenic potential to humans is **highly suspect**"

"(…) an **appropriate tumour to use** for the BMDL derivations"

"**... more clarification should be given about the choice of BMDL**"

… on the draft assessment on human health risks

… epidemiology data

"FFQ data are not very reliable, and the **limitations should be explained better**"

"... clearly describe and outline **how the statistical power of human epidemiological studies can and should be included in the evaluation of the epidemiological evidence**"

"Data on **exposures resulting in neurotoxicity, or discussion of why such exposures cannot be meaningfully characterised,** would be helpful"

… on the draft assessment on human health risks

… epidemiology data

"clearly outline the perspectives as per **how unequivocal and clear results from animal toxicological studies should be interpreted in a situation where human epidemiological studies are equivocal**"

"... when reviewing reproductive and developmental outcomes, **background data on associations of relevant outcomes with smoking might provide an upper estimate of risk for effects from dietary exposures to acrylamide**"

"... it would be valuable also to consider the **human evidence on risks in relation to total exposure to acrylamide from all sources**"

… on the draft risk characterization

"... use a **more descriptive language to communicate the level of concern** in the risk characterization"

"... should be expanded to **consider the context of other sources of exposure**"

… on the draft uncertainty section

"... suggesting that studies in which estimated dietary acrylamide intake (e.g., assessed with an FFQ) is correlated to AA Hb adducts are "validation studies" is overreaching"

"... it is questionable to state that the fact that the occupational epidemiological studies did not observe clear risks contributes to the uncertainty whether acrylamide is a human carcinogen"

… on the draft recommendations

"the CONTAM Panel asks for better reporting data for a more accurate exposure assessment, which is **certainly justified for pure science, but is not of high priority for the consumers**"

"Is EFSA not of the opinion that **more epidemiological studies on dietary acrylamide intake and cancer risk are needed**?"

"**Does EFSA really not recommend any risk management action** facing a MOE which is below 500?"

"Further recommendations that would **support AA risk assessment for potentially vulnerable lifestages, like infants, toddlers and children** (would be appropriate)"

WHAT HAPPENS AFTER THIS MEETING?

The comments submitted through the public consultation and today's discussion:

- ✓ will be considered by the WG and the CONTAM Panel during its meetings
- ✓ will feed into the final version of the risk assessment before its adoption (first half of 2015)

An **EFSA technical report** will be developed:

- ➢ all original comments will be listed as submitted
- ➢ overall summary of the comments and explanation of the actions taken and the rationale

The technical report will be published at the same time the adopted opinion is published (first half of 2015)

Thank you very much…

… for being here

… for your comments and sharing your views with EFSA

… for contributing to the work of EFSA