# EFSA CEF Panel opinion on "Recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in FCM"

**L. Castle – CEF Panel member, Chair of FCM WG**
**E. Barthélémy – EFSA Scientific Officer for FCM**

*3rd FIP FCM Network meeting on 24-26 May 2016, Parma*

# SCOPE AND LIMITATIONS

Although only for substances (i) used in plastics and (ii) subject to EU authorisation, **the opinion indicates our thinking about the science underpinning the safety assessment of any substance that migrates from any FCM**

# STATUS

- ✓ **Study on implications** (ISP, version 2013)
- ✓ **Public consultation for 3 months** (2015)
  - Comments have been addressed
  - Draft opinion was modified
  - Technical report with comments and answers
- ✓ **Opinion was adopted** at EFSA CEF Panel plenary on 2 December 2015 and **published on 28 January 2016** together with report on public consultation

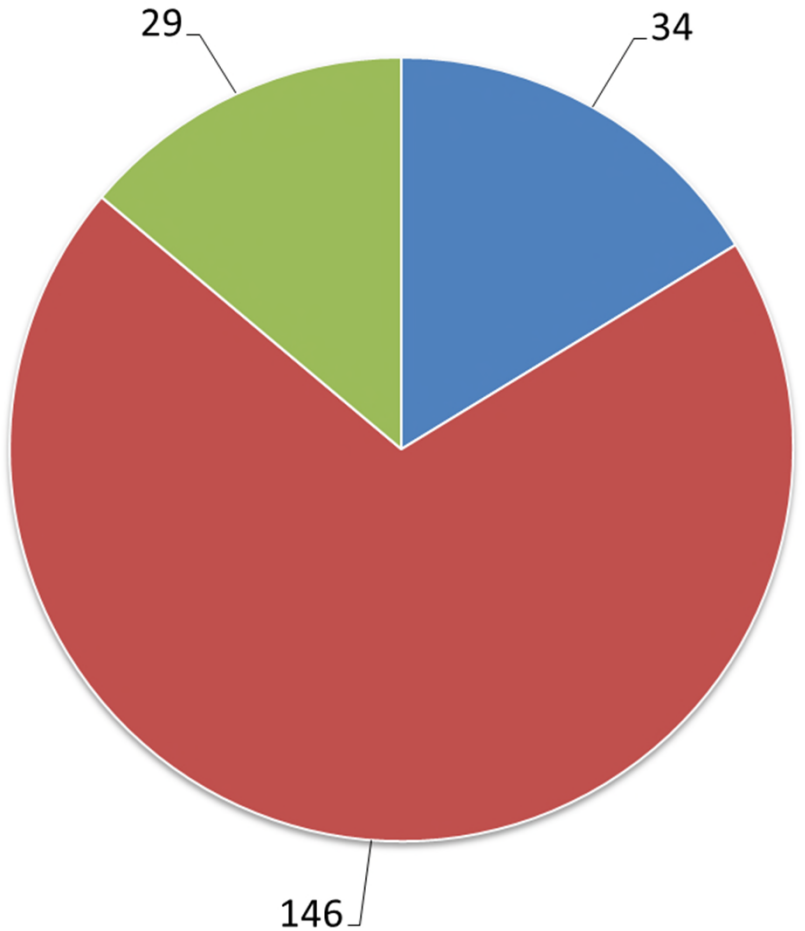
# PUBLIC CONSULTATION

**209 comments and data were received** (all available in the published technical report) of which approx. 25% were repeated comments

# COMMENTS PROVIDED BY COUNTRY

## Organisations from 11 countries submitted comments

# COMMENTS PROVIDED BY ORGANISATION'S TYPE




## 21 organisations submitted comments

- Governmental Organisation (9 contributors)
- Private Organisation (9 contributors)
- NGOs (3 contributors)

- ✓ Governmental Organisations are management, assessment
- ✓ Private Organisations are industry association, consultancy

# OUTCOME OF THE PUBLIC CONSULTATION

- ✓ **The draft opinion was revised**
- ✓ **Main changes in the opinion**
  - Clarifications on context, calculation of exposure, genotoxicity requirement and more generally on toxicity, read-across
  - Additional tier in tox data requirement
  - Additional food consumtion category

# PRINCIPLE FOR TOXICOLOGICAL DATA REQUIREMENT

**Tiered approach**

**The higher the "exposure", the greater the amount of data is required**

**Applicable for all substances**: monomers, additives, reactions products, etc.

# CONSUMPTION SCENARIO ACCORDING TO USES

- ✓ Based on use(s) of the FCM containing the substance under evaluation: **4 scenarios**

| Cat. No | Food categories for which the FCMs containing the substances under evaluation are intended to be used | Population driving the highest consumption | Food Consumption to be considered for the estimation of the exposure |
|---|---|---|---|
| 1 | Water and baby bottles' contents such as reconstituted milk formula | **Infants** | **150** g/kg bw/day |
| 2 | Beverages such as non-alcoholic drinks, milk, other liquid milk based products | **Toddlers** | **80** g/kg bw/day |
| 3 | Solid foods specifically intended for infants and toddlers **(NEW)** | **Toddlers** | **50** g/kg bw/day |
| 4 | Foodstuffs not covered by Categories 1 and 2 | **Toddlers** | **20** g/kg bw/day |

# HOW EXPOSURE COULD BE CALCULATED? (NEW)

- ✓ **By combining migration with food consumption category figures**
- ✓ To estimate the exposure from each food category covered by the intended uses of the food contact materials/articles
- ✓ The highest calculated exposure would determine the toxicological data required

# OTHER SOURCES (NEW)

- ✓ **Other sources need to be considered**

  Known or anticipated exposure from:

  - other plastics, non-plastic FCMs
  - other food sources
  - non-dietary sources when exposure is significant

# TIERED APPROACH TO TOX DATA REQUIREMENTS

✓ Based on highest calculated exposure (µg/kg bw/day)

| | |
|---|---|
| **Exp < 1.5**<br><br>**or if substance is classified as Cramer class I Exp < 30 (NEW)** | – 2 genotoxicity tests *in vitro*<br>– available information including an appropriate literature search **(NEW)**<br>More data if (1) if existing data indicate potential to affect endocrine or *neural systems*; (2) for substances with a high potential to accumulate in humans; (3) for nano |
| **1.5 (or 30) ≤ Exp ≤ 80** | As above, PLUS:<br>– extended 90-day oral toxicity study in rodents (* with, if there are existing data indicating endocrine activity suggesting potential effect from prenatal exposure, prenatal treatment period or an extended one generation reproduction study (EOGRTS) **(NEW)**)<br>– an ADME for substances for which a potential for accumulation in man could be anticipated |
| **Exp > 80** | As above, PLUS:<br>– study on ADME<br>– studies on reproduction (EOGRTS) & developmental toxicity<br>– studies on long-term toxicity (*)/carcinogenicity |

# ADDITIONAL REQUIREMENTS - ENDOCRINE EFFECTS

- **For all tiers, additional studies on specific endpoints may be needed**
- ***In vitro* studies on endocrine effects** are useful to identify potential modes of action but do not necessarily reflect *in vivo* situation and should be interpreted carefully... **(NEW)**

# READ-ACROSS

- ✓ Read-across may also be used in the hazard characterisation of **all migrating substances**
  - **A chemical for which toxicological effects have been tested** can be used to predict the same toxicological endpoints for an untested chemical...
  - Case-by-case and if adequate justification and supporting data available
  - Possible additional uncertainty factor
  - Guidances: OECD 2014; ECHA 2013, 2015

# CONSIDERATION ON NIAS INC. OLIGOMERS

- ✓ **Tiered approach applies to all migrating substances**
- ✓ For NIAS which migrate into foods, **further considerations on genotoxicity** testing e.g.
  - Oligomer: "read-across" from monomers, hydrolysis
  - NIAS other than oligomers: computational methods (SAR, QSAR), TTC

# NEXT STEPS

✓ **Stepwise approach agreed with EC**

- **Next step is for EC to set level of protection for consumers**
- As further step, EFSA will prepare a **guidance for submitting an application** followed by public consultation

# THANK YOU FOR YOUR ATTENTION

***Any comments, questions?***

***Let us contribute together to a safe food…***