INFANTS

Feedback on the EFSA SC "Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age"

Laurence Castle

Cross-cutting documents from the SC

The Scientific Committee and the Panels are responsible for providing the scientific opinions of EFSA.

Cross-cutting Guidance Documents are prepared by the Scientific Committee.

- All GDs are public and are valuable resources for risk assessors

Among the 24 GDs available from the EFSA SC, many are particularly relevant to the work of the CEF Panel.

RA for infants aged up to 16 weeks

Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age

SC 2017

RA for Infants < 16 weeks

Considering specificities of the infant population:

- deals both with higher sensitivity

…. (absorption, distribution, organ development, etc.)

- and higher exposure (food consumption)

at age up to 16 weeks.

RA for infants aged up to 16 weeks

In its approach to develop this guidance, the EFSA SC took into account, among others

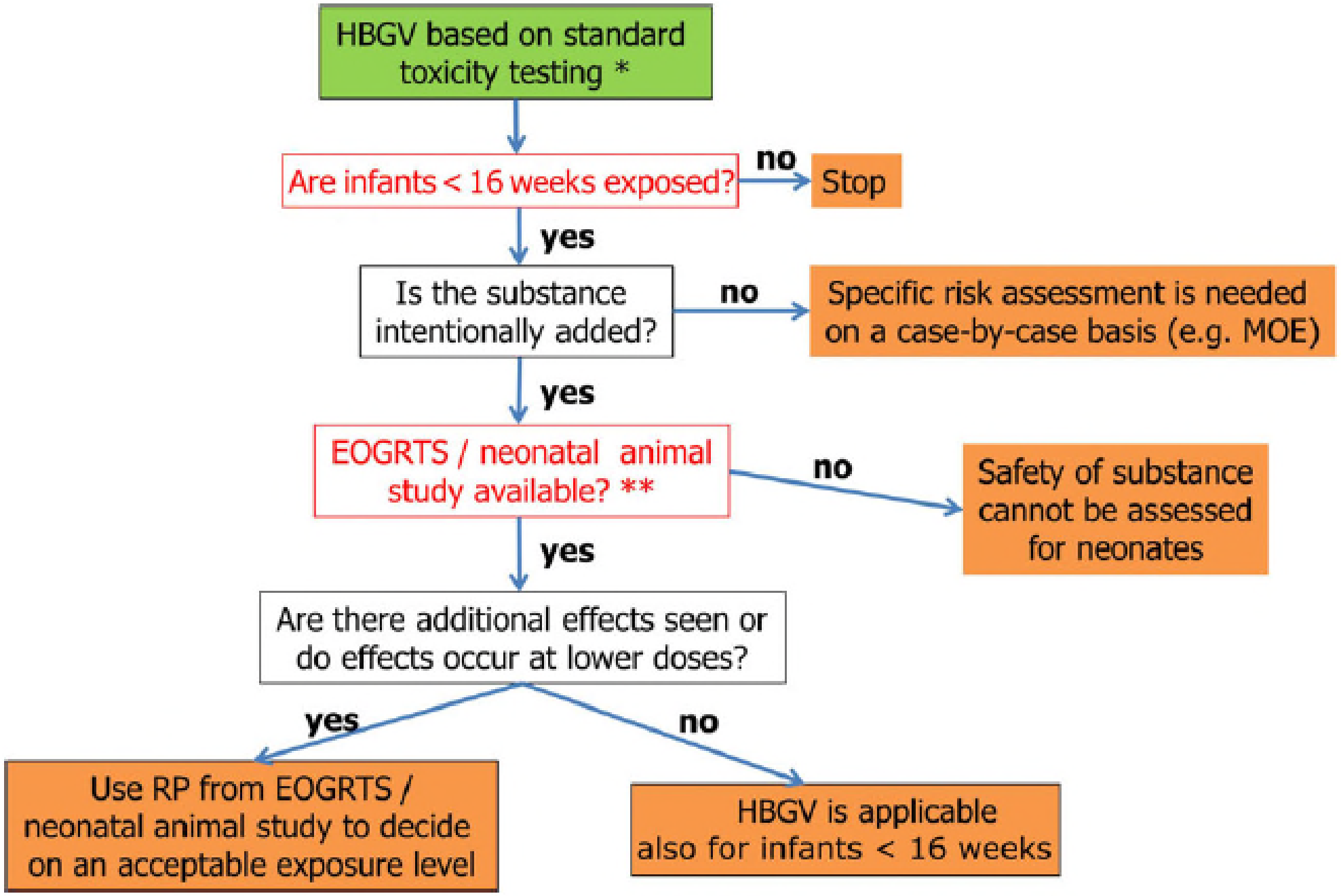
(i) an exposure assessment based on infant formula as the only source of nutrition;

(ii) knowledge of organ development in human infants, including the development of the gut, metabolic and excretory capacities, the brain and brain barriers, the immune system, the endocrine and reproductive systems;

(iii) the overall toxicological profile of the substance identified through the standard toxicological tests, including critical effects;

(iv) the relevance for the human infant of the neonatal experimental animal models used.

Decision tree approach



Data limitations for FCM ?

- The decision tree assumes that a standard risk assessment has already been performed for the substance. The GD notes that 'standard' toxicity testing varies in the different areas within the remit of EFSA.
- EOGRTS - extended one-generation reproductive toxicity study. If the substance is systemically available, neonatal animal study if it is not absorbed from the GI tract and is not systemically available. deviation from guidance is possible if justification is given..

RA for infants aged up to 16 weeks

The EFSA SC views this period as the time where health-based guidance values for the general population do not apply without further considerations.

The EFSA SC notes that during the period from birth up to 16 weeks, infants are expected to be exclusively fed on breast milk and/or infant formula. High infant formula consumption per body weight is derived from 95th percentile consumption. The first weeks of life is the time of the highest relative consumption on a body weight basis.

Therefore, when performing an exposure assessment, the EFSA SC proposes to use the high **consumption value of 260 mL/kg bw per day.**

Consumption scenarios from 2016

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

Relevant FCM applications?

consumption value of 260 mL/kg bw per day?

- **Foodstuffs**: packaged water & infant formula (mostly dried but also liquid RTF)
- **Materials and articles**: kettle (water boiler), bottles for water, baby bottles, teats, ...
- **Substances**: IAS, NIAS, Recycling, ..?

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