

When Risk-Based Approach Doesn't Work: **iAs**

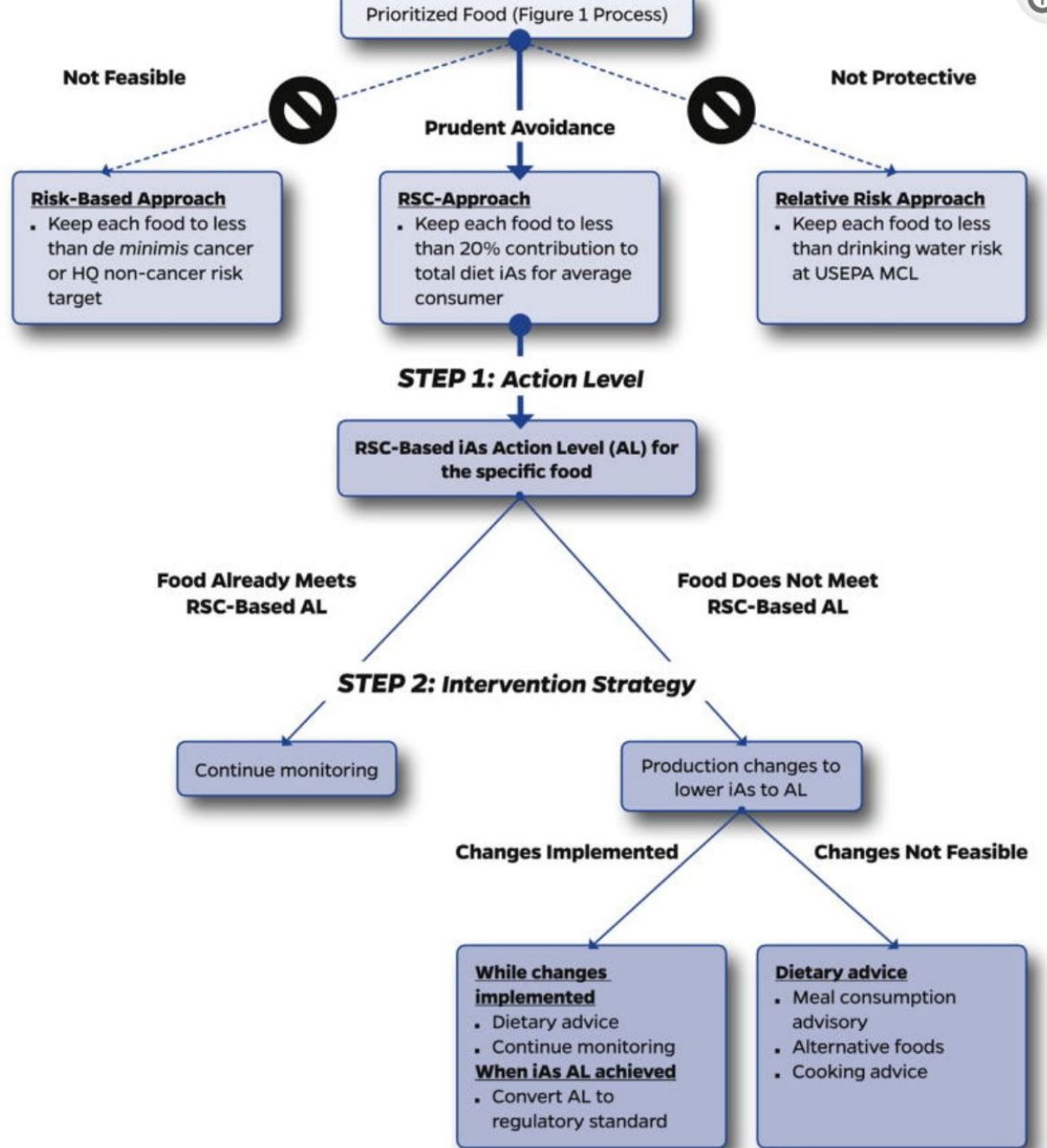
Gary Ginsberg

Food Forum : 09/03/2024

Disclaimer: GG has no conflicts of interest with regards to this presentation

US FDA: Closer to Zero

- Research/Consensus Building/Action Level/Guidance/Implementation
- Arsenic status
 - Dec 2024: Develop draft iAs action level in “foods intended for babies and young children”
 - Dec 2025: Finalize iAs action level and guidance
 - 2016/2020: iAs action level in baby rice cereal of 100 ug/kg
 - FDA cancer risk estimate for 1 year infant exposure = 3.2 to 9.5 E-06
 - 2013/2023: iAs action level in apple juice of 10 ug/L
 - 1 juice box/day for 3-6 yr olds = 7E-05 cancer risk



Nachman et al. 2017, Mitigating dietary arsenic exposure.... Sci Tot Env 581-582: 221-226

Fig. 2

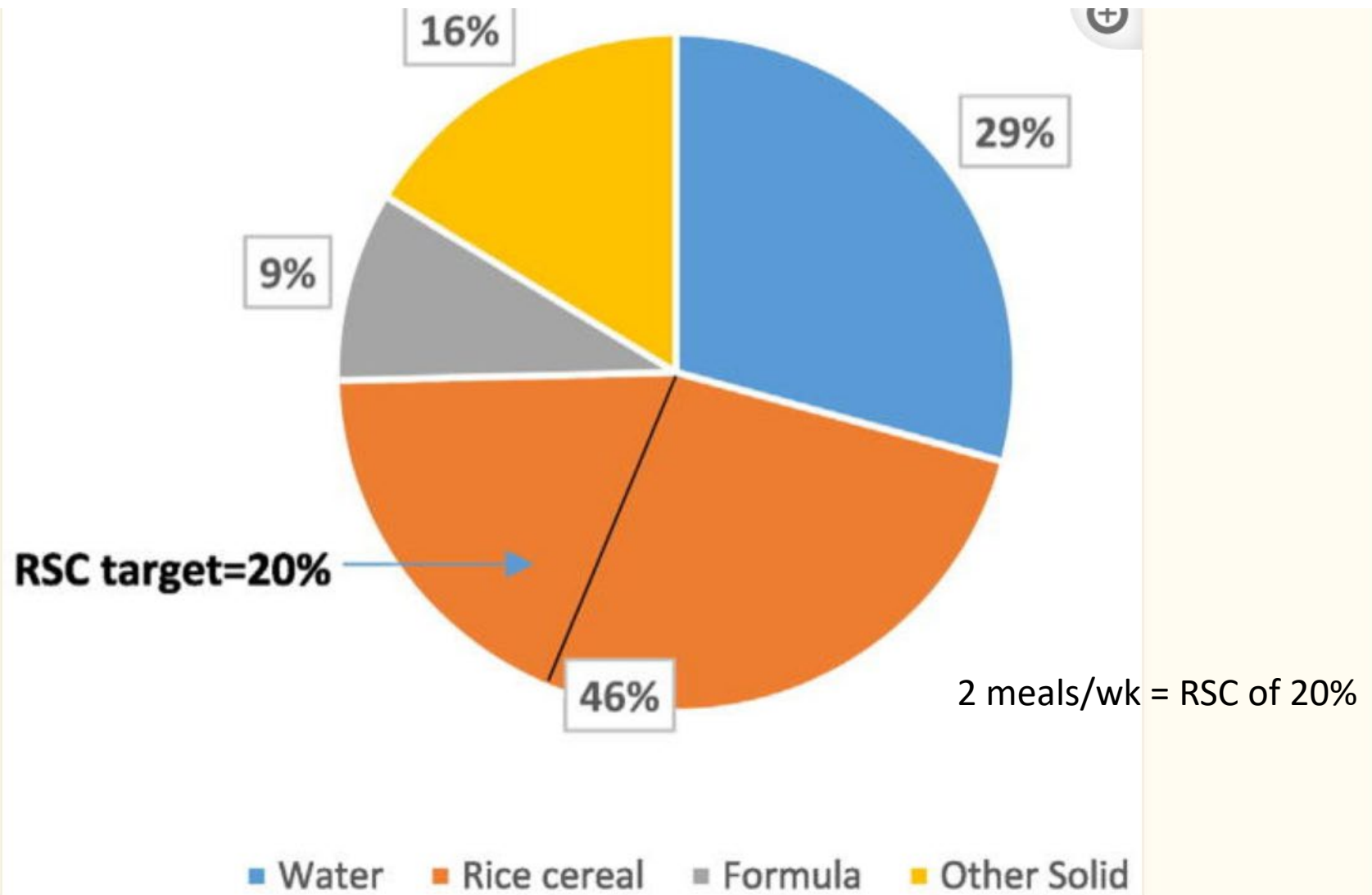


Fig. 3

Inorganic arsenic pathways analysis in 6–8 month old infants. (Adapted from [Shibata et al., 2016](#).)

RSC Approach for Apple Juice

- 2-6 yr old dietary iAs = 4.5 – 9 ug/d (Tao and Bolger 1999; Yost et al. 2004)
- 1 juice box/d at 10 ug/L = 2 ug/d
- Apple juice contributes 20-40% of daily dose, > RSC
- Options: consider whether lowering action level feasible
 - Consumption advisory: reinforce AAP recommendations
 - < 1 yr – no fruit juice
 - 1-3 yr – 4 oz/d
 - 3-6 yr – 6 oz/d

Summary

- Food contaminants for which risk-based targets are not attainable
 - Consider action level based upon RSC approach
 - Where RSC-based action level can't be attained
 - Consider guidance/advisories that limit daily ingestion rate
 - Benefits
 - Lower exposures to high risk foods at vulnerable life stages
 - Encourage industry to produce lower iAs products
 - Concerns
 - Compliance with food advisories always an issue
 - Some ignore the advice
 - Some over react to advice
 - Fairness to foods targeted for advisories – how prioritized?
 - Are there good alternatives