



# ASSESSMENT OF EXPOSURE FROM EFSA OPINION (2016)\*: ANY NEW DATA THAT CHALLENGES THE PROPOSED APPROACH?

## WITH A FOCUS ON THE SA:V RATIO

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\*Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA CEF Panel Opinion 2016

## UPDATING THE SA:V RULES?

SLIDE 2

Abstract: This presentation will focus on aspects of the surface area-to-volume considerations that go into the calculations behind estimates of exposure. It will cover those aspects described in the 2016 EFSA CEF Panel Opinion “Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials”. It seems likely that any updating of the assumptions and rules on SA:V is more important for materials and articles used in industry than for ‘retail’ food packaging plastics. The short presentation does not bring new data to the table but aims to promote the discussion amongst network members.



## UPDATING THE SA:V RULES?

SLIDE 3

Article 17 of the Plastics Regulation (consolidated 2013)

... For M/A containing less than 500 mL (g), or more than 10 litres, or where the SA/V ratio intended cannot be estimated, the migration value shall be expressed in mg/kg applying the default surface to volume ratio of 6 dm<sup>2</sup> per kg of food.



## UPDATING THE SA:V RULES?

SLIDE 4

Rationale was provided in the 10/2011/EC original version

“Art.(33) When testing articles not yet in contact with food, for certain articles, such as films or lids, it is often not feasible to determine the surface area that is in contact with a defined volume of food. For these articles specific rules should be set out for verification of compliance.

Art.(34) The setting of migration limits takes into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm<sup>2</sup> surface area releasing the substance. For very small and very large containers the real surface area to volume of packaged food is varying a lot from the conventional assumption. Therefore, their surface area should be normalised before comparing testing results with migration limits. These rules should be reviewed when new data on food packaging uses become available.



## UPDATING THE SA:V RULES?

SLIDE 5

What information do we have / do we assume on food packaging use \*

- the actual/assumed SA:V of 'packaged' food on the market
- the conventional assumption that 1 kg of 'packaged' food is consumed daily by a person of 60 kg body weight.

\* In fact, the SA:V ratio rules are likely to be more important for M&A used in- and by- industry (hoses, conveyor belts, machinery parts, large vessels etc) than for packaging used for food sold to the consumer.



## UPDATING THE SA:V RULES?

SLIDE 6

EFSA 2016. Section 6.2.2. The ratio of food mass to contact area  
the SA:V ratio is in many cases higher than 6 dm<sup>2</sup>/kg (VKM, 2009).  
the average ratio was 11.7 for the diet of the general population in Portugal (Poças et al., 2009),  
for infants (<12 months) the average SA:V was less than 6 due to the large contribution of either breast milk or tap water used to reconstitute infant formula. The average ratio was 8 for children aged 1-4 years and 10 for aged 4-6 years (UK data, Foster et al., 2010)  
The range was 0.8–11.6, 4.2–18.5 and 2.7–20.8 for those 3 age groups. The top end of each range is effectively the 99th percentile, given the survey group sizes.



## UPDATING THE SA:V RULES?

SLIDE 7

### Considerations in EFSA 2016

“Taking high percentiles of consumption of food/beverage potentially in contact with the FCM of interest, and combining them with high percentiles of surface area/mass ratios for such applications, would lead to conservative scenarios that have a low probability of occurring in the population.

High surface area to food mass ratio is observed for foods that are not generally consumed in large quantities on a daily basis.

Even the estimated average surface to mass ratio in the population group of interest may not be appropriate for combining with a high level of consumption, as high consumers of food products are more likely to purchase these products in large pack sizes.



## UPDATING THE SA:V RULES?

SLIDE 8

### Conclusions in EFSA 2016

“Based on high potential consumption of water, milk, beverages and soup, the standard value of 6 dm<sup>2</sup>/kg is an appropriate conversion factor to represent the surface to mass ratio of packaged foodstuffs when these other considerations are also taken into account.

In the case of an FCM intended for specific applications only **and if reliable data were available** then a different surface area/mass ratio along with packaging use factors and other relevant parameters could be justified. For instance, in the case of foods or beverages typically sold in small packages (e.g. snacks and confectionery), this ratio is likely to be significantly higher than 6 dm<sup>2</sup>/kg, whereas for, for example, plastic parts of food-processing equipment, hoses and tubes, etc., it is likely to be significantly lower than 6 dm<sup>2</sup>/kg.



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