

OFCA Position Statement

The trade association representing manufacturers of cellulose derivates (OFCA) responds to the recent study in Nature:

**Dietary emulsifiers impact the mouse gut microbiota promoting colitis and metabolic syndrome.
Nature Letter, B. Chassaing et al., February 2015.**

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A study published in the journal *Nature*¹ alleging that emulsifiers in foods may be altering gut microbiota composition and driving changes that lead to inflammatory conditions and obesity, does not reflect the extensive body of evidence in support of the safety of these food additives.

OFCA does not agree with the interpretation of the results of the study and finds the study difficult to correlate to the use of sodium carboxymethylcellulose (Na-CMC) in food products today.

OFCA has reviewed the article and wishes to make the following points:

1. Substance identification

Carboxymethylcellulose (CMC, free acid) and sodium carboxymethylcellulose (Na-CMC) are two different substances with different CAS numbers. CMC is not a food additive whereas Na-CMC is a food additive (INS 466 / E466). The safety of Na-CMC as a food additive has been extensively studied and evaluated by numerous food safety authorities around the world.

The cellulose product used in the study was sodium carboxymethyl cellulose (source: Sigma Aldrich) with an average molecular weight of 250.000 D. This grade is not equivalent to food grade Na-CMC, i.e E 466 / INS 466, and would not normally be consumed.

2. Safety of Sodium Carboxymethylcellulose (Na-CMC)

The safety of cellulose and cellulose derivatives as food additives, including Na-CMC, has been extensively evaluated by regulatory bodies including the former EU Scientific Committee on Food² and the WHO/FAO Joint Expert Committee on Food Additives (JECFA)³. These evaluations led to all food grade cellulose ethers being allocated an Acceptable Daily Intake (ADI) of “not specified”. This means that Na-CMC, when used as a food additive at normal use levels, will not have adverse effects on human health at any point in a person’s life, even if consumed daily.

In the US, the Food and Drug Administration’s Select Committee on GRAS substances⁴ concluded: “There is no evidence in the available information on sodium carboxymethylcellulose that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future.”

3. Extrapolation to human gastrointestinal gut

The human gut hosts a large variety of microbial species. The article provides no demonstration or reference to show that the human gut flora is similar to that of the mouse, nor any verification that data from the mouse gut flora can be extrapolated to that of the human population. Different microbial species in the gut have different resistance/tolerance and so the effect seen in the mouse model cannot be directly compared with the human gut without further data.

4. Methods used in the study

Based on the available information, methods could not be properly assessed.

The major methodological issues include:

- A lack of proper control groups in both the water- and food-exposed studies. In both cases, food and water intake was significantly increased resulting in increased body weights.
- No attempt was made to address the impact of increased caloric intake on intestinal flora and no corresponding control for increased water consumption.
- Water intake methods are not described and food intake measurements did not appear to be taken daily throughout the study but one day per week for only three weeks.
- Individual food and water intake cannot be determined for group-housed animals and thus neither can individual exposures. Relative food intake figures do not explain how the food intake was normalised.

The administration of Na-CMC in drinking water is not a typical use; Na-CMC is added to food as a functional additive. There will be different interactions with the gut microflora based on whether the Na-CMC is administered via water, admixed in rodent food or both.

The concentration, duration and form of the Na-CMC administered is highly unrealistic. Any constituent of the human diet when administered to that magnitude in similar unnatural conditions would be expected to have an impact on the body.

The exposures and methodology used in the study are not sufficient to conclude that the findings are relevant to the human population.

5. Extrapolation to human consumption of Na-CMC

No levels of water consumption are provided, therefore, comparison of the actual exposure of the water-treated group to human exposure is impossible. However, extrapolation using generic water consumption values and body weight (20g mouse body weight and 5 ml water intake/day) provides an estimated 2500 mg/kg exposure to Na-CMC.

In reference 5, Gray attempts to estimate the relative level of Na-CMC consumption in a human of 60kg (132lb). The calculation assumes that 150g of Na-CMC are consumed daily for 12 weeks. The quantity of food that this 150g daily intake represents can be calculated using the typical level of Na-CMC that is added to the food.

The 150g daily intake is unrealistically high because it represents a daily consumption of:

- 75kg (165lb) of ice cream at 0.2% Na-CMC
- 50kg (110lb) of bread at 0.3% Na-CMC
- 30kg (66lb) of yogurt drink at 0.5% Na-CMC
- 150litres (40 US gallons) of beverage at 0.1% Na-CMC
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and assumes that this consumption level is continued for 12 weeks (84 days). These calculated levels are around 100x the maximum normal consumption of these foodstuffs.

These high and prolonged exposure rates of Na-CMC as administered to mice in the subject study are outside the realm of human experience. As such, these exposures should not be used to draw broad conclusions about the presence of emulsifiers in food and their role in the promotion of specific inflammatory diseases and obesity in humans.

6. References

- 1 Dietary emulsifiers impact the mouse gut microbiota promoting colitis and metabolic syndrome; doi:10.1038/nature14232, 25 February 2015
- 2 SCF reports_Re-evaluation of five modified celluloses (March 1992)
- 3 WHO Food Additive Series 26. 687. Modified Celluloses
- 4 Select Committee on GRAS Substances (SCOGS) Opinion:
Carboxymethylcellulose
<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/SCOGS/ucm261244.htm>
- 5 N. Gray in "Food Navigator", 26 February 2015
<http://www.foodnavigator.com/Science/Food-emulsifiers-linked-to-gut-bacteria-changes-and-obesity>

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