Risk assessment of formaldehyde present in food and drinking water

Formaldehyde occurs naturally in the environment and is ubiquitous in the environment. Formaldehyde occurs in very low levels in water as it is rapidly hydrated and therefore, predominantly is found as methylene glycol. Formaldehyde occurs naturally in food. Reported background levels vary considerable. Formaldehyde can also occur in food if released from melamine resin food contact materials. Being very reactive, formaldehyde is essentially present in food bound reversibly and irreversibly to different constituents. In humans, as in other animals, formaldehyde is an essential metabolic intermediate in the physiological one-carbon pool (central to many biological processes).

The general population is exposed to formaldehyde from many sources. The European Food Safety Authority has estimated that the contribution of formaldehyde from food does not exceed 100 mg/person/day. Drinking water is only a minor source of exposure.

The critical effects of formaldehyde following repeated oral exposure are considered to be the non-neoplastic histopathological changes observed in the forestomach and stomach (erosion, ulceration, inflammation and hyperplasia, most likely due to the irritative potential of formaldehyde) in experimental animals (long term studies drinking water). A NOAEL of 260 mg/l is considered.

Formaldehyde is genotoxic, with effects observed in vivo in cells from first site of contact tissues (i.e. nasal tissue); however, there is no evidence of genotoxicity locally in the gastro-intestinal tract. The weight of evidence indicates that formaldehyde is not carcinogenic by the oral route.

A tolerable concentration of formaldehyde in drinking water is estimated to 30 mg/l (rounded value) based on the NOAEL of 260 mg/l and assessment factors of 2.5 and 3.2 for interspecies and inter-individual variability, respectively, in toxicodynamics. Based on this tolerable concentration and an estimated (worst-case) concentration of formaldehyde in drinking water of 30 μg/l, no risk for adverse effects from intake of formaldehyde in drinking water is identified.

Based on the available data, a tolerable concentration of formaldehyde in food cannot be estimated. Therefore, the risk for adverse effects from intake of formaldehyde in beverages and foods could not be evaluated.