

DFG Senate Commission on Food Safety

SKLM

Science Communication

**Acetaldehyde as Flavouring Substance:
Need for Re-evaluation**

Published: 29th May 2024

German Research Foundation (Deutsche Forschungsgemeinschaft – DFG)

Kennedyallee 40 • 53175 Bonn

www.dfg.de/sklm

DFG

Summary

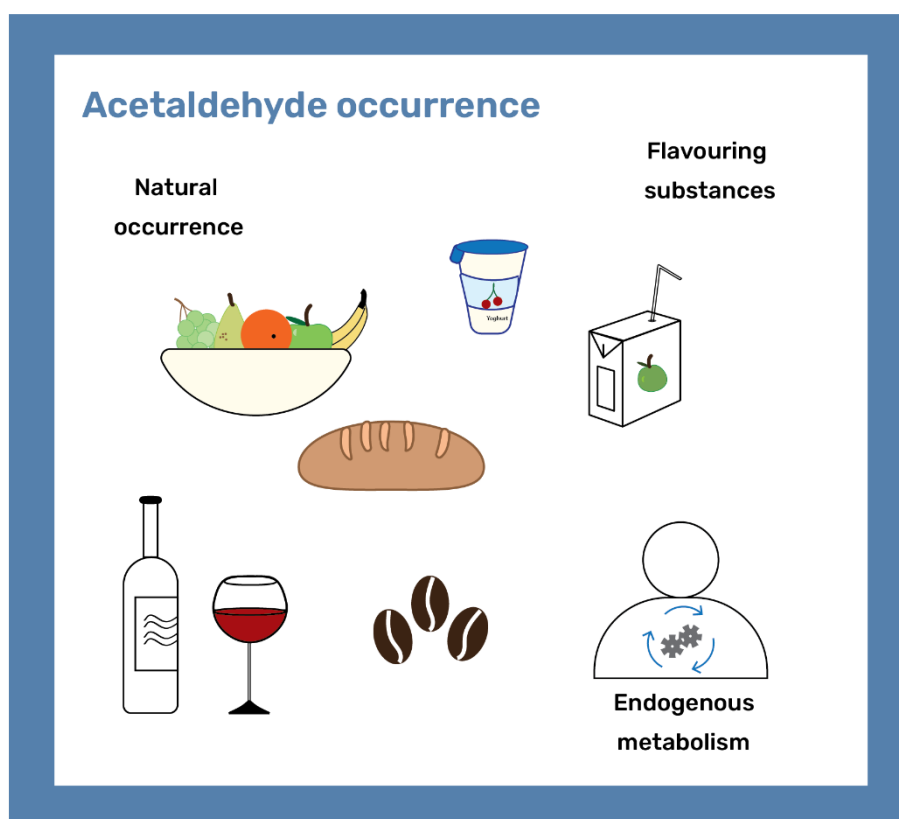
Acetaldehyde occurs naturally in many foods, but is also used as a flavouring agent because of its fruity aroma. Due to emerging concerns about the potential carcinogenicity of acetaldehyde, the Senate Commission on Food Safety (SKLM) of the German Research Foundation (Deutsche Forschungsgemeinschaft - DFG) has reviewed the currently available data to assess the health risk of using acetaldehyde as a flavouring agent and has outlined the results in a scientific opinion^{1,2}. Because of data gaps and the resulting uncertainties, the SKLM expressed concerns regarding the safety of acetaldehyde as a flavouring substance for human health. For reasons of precautionary consumer protection, the use of acetaldehyde as a food additive should be re-evaluated.

¹ Hengstler JG, Baum M, Cartus AT et al. Stellungnahme zu Acetaldehyd als Aromastoff: Aspekte der Risikobewertung. *J Consum Prot Food Saf* (2022)17, 285–293. doi: 10.1007/s00003-022-01386-w

² Cartus AT, Lachenmeier DW, Guth S et al. Acetaldehyde as a Food Flavoring Substance: Aspects of Risk Assessment. *Mol Nutr Food Res* (2023) 67(23): e2200661. doi: 10.1002/mnfr.202200661

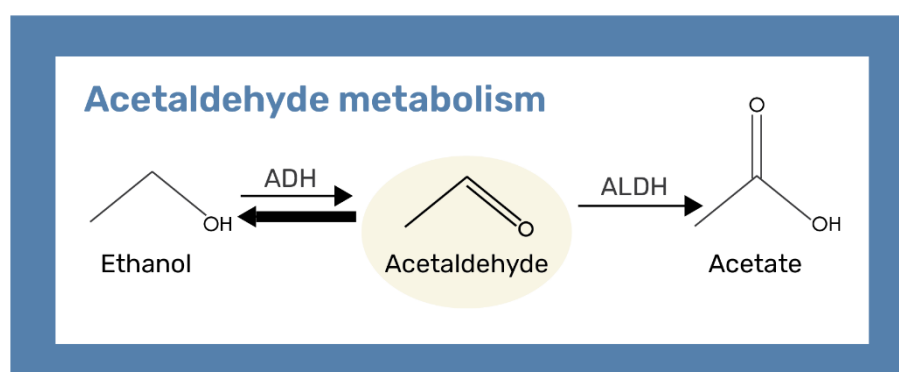
Occurrence of acetaldehyde

Acetaldehyde occurs in numerous foods either naturally and/or due to its use as a flavouring agent. Since acetaldehyde is a component of flavouring mixtures and does not require separate labelling on food packaging, it appears as the ingredient “flavouring” within a collective group designation, without specifying concentrations. Therefore, a quantitative estimate is not possible based on the declaration of the foodstuffs. In addition, acetaldehyde occurs in alcoholic beverages as a by-product of alcoholic fermentation. The main sources of exposure to acetaldehyde include tobacco smoke, alcoholic and non-alcoholic beverages, as well as foodstuffs such as coffee, bread, fruits and yoghurt.



Acetaldehyde is also formed in the human body during the degradation of ethanol. In addition, it occurs endogenously as a result of human metabolism and can also be formed by microorganisms of the oral cavity and the gut. As yet, data on endogenous

acetaldehyde formation are limited and therefore reliable estimates of total endogenous exposure to this substance are not available. In the organism, acetaldehyde is converted to ethanol by the enzyme alcohol dehydrogenase (ADH), and to acetic acid by aldehyde dehydrogenase 2 (ALDH2). For both enzyme groups, several gene variants can occur within a population (so-called “polymorphisms”), which leads to interindividual differences in the formation and degradation of acetaldehyde.



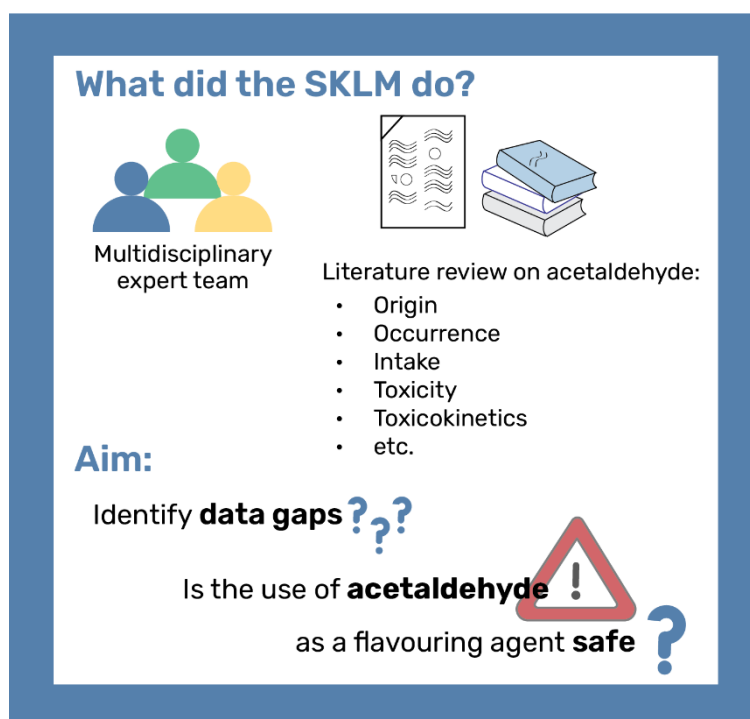
Current regulations

Currently, acetaldehyde is included in the list of flavouring substances that may be used in or on foodstuffs in the European Union (EU) and has the “Generally Recognized as Safe” status (“GRAS”) in the USA. However, since the International Agency for Research on Cancer (IARC) classified acetaldehyde as possibly carcinogenic to humans and, in combination with oral intake via alcoholic beverages, as a human carcinogen, concern has been raised on whether the addition of acetaldehyde to foodstuffs is safe and still justifiable.

In 2010, the Commission on Food Additives, Flavourings and Processing Aids (LAV Commission) of the Federal Institute for Risk Assessment (BfR) already evaluated the safety and risks of acetaldehyde³. Based on the available data at that time, it was not possible to conclusively assess the safety of acetaldehyde as a flavouring substance.

³ Commission on Food Additives, Flavourings and Processing Aids (LAV Commission) of the Federal Institute for Risk Assessment (BfR) (2010). https://www.bfr.bund.de/de/a-z_index/acetaldehyd-51028.html

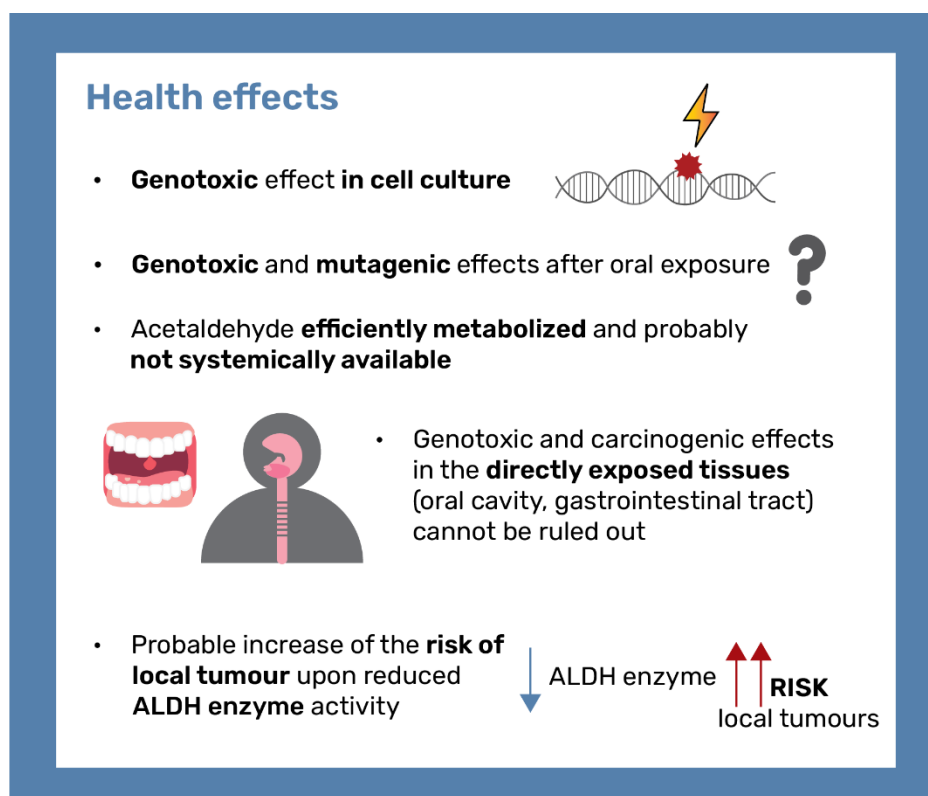
A multidisciplinary group of experts of the SKLM reviewed the current state of knowledge concerning the origin, occurrence, intake/exposure and potential health hazards of acetaldehyde. The aim was to identify knowledge gaps that need to be filled for a scientifically sound risk assessment.



Carcinogenic effects cannot be ruled out

Acetaldehyde has a genotoxic effect in cell culture as well as in animals after inhalative acetaldehyde exposure, but also after oral administration of ethanol. In various animal and cell culture studies, dose-dependent binding of acetaldehyde to DNA was observed. By contrast, data on the carcinogenicity of acetaldehyde after oral intake without concurrent intake of ethanol are limited and do not allow a conclusive answer to the question of whether acetaldehyde is genotoxic and mutagenic after oral exposure.

Since acetaldehyde is efficiently and rapidly metabolised in the liver and intestine after oral intake, it appears unlikely that it becomes systemically available at higher concentrations. Yet, a genotoxic and carcinogenic effect on directly exposed tissues (upper airways, oral cavity, gastrointestinal tract, especially oesophagus) cannot be ruled out, based on the current state of knowledge.



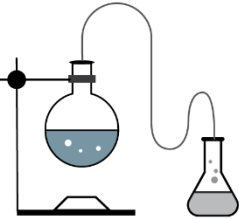
Acetaldehyde exposure: data are lacking


Another uncertainty concerns the exposure resulting from daily intake of acetaldehyde as a flavouring substance. For instance, there are no detailed and up-to-date exposure estimates because acetaldehyde does not have to be specifically and quantitatively declared in food and systematic chemical analyses of the most important food groups are lacking.


Furthermore, analytical data do not allow to distinguish the source (flavouring agent, transfer from packaging materials or natural occurrence) of the measured acetaldehyde levels.

Acetaldehyde exposure

- Standardised **analytical methods** to determine acetaldehyde needed
- Not possible to discern between **naturally occurring** and **added** acetaldehyde in food



- No specific **labelling** of acetaldehyde: only as "**flavouring substance**"
- Acetaldehyde **intake** from its use as a **flavouring substance unknown**
- Acetaldehyde **formation in the organism** 



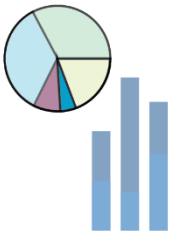
Moreover, data on endogenous acetaldehyde formation are scarce and there is a need for reliable estimates of the endogenous exposure to this substance. Therefore, it is presently not possible to reliably estimate the contribution to overall exposure from the use of acetaldehyde as a flavouring substance, compared to the intake via natural occurrence in food and to the endogenous background exposure. Thus, a conclusive scientific assessment of the health risk associated with the use of acetaldehyde as a flavouring substance is currently not possible.

Future research needs for a comprehensive risk assessment


In order to carry out a comprehensive risk assessment, more research on several aspects is needed. For example, analytical methods to perform systematic chemical analyses of acetaldehyde levels in major food groups should be standardised. Likewise, biomarker studies monitoring exposure to acetaldehyde from foodstuffs, specially to detect effects in the upper digestive tract, are necessary. It should also be clarified whether genotoxic/mutagenic effects following oral acetaldehyde ingestion may also occur.

Data gaps and research needs

- Need for up-to-date **exposure** assessment
- **Genotoxicity** and **mutagenicity** unclear
- Need for **toxicokinetic** studies
- Need for **biomarkers** to allow distinction between acetaldehyde formed in the organisms and added acetaldehyde



- Need for standardized **analytical methods** to determine acetaldehyde
- Need for **chemical analyses** of acetaldehyde in most relevant food groups



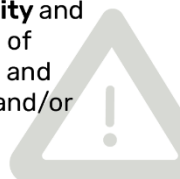
SKLM conclusions: re-evaluation of acetaldehyde needed

Altogether, due to the present knowledge gaps and ensuing uncertainties, especially concerning a potential genotoxic/mutagenic effect of orally ingested acetaldehyde, the SKLM expressed concerns about the safety of acetaldehyde as a flavouring substance.

The SKLM recommends that the use of acetaldehyde as a food additive should be re-evaluated for reasons of precautionary consumer protection.

Acetaldehyde re-evaluation needed

Due to **insufficient toxicokinetic, toxicity and exposure** data regarding the oral intake of acetaldehyde as a flavouring substance and **uncertainties** regarding its **genotoxic** and/or **carcinogenic** hazard potential, **health concerns** cannot be ruled out.



SKLM concludes:

For reasons of **precautionary consumer protection** the scientific basis for approval of the intentional addition of acetaldehyde to food as a **flavouring substance** should be **re-evaluated**.

