PETRA

PET Resin Association

ISSUE: DO ACETALDEHYDE AND FORMALDEHYDE FROM PET BOTTLES RESULT IN UNACCEPTABLE FLAVOR OR AROMA IN BOTTLED WATER?

BACKGROUND: Since the 1970's, PET has been accepted by regulatory authorities all over the world as a safe food-packaging material. Although the safety of PET food containers has been convincingly demonstrated over three decades, some concern has been raised recently about the potential influence of acetaldehyde or formaldehyde, PET decomposition products, on the organoleptic properties (taste and aroma) of PET bottled water. Concerns have been raised that these aldehydes migrating from PET bottles might impart a flavor to the water that would be detected by consumers[1 - 4] and judged to be deterioration in the organoleptic characteristics, thereby rendering the package out of compliance with European Community and U.S. Food and Drug Administration (FDA) regulations.

THE SCIENCE: All polyesters undergo some degree of thermal degradation, both during the polymerization stage and in processing into bottles, leading to formation of acetaldehyde[5, 6] and, to a much lesser extent, formaldehyde. The presence of both acetaldehyde and formaldehyde in foodstuffs from the use of plastics packaging has been thoroughly evaluated and regulated. In 1998, the Scientific Committee for Food (SCF, now the European Food Safety Authority (EFSA)) established a Tolerable Daily Intake (TDI), - a level considered to be safe - for acetaldehyde of 0.1mg/kg body weight.[7] Based on this TDI, which includes a safety factor of at least 100, the SCF has established a specific migration limit (SML) for migration of acetaldehyde from plastic packaging of 6 mg/kg. Maintaining migration of acetaldehyde below this level will assure that exposure will be will under the Tolerable Daily Intake. This European SCF SML has been implemented in legislation by Directive 1999/91/EC. Similarly, formaldehyde was regulated by Directive 90/128/EEC with an SML(T)=15 mg/kg. Reported maximum levels of acetaldehyde and formaldehyde in PET bottled water are far below these threshold limits.[1,2]

Several factors, mainly carbonation of the water, influence both aldehyde migration behavior and the detection threshold. Actually detecting such low levels in water becomes extremely difficult, either by the currently available analytical techniques or by human perception.[4]

Although levels that are detected to date by trained organoleptic experts vary considerably, the water industry generally recognizes 20-40 ppb as the taste/odor threshold for acetaldehyde.[1, 2] Other than highly trained experts and rare individuals with a highly discriminating sense of taste, the slight fruity – non-objectionable - flavor from the trace amount of acetaldehyde in water in PET bottles cannot be detected by most consumers. The level at which an average consumer could detect acetaldehyde is still considerably lower than any toxic amount. Since consumers are generally less sensitive to any organoleptic shift, any additional regulation or restriction on the use of PET due to "*deterioration in the organoleptic characteristics*" is unwarranted.

ALDEHYDES HEALTH HAZARD RISK ASSESSMENT: Acetaldehyde toxicology has been thoroughly tested and is well understood. The weight of evidence has resulted in the view that acetaldehyde at high concentrations can be an irritant at the site of contact. Although long-term exposure to irritant concentrations can lead to irreversible changes, at lower doses in the absence of irritancy, no toxic effects are noted. The Scientific Committee for Food (SCF) has expressed a similar opinion.[7]

Acetaldehyde is a natural constituent of many foods and drinks and is present in many ripe fruits e.g., apples, grapes and citrus fruits at levels up to 230 ppm. [8] It is produced during the fermentation of sugar to alcohol, and is a natural constituent of butter, olives, frozen vegetables and cheese. It forms in wine and other alcoholic beverages up 140 ppm after exposure to air. It even occurs as an intermediate in the decomposition of sugars in the body and hence can be found in traces in blood. As an FDA-approved flavor ingredient, it can be found in ice creams, sweets, baked goods, chocolates, rum and wine. The potential intake of acetaldehyde from a typical Western diet is estimated to be approximately 50 - 200 mg per day.[9] These levels are efficiently and rapidly assimilated in the human body. The normal intake level is well below a threshold for irritancy. Acetaldehyde from PET bottles constitutes a minor contribution (less than 0.5%) to the overall intake from foods.

Formaldehyde is still the subject of scientific debate regarding its potential health effects. Recently the International Agency for Research on Cancer (IARC) has reclassified formaldehyde to a 1 (carcinogenic to humans), based exclusively on inhalation by workers who had been exposed to high levels of formaldehyde for decades.[10] Studies such as this of exposure by inhalation are of doubtful value in assessing potential health effects from ingestion. In assessing the carcinogenicity of formaldehyde present as an impurity in a food additive, FDA concluded that "…. there is no basis to conclude that formaldehyde is a carcinogen when ingested".[11]

Like acetaldehyde, formaldehyde is present in almost all foodstuffs at concentrations greatly in excess of those sometimes found in PET bottled water, and like acetaldehyde, it is also naturally present in the human body as part of the normal metabolic processes.[12] The contribution of formaldehyde from PET bottles to the total amount naturally present in the body is insignificant and would not lead to any measurable increase.[13]

Conclusion:
The trace amounts of acetaldehyde and formaldehyde that may migrate to water from PET bottles are below levels that can be detected by most consumers and do not present any risk of harm. PET water bottles are in full compliance with European Community and FDA regulations.

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QUESTIONS CONCERNING PET AND ALDEHYDES

Do bottles made from PET contain acetaldehyde and formaldehyde?

Yes. All PET food containers such as water bottles contain trace (parts per million) amounts of acetaldehyde and lesser amounts of formaldehyde. These aldehydes are unavoidable byproducts or decomposition products of PET manufacture and bottle fabrication. Proper manufacturing conditions minimize the formation of these aldehydes.

Can acetaldehyde or formaldehyde migrate to water bottled in PET bottles?

Yes. But only very small amounts of these aldehydes may migrate to water packaged in PET bottles.

Can acetaldehyde and formaldehyde be found in places other than PET bottles?

Yes. Acetaldehyde and formaldehyde are naturally occurring substances that are found in foods at much higher levels than would be present in PET or in water packaged in PET bottles. Foods that contain acetaldehyde include many ripe fruits e.g., apples, grapes and citrus fruits at levels up to 230 ppm. It is produced during the fermentation of sugar to alcohol, and is a natural constituent of butter, olives, frozen vegetables and cheese. It forms in wine and other alcoholic beverages up 140 ppm after exposure to air. Acetaldehyde and formaldehyde are also formed in the body when certain foods are digested. For example, alcohol is converted to acetaldehyde in the body.

Do the acetaldehyde or formaldehyde that migrate to bottled water affect the taste of the water?

For a few individuals with highly developed olfactory senses, yes. The amount of aldehydes present in bottled water is generally well below the level that can be detected by average consumers. Highly trained taste specialists at times can detect the faint fruity taste conferred to the water by these aldehydes.

Are the acetaldehyde or formaldehyde that migrate to bottled water harmful to health?

No. The amount of acetaldehyde and formaldehyde that may migrate to the water is well under the “tolerable daily intakes” (safety limits) established for these materials by the European Scientific Committee for Food and other regulatory bodies.

Do PET water bottles comply with food packaging regulations in Europe and the US?

Yes. PET water bottles made using good manufacturing practices comply in all respects with food packaging regulations in Europe and in the US.