# The Biotappo: A New Tool For Food Safety And Consumers' Protection

Maria Anna Coniglio<sup>1</sup>, Cristian Fioriglio<sup>2</sup>

<sup>1</sup>Department of Medical, Surgical Sciences and Advanced Technologies "G.F. Ingrassia", University of Catania, Italy.

<sup>2</sup> General Prevention and Public Aid Office, Police Headquarters, Catania, Italy.

**ABSTRACT:** Among the plastics commonly used for bottled water and other non-alcoholic refreshment beverages, polyethylene terephthalate (PET) is the most favorable packaging material. Monitoring of the temperatures to which PET-bottled waters are exposed during transportation and/or storage may be crucial in predicting the migration of NIAS (non-intentionally added substances) from PET to water or other beverages. For PET-bottled water and other beverages the monitoring program of the temperature made up of a physical measurement is not easy to perform and sometimes it is even impossible. On the contrary, visual observations of the bottles could provide information in a time frame that allows the stakeholder to take action if an out of control situation occurs. A new tool specifically aimed at monitoring the critical limit for the temperature to which PET bottles are exposed is the BioTappo. The BioTappo is an acrylic, white cap. The top of the cap is covered with a special paint which, when exposed to high temperatures changes its color. The BioTappo could be useful to identify at what steps in the process – transportation and/or storage - the controls should be applied to prevent or eliminate the hazards that have been identified.

**KEYWORDS:** Biotappo, Consumers' protection, Food Safety, HACCP, Water

## I. INTRODUCTION

Data on the increase of bottled water consumption raise concerns over water quality and the packaging material. In fact, the statistics show that by 2017, people all over the world are expected to consume about 391 billion liters of bottled water [1]. At the moment, bottled water quality is subjected to intensive investigation in many countries worldwide in order to evaluate its suitability for human consumption. In the US, bottled drinking water is regulated by the U.S. Food and Drug Administration (FDA), which has set Current Good Manufacturing Practices specifically for bottled water. In Europe, the EU Regulation No. 1935/2004 [2] and the EU Regulation No. 10/2011 [3] set out general principles of safety and inertness for all Food Contact Materials (FCMs) and rules on the composition of plastic FCMs, respectively.

Among the plastics commonly used for bottled water and other non-alcoholic refreshment beverages, polyethylene terephthalate (PET) is the most favorable packaging material due to its chemical and physical stability, its transparency, light weight and good recyclability. PET is also a polymer with very few additives used for its manufacture [4]. Nonetheless, NIAS (non-intentionally added substances) which may be cancerogenic or toxic chemicals substances or which may have potential estrogenic and/or anti-androgenic activities can be found in the final plastic material, due to complex formulations of polymers, processes and storage [5].

The effect of storage temperature and sunlight on PET has been studied extensively in many countries, showing that high temperature and sunlight influence the rate and magnitude of leaching of organic and inorganic compounds from PET bottles. Thus, monitoring of the temperatures to which PET-bottled waters are exposed during transportation and/or storage may be crucial in predicting the migration of NIAS from PET to water or other beverages.

This paper is aimed at the presentation of the BioTappo, a new, special bottle cap for the control of exposure of PET-bottled waters to high temperatures.

## II. MAIN STUDIES ABOUT THE EFFECT OF HIGH TEMPERATURES ON THE RELEASE OF NON-INTENTIONALLY ADDED SUBSTANCES (NIAS) IN PET-BOTTLED WATERS

Several studies have shown that PET contains detectable amounts of acetaldehyde, which has multiple mutagenic effects [6,7] and which is able to migrate from bottle walls to the water itself. For carbonated waters, high storage temperature along with high pressure of the carbonated waters or low pH of waters seem responsible for higher concentration of acetaldehyde [8]. Linssen et al. (1995) showed that under high temperature the contents of acetaldehyde found in carbonated mineral water and lemonades ranged between 11 ng/ml and 7447 ng/ml, while the contents of acetaldehyde in the PET packages ranged from 1.1  $\mu$ g/g to 3.8  $\mu$ g/g [9]. Finally, Al Rayes et al. (2012) showed that PET exposure to sunlight during 5 months increased the migration of formaldehyde and acetaldehyde. Similar migration increase was observed when the samples were incubated at 40°C during 10 days [10].

High temperature storage can also be responsible for the migration of antimony (Sb) from PET into beverages [11]. Antimony is a cumulative toxic element with unknown biological functions. The International Agency for Research on Cancer (IARC) has reported evidence of the carcinogenicity of antimony in experimental animals. In water, the presence of antimony may be the result of leaching from packaging or from the bottling process [12]. According to the EU Directive 2005/79/EC18, a specific migration limit (SML) of 0,04 mg Sb/kg has been set for packaged food [13]. Nonetheless, it has been shown that the residual antimony content in PET may vary between 0,1 and 216,5 mg/kg and that the extent of antimony leaching from the PET recipients can vary between 0,3 and 1,6  $\mu$ g/L due to storage condition and time, temperature, illumination, bottle volume, with temperature over 70°C being the most important factor contributing to the release of antimony [14].

Benzene is an aromatic hydrocarbon widely used as an intermediate in the chemical industry for manufacturing of polymers [15]. Thus, it can enter foods in many ways, including by means of packaging materials. Benzene is classified by the International Agency for Research on Cancer (IARC) as a human carcinogen and consumption of contaminated foods and water play an important role in the human exposure. It is known that benzene can form when benzoate is decarboxylated in the presence of ascorbic acid and some transition metals (e.g. Cu and Fe) [16]. Benzoate and ascorbic acid are widely used as preservatives and antioxidants, respectively, in nonalcoholic beverages but they may also occur naturally in foods [17]. It has been demonstrated that the exposure to heat and UV light of beverages (e.g. cranberry juice) that contain benzoate salts and ascorbic acid accelerates the production of benzene. In particular, Nyman et al. (2010) demonstrated that PET bottles stabilized with a UV light filter reduced benzene formation in beverages containing orange juice only marginally and that benzene formation was high in samples heated to 40°C, indicating that the exposure of PET to the sunlight and high temperatures increases the level of benzene in beverages naturally containing benzene precursors [18].

High temperatures along with CO2 may also increase the presence in PET-bottled waters of formaldehyde and 2,4-di-tert-butylphenol, a degradation compound of phenolic antioxidants, as well as an intermediary monomer, bis(2-hydroxyethyl)terephthalate [12]. Although none of these compounds are on the positive list of EU Regulation No. 10/2011, their presence indicates leaching of non-desired, unexpected compounds from PET bottles [3].

Finally, high temperatures may play a role also in leaching of phthalates from PET bottles into the water and other beverages. This evidence my pose severe risks for public health because a growing literature links many of the phthalates with a variety of adverse outcomes for humans, including increased adiposity and insulin resistance [19], as well as decreased levels of sex hormones [20].

### III. METHODS

A new tool specifically aimed at monitoring the critical limit for the temperature to which PET bottles are exposed is the BioTappo. The BioTappo (designed by Dott. Cristian Fioriglio, 2016) is an acrylic, white cap. The top of the cap is covered with a special paint which, when exposed to high temperatures changes its color. At the moment, two different prototypes have been designed and controlled with different laboratory assays in order to verify the effect of the temperature.

Figure 1 shows the BioTappo covered with a reversible paint: it changes color from pink to lilac when exposed at 80°C at least for 1h. When left at room temperature, the color turns again from lilac to pink.

Figure 2 shows the BioTappo covered with an irreversible paint that changes immediately color from pink to magenta when exposed at 40°C.



**Figure 1.** The BioTappo prototype covered with a reversible paint exposed at room temperature (on the left) and at 80°C for 1 h (on the right)

**Figure 2.** The BioTappo prototype covered with an irreversible paint exposed at room temperature (on the left) and at 40°C (on the right)



# IV. DISCUSSION

Companies involved in the manufacturing, processing or handling of food products ought to minimize or eliminate food safety hazards in their product. To this aim, companies should use the Hazard Analysis and Critical Control Point System or HACCP. The HACCP System requires that biological, chemical or physical potential hazards are identified and controlled at specific critical control points (CCP) in the process. For PET-bottled waters, high temperature is a critical limit for the CCP. If this limit is exceeded corrective actions must be taken.

In some countries, the summer season is really hot and the storing of bottled water out the of markets under sunlight is a very common practice. Moreover, generally trucks that transport water bottles are not refrigerated. Since the high storage temperature and sunlight influence the rate and magnitude of leaching of non-desired compounds from PET bottles, the BioTappo could be a useful tool for the CCP in order to identify the preventive measure and to make sure the hazards are eliminated or controlled. In fact, once it has been established 'what' must be measured it is also necessary to establish 'how' to measure it. This implies specific procedures to monitor the process at the CCP and keep records to show that the critical limits have been met. For PET-bottled water and other beverages the monitoring program of the temperature made up of a physical measurement is not easy to perform and sometimes it is even impossible. On the contrary, visual observations of

the bottles could provide information in a time frame that allows the stakeholder to take action if an out of control situation occurs. In particular, the BioTappo could be useful to identify at what steps in the process – transportation and/or storage - the controls should be applied to prevent or eliminate the hazards that have been identified.

Moreover, it is also important to understand whether it is necessary to do continuous monitoring of the CCP or not. This is the reason why two different prototypes of the BioTappo have been designed. The one covered with the reversible paint (Figure 1) changes its color at very high temperatures after 1 hour. Thus, it can be useful for the determination of the degree of risk to the user from the identified hazard. In fact, literature data show that the magnitude of the migration of NIAS within PET into the water is related to the time of exposition to high temperatures. Otherwise, sometimes it could be more useful to provide information on the CCP immediately. It is the situation, for example, of milk or other foods that can deteriorate when exposed to high temperatures. In this case, the BioTappo covered with the irreversible paint, which changes color immediately when exposed to high temperatures, could be more useful for the protection of the final consumer.

#### V. CONCLUSION

Literature data assess the migration or potential migration of substances within PET into the liquid contents mainly when they are exposed to high temperatures. The levels of migration to food of the substances in plastics are often well within the margin of safety based on toxicological testing. Nonetheless, health effects are likely to occur taking into consideration life-long, daily dietary exposure to these substances.

In some countries, temperature often exceed  $45^{\circ}$ C at the summer time and the storing of bottled water out the of markets under sunlight is a very common practice. On the other hand, generally trucks that transport water bottles are not refrigerated. Thus, transportation and storage of PET-bottled water raise concerns over water quality and the packaging material.

In bottled waters, the cap is typically made of plastic and colorless or light pink. In this paper, we report data about the possible use of a special cap covered by a paint able to change color when exposed to high temperatures. Monitoring the CCP is essential to the effectiveness of the HACCP program. In the case of PET-bottled waters and other beverages, the monitoring program made up of physical measurement of the temperature sometimes could be difficult. Observations by the means of the BioTappo could provide information in a time frame that allows to take actions and control product if an out of control situation occurs.

A possible limitation of the study is that comparisons of the effects of the exposure of the BioTappo to different types of heat (e.g. dry or wet heat) have not been performed. Moreover, all the assays have been performed under laboratory conditions because the two different prototypes of the BioTappo have been achieved in autumn, a season not particularly hot. Thus, it is important to verify if and how the BioTappo changes color under the UV light. This will be performed next year during the summer time.

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