

Surveillance and official control of food contact materials in Cyprus- The case of Bisphenol A

***Dr Eleni Ioannou Kakouri
Chief chemist, EFSA focal point
State General Laboratory
44 Kimonos street , Nicosia, Cyprus***

National Expert meeting on BPA , 29-30 October 2012

1. INTRODUCTION

- **Bisphenol A (BPA)** is one of a number of chemicals that may have the potential to interact with hormone systems in the human body, *especially at early stages of life!*
- BPA is an organic compound used to make polycarbonate plastic and epoxy resins, along with other applications especially in **Food Contact Materials (FCM)**.
- But it is an **endocrine disruptive substance!**
- In EU level, the report on the **State of the Art of the Assessment of Endocrine Disruptors** has been finalized at the end of January 2012 .
- The fourth implementation report of the **Community Strategy for Endocrine Disruptors** was published in August 2011 (**SEC(2011) 1001**)
- So the **State General Laboratory (SGL)** of Cyprus put a great concern and priority since 2003 to investigate the presence and **levels of BPA**, between many others with endocrine disruptive properties, as are the **phthalate esters**, or substances of **toxicological concern**, and to include it within its official control or research programmes!

■ **The SGL is designated by Law**

as the Cyprus **Official Food Control Laboratory** for many fields of

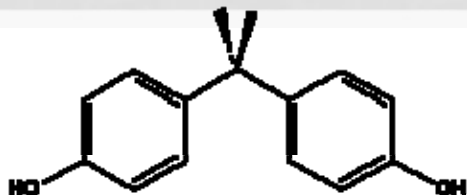
- food **quality** (nutrition, adulteration, authenticity) and
- food **safety** (additives, contaminants, food contact materials,

residues, GMO's, microbiological parameters, allergens).

- **SGL comprises of 21 specialized Labs** and **is accredited** according to EN ISO/IEC 17025:2005 in many fields of food safety.
- **All data** produced within the years, since 1996, are kept **in the LIMS data base of SGL**

■ The **SGL** is designated as the **National Reference Laboratory** (NRL, Regulation EC No. 882/2004) for many fields of food sector:

- pesticides residues, PCBs, dioxins
- veterinary drugs residues
- mycotoxins
- heavy metals
- PAHs
- **food contact materials**
- some microbiological parameters
- GMOs



BISPHENOL A

- **In the case of FCM, BPA** is a substance /**monomer** that is used:
- In the manufacturing of plastic food containers, water bottles, infant feeding bottles etc. made of **polycarbonate esters (PC)** and
- in **epoxy-resins** that are used as coating on the inside of **metallic** cans.
- **Other applications** : in thermal paper
- use of BPA as an antioxidant in PVC plastics and as an inhibitor in the production of PVC....
- But it is an **endocrine disruptoretc**
- **Due to the above and other concerns** :
- **EFSA published in 2010** a Scientific Opinion on BPA and keeps TDI= 0.05 mg BPA/kg body weight (b.w.)/day as set by EFSA in 2006.
- **AFFSA** published opinion 2010 , **Danish** research...
- Denmark and France in 2010 , **banned BPA in baby feeding bottles** and Denmark in food contact materials for children up to 3 years of age.



- **E. Commission** published the Regulation (EU) No 321/2011 which amends Regulation (EU) No 10/2011 for plastic FCM that sets limitations in the **use** and **migration limits (SMLs)** for substances that might be released into food, including **BPA**, and **prohibits the use of BPA** in PC feeding bottles for infants (<12 months).
- **EFSA launches** full re-evaluation focusing on exposure and possible low dose effects (April2012) and **called for Bisphenol A occurrence data** in food and beverages and migration occurrence data from food contact materials(deadline 31July 2012)
- **State General Laboratory (SGL) of Cyprus** has already sent these data to EFSA, which are produced within its **multiannual control and research plans** as **SGL** is the official control laboratory of Cyprus.

2. AIM OF THE STUDY

- The **purpose of the study and control**, which started in 2003 and is conducted by the State General Laboratory(SGL) of the Ministry of Health, was:
 - To investigate the **levels of BPA in polycarbonate plastics**, such as baby feeding bottles, bottles of water, cans with epoxy resin coating
 - To use /sent the occurrence data to EFSA for exposure assessments
 - To notify the results to the **Competent Authority** (Health Services of Ministry of Health) for taking the appropriate measures, when needed.



3. RESULTS AND DISCUSSION

BPA

- **All the examined samples**, within the years 2003-Sept 2012, of plastic polycarbonate **baby feeding bottles**, water bottles and cans (fig. 1) **were found to be compliant for BPA** and **within the Specific Migration limit (SML)** set by the relevant EU legislation and most of them were below the Limit of Detection(LOD).
- The **SML for BPA is 0,6 mg/kg** (Reg. 10/2011) **except for baby feeding bottles** made from polycarbonate for which the use of BPA **has been forbidden in 2011**(Reg. 321/2011).



3. RESULTS AND DISCUSSION (CONTINUE)



- The observed levels of BPA could be marked as “low” levels/ concentrations < LOD = 15 µg/L and analysis is done by an HPLC/ UV accredited method by SGL.
- **The occurrence data for BPA** are already sent to EFSA, according to **Standard sample description** deadline for submission 31 July 2012.
- In total 79 results/data for BPA were sent to EFSA for the years 2007-2011.
 - 58 baby feeding bottles from PC, covering all the trade names sold in Cyprus
 - 6 plastic bottles and bowls
 - 6 metallic cans with epoxy resin inside layer

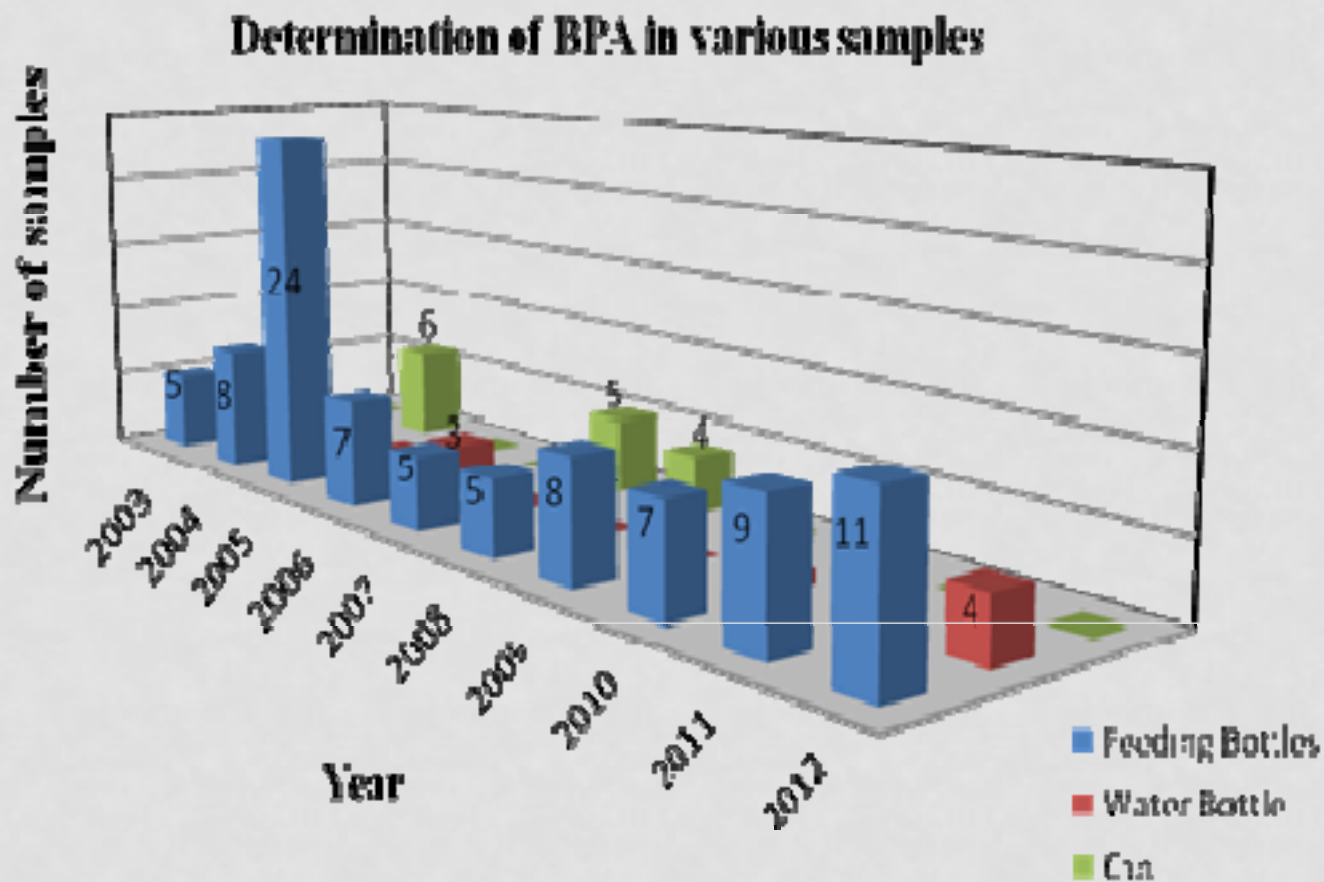
Almost all the results for specific migration < LOD

In contrast to the above findings are the results for other endocrine disruptor's i.e. phthalates esters where high violations and levels were observed in gaskets of glass jars e.g. DEHP with up 29%w/w of plasticised material, or in children toys (DEHP up to 52,6% w/w).



BPA IN VARIOUS SAMPLES 2003- 2012

FIGURE 1



4. CONCLUSIONS

- The results for bisphenol A in Cyprus can be considered as **“satisfactory”** (no detected concentrations due to migration) for the analysed samples of Food Contact Materials (FCM).
- The observed concentrations of BPA could be marked as **“low” levels/ concentrations < LOD = 15 µg/L** (HPLC / UV method of analysis) but....
- **What concentration can be considered as low?** with another technique/ method of analysis we can have even lower Limit of Detections e.g. by LC MS/MS the LOD can be ng/L
- the **uncertainties at lower concentration are usually higher**
- So concentrations even they are lower than the Limit of Detection they can take all the values between LOD and zero (**Uncertainty**) ->
- Thus the **resulting exposure is uncertain!**

- **The problem** lies on the effect of “*very low doses*” of BPA, which even they are low may **have higher endocrine disruptive action** in the human body especially of children than in high doses ...
- “*non monotonic response*”, “*hormesis*” effect, *critical period of exposure in experimental design* are some issues of great concern!
- Due to the above and other concerns
 - **EFSA launches** full re-evaluation focusing on exposure and possible low dose effects (April2012) and organized
 - the “*17th EFSA Scientific Colloquium on low dose response in toxicology and risk assessment*” 14-15 June 2012.

4. CONCLUSIONS (4)

- **The above results and all the results** produced within the official control of FCM and other products, are notified **to the Competent Authorities** for **taking appropriate measures if needed** i.e.: retrieval from the market, information of consumers and notification to the rapid alert system (RASFF), according to the requirements of the relevant EU legislation.
- The results indicate the effectiveness of the applied control, but also the **need of constant surveillance and control** especially at critical control points to **prevent unfit products**, especially cheap ones from third countries, as **e.g. is the case of phthalate esters in gaskets or children toys**, entering Cyprus and EU market!
- Furthermore there is a **need for further research !**

EU PROJECTS FOR HUMAN BIOMONITORING

- **Several research projects** for human biomonitoring including some BPA.
- **COPHES and DEMOCOPHES (LIFE 09 ENV/BE/000410), 7FP**
 - In Cyprus and other EU countries within the DEMOCOPHES project, some **phthalate ester metabolites** were examined in human urine (from pairs of mother & child) as well as cadmium in human urine and mercury in human hair.
 - Some countries will also measure **BPA** in urine .
 - *Cyprus Presidency Conference "Human Biomonitoring: Linking Environment to Health and Supporting Policy", 22-25/10/2012, Larnaca ,Cyprus*
- **Other countries in Europe , USA** and other carry out several biomonitoring projects and other research in the field of endocrine disruptors, due to many gaps in knowledge and uncertainties!

- **Many thanks to my colleagues of the**
- *“Food Contact Materials and Safety of Toys Laboratory”*
- **of SGL**
- ***Evgenia Paraskeva Vatyliotou, Antigoni Achilleos, Nektaria Varnava and M. Hadjigeorgiou***
- **Thank you very much for your attention!**