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*Exposure to Bisphenol A well below the new safety level for all age groups*

**Scientifically highly conservative t-TDI provides solid protection**

*The PC/BPA and ERC Groups of PlasticsEurope continue to thoroughly review EFSA's latest draft assessment on the potential health risks of Bisphenol A (BPA). The Groups will provide their detailed scientific input within the framework of the ongoing public consultation.*

*Based on the analysis conducted so far, and to avoid potential misinterpretations, industry would like to provide responses on a number of aspects which have, in some cases, been misleadingly reported:*

- ❖ **EFSA did not conclude that BPA causes effects on the liver, kidney and the mammary gland at dose levels relevant to human exposure, but identified these areas to require risk assessment**

EFSA applied a comprehensive and fully transparent weight of the scientific evidence approach in assessing over 450 studies for possible effects and then assessed whether human exposure was high enough to risk any effects. Importantly, EFSA concluded that "exposure even for the highest exposed groups in the population is well below the t-TDI of 5 µg/kg/bw per day, indicating that the health concern for BPA is low at the current level of exposure."

EFSA ranked the studies based on potential association of BPA to particular health effects. The likelihood of an association was classified in a six-staged ranking system, from "very likely" to "very unlikely".

Two areas were classified to show "likely" associations: liver and kidney. "Likely" association was also identified for the mammary gland, with however, a larger amount of uncertainty on the likelihood compared to liver and kidney. Other endpoints, including reproduction and fertility, brain and behavioural development, immune, cardiovascular, metabolic, genotoxic and carcinogenic effects, were judged to be "less than likely".

Therefore, whilst EFSA pointed at possible associations, at no time does the Authority conclude that there is a "likely" risk for humans. The "likely" association with kidney, liver and mammary gland is related to effects on the three organs which were observed in animals exposed to dose levels of BPA 1000 times above the new temporary Tolerable Daily Intake (t-TDI) proposed by EFSA.

- ❖ **The new temporary TDI is the result of a highly conservative approach – not of increased uncertainty**

EFSA consistently selected the most sensitive data to conduct its assessment; it used both the lowest value for which an effect could be associated with the substance, and it applied the most conservative calculation factors.

EFSA derived the t-TDI by using worst case data and by applying a modern, sophisticated mathematical model. The new t-TDI actually covers remaining uncertainty related to liver, kidney and mammary gland as well as all other effects which were found "less than likely" by EFSA.

❖ **Exposure to BPA for consumers remains extremely low and is well below the new t-TDI**

Even after setting the new t-TDI, EFSA confirmed that exposure to BPA is extremely low, and well below the temporary TDI. This applies also to the highest exposed groups among fetuses, newborns, young children and adults. It confirms once again that the health concern for BPA is low at the current level of exposure.

Based on the considerations above, the PC/BPA and Epoxy Resin Groups of PlasticsEurope believe any call for further restriction on the use of BPA based food contact applications is unwarranted.

*For further information, please contact:*

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