

09.11.2016

## Screening tests show no concern with regards to endocrine disruptors migrating from Borealis polyolefin products

In recent years, consumers have been concerned by studies showing hormone-like substances leaching from packaging materials into food, endangering the health of infants in particular. To clarify whether its polymers contain such "endocrine disruptors", Borealis participated in the "Xenohormone-project" initiated by the Austrian testing institute [OFI](#). More than forty Borealis PE and PP-grades were tested in relation to their endocrine activity. The results and final conclusions are now available.

### Background to the project

The hormone system controls essential body functions such as metabolism, growth, development and mood. It is especially important during an unborn child's critical development stages and during infancy. The system is very complex and influenced by many factors. Distortions can cause severe health defects like cancer or developmental diseases.

**Endocrine active substances** (EAS) can interact or interfere with normal hormonal action, due to their comparable chemical structure. When this leads to adverse effects, they are called **endocrine disruptors** (ED).

There is a wide range of EASs in our daily life. These can come from natural sources, such as phytoestrogens in soy. There are also man-made sources of EASs. Many pesticides are suspected to be ED, and bisphenol A and phthalates are heavily discussed.

The endocrine activity of a substance can be a **potential hazard**, which, depending on the dose, duration and timing of exposure to it, may become a **risk** for humans or animals. In general, it is very important to distinguish between hazard and risk, since  $\text{risk} = \text{hazard} \times \text{exposure}$ . If there is little or no exposure to a substance, it may not cause any harm. There may only be a significant risk at much higher exposure levels.

## Scope of the Xenohormone project

The project's main intention was to develop and standardise a screening method to determine EASs migrating from packaging materials to food. For that purpose, bioassays and analytical measures were used to identify the source of any endocrine activity found.

## Methods used

After applying the standard migration test procedure as described in EU food contact legislation (migration into 95% ethanol for 10d/60°C), the eluent was measured with yeast based activity tests - Yeast Estrogen Screen (YES) and Yeast Androgen Screen (YAS). However, this did not provide reliable results.

Human Cell Assays (CALUX) were therefore used instead for screening oestrogenic activity, which was mainly observed. Validated GC/HPLC – MS methods were used to identify any active substances in the test.

## Test results

Overall, approximately 150 samples of polyolefins used in food and drinking water applications were analysed by biological and analytical methods. These samples included about 40 Borealis PE and PP grades. The vast majority of the samples did not show any endocrine activity. Less than ten samples (including two Borealis products) were slightly active in a range close to the limit of detection: 0,5 ng/l estradiol equivalents (EEQ\*).

\*) Estradiol equivalents describe the amount of natural estrogen needed to achieve the same biological effect. Examples for typical EEQ values measured for common food are: milk - up to 10 ng/kg EEQ; Cheese - up to 30 ng EEQ/kg; Tofu - up to 1.000 ng EEQ/kg.

The two Borealis products showing slight positive endocrine activity were analysed and the source was identified as a decomposition product of the antioxidant used. Although the results for these products were of low concern, as a precautionary measure Borealis stopped using this antioxidant in these grades and replaced it with alternatives.

## Final conclusion

**Screening with the method developed by the Xenohormone project shows that Borealis polyolefins, used for manufacturing food and drinking water contact materials, are not a source of endocrine active substances and thus of endocrine disruptors.**