

## Hormonally active substances in mineral water from PET bottles

Information No. 006/2009 of the [German] Federal Institute for Risk Assessment [Bundesinstitut für Risikobewertung (BfR)] of March 18, 2009 with respect to a study carried out by the University of Frankfurt am Main

In a recently published study of mineral waters produced by various different manufacturers scientists working at the Johann Wolfgang Goethe University in Frankfurt am Main established that some of the samples tested in an in vitro test system showed the presence of substances with a hormonal effect which were not identified more specifically. The scientists state that the effect was in particular detected in samples packaged in bottles made of the plastic PET. This has raised questions from the public about the possible effects on health of drinking mineral water from PET bottles. The Federal Institute for Risk Assessment has carried out an initial preliminary assessment of the study.

During its initial review of the study the BfR established that the study indicates the presence of contaminants with estrogenic activity in some of the samples tested. Which substances were responsible for the results was not, however, investigated. The effect was detected in an artificial in vitro system with genetically modified yeast cells (YES test). The yeast cells contain parts of the human hormone signaling cascade and react very sensitively to the hormone 17 $\beta$ -estradiol and substances with a similar effect. The authors interpret their results to the effect that the substance must exist in an effective estrogenic concentration. It is, however, to be taken into account in this respect that known xenoestrogens also have a significantly weaker effect in the test system used here, e.g., nonylphenol has an effect which is weaker by a factor of approximately 10,000 compared to the natural hormone 17 $\beta$ -estradiol. This means that correspondingly high concentrations of substances would have to be present, which does not appear plausible.

Samples of various different brands of mineral water showed considerable differences in the test system used. Differences with respect to the package (glass compared to PET) cannot, however, be inferred from the data. The possibility discussed by the authors that these substances originate from the plastic PET itself is rather doubtful because comparable hormonal activity was measured both in water samples from glass bottles and in water samples from PET bottles of the same mineral water brand. Differences were in particular seen in waters of different origin. Comparative data from mineral water samples taken directly from source would therefore have been desirable.

In a second test the snail model was used. The snails were kept here in standard glass or PET bottles with specially added water a culture medium (i.e., not mineral water). After 54 days the number of embryos produced by the snails was counted. The reproduction rate of the animals kept in glass or PET bottles was compared with the reproduction rate of animals kept in estrogen-enriched water. It was observed that the reproduction rate of the animals kept in PET bottles and the animals kept in the estrogen-enriched water was comparable. By comparison, the reproduction rate of the animals in the glass bottles was lower. Whether this test system allows any relevant conclusions with respect to a health risk for consumers is rather doubtful.

The BfR does not know of any substances used in the manufacture of PET which migrate into the mineral water and could be responsible for the estrogenic activity in the samples from PET bottles. It is known that certain plasticizers are used for example in plastics such as PVC, which have proven to be endocrine modulators. Such plasticizers are not, however, used in the manufacture of PET. The results of the study therefore primarily raise questions with respect to the active substances themselves and their origin. These questions cannot, however, be answered on the basis of the available data from the study.

A possible explanation for the contamination in the mineral waters tested could be cap seals. There have been problems here in the past with nonylphenol, a chemical which demonstrates an estrogenic effect. In recent years, however, the BfR has no longer received any reports of nonylphenol being found during cap screening. It also has to be taken into account that different caps are used for glass and PET bottles and therefore a similarly high level of estrogenic activity in the water samples from glass and PET bottles as seen in the YES test should not result.

It is not to date known that untreated mineral water directly from source shows estrogenic activity. Mineral water is pumped up from deep strata and can therefore hardly come in contact with estrogenic environmental contaminants. Contamination by relevant substances via materials used in the manufacture and bottling process cannot, however, be ruled out.

The BfR fundamentally regards estrogenic effects caused by mineral waters as problematic. In the opinion of the BfR, however, a validation of the currently available results is necessary. In addition, for a rational evaluation of the reported effects, the identification of the responsible contaminants and the analytical definition of the concentrations are of paramount importance. The BfR also considers it important that possible routes of contamination are identified. Any assessment of a health risk to consumers would require additional in vivo studies with robust endpoints.

In the opinion of the BfR, the results of the study do not result in any need for consumers to refrain from drinking mineral water in PET bottles or to switch to products in glass bottles.