ECJ Ruling on Mutagenesis:
Effects on “ohne Gentechnik” labelling

In its ruling dated 25 July 2018, the European Court of Justice (ECJ) stated that organisms obtained by mutagenesis constitute genetically modified organisms (GMOs) within the meaning of Directive 2001/18/EC on the deliberate release of GMO. This Directive’s scope of application only excludes organisms obtained through techniques of mutagenesis which have conventionally been used in a number of applications and have a long safety record. These are techniques of conventional random mutagenesis produced through chemical mutagens or radiation.

For the “ohne Gentechnik” label, that means that organisms obtained with new mutagenesis methods are subject to the same restrictions as GMO that were produced with conventional genetic engineering methods. Such organisms may be marketed in the EU only if they are authorised under genetic engineering law. Once authorisation has been granted, they must be labelled according to general genetic engineering law with a reference to GMO if the corresponding labelling thresholds are exceeded.

Products from plants or animals that were cultivated with conventional mutagenesis may continue to be used without limitation for “ohne Gentechnik” food.

Such organisms are not GMOs under food law. Although, according to the ECJ ruling, they represent GMOs within the meaning of Directive 2001/18/EC on deliberate release of GMO, they are excluded from its scope of application. Subsequent to this, the concept of GMO in food law, as opposed to what is stipulated in the Directive on deliberate release, is defined from the start such that it does not apply to organisms obtained by conventional mutagenesis techniques.

As a consequence, it is irrelevant for “ohne Gentechnik” food to contain substances from plants or animals that were cultivated with conventional mutagenesis. Such substances do not fall under the prohibitions of the relevant labelling regulations, nor do general food and competition law provisions on misleading information of consumers prohibit “ohne Gentechnik” labelling in these cases.

Details may be found in the opinion by the law firm GGSC, which can be accessed here.

Berlin, 14 November 2018