

BfR proposes maximum levels for coumarin in food

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Since 1988 there has been a statutory maximum level for coumarin in Europe of 2 milligrams per kilogram (mg/kg) food. This value corresponded to the analytical detection limit at that time. Back then the setting of this maximum level was based on the assumption that the carcinogenic effect of coumarin observed in animal experiments was mediated via a change in genotype. The exposure of consumers to carcinogenic substances with a mode of action of this kind is to be minimised as far as possible according to international scientific agreement. In 2004 the European Food Safety Authority (EFSA) came to the conclusion on the basis of more recent research findings that carcinogenesis is not mediated via a change in the genotype. This meant it was possible for the first time to establish a tolerable daily intake (TDI) and toxicologically based maximum levels for coumarin. Against this backdrop discussions are currently ongoing on the European level about which values should be laid down for coumarin in the forthcoming amendment to the flavourings legislation. The Federal Ministry of Food, Agriculture and Consumer Protection had asked BfR to submit corresponding proposals.

Coumarin is a flavouring that is found in many plants. Besides woodruff, Cassia cinnamon contains comparatively high levels of this substance. In contrast, only small amounts of the substance are found in Ceylon cinnamon. Coumarin can harm the liver and higher levels trigger cancer in animal experiments. Hence a dose was established that can be ingested daily over a lifetime without any negative effects on health. This TDI value is 0.1 mg/kg body weight.

Measurements by the regional health control bodies from 2006 had detected high levels of coumarin in many cinnamon-containing foods. In some cases they were far higher than the currently valid maximum level of 2 mg/kg food and were caused by the predominant use of Cassia cinnamon. An exposure assessment by BfR showed that consumers with a high level of consumption of cinnamon and cinnamon-containing foods exceed the safe coumarin dose based on the levels detected. In order to protect these consumers, too, from the possible negative health effects of coumarin, BfR derived maximum levels for cinnamon and cinnamon-containing food. In this context BfR is of the opinion that maximum levels should be established in such a way that the TDI value is only partly exhausted by one food category in order to leave enough scope for the intake of coumarin from other foods or cosmetic products containing coumarin as a fragrance. When elaborating the action options BfR, therefore, took a TDI exhaustion of around one third as the basis.

Four action options (options A-D) were proposed which either envisaged the exclusive use of low-level coumarin Ceylon cinnamon (A), the laying down of a general maximum level for coumarin in cinnamon (B), the raising of the existing maximum level to 4 mg/kg food (C), or – option D – the laying down of maximum levels for individual food categories. In the case of options A-D the additional laying down of a maximum level for coumarin in cinnamon powder is recommended in order to protect those consumers who also use cinnamon directly as a spice.

The maximum levels mentioned in option D were submitted by Germany within the framework of the deliberation process for the new European flavouring legislation in the European

¹ In the introduction this opinion also takes into account a supplementary commentary by BfR from 25 June 2007 on maximum levels for coumarin in cinnamon-containing food. In that commentary the Institute voiced its opinion on a compromise proposal elaborated during deliberations by the European Council.

Council. During the deliberations a compromise proposal was drawn up in which the values for two food categories envisage higher coumarin levels than originally proposed by BfR. According to them cinnamon-containing bakery goods (aside from cinnamon star biscuits) may contain 15 instead of 10 mg coumarin per kg food and breakfast cereals 10 instead of 6 mg/kg. BfR has assessed this proposal and has come to the conclusion that the higher values lead to an approximate 50% exhaustion of the TDI. In increasing the exhaustion of the TDI value from one third to one half there is a greater likelihood that high level consumers will exceed the TDI. According to BfR this increase can, however, be justified because there are still uncertainties concerning the exposure situation. However, the maximum values should remain considerably lower than the values that are taken as the basis by the official German food control authorities when they classify products on sale on the market as “safe”. These “intervention values” are 50 mg/kg for the above-mentioned bakery goods and 20 mg/kg for cereals. In the case of these values the TDI would already be completely exhausted leaving no scope for coumarin intake from other foods or products. This applies in particular to breakfast cereals that are consumed throughout the year, frequently by children.

The laying down of a maximum level for coumarin in cinnamon that is used directly as a spice by consumers is not currently envisaged on the European level. This means that consumers who bake or prepare cinnamon-containing dishes like rice pudding with sugar and cinnamon ingest high levels of coumarin. In principle, the Institute advises consumers to use Ceylon cinnamon with a low level of coumarin instead of Cassia cinnamon with a higher cinnamon content. Hence, the Institute welcomes efforts to introduce corresponding labelling of the spice, cinnamon.

The full version of this BfR Opinion is available in German on http://www.bfr.bund.de/cm/208/bfr_schlaegt_cumarin_hoehstwerte_fuer_lebensmittel_vor.pdf