Risk assessment of 1,3-Dimethylamylamine (DMAA) as an active ingredient of products marketed as food

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1,3-Dimethylamylamine (DMAA) is offered for sale on the Internet as an active ingredient of so-called “pre-workout products” and weight loss products. The Federal Institute for Risk Assessment (BfR) has scientifically assessed these products which appear to be taken by athletes in particular.

Depending on the administered dose, DMAA can lead to an acute temporary increase in blood pressure in humans. There are now early provisional indications that continued use may, in combination with caffeine, lead to a chronic increase in blood pressure. A pronounced rise in blood pressure may increase cardiac work to such a degree that undesirable cardiovascular effects are precipitated which range from shortness of breath to tightening of the chest or a possible myocardial infarction. In addition, a significant acute increase in blood pressure can increase the risk of cerebral haemorrhage. This notably applies to persons with increased individual risks such as cerebral aneurysms (local dilation of blood vessels in the brain). The extent of possible health risks is influenced by the DMAA dose administered and the blood pressure of the individual concerned. In addition, other individual factors such as risk factors for coronary heart disease can influence the health risk[1].

According to its own statements, the US-American Food and Drug Administration (FDA) has received 42 adverse event reports in connection with the use of DMMA-containing products. Some reports include cardiac disorders, nervous system disorders, psychiatric disorders and death. Details on the reports, for example regarding the ingested quantities of DMAA, the type of adverse events observed, the closer circumstances of the incidents, and the question whether other substances were taken concomitantly, are not available. According to the statement of the FDA, the reports did not establish that DMAA was the cause of the adverse incidents. With its communication released on 27 April 2012, the FDA has classified DMAA-containing products which are marketed by various manufacturers in the USA as non-compliant with the law for formal reasons. The BfR does not know whether such products continue to be sold in Germany.

The current state of knowledge on the health effects of DMAA oral intake in humans is full of gaps. Even based on current knowledge, persons with increased blood pressure and those suffering from other cardiovascular diseases should refrain from taking DMAA-containing products. Some providers specifically mention this risk group.

The BfR recommends investigating whether the formal requirements for the sale of DMAA products as food are met in Germany, in particular whether DMAA is to be classified as novel food or novel food ingredient. Classification of DMAA as a pharmaceutical product too should be considered. If DMAA containing products can be sold as food, it is to be established whether or not they are to be classified as “unsafe foods”.

[1] Coronary heart disease is a narrowing of the coronary vessels which supply the heart muscle with blood. Typical risk factors include nicotine use and an increased LDL cholesterol level.

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