

The area of application of Natamycin as a food additive should not be extended

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Natamycin is a food additive (E 235) permitted for surface treatment of various types of cheese and dried and cured sausages. The Federal Institute for Risk Assessment (BfR) originally assessed the additive in terms of its health effects in 2003. Since Natamycin is, due to its effectiveness against fungal infections, also used as an antimycotic in human medicine, the BfR has taken a stand against an extension of its application area in order to counteract the potential development resistant pathogens. In November 2009, the European Food Safety Authority (EFSA) presented a new assessment of the additive. The BfR checked whether the two assessments of its health effects diverged and possibly even partially contradicted each other. The critical point here concerns statements regarding the resistance issue.

In its opinion, the EFSA sees the resistance risk arising from Natamycin as negligible. Its statement is expressly restricted to the already regulated use of Natamycin as a food additive. At the time of its opinion in 2003, the BfR was aware of indications that the use of Natamycin in the treatment of patients with fungal infections may cause resistance. Nevertheless, the institute had not voiced any objections against its further use within the regulated domain of food additives. However, the BfR did oppose an extension of the approval of Natamycin as an additive for surface treatment for other foods such as cured ham at the time. Since the substance continues to be used as an active ingredient in human medicine, the BfR adheres to its recommendation that its use as an additive should be as limited as possible and that the current application area should not be extended.

The full version of this BfR Opinion is available in German on http://www.bfr.bund.de/cm/343/der-einsatzbereich-von-natamycin-als-lebensmittelzusatzstoff-sollte-nicht-erweitert-werden.pdf