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EDITORIAL

Cannabidiol (CBD): a strong plea for mandatory pre-marketing approval of food supplements

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The case of cannabidiol (CBD) makes the deficits in the current regulatory approach for food supplements clearly evident. Therefore, we strongly urge for a paradigm shift towards pre-marketing approval. The issue of CBD products mass marketing, typically in form of so-called CBD oils (i.e., hemp extract mixed into edible oil), started in 2018. According to Google Trends (2020), the interest in CBD in Germany strongly increased during 2018 and peaked from August to November 2019 and is currently on the decline, but still on a high level (80% of peak interest).

The regulatory approach for CBD is specifically difficult. "Extracts and tinctures" from the hemp plant *Cannabis sativa* may be considered narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs (1961) and could therefore be excluded from being a food or food supplement according to Regulation (EC) No 178/2002. Furthermore, CBD could be a medicinal product, and likewise be excluded from being "food". Indeed, some EU member states such as France enforce a restrictive policy and consider CBD as being a narcotic drug. Others, such as Denmark, Ireland or Germany consider CBD as food product and try to enforce the requirements of the food law. Some CBD products are currently marketed as "non-food" (e.g., CBD room scents) in a questionable manner to circumvent any narcotic, medicinal or food laws, but these products would still be covered by the food definition of Regulation (EC) No 178/2002 as these products are reasonably expected to be ingested by humans.

We believe that it would be disproportional to regulate CBD products as narcotic drug, according to the principle of "ultima ratio" in criminal law, while the pharmacological action required to regulate CBD as medicinal product is difficult to substantiate (Lachenmeier et al. 2019). Therefore, it is reasonable to regulate CBD products as food supplements within the requirements of food law, such as Regulation (EC) No 178/2002 regarding general food safety requirement, Directive 2002/46/EC relating to food supplements, Regulation (EU) No 1169/2011 regarding food information, and Regulation (EC) No 1924/2006 on nutrition and health claims.

Food control authorities in Europe have reported various offences of food business operators selling CBD products against the European food law. More than 100 notifications regarding CBD as unauthorised novel food ingredient and unauthorised tetrahydrocannabinol (THC) in CBD product were shared in the Rapid Alert System for Food and Feed (RASFF). The Food Safety Authority of Ireland (FSAI) reported that from 38 tested CBD products, 37% exceeded the safe limit of THC dosage set by EFSA (1 µg/kg body weight/day), 34% were classified as novel food lacking approval, 36% were food supplements lacking the necessary notification of the competent authority, 92% were tested to contain differences between analytical and declared CBD content of more than 10%, and finally 50% contained misleading claims such as unauthorised health claims or medicinal claims (FSAI 2020). Very similar results were published from our own institute. Within the category of cannabidiol products, the quota of offences was 100%, meaning that every single sample showed some violation, starting with lack of novel food approval, deficits in mandatory labelling requirements, or the use of non-approved health claims, or prohibited disease-related claims, but most critically, 46 out of 67 samples (69%) showed THC dosages above the EFSA limit (Lachenmeier et al. 2020).

However, extreme quotas of offences against food law are not restricted to CBD supplements. Actually, in official food control practice, the category of foods for particular nutritional uses has the highest rate of complaints among all food categories, e.g., 23.1% of all official samples evaluated in this category in Germany in 2018 showed violations against

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the food law (BVL 2019). If we look at the sub-category of food supplements, this quota is even higher. For example, in the German Federal State of Baden-Württemberg, 77% of all evaluated samples of food supplements had violations (own data for 2019).

In the EU, the food business operator has the primary responsibility to ensure the requirements of food law. Obviously, some food business operators, and specifically those selling CBD, do not have any intention to do so. Actually for CBD, this would mean to end the current activity and waiting for the novel food approval of the compound. In the context of other food supplements, it would mean to stop marketing products with unapproved or overstated health claims, disease-related claims or other misleading claims, which typically is the basis for a consumer wanting to buy such a supplement. Hence, we constantly see supplement products beyond legality, which are still placed on the market with the knowledge that enforcement of food control including the typical judicial proceedings has such a long lag-time that the product is sold out before ultimately forbidden, and the cat-and-mouse game can start with slightly modified products from the beginning. Normally, the consumer is only economically disadvantaged by misleading supplements, but sometimes, as in the case of CBD, the consumer health might be at risk, when the undeclared presence of THC can pose a risk for children, drivers, as well as athletes who may be buying and consuming these products without knowing they contain a psychotropic substance (FSAI 2020).

We believe that the current legal system for food supplements as specified in Directive 2002/46/EC on the approximation of the laws for the Member States relating to food supplements has proven to be completely inefficient and ineffective. Recital #4 of the directive states: "In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling". This goal has clearly not been reached in almost 20 years of application of the directive. Therefore, we suggest a paradigm shift towards pre-marketing approval. The current notification procedure should be amended by mandatory pre-market verification of composition as well as labelling. Specific rules should be made for nutrients and other substances besides vitamins and minerals, most preferably by positive lists with minimum/maximum approved amounts; i.e., everything is forbidden, if not specifically allowed.

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