COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT)

Paper for Information: Potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). Relevant UK regulatory aspects

Introduction

1. This paper has been prepared for information to support the ongoing consideration of the potential toxicological risks associated with electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) (collectively abbreviated to E(N)NDS). It outlines relevant aspects of UK regulations which may differ to other countries in which research studies on E(N)NDS may have been carried out.

UK Regulations

Nicotine-containing products

2. In the UK, ENDS are regulated as electronic cigarettes under the Tobacco and Related Products Regulations 2016, which implements the EU Tobacco Products Directive (2014/14/EU). This section flags relevant aspects of the regulations for the Committee's work.

3. The definition of an electronic cigarette in the regulations is one that can be used for consumption of nicotine-containing vapour (see paragraph 8 below with respect to regulation of products not containing nicotine).

4. Producers are required to notify MHRA six months in advance of supply to the UK market, with a submission of information on the product concerned.

5. In terms of product requirements, the maximum permitted concentration of nicotine in the e-liquid is 20 mg/ml, and there is a limit on the volume of nicotine-containing liquid in a device of 2 ml, and a dedicated refill container of 10 ml. The nicotine-containing liquid, must not contain any additives, vitamins or colourings prohibited in tobacco products. All ingredients of the liquid, unless at trace levels and technically unavoidable, and emission must be listed in the notification submitted to MHRA, and no ingredient, other than nicotine, which pose a risk to human health in heated or unheated form are allowed.

6. A number of safety requirements are also imposed, e.g. child-resistant and tamper-evident, as well as requiring manufacture using ingredients of high purity. The products much be labelled with the statement “This product contains nicotine which is a highly addictive substance.”, and must not resemble cosmetic or food products.

7. The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 prohibit sale of ENDS to anyone under 18, except in medical circumstances.

8. The main differences in the regulatory framework between the UK and US, as an example, is the UK limit on nicotine concentration in products as well as limits on volumes in products and refill bottles. Very recently, the US has now started the process to ban the use of flavoured products unless they are specifically approved, whereas the UK has partial restrictions on flavourings linked to the ingredients.

Products not containing nicotine.

9. Products that do not contain nicotine are outside the scope of the EU Tobacco Products Directive and thus the UK regulations, and do not have to meet their requirements. They will continue to be regulated under the General Product Safety Regulations 2005. This may include liquids to which nicotine may be added by the user.

10. Non-nicotine e-liquid products also remain subject to chemicals legislation, e.g. REACH and CLP requirements. While the absence of nicotine means many such products won’t be classified as hazardous under CLP, some still will. Some flavourings used in these products are hazardous, typically skin sensitisers, and may result in the products being classified the same way, or at least triggering some CLP labelling requirements.

PHE COT Secretariat
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