

**EX-ANTE IMPACT ASSESSMENT**  
of the draft Act amending and supplementing the Tobacco, Tobacco and  
Related products Act

**1. Grounds for the legislative initiative**

The legislative initiative is related to the need to ensure a high level of protection of public health of citizens, especially children, by introducing a complete ban on the placing on the market of electronic cigarettes containing or not containing nicotine - the so-called 'vape products' and devices similar to them.

The ever-increasing marketing of e-cigarettes whose liquids contain flavourings / flavouring additives that impart a taste and smell resembling fruit, confectionery such as desserts and pastries, or other sweet foods, or any drinks are particularly attractive and seductive for children and adolescents. This trend is particularly dangerous given the health risks associated with the use of these products due to the potential for exposure to high levels of nicotine and other substances of unclear origin, including narcotic drugs and their analogues. The most recent data on induced acute intoxications after children's use of these products, including those with fatal outcomes, are extremely alarming.

On 22 May 2024 the World Health Organisation (WHO) and Stopping Tobacco Organizations and Products (STOP) published a report 'Addiction of the Next Generation' that shows that despite significant progress in the overall reduction of smoking in the world, the use of e-cigarettes is increasing, especially among young people - almost threefold.

Disposable and refillable e-cigarettes, whether or not containing nicotine, resemble tobacco products and thus generate habits and perceptions in young people that smoking is a harmless and pleasant habit. Any product resembling a smoking product other than a tobacco product, regardless of its composition and mode of consumption, shall embed in children and adolescents a positive attitude towards these products, including tobacco products. The harms of such products are both direct and indirect. In addition to formation of harmful habits, the composition of new products that are introduced on a daily basis and that are widely used by both adults and children is also questionable. The apparent 'lack of harmful substances' or 'reduced harm' incentivises people to use these products in unmeasured quantities and for a prolonged period of time without interruption, and thus also increases their harm to health. The legislative change is in fulfillment of the constitutional duty of the state to protect the health of citizens, in particular that of children.

Despite the ban introduced in the Child Protection Act on the offer, sale and consumption of a wide range of tobacco and related products by persons under the age of 18, including 'vape products', the measure has proven not to be sufficiently effective. A lot of children and adolescents are in practice gaining unauthorised access to e-cigarettes, both at physical points of sale and, above all, on the internet, as a result of non-compliance with legal provisions. In order to achieve effective protection of life and health of citizens, this legislative initiative proposes a complete ban on the marketing, sale, distribution and advertising of disposable and reusable e-cigarettes, whether or not containing nicotine.

Also the proposed amendments to the Child Protection Act introduce a ban on the use, marketing and sale to children of all nicotine-containing products, including pouches, snuses, chewing gums, etc., and of energy drinks.

According to the opinion of the European Food Safety Authority, when consuming two or more energy drinks a day, due to increased intake through them of caffeine in combination with other ingredients with a stimulating effect, adverse effects on the body are possible: increased nervousness, anxiety, tremor, insomnia, headache, palpitations, respiratory disorders, erosive changes of the mucous membrane of the gastrointestinal tract, dehydration due to loss of water and salts from the body. Children and adolescents are a riskier group due to the occurrence of the adverse effects of caffeine in much lower doses in them compared with their occurrence in adults. It should be emphasised that the combined intake of energy drinks with alcohol and/or narcotic substances poses a significant health risk, especially for young people, as the stimulating effect of energy drinks disguises the toxic effects of alcohol and narcotic substances.

Taurine and d-glucoronolactone are biologically active substances, often included in the composition of energy drinks, which are natural ingredients of food and are normal metabolites of metabolism in the body. With high intake, taurine may have adverse effects mainly on brain activity, and d-glucoronolactone on kidney activity.

Their energizing effect is not associated with high energy value, but with a stimulating effect on the functions of the body of the biologically active substances, vitamins and plant extracts included in their composition. Usually energy drinks contain different combinations and amounts of caffeine, B vitamins, plant extracts (guarana, mate, acacia, ginseng, ginkgo biloba), taurine, glucuronolactone, inositol, carnitine, creatine, etc. These drinks have been developed as functional to support mental and physical activity, to reduce signs of fatigue.

So-called 'energy drinks' are a well-established but relatively new product category for which there is no specific definition and legislation at European level. However, specific definitions of the products included in the national legislation of some EU Member States have become over the years the common reference within the EU. The national legislation of some EU Member States has specific requirements relating mainly to the content of energy drinks. The main focus of specific national measures taken by some Member States with regard to energy drinks relates to setting maximum limits/bounds of some of the ingredients used in energy drinks. Several countries (Germany, Denmark, Austria, Switzerland, Sweden, Norway) have set maximum limits for the incorporation of caffeine into energy drinks.

Age restrictions apply in Latvia since 2014 and in Lithuania since 2016, where the sale of energy drinks to children up to 16 years of age is prohibited.

This draft Act is consistent with European Union law in so far as, pursuant to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (Text with EEA relevance), any Member State may prohibit certain categories of tobacco or related products on grounds relating to the particular situation in that Member State and provided that the provisions are justified by a need to protect public health.

## 2. Stakeholder groups

The Ministry of Economy and Industry, the Ministry of Agriculture and Food, the Ministry of Health, the Ministry of the Interior, the State Agency for Child Protection, the Commission for Consumer Protection, manufacturers, importers and traders of tobacco and related products and all Bulgarian citizens.

3. Cost-benefit analysis

The proposed draft Act will result in an impact on the state budget in connection with changes to the Excise Duties and Tax Warehouses Act.

4. Administrative burden and structural changes

The proposed amendments and supplements do not lead to an increase in the administrative burden and do not require structural changes to be made.

5. Regulatory impact

The adoption of this draft Act entails a corresponding amendment to the Child Protection Act, the Food Act and the Excise Duties and Tax Warehouses Act.

6. Equal treatment by the state and balanced demographic development.

The proposed draft Act will create an opportunity to protect the life and health of Bulgarian citizens from the harmful effects of e-cigarettes, which have gained popularity as 'vape products' with unclear content, as well as energy drinks consumed by children.