SOŁTYSIŃSKI KAWECKI SZLĘZAK

LIFE SCIENCES MONITOR

APRIL 2025

DANGEROUS PRODUCTS

European Commission annual report on Safety Gate

On April 16, 2025, the European Commission ('**EC**') unveiled its annual report on *Safety Gate* - the rapid alert system for dangerous non-food products in 2024.

Key findings from the report are as follows:

i. in 2024, Safety Gate featured the **highest number of alerts validated since the system was created: 4 137**,

ii. the 5 most frequently reported product categories in 2024 were: **cosmetics** (36%), **toys** (15%), **electrical appliances & equipment** (10%), **motor vehicles** (9%), and **chemical products** (6%),

iii. as a result of the alerts registered in Safety Gate, **over 4,200 follow-up actions have been taken** to stop the sale of reported products or even take them off the market in 2024,

iv. the main cause of risk in almost half of the warnings was chemical components.

The EC press release on the report can be read here: **link**. You can read the report here: **link**.

MEDICAL PROFESSIONS AND MEDICAL ENTITIES

Amendments to the Ministry of Health prescription regulation

On April 1, 2025, a draft regulation amending the prescription regulation was published on the website of the Government Legislation Centre (PL: *Rządowe Centrum Legislacji*, "**RCL**").

The draft regulation would allow a person filling a prescription at a pharmacy or pharmacy point to modify it, i.e. to add an additional entitlement code "DZ" for recipients under the age of 18, or code "S" - for recipients over the age of 65. The draft regulation is directly related to the amendment of the Act on publicly funded healthcare services, which we reported on in more detail in: **SKS Life Sciences Monitor**.

You can read the regulation here: **link**.

Regulations on medicinal products advertising in the form of free provision of samples - amendment

On April 28, a draft act amending the Pharmaceutical Law was published on the RCL website.

The draft introduces amendments to the regulations on advertising medicinal products involving the free provision of samples by introducing **the possibility for a person authorised to issue prescriptions to request a sales representative or medical representative to provide a free sample of a medicinal product in a documentary and written form** (previously only in written form). The draft aims to eliminate the current overly formalistic requirements in this regard.

You can read the entire draft here: **link**.

FOOD

Placing an aroma extract from hemp seeds on the market – Chief Pharmaceutical Inspector decision

On April 17, 2025, the Chief Pharmaceutical Inspector (PL: *Główny Inspektor Farmaceutyczny* „**GIF**") published a decision dated January 9, 2025, on the issuance of an individual interpretation of Article 35(1) of the Polish Act of July 29, 2005, on Counteracting Drug Addiction[1]. The decision upholds GIF's decision of April 29, 2022, stating that **it is necessary to obtain a GIF's permit to produce and place aroma extract from hemp seeds on the market**.

In the decision, GIF indicates, among other things, that **the product which is the subject of the decision, due to its percentage content of Δ-9-tetrahydrocannabinol and tetrahydrocannabinolic acid is a psychotropic substance, and therefore any activity involving its manufacture, processing, conversion, import or distribution requires a relevant permit** - according to Article 35 (1) of the Act on Counteracting Drug Addiction.

You can read GIF's decision here: **link**.

Detailed requirements for the commercial quality of fruit jams, jellies, marmalades, plum jam and sweetened chestnut puree - draft regulation

The draft regulation aims to implement Directive 2024/1438/EU[2] and provides for, among other things:

i. the introduction of the **possibility of adding concentrated fruit juices as optional ingredients to jams or fruit jellies**,

ii. a clarification of the current product name "marmalade" to **"citrus fruit marmalade"**, and

iii. an increase in the **minimal fruit content** required to produce jams and extra jams.

You can read the entire draft here: **link**.

[1]A GIF permit is required to engage in the business of: 1) the manufacture, processing, conversion, import or distribution of narcotic drugs or psychotropic substances; 2) the manufacture, processing, conversion, import, distribution or use for scientific research, within the scope of its statutory activity, of category 1 precursors; 3) the manufacture, processing, conversion for scientific research, by scientific units within the scope of their statutory activity, of narcotic drugs of groups I-N, II-N and IV-N or psychotropic substances of groups I-P, II-P, III-P and IV-P.

[2] Directive (EU) 2024/1438 of the European Parliament and of the Council of 14 May 2024 amending Council Directives 2001/110/EC relating to honey, 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption, and 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.

FOOD

Advertising using health claims relating to botanical substances currently prohibited – ruling of the Court of Justice of the European Union

On April 30, 2025, the Court of Justice of the European Union ("**CJEU**") ruled[3] on a precedent-setting case concerning the use of health claims relating to botanical substances in food advertising. The court ruled that using such claims is currently prohibited.

The case was initiated in Germany between a trade association and a national company marketing a food supplement containing extracts of saffron and melon juice. The company advertised the products suggesting that those extracts improved mood or reduced feelings of stress and fatigue - even though the EC had not completed a formal evaluation or admissibility of these health claims.

Doubts were mainly related to the interpretation of Article 10 (1) and (3) of Regulation 1924/2006[4], according to which health claims are, in principle, allowed only if they are on the list of permitted claims. For thousands of claims on botanical substances, the evaluation procedure has been suspended ("**on hold**") by the EC and has still not been completed.

In view of the above, the CJEU ruled that health claims concerning botanical substances cannot, at this stage, be used to advertise food supplements. A possible exception could apply if the conditions of the transitional system provided for in the above-mentioned regulation were met, but this was not the case in this matter.

You can read the CJEU's judgment here: **link.**

[3] *CJEU judgment of April 30, 2025 in Case C-386/23 Novel Nutriology GmbH v. Verband Sozialer Wettbewerb eV.*
[4] *Regulation (EC) no 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.*
[5] *Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products.*

TOBACCO PRODUCTS

The law on heated tobacco products – entry into force

On April 17, the Act of February 21, 2025, amending the Act on Health Protection against the Consequences of Tobacco and Tobacco Products, the so-called '***Flavours Act***' entered into force. The amendment aims to implement Commission Delegated Directive (EU) 2022/2100[5], and provides for, among other things:

- the introduction of a **definition of a heated tobacco product**, and
- the establishment of regulations **prohibiting the placing on the market of heated tobacco products with a distinctive flavour**.

You can read the full text of the act here: **link**.

Excise duty on nicotine pouches and other nicotine products

On April 1, subject to the schedule for the gradual increase in excise tax rates (‚**excise duty map**') and regarding the amnendments in excise duty regulations, the Act of February 20, 2025, amending the Act on Excise Duty, the Public Health Act, and certain other acts, entered into force.

The Act provides, among other things, for the **introduction of excise duty on new categories of products, including vaporisation devices (reusable electronic cigarettes, heaters, multifunctional devices), nicotine pouches, and other nicotine products,** as well as an **increase in excise duty on e-cigarette liquid contained in a single disposable e-cigarette**.

You can read the entire act here: **link**.

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