



NOTIFICATION

1. Notifying Member: <u>ISRAEL</u> If applicable, name of local government involved:
2. Agency responsible: Health Regulation Directorate (Food, Alcoholic Beverages and Cosmetics), Ministry of Health
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Food additives (ICS code(s): 67.220.20)
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Public Health Protection Notice (Food) (Application of Changes to the Annex to European Union Directives) (Regulation 1334/2008 - Food flavoring substances and certain food ingredients with flavoring properties for use in food and on food (Amendment No. 2), 5786-2026. Language(s): Hebrew. Number of pages: 8 https://members.wto.org/crnattachments/2026/SPS/ISR/26_03464_00_x.pdf
6. Description of content: Commission Regulation (EC) No. 1334/2008 of the European Parliament and of the Council of 16 December 2008 regarding Food flavoring substances and certain food ingredients with flavoring properties for use in food and on food, replacing Council Directives 1601/91 (EEC), 2232/96 (EC), 110/2008 (EC) and EC/2000/13, was adopted in Israel as part of Amendment No. 10 to the Public Health Protection (Food) Law, 5776-2015 (hereinafter - the Law/Food Law), and appears in Item 11 of Appendix II A to the Law. Regulation 1334/2008 was fully applied in Israel on 1 January 2025, with the expansion stated in column C in Item 11 of Appendix II A to the Law, in addition to the exceptions as stated in Section 3A(a1) to (a5) of the Law. To date, notices have been published in the Official Gazette (Reshumot), that included changes that took place in the European Union in Regulation 1334/2008, and which were applied in Israel (updates), with the most recent being published on 17 August 2025, being the Public Health Protection (Food) Notice (Application of Changes in the Annex to the European Union Directives) (Regulation 1334/2008 - Food flavoring substances and certain food ingredients with flavoring properties for use in food and on food)(Amendment), 5785-2025, signed by the director of Health Regulation Directorate (Food, Alcoholic Beverages and Cosmetics) at the Ministry of Health. The latest updated consolidated version, adopted and published on the Food Service website following the publication of the aforementioned notice, is the version valid in European legislation as as it stood on 25 June 2025. It is now proposed to implement in Israel the changes that took place in the European Union in Regulation 1334/2008, as will be detailed extensively below, without modifications, conditions, exceptions, or expansions, while integrating them into the text

of Regulation 1334/2008, as adopted today. The essence of the changes relates to the addition of flavoring substances and updating CAS numbers.

The changes included in this proposed amendment combine the following EU Regulations amending various Annexes of Regulation (EC) 1334/2008, after Item No. 4:

- Item 5 - Commission Regulation (EU) 2026/172 of 26 January 2026. amending Annex I to Regulation (EC) 1334/2008 of the European Parliament and of the Council as regards the inclusion of 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester in the union list of flavorings and correcting certain CAS numbers:

1. **Add the reference in Annex I regarding 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester.** Explanation: The regulation approves the addition of the flavoring substance 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester (FL 16.136) to the list. This substance is intended to provide technological flavoring properties. The European Food Safety Authority (EFSA) conducted a comprehensive risk assessment and determined that the use of this substance does not raise any safety concerns (including the absence of genotoxicity concerns), provided that its use is limited to specific food categories and maximum permitted levels (MPL). In light of this conclusion, no additional safety restrictions are required.

2. **Replace the CAS numbers in 4 references in Annex I part A item 2.** Explanation: For reasons of transparency and scientific accuracy, the regulation corrects the CAS numbers (chemical registry numbers) of four flavoring substances already approved for use (FL numbers: X, Y, Z, W): FL No 08.017 – The number in the third column will be replaced with number 97-67-6; FL No 08.127 – The number in the third column will be replaced with number 13794-15-5; FL No 16.041 – The number in the third column will be replaced with number 150436-68-3; FL No 16.132 – The number in the third column will be replaced with number 67604-48-2. It should be emphasized that this is a technical-administrative correction only, intended to align the regulation with the updated international registry, that has no impact on the safety profile of these substances or on the conditions of their use.

- Item 6 - Commission Regulation (EU) 2026/175 of 26 January 2026. amending Annex I to Regulation (EC) 1334/2008 of the European Parliament and of the Council as regards the inclusion Hesperetin Dihydrochalcone in the Union list of flavourings:

1. **Add the reference in Annex I, part A, item 2, Table 1, regarding Hesperetin Dihydrochalcone.** Explanation: Regulation 2026/175 amends the list of permitted flavoring substances in the European Union and approves the addition of the substance hesperetin dihydrochalcone (FL number 16.137). The approval of this substance is intended to provide the food industry with an additional technological alternative for flavoring, while ensuring that its use does not mislead consumers. The arrangement is based on an opinion from the European Food Safety Authority (EFSA) from October 2024, which unequivocally determined that the use of this substance is completely safe. Furthermore, the examination confirmed that even cumulative exposure to this substance together with flavoring substances with similar structures does not pose any health risk, and therefore no stricter restrictions are required beyond those established. In order to ensure proportionality and consumer protection, a strict and uniform maximum use level of 10 mg/kg has been established. The use has been limited to specific food categories only, including dairy products and their substitutes, savory crackers, beverages, and fruit and vegetable-based products.

7. **Objective and rationale:** food safety, animal health, plant protection, protect humans from animal/plant pest or disease, protect territory from other damage from pests.

8. **Is there a relevant international standard? If so, identify the standard:**
 Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):

<p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard: This regulation follows the European regulation (1334/2008) of the European Parliament and of the Council from 16 December 2008 regarding Food flavoring substances and certain food ingredients with flavoring properties for use in food and on food.</p>
<p>9. Other relevant documents and language(s) in which these are available:</p> <ol style="list-style-type: none"> Commission Regulation (EU) 2026/172 of 26 January 2026 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of 3-[3-(2-isopropyl-5-methyl-cyclohexyl)-ureido]-butyric acid ethyl ester in the Union list of flavourings and correcting certain CAS numbers Commission Regulation (EU) 2026/175 of 26 January 2026 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the inclusion of hesperetin dihydrochalcone in the Union list of flavourings (available in English)
<p>10. Proposed date of adoption (dd/mm/yy): The regulation is open for public comments until 24 June 2026.</p> <p>Proposed date of publication (dd/mm/yy): Publication in the Official Gazette (Reshumot) is expected not before 25 June 2026.</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 15 July 2026</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 4 September 2026</p> <p>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Health Regulation Directorate (Food, Alcoholic Beverages and Cosmetics) Ministry of Health E-mail: matan.shiner@moh.gov.il</p>
<p>13. Text(s) available from: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Health Regulation Directorate (Food, Alcoholic Beverages and Cosmetics) Ministry of Health E-mail: matan.shiner@moh.gov.il</p>