Is áis doiciméadúcháin amháin an téacs seo agus níl aon éifeacht dhlíthiúil aige. Ní ghabhann institiúidí an Aontais aon dliteanas orthu féin i leith inneachar an téacs. Is iad na leaganacha de na gníomhartha a foilsíodh in Iris Oifigiúil an Aontais Eorpaigh agus atá ar fáil ar an suíomh gréasáin EUR-Lex na leaganacha barántúla de na gníomhartha ábhartha, brollach an téacs san áireamh. Is féidir teacht ar na téacsanna oifigiúla sin ach na naisc atá leabaithe sa doiciméad seo a bhrú

►**B** **COMMISSION IMPLEMENTING REGULATION (EU) No 307/2012**

of 11 April 2012

establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods

(IO L 102, 12.4.2012, lch. 2)

Arna leasú le:

		Iris Oifigiúil		
		Uimh	Leathanach	Dáta
►**M1**	Rialachán Cur Chun Feidhme (AE) 2021/842 ón gCoimisiún an 26 Bealtaine 2021	L 186	16	27.5.2021

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COMMISSION IMPLEMENTING REGULATION (EU) No 307/2012

of 11 April 2012

establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods

Article 1

Subject matter

This Regulation establishes implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 and in particular:

(a) the conditions for the use of the procedure referred to in paragraphs 1 and 2 of Article 8 of Regulation (EC) No 1925/2006; and

(b) the procedure referred to in paragraphs 4 and 5 of Article 8 of Regulation (EC) No 1925/2006 concerning substances listed in Annex III, Part C thereto.

Article 2

Definitions

For the purpose of this Regulation the following definitions shall apply:

(a) ‘request’ means the submission to the Commission by a Member State of information, including scientific data, for the purpose of initiating the procedure under paragraph 2 of Article 8 of Regulation (EC) No 1925/2006;

(b) ‘file’ means a file as referred to in paragraphs 4 and 5 of Article 8 of Regulation (EC) No 1925/2006 that is submitted by a food business operator or interested party to the Authority;

(c) ‘placing on the market’ as defined by Article 3(8) of Regulation (EC) No 178/2002.

Article 3

Conditions to be met for the request

1. In the assessment of the conditions under which the concerned substance is added to foods or used in the manufacture of foods, as laid down in paragraph 1 of Article 8 of Regulation (EC) No 1925/2006, the placing on the market in one or more Member States of the food product to which the substance has been added shall be taken into account.

2. Member States may submit a request to the Commission when the assessment referred to in paragraph 1 shows at least one of the following:

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(a) a potential risk to consumers is associated with the ingestion of amounts of the substance that greatly exceed those reasonably expected under normal conditions of consumption of a balanced and varied diet, due to the conditions under which the substance is added to food or used in the manufacture of food;

(b) a potential risk to consumers is associated with the consumption of this substance by the general adult population or other specified population group for which a potential risk has been identified.

3. For the purposes of this Regulation those conditions that would result in the ingestion of amounts of a substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet shall occur under actual circumstances and shall be assessed on a case-by-case basis in comparison with the average intake of the concerned substance by the general adult population or other specified population group for which health concerns have been raised.

4. The conditions and requirements laid down in paragraphs 1, 2 and 3 of this Article and the requirements laid down in Article 4 of this Regulation, shall apply *mutatis mutandis* where the procedure under Article 8 of Regulation (EC) No 1925/2006 is initiated by the Commission.

Article 4

Content of the request

1. The request shall contain the available and relevant generally accepted scientific evidence demonstrating that the conditions specified in Article 8(1) of Regulation (EC) No 1925/2006 are met and shall include:

(a) Evidence demonstrating the addition of the substance to food or use of the substance in the manufacture of food.

Such evidence shall include information on the current placing on the market of food products containing the substance as referred to in paragraph 1 of Article 3 of this Regulation.

(b) In cases referred to in Article 3(2)(a), evidence demonstrating that intake of the substance greatly exceeds normal conditions of consumption of a balanced and varied diet, as assessed in accordance with Article 3(3).

Such evidence shall include scientific data that represents actual dietary intake of the substance obtained from the most recently available dietary intake surveys or food consumption surveys. The inclusion of foods to which the substance has been added and/or food supplements containing the substance may be taken into account. Member States shall provide justification for the basis of their assessment of ‘normal conditions of consumption of a balanced and varied diet’ when making the request.

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(c) Evidence demonstrating a potential risk to consumers from consumption of the substance.

This evidence shall consist of relevant scientific data including unpublished validated reports, scientific opinions by a public risk assessment body or independent and peer-reviewed articles. A summary of the scientific data and the list of references of the scientific data shall be provided.

2. The Commission may ask the Member State to provide clarifications or additional information if the request is incomplete.

3. The Commission shall publish any complete request made by a Member State on its official website.

4. The Commission shall send the request to the Authority accompanied by all the available information, following consultation of the Member States. The Authority shall adopt a scientific opinion within a specified time limit as laid down by Article 29(3) of Regulation (EC) No 178/2002.

5. Interested parties may submit comments to the Commission within 30 days from the publication by the Authority of its opinion.

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Airteagal 5

An tsubstaint a liostaítear i gCuid C d'Iarscríbhinn III a ghabhann le Rialachán (CE) Uimh. 1925/2006

1. Go dtí go nglacfar formáidí caighdeánacha sonraí de bhun Airteagal 39f de Rialachán (CE) Uimh. 178/2002, ní mheasfaidh an tÚdarás comhad a bheith bailí ach amháin má thíolactar i bhformáid leictreonach é ionas gur féidir na doiciméid a íoslódáil, a phriontáil agus a chuardach.

Nuair a ghlacfar na formáidí caighdeánacha sonraí, ní mór an comhad a thíolacadh i gcomhréir leis na formáidí caighdeánacha sonraí sin ionas go measfar é a bheith bailí.

I gcás ina measfaidh an tÚdarás nach bhfuil an comhad bailí, cuirfidh sé an t-oibreoir i ngnó an bhia nó an páirtí leasmhar a chuir an comhad isteach agus an Coimisiún ar an eolas faoi na cúiseanna is dóigh leis nach bhfuil an comhad sin bailí.

2. Chun críocha an chinnidh dá dtagraítear in Airteagal 8(5) de Rialachán (CE) Uimh. 1925/2006, ní chuirfidh an tÚdarás san áireamh ach comhaid a thíolacfar laistigh de 24 mhí ó theacht i bhfeidhm cinnidh ina liostaítear substaint i gCuid C d'Iarscríbhinn III a ghabhann leis an Rialachán sin, de bhun Airteagal 8(2) de.

Airteagal 5a

Comhairle réamhthíolactha

Má iarrann oibreoir i ngnó an bhia nó aon pháirtí leasmhar eile é, cuirfidh foireann an Údaráis comhairle ar fáil maidir leis na rialacha is infheidhme, agus maidir leis an inneachar is gá, chun comhad a thíolacadh ina bhfuil sonraí eolaíocha arb é is aidhm dóibh sábháilteacht substainte a liostaítear i gCuid C d'Iarscríbhinn III a ghabhann le Rialachán (CE) Uimh. 1925/2006 a léiriú.

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Féadfaidh oibreoirí i ngnó an bhia agus páirtithe leasmhara eile comhairle réamhthíolactha a iarraidh i dtaca le tíolacadh féideartha ón lá a ghlacfaidh an tÚdarás an tuairim faoi Airteagal 8(2) de Rialachán (CE) Uimh. 1925/2006, lena sainaithnítear go bhféadfadh éifeachtaí díobhálacha a bheith ar shláinte na ndaoine de thoradh iontógáil substainte.

Tabharfar an chomhairle réamhthíolactha sin i gcomhréir le hAirteagal 32a de Rialachán (CE) Uimh. 178/2002, a mbeidh feidhm aige *mutatis mutandis*.

Airteagal 5b

Fógra a thabhairt faoi staidéir

1. Tabharfaidh oibreoirí i ngnó an bhia agus páirtithe leasmhara eile fógra don Údarás gan mhoill faoi theideal, raon feidhme, agus dáta tosaithe agus dáta críochnaithe beartaithe aon staidéir a choimisiúnóidh siad nó a dhéanfaidh siad féin, chun sábháilteacht substainte a léiriú a liostaítear i gCuid C d'Iarscríbhinn III a ghabhann le Rialachán (CE) Uimh. 1925/2006, agus an tsaotharlann nó an tsaoráid tástála san Aontas atá i mbun an staidéir sin.

2. Tabharfaidh saotharlanna agus saoráidí tástála eile atá suite san Aontas fógra don Údarás gan mhoill freisin faoi theideal agus raon feidhme aon staidéir a choimisiúnóidh oibreoirí i ngnó an bhia agus páirtithe leasmhara eile a dhéanfaidh na saotharlanna sin nó a dhéanfaidh na saoráidí tástála eile chun sábháilteacht substainte a liostaítear i gCuid C d'Iarscríbhinn III a ghabhann le Rialachán (CE) Uimh. 1925/2006, a léiriú, an dáta tosaithe agus an dáta críochnaithe atá beartaithe ina leith, agus ainm an oibreora i ngnó an bhia nó an pháirtí leasmhair a rinne an staidéar sin a choimisiúnú.

3. Áireoidh an tÚdarás na staidéir faoina dtabharfar fógra i gcomhréir leis an Airteagal seo sa bhunachar sonraí dá dtagraítear in Airteagal 32b(1) de Rialachán (CE) Uimh. 178/2002.

Airteagal 5c

Trédhearcacht

I gcás ina mbeidh tuairim le tabhairt ag an Údarás maidir le substaint faoi ghrinnscrúdú a liostaítear i gCuid C d'Iarscríbhinn III a ghabhann le Rialachán (CE) Uimh. 1925/2006, ar bhonn comhad bailí, déanfaidh sé an méid seo a leanas:

(a) na sonraí a tíolacadh sa chomhad sin a phoibliú i gcomhréir le hAirteagal 38(1)(c) de Rialachán (CE) Uimh. 178/2002, a mbeidh feidhm aige *mutatis mutandis*;

(b) dul i gcomhairle le páirtithe leasmhara agus leis an bpobal, de bhun Airteagal 32c(2) de Rialachán (CE) Uimh. 178/2002, a mbeidh feidhm aige *mutatis mutandis*, ar bhonn leagan neamhrúnda na sonraí a tíolacadh i gcomhréir leis an Rialachán seo.

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Airteagal 5d

Rúndacht

Nuair a dhéanfar comhad a thíolacadh, féadfaidh an t-oibreoir i ngnó an bhia nó páirtí leasmhar eile a thabhairt le fios gur mhian leis go gcoinneofaí codanna áirithe den fhaisnéis nó codanna áirithe de na sonraí a tíolacadh ina rún.

Ní mór réasúnú infhíoraithe a chur leis an iarraidh sin ar rúndacht, agus ba cheart a léiriú ann go ndéanann nochtadh na faisnéise nó na sonraí sin dochar suntasach do leasanna an iarrthóra, de réir bhrí Airteagal 39(2) agus (3) de Rialachán (CE) Uimh. 178/2002, a bhfuil feidhm aige *mutatis mutandis*.

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Article 6

Opinion of the Authority

1. The Authority shall give its opinion on files referred to in Article 5(1) of this Regulation within nine months from the date of receipt of a valid file. The Authority shall assess the validity of the file within 30 days from receipt of the file.

2. The Authority may request the food business operator or interested party to supplement the data or information submitted in a file within a specified time limit. When the Authority seeks supplementary information from the food business operator or any other interested party, the time limit referred to in paragraph 1 shall be extended only once by up to three months and shall include the time needed by the food business operator or any interested party to provide this supplementary information. The food business operator or interested party shall submit the requested information within 15 days from the date of receipt of the Authority's request.

Article 7

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.