

Call for food additives usage level and/or concentration data in food and beverages intended for human consumption

Deadline for data submission: 15 September 2013

This document published on 31 July 2013, replaces the earlier version published on 27 March 2013.

Background

Regulation (EC) No 1333/2008ⁱ of the European Parliament and the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under Commission Regulation (EU) No 257/2010 of 25 March 2010ⁱⁱ. This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong. The order of specific priorities for the re-evaluation of the currently approved food additives is listed in Annex II of Commission Regulation (EU) No 257/2010. In addition, the Panel on Food Additives and Nutrient Sources added to Food (ANS) discussed and agreed on a draft work programme for the re-evaluation of food additives for 2013 and 2014 during the 39th and 40th plenary meeting.

EFSA has also initiated an internal mandate for preparing refined exposure calculations for food colours already re-evaluated, for which a possible exceedance of the ADI was identified. The list of priorities for providing these refined exposure assessments is set as follows: curcumin (E 100)ⁱⁱⁱ, brown HT (E 155)^{iv}, azorubine/carmoisine (E 122)^v, allura red AC (E 129)^{vi}, brilliant black BN (E 151)^{vii}, quinoline yellow (E 104)^{viii}, sunset yellow (E 110)^{ix} and ponceau 4R (E 124)^x.

Moreover, the European Commission, in accordance with article 29 (1) (a) of Regulation No 178/2002 has asked EFSA to carry out a refined exposure assessment for β -apo-8'-carotenal (E 160e)^{xi} further to the evaluation carried out by EFSA's ANS Panel in 2011.

The exposure assessments will be prepared taking into account the restrictions/exceptions listed in Regulation (EU) No 1129/2011^{xii}, especially in the case of main contributors.

Deadline for submission of data

The deadlines for the submission of data for the 2013 and 2014 draft work programme is September and November 2013, details are listed in Table 1.

Further calls for data in relation to the food additives re-evaluation work programme for 2015 onwards will be published at a later stage.

Table 1. List of food additives for which usage levels and/or concentration data are requested in relation to the 2013 and 2014 draft work programme.

<i>Batch of submission</i>	<i>SSD code</i>	<i>E number</i>	<i>Substance</i>	<i>Mandate number/Question number</i>	<i>Deadline for data submission</i>
Batch 1	RF-00000108-ADD	E 100	Curcumin	M-2012-0247/EFSA-Q-2012-00882	15-Sep-13
	RF-00000047-ADD	E 122	Azorubine/Carmoisine	M-2012-0247/EFSA-Q-2012-00885	15-Sep-13
	RF-00000028-ADD	E 129	Allura red AC	M-2012-0247/EFSA-Q-2012-00886	15-Sep-13
	RF-00000159-ADD	E 132	Indigotine, Indigo carmine	M-2011-0160/EFSA-Q-2011-00358	15-Sep-13
	RF-00000059-ADD	E 155	Brown HT	M-2012-0247/EFSA-Q-2012-00884	15-Sep-13
	RF-00001291-PAR	E 140i	Chlorophylls ¹	M-2011-0160/EFSA-Q-2011-00357	15-Sep-13
	RF-00001292-PAR	E 140ii	Chlorophyllins ¹	M-2011-0160/EFSA-Q-2011-00371	15-Sep-13
	RF-00001293-PAR	E 141i	Copper complexes of chlorophylls ²	M-2011-0160/EFSA-Q-2011-00356	15-Sep-13
	RF-00001294-PAR	E 141ii	Copper complexes of chlorophyllins ²	M-2011-0160/EFSA-Q-2011-00372	15-Sep-13
	RF-00000054-ADD	E 160e	β-Apo-8'-carotenal	M-2012-0353/EFSA-Q-2012-01001	15-Sep-13
	RF-00000335-ADD	E 171	Titanium dioxide	M-2011-0160/EFSA-Q-2011-00348	15-Sep-13
	RF-00000162-ADD	E 172	Iron oxides and hydroxides	M-2011-0160/EFSA-Q-2011-00347	15-Sep-13
	RF-00000257-ADD	E 310	Propyl gallate*	M-2011-0160/EFSA-Q-2011-00479	15-Sep-13
	RF-00000204-ADD	E 311	Octyl gallate*	M-2011-0160/EFSA-Q-2011-00480	15-Sep-13
	RF-00000120-ADD	E 312	Dodecyl gallate*	M-2011-0160/EFSA-Q-2011-00481	15-Sep-13
Batch 2	RF-00000260-ADD	E 104	Quinoline yellow	M-2012-0247/EFSA-Q-2012-00888	30-Nov-13
	RF-00000326-ADD	E 110	Sunset Yellow	M-2012-0247/EFSA-Q-2012-00889	30-Nov-13
	RF-00000105-ADD	E 120	Cochineal, Carminic acid, Carmines	M-2011-0160/EFSA-Q-2011-00360	30-Nov-13
	RF-00000228-ADD	E 124	Ponceau 4R	M-2012-0247/EFSA-Q-2012-00890	30-Nov-13
	RF-00000057-ADD	E 151	Brilliant black BN	M-2012-0247/EFSA-Q-2012-00887	30-Nov-13
	RF-00000043-ADD	E160b	Annatto, bixin, norbixin	M-2011-0160/EFSA-Q-2011-00362	30-Nov-13
	RF-00000324-ADD	E 220	Sulphur dioxide	M-2011-0160/EFSA-Q-2011-00445	30-Nov-13
	RF-00000300-ADD	E 221	Sodium sulphite ^a	M-2011-0160/EFSA-Q-2011-00446	30-Nov-13
	RF-00001295-PAR	E 222	Sodium bisulphite ^a	M-2011-0160/EFSA-Q-2011-00447	30-Nov-13
	RF-00000291-ADD	E 223	Sodium metabisulphite ^a	M-2011-0160/EFSA-Q-2011-00448	30-Nov-13
	RF-00000243-ADD	E 224	Potassium metabisulphite ^a	M-2011-0160/EFSA-Q-2011-00449	30-Nov-13
	RF-00000089-ADD	E 226	Calcium sulphite ^a	M-2011-0160/EFSA-Q-2011-00450	30-Nov-13
	RF-00001296-PAR	E 227	Calcium bisulphite ^a	M-2011-0160/EFSA-Q-2011-00451	30-Nov-13

<i>Batch of submission</i>	<i>SSD code</i>	<i>E number</i>	<i>Substance</i>	<i>Mandate number/Question number</i>	<i>Deadline for data submission</i>
Batch 2	RF-00001297-PAR	E 228	Potassium bisulphite ^a	M-2011-0160/EFSA-Q-2011-00452	30-Nov-13
	RF-00000151-ADD	E 239	Hexamethylene tetramine*	M-2011-0160/ EFSA-Q-2011-00458	30-Nov-13
	RF-00000245-ADD	E 249	Potassium nitrite ^b	M-2011-0160/EFSA-Q-2011-00460	30-Nov-13
	RF-00000294-ADD	E 250	Sodium nitrite ^b	M-2011-0160/EFSA-Q-2011-00461	30-Nov-13
	RF-00000293-ADD	E 251	Sodium nitrate ^c	M-2011-0160/EFSA-Q-2011-00462	30-Nov-13
	RF-00000244-ADD	E 252	Potassium nitrate ^c	M-2011-0160/EFSA-Q-2011-00463	30-Nov-13
	RF-00000046-ADD	E 300	Ascorbic acid	M-2011-0160/EFSA-Q-2011-00470	30-Nov-13
	RF-00000278-ADD	E 301	Sodium ascorbate ^d	M-2011-0160/EFSA-Q-2011-00471	30-Nov-13
	RF-00000067-ADD	E 302	Calcium ascorbate ^d	M-2011-0160/EFSA-Q-2011-00472	30-Nov-13
	RF-00001298-PAR	E 304i	Ascorbyl palmitate ³	M-2011-0160/EFSA-Q-2011-00473	30-Nov-13
	RF-00001299-PAR	E 304ii	Ascorbyl stearate ³	M-2011-0160/EFSA-Q-2011-00474	30-Nov-13
	RF-00000336-ADD	E 306	Tocopherol-rich extract	M-2011-0160/EFSA-Q-2011-00475	30-Nov-13
	RF-00000029-ADD	E 307	Alpha – tocopherol	M-2011-0160/EFSA-Q-2011-00476	30-Nov-13
	RF-00000135-ADD	E 308	Gamma – tocopherol	M-2011-0160/EFSA-Q-2011-00477	30-Nov-13
	RF-00000110-ADD	E 309	Delta – tocopherol	M-2011-0160/EFSA-Q-2011-00478	30-Nov-13
	RF-00000140-ADD	E 422	Glycerol	M-2011-0160/ EFSA-Q-2011-00519	30-Nov-13
	RF-00000321-ADD	E 444	Sucrose acetate isobutyrate	M-2011-0160/EFSA-Q-2011-00530	30-Nov-13
	RF-00000216-ADD	E 475	Polyglycerol esters of fatty acids	M-2011-0160/ EFSA-Q-2011-00564	30-Nov-13
	RF-00000308-ADD	E 491	Sorbitan monostearate	M-2011-0160/ EFSA-Q-2011-00571	30-Nov-13
	RF-00000309-ADD	E 492	Sorbitan tristearate	M-2011-0160/ EFSA-Q-2011-00572	30-Nov-13
	RF-00000305-ADD	E 493	Sorbitan monolaurate	M-2011-0160/ EFSA-Q-2011-00573	30-Nov-13
	RF-00000306-ADD	E 494	Sorbitan monooleate	M-2011-0160/ EFSA-Q-2011-00574	30-Nov-13
	RF-00000307-ADD	E 495	Sorbitan monopalmitate	M-2011-0160/ EFSA-Q-2011-00575	30-Nov-13

Table 1 notes

¹ analytical results for combined chlorophylls and chlorophyllins (E 140i and E 140ii) may be reported under code RF-00000102-ADD.

² analytical results for combined copper complexes of chlorophylls and copper complexes of chlorophyllins (E 141i and E 141ii) may be reported under code RF-00000106-ADD.

³ analytical results for fatty acid esters of ascorbic acid (E 304i and E 304ii) may be reported under code RF-00000130-ADD.

*only concentration data are requested to be submitted (E 239, E 310, E 311 and E 312).

^a analytical results expressed as SO₂ (RF-00000112-CHE) (E 221, E 222, E 223, E 224, E 226, E 227 and E 228).

^b analytical results expressed as nitrite (RF-00000087-CHE) (E 249 and E 250).

^c analytical results expressed as nitrate (RF-00000085-CHE) (E 251 and E 252).

^d analytical results expressed as ascorbic acid (RF-00000046-ADD) (E 301 and E 302).

The procedure for data submission is described below. Please note that submission of data through the “Data Collection Framework (DCF)” will be possible from 1st May 2013 onwards.

Data provided may be used in the EFSA opinions depending on their quality, and exclusion criteria will be indicated in the EFSA opinions. Only the data provider organisation will be cited in the EFSA opinions. Data provider organisations wishing to remain anonymous in the publications should indicate it in the email they will use to submit data to EFSA.

Contact details

Please address any technical inquiries regarding the reporting of data to: dcmdata@efsa.europa.eu.

Submission of usage level data

Food manufacturers eventually coordinated by the food manufacturers associations are invited to submit data on usage levels of additives in food and beverages for human consumption listed in Table 1.

Data submission on usage level of approved food additives in food and beverages intended for human consumption should follow the requirements provided in Table 1a of the Annex.

Where possible, the requirements provided use the same lists of Controlled terms as defined in the Guidance of Standard Sample Description^{xiii} (<http://www.efsa.europa.eu/en/efsajournal/doc/1457.pdf>), which are currently in place for the transmission to EFSA of analytical results.

In order to streamline the data collection exercise food manufacturers are invited to liaise with the relevant food manufacturer associations.

Food manufacturers and food manufacturer associations wishing to submit data directly to EFSA can do it using the provided MS Excel® files (Annexes Table 1b_1 – (“ADD_USAGE_structure.xls”) or Table 1b_2 - (“AddUseLevTemplate.xls”). Data providers should choose reporting data either using “ADD_USAGE_structure.xls” or “AddUseLevTemplate.xls”.

The “ADD_USAGE_structure.xls” is a MS Excel® file, it has to be filled manually with codes, numbers and free text.

The “AddUseLevTemplate.xls” is a MS Excel® file offering additional help for manual data entry. This MS Excel® file embeds pick lists linked with “predefined lists” of standard terms included in the “StandardSampleDescription.xls” (Table 2b). The “AddUseLevTemplate.xls” require that Excel macros are enabled.

In case of data collected in a MS Excel® structure, as reported above, the files should be submitted by email to dcmdata@efsa.europa.eu. Where the number of records to be submitted is above 10,000 rows, food manufactures are invited to contact EFSA to evaluate the need of an electronic transmission to the DCF system.

Food manufacturer associations will be provided of access to EFSA Web interface for data collection “Data Collection Framework (DCF)” (<https://dcf.efsa.europa.eu/dcf-war>) and will be able to submit additive usage level data electronically in XML format. In order to receive access to the DCF web interface and further guidance on the electronic data transmission (<http://www.efsa.europa.eu/de/efsajournal/pub/1895.htm>) please contact dcmdata@efsa.europa.eu. The data collection group to be selected when submitting usage level data on the DCF is the group “ADD_USAGE”.

The following links list the documentation needed to support the data collection on food additives usage levels:

Table 1a: Call for food additives usage level data in food and beverages intended for human consumption - Mandatory, recommended or optional information to be reported.

Table 1b_1: MS Excel® file “ADD_USAGE_structure.xls” (Free structure file).

Table 1b_2: MS Excel® file “AddUseLevTemplate.xls” (File with predefined lists of elements linked and macros).

Table 2c: [MS Excel® Standard Sample Description.xls](http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm) available at <http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm>

Table 3: MS Excel file “Food classification related to food additives including exceptions and restrictions” (Amended for reporting substance of Batch 1 and Batch 2)^{xiv}.

Submission of concentration data (analytical results)

Food manufacturers, national food authorities, research institutions, academia, food business operators, and other stakeholders are invited to submit analytical data on concentration levels in food and beverages intended for human consumption listed in Table 1.

It should be noted that the present call is not aiming at collecting compliance sample information but the actual concentration level of additives in the analysed food.

Data submission of concentration data (analytical results) should follow the requirements identical to those described in the call for continuous collection of chemical contaminants occurrence data in food and feed (<http://www.efsa.europa.eu/en/data/call/datex101217.htm>) and reported in Table 2a of the Annex.

Data should be transmitted using the EFSA web interface “Data Collection Framework (DCF)” (<https://dcf.efsa.europa.eu/dcf-war>). The data collection group to be selected when submitting data on these substances through Data Collection Framework is the group “OCC_GROUP5”. In order to receive access to the DCF web interface please contact: dcmdata@efsa.europa.eu.

In case data are compiled using the Table 2b, MS Excel® file “Simplified reporting format” available at <http://www.efsa.europa.eu/en/datexdata/docs/GenericReportingFormat.xls>, they cannot be transmitted using the DCF web interface. In this case data should be sent to the e-mail address: dcmdata@efsa.europa.eu.

For the collection of this type of data the general recommendations and mandatory fields apply as specified in the Guidance on Standard Sample Description (<http://www.efsa.europa.eu/en/efsajournal/doc/1457.pdf>).

The following links summarise the mandatory fields and recommended fields applicable for the data collections defined in this call and the food classification related to additives, exceptions and restrictions.

Table 2a: Call for concentration data of food additives in food and beverages intended for human consumption - Mandatory or recommended information to be reported.

Table 2b: MS Excel® file “Simplified reporting format” available at <http://www.efsa.europa.eu/en/datexdata/docs/GenericReportingFormat.xls>.

Table 3: MS Excel® file “Food classification related to food additives including exceptions and restrictions” (Amended for reporting substance of Batch 1 and Batch 2)^{xiv}.

Annexes

The following links list the documentation needed to support the data collection on additives.

Table 1a: Call for food additives usage level data in food and beverages intended for human consumption - Mandatory, recommended or optional information to be reported.

Table 1b_1: MS Excel® file “ADD_USAGE_structure.xls” (Free structure file)

Table 1b_2: MS Excel® file “AddUseLevTemplate.xls” (File with predefined lists of elements and macros)

Table 2a: Call for concentration data of food additives in food and beverages intended for human consumption - Mandatory or recommended information to be reported.

Table 2b: MS Excel® file “Simplified reporting format” available at <http://www.efsa.europa.eu/en/datexdata/docs/GenericReportingFormat.xls>.

Table 2c: MS Excel® Standard Sample Description.xls available at <http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm>

Table 3: MS Excel® file “Food classification related to food additives including exceptions and restrictions” (Amended for reporting substance of Batch 1 and Batch 2)^{xiv}.

ⁱ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p.16.

ⁱⁱ Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.03.2010, p. 19.

ⁱⁱⁱ Scientific Opinion on the re-evaluation of curcumin (E 100) as a food additive. EFSA Journal 2010; 8(9):1679.

^{iv} Scientific Opinion on the re-evaluation of Brown HT (E 155) as a food additive. EFSA Journal 2010;8(4):1536.

^v Scientific Opinion on the re-evaluation of Azorubine/Carmoisine (E 122) as a food additive. EFSA Journal 2009; 7(11):1332.

^{vi} Scientific Opinion on the re-evaluation of Allura Red AC (E 129) as a food additive. EFSA Journal 2009; 7(11):1327.

^{vii} Scientific Opinion on the re-evaluation of Brilliant Black BN (E 151) as a food additive. EFSA Journal 2010;8(4):1540.

^{viii} Scientific Opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive. EFSA Journal 2009; 7(11):1329.

^{ix} Scientific Opinion on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive. EFSA Journal 2009; 7(11):1330.

^x Scientific Opinion on the re-evaluation of Ponceau 4R (E 124) as a food additive. EFSA Journal 2009; 7(11):1328.

^{xi} Scientific Opinion on the re-evaluation of β -apo-8'-carotenal (E 160e) as a food additive. EFSA Journal 2012;10(3):2499.

^{xii} Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295, 12.11.2011, p.1.

^{xiii} European Food Safety Authority; Standard sample description for food and feed. EFSA Journal 2010; 8(1):1457 [54 pp.].

^{xiv} Substances included in Batch 1 with deadline for submission of data 15 September 2013 and in Batch 2 with deadline for submission of data 30 November 2013.