

INSTRUCTIONS ON HOW TO COMPLETE THE TEMPLATES FOR FOOD ADDITIVES AND NOVEL FOODS USE LEVEL DATA



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HOW TO COMPLETE THE 'ADDUSELEVTEMPLATE' AND 'NOVELFOODUSELEVTEMPLATE' FILES

These files are designed for inputting use level data on the food additive that remains to be re-evaluated in accordance with Regulation (EU) No 257/2010 and for novel foods in accordance with the Commission Implementing Regulation (EU) 2017/2470.

Once the Data Provider opens both templates, two worksheets will be displayed.

The first worksheet named "Readme", indicates the steps which need to be followed as well as a table with the explanation of the colors related to different types of data elements and their reportability (Figure 1).

Sample ID (AD.01)	Mandatory variable
Maximum permitted level (AD.20)	Mandatory in conjunction with the value of another variable
Parameter text (AD.14)	Recommended variable
Brand name (AD.07)	Optional variable
EFSA Product code (text preview) (AD.03P)	Filled in automatically after choosing another variable in conjunction with it
Length of sample Id (AD.01)	Checking / Basic validation of certain reported data

Figure 1: Descriptive highlighted colors for data reportability

The second worksheet "Data reported" is the main one, where data shall be entered. By placing the mouse on the column headings in the template, a brief description of the item to be reported will be displayed. As figure 1 shows, columns headed in red are the mandatory to complete, dark red columns are mandatory elements which their value is dependent to another variable, orange headed columns are recommended while blue columns are optional. Grey columns contain formulas, therefore, should never be filled in manually or deleted.

The maximum number of records that can be inputted in the templates is 500. If is needed to report more than 500 results to EFSA, please input these in an additional file. For the creation of additional files, as a continuation of the first file, it is advised to use the empty "AddUseLevTemplate" or "NovelFoodUseLevTemplate" and insert the new set of results.

For each data element in the template, please find below a brief description of the information needed.



SAMPLE ID (AD.01)

Mandatory field.

This data element is characterized by a **unique** identification code for each sample. The unique identification code cannot exceed 20 characters and special characters must be avoided.

For this call, the examples below (Figure 2) show how to report six records: where ABC is the abbreviation/acronym of the data provider followed by the sample and a sequential number.

If use levels are reported for the same sample (i.e. same food category, same food category with restriction or exceptions, same product full text description, etc.), for different food additives or novel foods, then the sample ID should be the same as displayed in rows 2 and 3.

	A	B	C	D	E	F	M	N	O	P
	Sample ID (AD.01)	Country, where the product is sold (AD.02)	EFSA Product Code Recode food	EFSA Product code (text preview) (AD.03P)	Food category (AD.04)	Food category with restrictions or exceptions (AD.04B)	Result code (AD.10)	Parameter code (AD.11)	Parameter E-code (AD.12)	Parameter code text selection (AD.13)
1	ABC_sample1	Bulgaria, Romania	A.01.001032	Yoghurt, cow milk, with fruit	01.4 Flavoured fermented milk products including heat-treated products	01.4_03 Flavoured fermented milk products including heat-treated products_only fruit-flavoured desserts	ABC_sample1RF-00000080-ADD	RF-00000080-ADD	E 633	Calcium inosinate
2	ABC_sample1	Bulgaria, Romania	A.01.001032	Yoghurt, cow milk, with fruit	01.4 Flavoured fermented milk products including heat-treated products	01.4_03 Flavoured fermented milk products including heat-treated products_only fruit-flavoured desserts	ABC_sample1RF-00000076-ADD	RF-00000076-ADD	E 578	Calcium gluconate
3	ABC_sample2	Belgium, France, Italy	A.01.000295	Brioche	07.2 Fine bakery wares	07.2 Fine bakery wares	ABC_sample2RF-00000076-ADD	RF-00000076-ADD	E 578	Calcium gluconate
4	ABC_sample3	Netherlands	A.01.000314	Biscuits, salty	07.2 Fine bakery wares	07.2_03 Fine bakery wares_only dry biscuits	ABC_sample3RF-00000076-ADD	RF-00000076-ADD	E 578	Calcium gluconate
5	ABC_sample4	Austria	A.01.001417	Juice, Mixed fruit	14.1.2 Fruit juices as defined by Directive 2001/112/EC and vegetable juices	14.1.2 Fruit juices as defined by Directive 2001/112/EC and vegetable juices	ABC_sample4RF-00000080-ADD	RF-00000080-ADD	E 633	Calcium inosinate
6	ABC_sample5	European Union	A.01.000659	Jam, Strawberries (Fragaria x ananassa)	04.2.5.2 Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC	04.2.5.2_03 Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC_only low-sugar and similar low calorie or sugar-free products spreads, mermeladas	ABC_sample5RF-00000076-ADD	RF-00000076-ADD	E 578	Calcium gluconate
7										

Figure 2: Example on how to report the Sample ID

As shown in figure 2, for samples with the same sample ID will be an alarming yellow highlight. However, this is only used as a Warning message to show that the exact sample ID was used more than one time. If this name convention was used intentionally, based on the previous paragraph's exceptional case (same food category, same product description, etc.), the change of the names is not needed.

The data element 'Sample ID' will be used as reference in communication between data providers and EFSA, if necessary.

COUNTRY, WHERE THE PRODUCT IS SOLD (AD.02)

Optional field.

Indicates in which European country the product is available by choosing the country name from the drop-down list.

- If the product is available in six or more European countries, please use "European Union".



- If the product is available typically only in a certain region, it is possible to report more than one country in this field by selecting the relevant country names.
For example, if the product is available in the Scandinavian region, the Data Provider may choose all the relevant Scandinavian countries from the drop-down list (Figure 3).

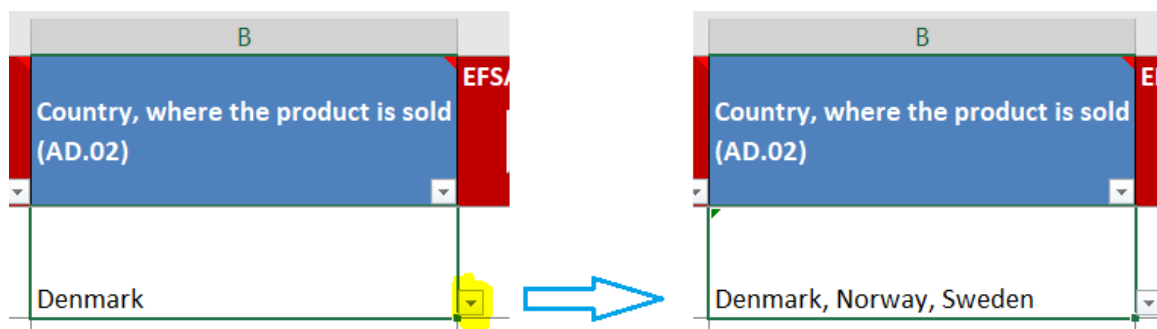


Figure 3: Example on how to report the Country

EFSA PRODUCT CODE (AD.03) AND EFSA PRODUCT CODE (TEXT PREVIEW) (AD.03P)

Mandatory field (AD.03) and automatically filled field (AD.03P).

Column 'EFSA Product code (AD.03)' and the next one 'EFSA Product Code text preview (AD.03P)' are linked and both completed by generating a code using the 'Recode food' button found in cell C1. A list of reportable food items is available.

Select the food that most closely matches the food which will be reported. The corresponding EFSA code will appear in the adjacent column 'EFSA Product code (AD.03P)' as shown in figure 4.

- Click on an empty cell in the column 'EFSA Product Code (AD.03)'.
- Click on the 'Recode food' button and a 'Search Matrix' window will pop up. This 'Search Matrix' window is linked to the FoodEx catalogue. The FoodEx catalogue contains the food items that can be selected to classify your product.
- Type the word "bread" in the field of 'Find' and press 'enter' or 'Go'. In the right-hand side of the 'Search Matrix' window a list will appear, which contains "bread". Click on the description which is the closest one to the product.
- In the left-hand side of the 'Search Matrix' window a tree view will appear, showing the 'product's family'.
- After double clicking on the chosen product, the FoodEx code and the linked Product text will be inserted in the column 'EFSA Product Code (AD.03)' and next column 'EFSA Product code (text preview) (AD.03P)' respectively. Please note that if the cursor is not in Column 'C', no insertion will be done. The above steps are illustrated in the figure 4.



If the exact product is not available, please choose the upper Matrix level.
Example: classification of a specialty beer made from red berries which does not exist in FoodEx catalogue. Therefore, choose the 'upper level', which is 'Beer and beer-like beverage' and provide additional information as a full description of the product in the field of '**Product full text description (AD.05)**'. For more information, please refer below to Section AD.05.

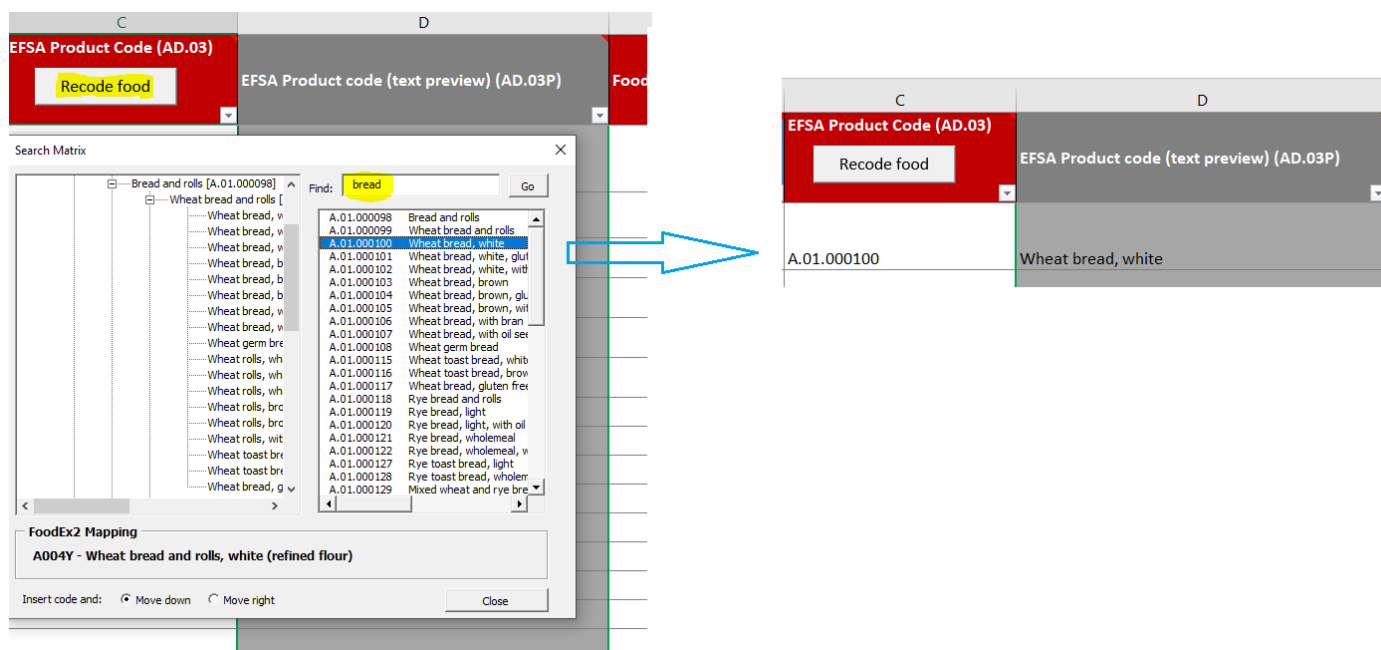


Figure 4: Example on how to insert the "EFSA product code"

Each FoodEx1 entry in column 'EFSA Product Code (AD.03)', generated with the 'Recode Food' form, will automatically populate column 'Comment of the result with FOODEX2 code (AD.26)' with the corresponding FoodEx2 code and description. In case elements in the current column are deleted, please recall updating column 'Comment of the result with FOODEX2 code (AD.26)' accordingly, as found on the right side of the template.

FOOD CATEGORY (AD.04)

Mandatory field.

Mandatory field to choose the additive food category using the available drop-down menu, as indicated in the figure below.

For food additives, this list contains the food categories listed in the additive legislation Regulation EC No. 1333/2008 (amended), Annex II part E.

For the novel foods, the list contains the specific food categories under which the novel food may be used accordingly to legislation Regulation (EU) 2017/2470.



Figure 5: Example of food categories (addUseLevTemplate)

FOOD CATEGORY WITH RESTRICTIONS OR EXCEPTIONS (AD.04B)

Recommended field. Only present in "AddUseLevTemplate".

This column is not present in the "NovelFoodUseLevTemplate" as restrictions are not applicable for novel foods.

This optional field is used for describing the food as precisely as possible by using the additive food category list in the column 'Food Category with restrictions or exceptions (AD.04B)'. This extended additive food category list contains the basic terms (AD.04) amended with the restrictions and exceptions described in the legislation. Please use the drop-down list to select the extended additive food categories from the restrictions/exceptions in the [Regulation \(EC\) No 1333/2008 \(amended\), Annex II, part E](#).

Considering that the element of 'Food Category with restrictions or exceptions (AD.04B)' includes a long picklist - with the available combinations of food category and restriction - data providers are invited to consult the annex file ('Annex Food Category Description' excel file) with the complete list of selectable terms. Searching by a specific keyword, it will allow to identify what code is related to the desired combination of food category with restriction/exception.

In case there are no specific restrictions related to the sample, please include the same food category as in the previous column 'Food category (AD.04)'.

The following example (Figure 6) illustrates how the food category should be selected:
Example: Burger meat with a minimum vegetable content of 4% mixed within the meat.

Therefore, 'Food Category (AD.04)' shall be '08.2 Meat preparations as defined by Regulation (EC) No 852/2004' and 'Food category with restrictions or exceptions (AD.04B)' shall be '08.2_06 08.2 Meat preparations as defined by Regulation (EC) No



852/2004_only breakfast sausages; Burger meat with a minimum vegetable and/or cereal content of 4 % mixed within the meat'.

E	F
Food category (AD.04)	Food category with restrictions or exceptions (AD.04B)
08.1 Fresh meat, excluding meat preparations as defined by Regulation (EC) No 853/2004	
08.2 Meat preparations as defined by Regulation (EC) No 853/2004	
08.3 Meat products	
08.3.1 Non-heat-treated meat products	
08.3.2 Heat-treated meat products	
08.3.3 Casings and coatings and decorations for meat	
08.3.4 Traditionally cured meat products with specific provisions concerning nitrites and nitrates	
08.3.4.1 Traditional immersion cured products (Meat products cured by immersion in a curing solution containing r	
08.2 Meat preparations as defined by Regulation (EC) No 853/2004	
	08.2_03 Meat preparations as defined by Regulation (EC) No 853/2004 _only breakfast sausages with a minimum cereal conte
	08.2_04 Meat preparations as defined by Regulation (EC) No 853/2004 _only breakfast sausages with a minimum cereal conte
	08.2_05 Meat preparations as defined by Regulation (EC) No 853/2004 _only merquez type products, salsicha fresca, butifarra
	08.2_06 Meat preparations as defined by Regulation (EC) No 853/2004 _only breakfast sausages, Burger meat with a minimum
	08.2_07 Meat preparations as defined by Regulation (EC) No 853/2004 _only salsicha fresca, longaniza fresca, butifarra fresca
	08.2_08 Meat preparations as defined by Regulation (EC) No 853/2004 _only lomo de cerdo adobado, pincho moruno, careta
	08.2_09 Meat preparations as defined by Regulation (EC) No 853/2004 _only prepacked preparations of fresh minced meat an
	08.2_10 Meat preparations as defined by Regulation (EC) No 853/2004 _only gehakt, prepacked preparations of fresh minced

Figure 6: Example of selection of Food category with restrictions or exceptions

PRODUCT FULL TEXT DESCRIPTION (AD.05)

Mandatory field.

The food item can be fully specified with free text up to maximum of 250 characters. This element is very important as it provides more specific information about the product than the information provided under the 'EFSA product code' field. The data provider can give all the information that is necessary for the description of the product.

CONSUMPTION INDEX (AD.06)

Optional field.

This field can be used to report if the product is a 'Niche product' or 'Widely consumed'.

Niche product refers to products used by a specific population group; foods which are consumed by few people, maybe a regional product, or a product for people needing a specific diet. While widely consumed products refer to the products that are representative of the food/food category.



IS IT A FOOD FORMULATED FOR INFANTS (<12 MONTHS) (AD.06B)

Optional field.

This column is not present in the "NovelFoodUseLevTemplate".

Report either 'Yes' or 'No' in the template for food additive usage level "AddUseLevTemplate".

BRAND NAME (AD.07)

Optional field.

Free text field to indicate the food brand.

MANUFACTURER (AD.08)

Optional field.

Free text field to indicate the food manufacturer.

The name of the manufacturer can be included in this field. Alternatively, it can be indicated whether the company is a food producer (additive user or novel food user) or if the company produces the additive or the novel food.

YEAR OF REPORTING (AD.09)

Mandatory field.

Provide the reporting year, this should be the year of the additive or novel food use – usually the current year. It should be reported as YYYY, e.g., 2023.

RESULT CODE (AD.10)

Mandatory dependent field.

This field is not present in the "NovelFoodUseLevTemplate".

Do not enter any data in this field. The code is automatically generated for each record by concatenating the 'Sample ID' and 'Parameter code'.

PARAMETER CODE (AD.11), PARAMETER-E CODE (AD.12), AND PARAMETER CODE TEXT SELECTION (AD.13)

Mandatory (AD.13) and automatically filled fields (AD.11, AD.12).



For Novel foods, the columns 'Parameter code (AD.11)' and 'Parameter E-code (AD.12)' are not present in the template. The only column available to input the data is 'Parameter code text selection (AD.13)'.

These fields are used to identify the food additive or novel food analyzed. The selection of the parameter under column 'Parameter code text selection (AD.13)' automatically completes the codes in 'Parameter code (AD.11)' and 'Parameter E-code (AD.12)'. Below two examples are presented (Figure 7):

N	O	P
Parameter code (AD.11)	Parameter E-code (AD.12)	Parameter code text selection (AD.13)
RF-00000076-ADD	E 578	Calcium gluconate
RF-00000286-ADD	E 576	Sodium gluconate

Figure 7: Example of Parameter code selection

The 'Parameter code' and 'Parameter E-codes' elements, are derived by the corresponding substances as found in the PARAM catalogue of Catalogue Browser.

PARAMETER TEXT (AD.14)

Optional field.

Recommended data element. Please describe the additive in this free text field with the E-code or the details of the novel food. This is particularly important if more than one additive is used together, for example E 316 in combination with E 315.

USAGE UNIT (AD.15)

Mandatory field.

It provides the unit of measurement for the additive or novel food. If there is a maximum permitted limit defined (MPL), the MPL value and the use values should be provided in the same unit.

USAGE LEVEL MINIMUM (AD.16), USAGE LEVEL TYPICAL (AD.17) AND USAGE LEVEL MAXIMUM (AD.18)

Optional field (AD.16) and Mandatory fields (AD.17 and AD.18)



Please provide the minimum, the typical and the maximum usage level of the additive or novel food. It is mandatory to report the typical and maximum usage level. Only a single numerical value can be reported in each element.

If only the typical use level is known, please specify the same value also as maximum level.

IS MAXIMUM PERMITTED LEVEL DEFINED (AD.19)

Mandatory field.

Drop-down menu choice between 'Maximum Permitted Level Defined' and 'Quantum Satis'.

Please indicate whether there is a maximum permitted level (MPL) defined for the additive or novel food in legislation or is regulated as Quantum satis. If a MPL is defined, the MPL value must be indicated in the 'Maximum permitted level (AD.20)' field.

MAXIMUM PERMITTED LEVEL (AD.20)

Mandatory dependent field.

For reporting the MPL only a numerical value can be reported. This field must be filled in when the column AD.19 corresponds to a defined MPL.

When compiling the template for food additive use level 'AddUseLevTemplate', please check the correspondent MPL as in the Regulation EC No. 1333/2008 (amended).

When compiling the template for Novel Foods, 'NovelFoodUseLevTemplate', please refers to the additional file provided in the call "Annex Food Category Description Novel Foods" which contains the information on the type of novel food, categories allowed for each novel food and maximum permitted level specific for each category.

FUNCTION OF FOOD ADDITIVE (AD.21)

Mandatory field.

This field does not apply for novel foods and it is not present in the novel food template.

Describe the function of the food additive by choosing from the drop-down list of additive functions.

PERCENTAGE OF MOISTURE IN THE ORIGINAL SAMPLE (AD.22)

Mandatory dependent field.



If the result under column 'Expression of the result (AD.24)' is expressed as dry matter (dry weight), please indicate the percentage of moisture as a number. The moisture content must be expressed as a percentage (%); i.e. report 40 for 40% moisture content. It is mandatory to report if the results are expressed on dry matter (dry weight).

PERCENTAGE OF FAT IN THE ORIGINAL SAMPLE (AD.23)

Mandatory dependent field.

If the result under column 'Expression of the result (AD.24)' is expressed as fat weight indicate the percentage of fat as a number.

The fat content must be expressed as a percentage (%); i.e. report 40 for 40% fat content. It is mandatory to report if the results are expressed on fat weight.

EXPRESSION OF THE RESULT (AD.24)

Mandatory field.

Please describe whether the results have been expressed in whole weight (as consumed), dry matter (dry weight) or fat weight. Please be aware that "active pigment" will be considered as "whole weight".

CONVERSION/DILUTION FACTOR (AD.25)

Optional field.

Complete this field to indicate the recommended conversion or dilution factor if the use levels apply to the food before it is consumed. Please provide information about the suggested dilution/conversion factor.

COMMENT OF THE RESULT WITH FOODEx2 CODE (AD.26)

Optional and partially automatically filled field.

Please note that for each FoodEx1 code entered by the 'Recode Food' form in column 'EFSA Product Code (AD.03)' the corresponding FoodEx2 code and description is entered in this column automatically. Comments on the reported results can be provided in this field. It is advised to include the additional information on the results by concatenating the text with the already prefilled FoodEx2 code. The concatenation can be included manually by adding a "\$" after the automatically prefilled information and before the text that is intended to be added. The limit is a maximum of 250 characters in total.

Example:



C	D	E	AB	AC
EFSA Product Code (AD.03)	EFSA Product code (text preview) (AD.03P)	Food category (AD.04)	Conversion/Dilution factor (AD.25)	Comment of the result with FOODEX2 code (AD.26)
Recode food				
A.01.001037	Yoghurt, goat milk			A02NM - Yoghurt, goat milk\$[additional comments]

Figure 8: Example of additional information as shown in column AC

Should the contents of columns 'EFSA Product Code (AD.03)' and 'EFSA Product Code (text review) (AD.03P)' be modified or deleted, please modify, or delete the text accordingly.

COLUMNS AD-AP

Check and validate your entered data.

These cells are not present in the "NovelFoodUseLevTemplate".

The columns check and validate your entered data. If there is any issue, e.g. one of the free text fields contains more characters than the maximum allowed 250, or the reported unit is incorrect or missing, the cell becomes red, as indicated below. If the information is correct the cell is green.

AD	AE	AF	AG	AH	AI	AJ	AK	AL	AM
Length of sample Id (AD.01)	Length of Product full text description (AD.05)	Validation of the "Usage of" (AD.15)"	Validation of "Function of fo additive (AD.21)"	Validation of "Expression of the result (AD.22)"	Length of Comment of the result (AD.26)	Missing FoodEX AD.03	Missing Food category AD.04	Missing Product text description AD.05	Missing Reporting year AD.09
LONG	OK	OK	OK	OK	OK	OK	OK	Missing Product te	OK

Figure 9: Example of validation checks



FULL LIST OF GENERAL BUSINESS RULES (GBR)

The data provided by Data Providers are further transmitted through the EFSA Data Collection Framework (DCF). Thus, the submitted data can be eventually used in EFSA's scientific assessments.

In addition to the quality checks automatically performed within the template (Columns AD-AP), there is a number of Business Rules (BRs) linked to the transmitted data through DCF (Table 1). Those rules are set to ensure that the submitted data are of good quality. For each data element below, please check the **rule** which needs to be respected.

Please ensure that the data are respecting the BRs described below. The BRs might be used as reference in communication between data providers and EFSA, if necessary.

Table 1. Overview of business rules for each data element

Data element	Rule	Output type	Error Description	NOTE
AD.01	The Sample ID is key for all variables describing the product	Error	All the variable listed, must have the same values reported when the Sample ID is the same. The affected variables are Country, EFSA Product Code, EFSA Product Code (text preview), Consumption Index, Is it a food formulated for infants, Brand name and Manufacturer.	
AD.01 & AD.11	Where Parameter Code <> "RF-XXXX-XXX-XXX" (Not in list) then (Parameter Code, Sample ID) must be unique for a data provider;	Error	When parameter text is not equal to 'Not in list' then the combination of each additive (Parameter Code) with the Sample ID should be unique for a data provider	This rule is meant to avoid that duplicated results are reported by the same data provider in the data collection.
AD.03	EFSA Product Code is mandatory	Error	The EFSA Product Code is mandatory	
AD.09	Year of reporting has to be less than or equal to the current year	Error	Year of reporting cannot be greater than the current year	
AD.11	Where Parameter Code = "RF-XXXX-XXX-XXX" (Not in list) then Parameter code text selection must be provided	Error	Parameter code text selection should be completed if Parameter Code is RF-XXXX-XXX-XXX	
AD.15	If at least one of Usage level minimum, Usage level typical, Usage level maximum is provided then Usage unit must be provided.	Error	If at least one of the numeric fields is reported the unit should be reported. The fields affected are Usage level minimum, Usage level typical and Usage level maximum	As the Usage level typical is mandatory, the Unit becomes mandatory as well.



How to complete the 'AddUseLevTemplate' and 'NovelFoodUseLevTemplate'

IDATA



AD.16	Usage level typical must be greater than or equal to Usage level minimum	Error	The Usage level typical must be greater or equal than the Usage level minimum	On the top of this, the Usage level typical is mandatory while the Usage level Minimum is not
AD.16	Usage level minimum must be greater than 0	Warning	If the Usage level minimum is reported it should be greater than 0	
AD.17	Usage level typical must be greater than 0	Error	The Usage level typical must be greater than 0	On the top of this, the Usage level typical is mandatory
AD.18	Usage level maximum must be greater than or equal to Usage level typical	Error	The Usage level maximum must be greater or equal than the Usage level typical	The Usage level typical is mandatory as the Usage level maximum
AD.18	Usage level maximum must be greater than 0	Warning	If the Usage level maximum is reported it should be greater than 0	
AD.19	The field Is maximum permitted level defined is mandatory	Error	It is mandatory to report whether the maximum permitted level is defined	
AD.20	If the field Is maximum permitted level defined is equal to Quantum Satis then Maximum permitted level must be null	Error	If the field Is maximum permitted level defined is equal to Quantum Satis the Maximum permitted level should not be completed	
AD.20	If the field Is maximum permitted level defined is equal to Maximum Permitted Level Defined then Maximum permitted level must be specified	Error	If the field Is maximum permitted level defined is equal to Maximum Permitted Level Defined then Maximum permitted level must be specified	
AD.24	The Expression of the result is mandatory	Error	It is mandatory to report the Expression of result	When reporting the expression of result as Whole weight nothing has to be reported as % Fat or % Moist which become rather mandatory when the expression of result is reported, namely, as 'Fat weight' or as 'Dry matter'
AD.24	If Expression of the result is equal to Dry matter, then Percentage of moist in the original sample must be specified	Error	If Expression of the result is equal to Dry matter, then Percentage of moisture in the original sample must be specified	
AD.24	If Expression of the result is equal to Fat weight, then Percentage of fat in the original sample must be specified	Error	If Expression of the result is equal to Fat weight, then Percentage of fat in the original sample must be specified	

