

CALL FOR DATA ON BACKGROUND CONCENTRATIONS OF TRACE ELEMENTS

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THE MANDATE OF THE EUROPEAN COMMISSION

- EFSA-Q-2024-00482
- To deliver a scientific opinion on the safety for the environment of the current maximum authorised levels of the following trace elements: cobalt, copper, iodine, manganese, molybdenum, selenium and zinc, on the basis of the available and/or new data.
- The opinion should take in consideration the target species for which the trace elements are currently authorised.



PHASE I ENVIRONMENTAL RISK ASSESSMENT (ERA)

- Decision tree of Phase I of the environmental risk assessment Guidance document (GD) of 2019: Evidence should be provided showing that... (comparable concentrations of the feed additive can be expected in other plant(s) and/or that)... the use of the feed additive will not significantly alter the concentration of the additive in the receiving environmental compartments of concern.
- The natural background concentration of a trace element in a given environmental compartment is derived from the distribution of its measured concentrations, taking the 10% of the 90th percentile, following a similar approach as in the Water Framework Directive (Guidance document No 38). This is not explained in the ERA GD of 2019 but is clarified in the minutes of the WG meeting of 12 December 2022.
- The distribution of measured concentrations in the different compartments are taken from the <u>FOREGS European geochemical atlas</u> 2005.



THE FOREGS EUROPEAN GEOCHEMICAL ATLAS (2005)

- Nearly 1000 samples of each trace element collected from whole Europe, for each different compartment
- Collected from pristine areas, not impacted by mining waters or agricultural activities
- Analysed by the same analytical methods
- Results in a dry matter basis
- Statistics of the distribution of measured concentrations given
- No data on marine sediment for any of the 7 elements
- No data on freshwater sediment for I and Se
- No data on soil for Se
- A call for data was launched that will last until 23rd January 2025



THE CALL FOR DATA

- Specific Objective 1: concentrations of trace elements (cobalt, copper, iodine, manganese, molybdenum, selenium or zinc) in European soil.
- Specific Objective 2: concentrations of the abovementioned trace elements in freshwater in European freshwater bodies (e.g., streams, lakes, ponds, ditches...)
- Specific Objective 3: concentrations of the abovementioned trace elements in freshwater sediment of European freshwater bodies.
- Specific Objective 4: concentrations of the abovementioned trace elements in marine sediment in coasts of the countries specified above, including fjords and estuaries.



MINIMUM DATASET NEEDED

- Measured concentrations of these elements (actual measurements), indicating the unit and if the results are on dry matter or on "as is" basis.
- Samples collected in the last 15 years (2009 onwards)
- Place of the sample collection (coordinates or nationality and municipality)
- Indicating if the sample originates from an area not affected by spot or diffuse sources of pollution (pristine area)
- Indicating if the data has been published (reference to the publication)
- Indicate the analytical method
- Indicate if total concentration of the trace element was measured, or a particular chemical species, e.g., total copper versus Cu(+I) or Cu (+II)



VALUABLE METADATA FOR FRESH WATER AND SEDIMENT

- FRESHWATER:
 - water pH,
 - water hardness, (e.g., total hardness, mg CaCO3/L, or mmol/L, German degrees (dGH/ °dH)...)
 - dissolved organic carbon (mg/L)
- SEDIMENT (marine or freshwater):
 - porewater pH,
 - Texture: % of clay (<2 μ m), % of silt (2 63 μ m), and % of sand (>63 μ m),
 - and content of organic matter (%)



- Electronically via the tool Submission Builder "Portalino"
- In excel format
- EFSA has prepared a **Reporting tool on Trace Elements** that can be used on a voluntary basis.
- Avoid sending pdf documents containing the data

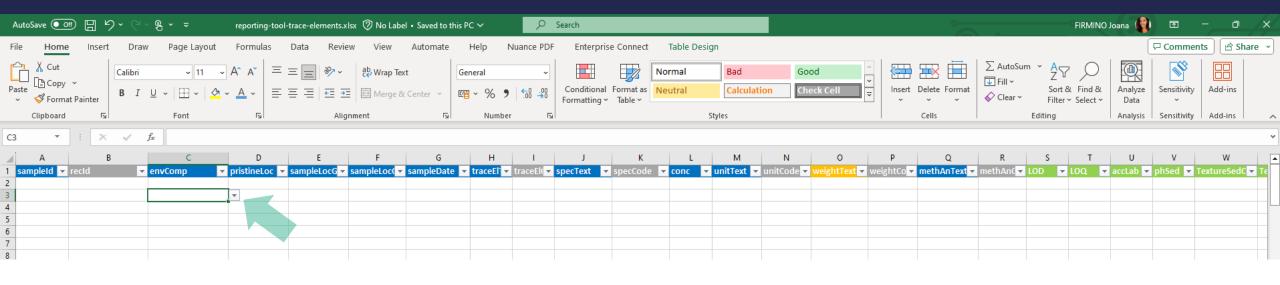


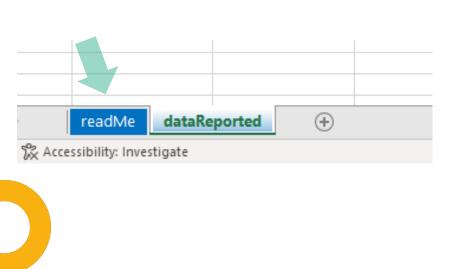




- A How to submit data on Trace Elements in Portalino
- Call for data for determination of natural background concentrations of trace elements (Co, Cu, I, Mn, Mo, Se or Zn) in the environment background document







Α Α	В	C	D	E	
Reporting Tool	Trace Elements				
Version Date	18/10/2024				
3					
Legend					
	Mandatory data elements				
	Optional data elements				
	Dependent mandatory data elements				
	Automatically filled data elements with codes fron	n EFSA Catalogue, Not required data elements.			
Glossary					
Field Label	Field Name	Description	Controlled terminology	Mandatory/Optional	
2 sampleId	Sample Identifier	Sample identification according to the data provider.		Mandatory	
		Automatically generated unique identifier by concatination of the sample identifier and the speciation. Allows communication between data			
3 recld	Record Identifier	providers and EFSA regarding specific reported data.		Mandatory	
4 envComp	Environmental Compartment	Select the compartment in which the sample was collected.	MTX (FoodEx2 Matrix)	Mandatory	
pristineLoc	Pristine Location	Select "YES" or "NO", indicating if the area sampled was affected by point or diffuse sources of pollution.	YESNO	Mandatory	
		Report the geographical coordinates where the sample			

- Electronically via the tool Submission Builder "Portalino"
- In excel format
- EFSA has prepared a <u>Reporting tool on Trace Elements</u> that can be used on a voluntary basis.
- Avoid sending pdf documents containing the data
- Confidentiality: EFSA must make public the information on which its scientific outputs are based. However (Articles 39-39e of the General Food Law 178/2002), confidential status may be awarded to information the disclosure of which might potentially harm the information owner to a significant degree.
- A non-confidential and a confidential version of the data would be needed





INTRODUCTION TO PORTALINO

Federico Morreale

Scientific coordinator – Team Advice



DATA SUBMISSION VIA PORTALINO

Interested parties are required to use Portalino to submit documents and datasets, including the corresponding confidentiality requests concerning this call for data.

The access to Portalino can be requested **on behalf of your organisation** or **as private citizen** by contacting the EFSA's Service Desk <u>servicedesk@efsa.europa.eu</u> providing the following details:

- Scope of the submission: Call for data on Trace Elements EFSA-Q-2024-00483
- Personal details of the user requesting the access:
 - First name and Last name, Corporate email (should be provided if contributing on behalf of your organisation), Private email (should be provided in case you are contributing on your personal capacity, as private citizen).
- Organisation details, in case of access requested on behalf of an organisation:
 - Organisation name, Organisation English name, if relevant Organisation Email
 Important: the domain of the email address should be linked to your organisation, e.g. john.smith@orgname.com
 - o Phone number, Billing address (street, city, zip/postal code), Billing Country (the service is free of charges)

Important: please check if your organisation is already registered on Connect.EFSA, and if yes specify this in the communication to service desk. If your organisation is not yet registered on Connect.EFSA, you are required to register and create an account.



DATA SUBMISSION VIA PORTALINO

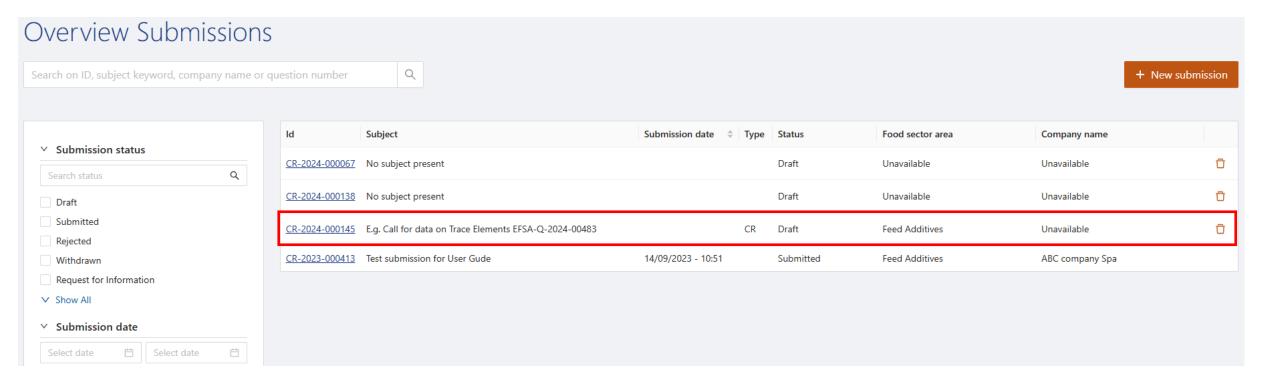
Useful guidance documents:

- <u>User guide on Portalino</u>: describes the steps to request the access to this portal and provides general guidance on the submission process.
- Connect.EFSA registration user manual: describes the registration process and provides information on the steps to follow. For the purpose of this call, interested parties do not need to request a pre-submission activities profile. Please follow the indications identifiable with a blue banner on the left side of the pdf.
- **EFSA's user guide on confidentiality**: provides instructions on how to submit confidentiality requests using Portalino, see Section D, Chapter 3.

How to contact EFSA in case of need:

- In case of any technical issues during the registration on Connect.EFSA or the submission of your contribution for this call please contact servicedesk@efsa.europa.eu.
- If you have any question or doubt you can contact EFSA by using the <u>Ask a Question tool</u>. We kindly suggest
 to put in the subject of the request a reference to this call.

OVERVIEW SUBMISSIONS



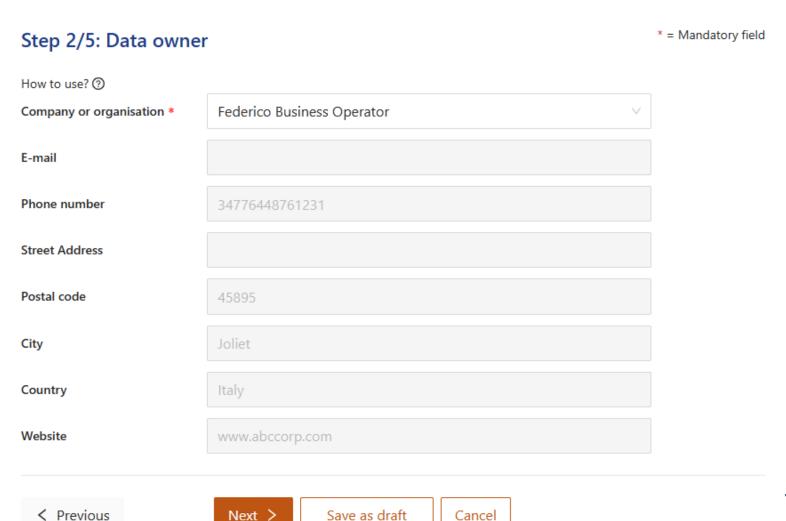
GENERAL INFO

Submission: CR-2024-000145 🗗 Print User Guide * = Mandatory field 1. General Info Step 1/5: General Info 2. Data owner How to use? ② Subject of the submission * 3. Submission Owner(s) E.g. Call for data on Trace Elements EFSA-Q-2024-00483 4. Contacts 5. Data Submission 54 / 4000 How to use? ② Food Sector Area * Feed Additives How to use? ② Submission Type * Initial Datasets Additional Datasets Next > Save as draft Cancel



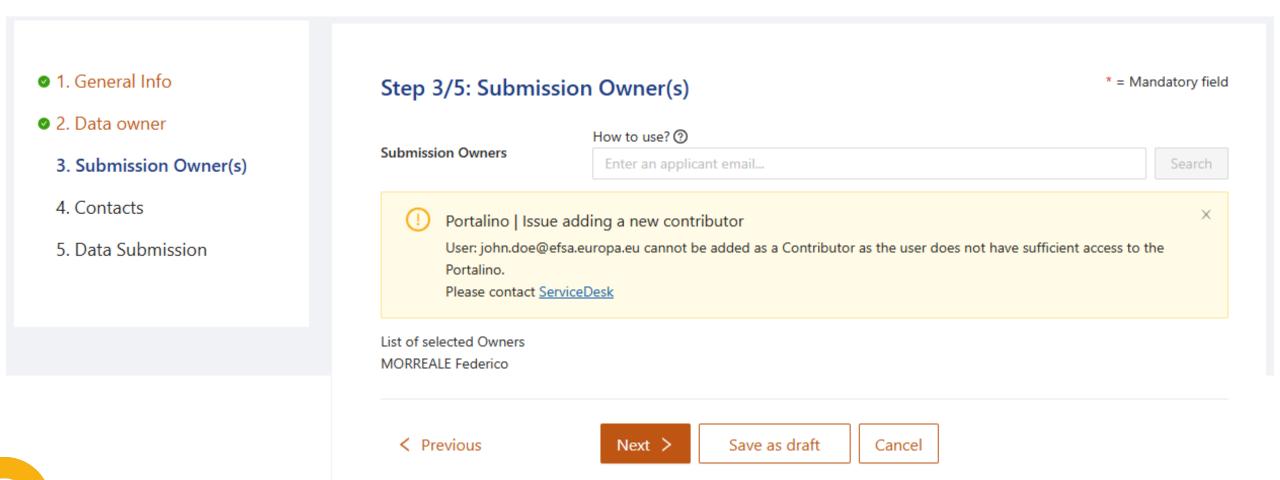
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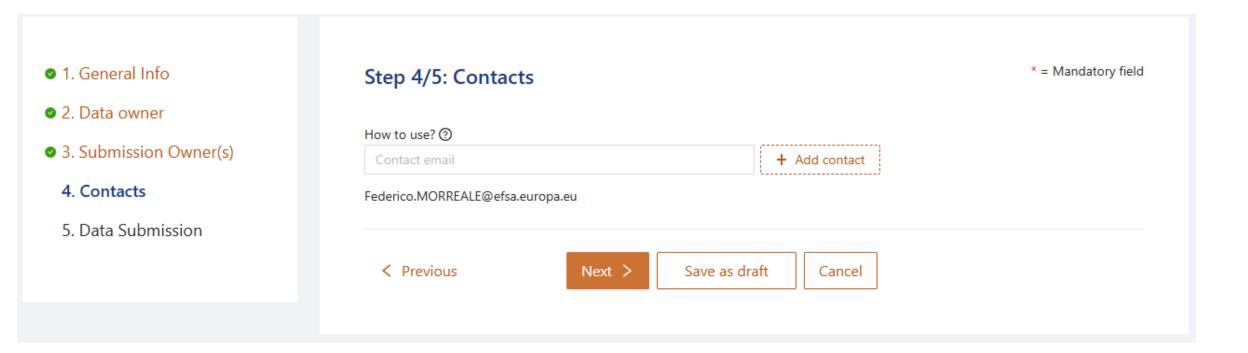




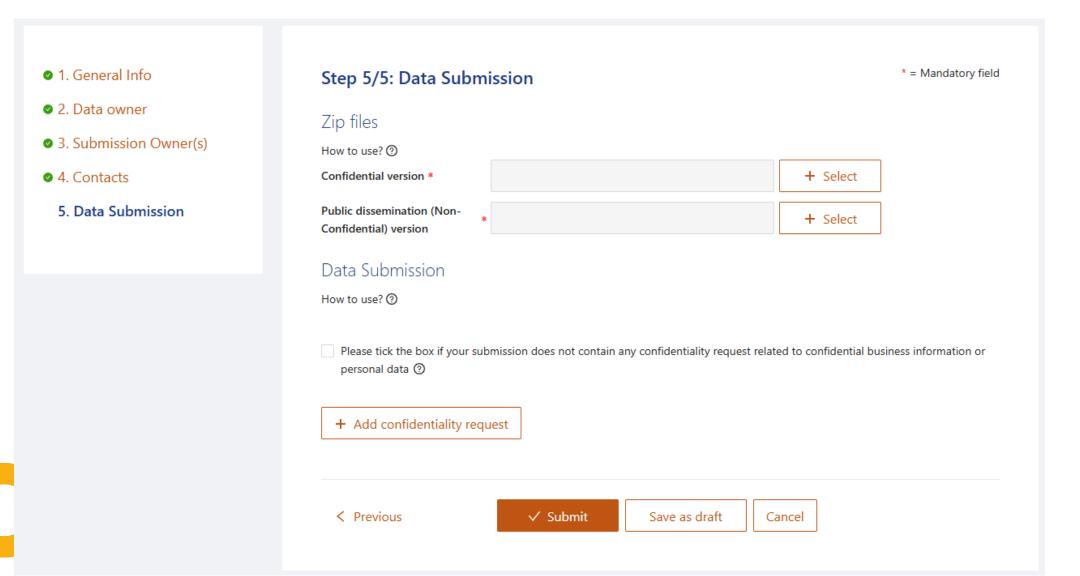
SUBMISSION OWNER



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QUESTIONS?