CONDITIONS OF TENDER

Open Tender Procedure

Framework Agreement:

Laboratory services to the national surveillance and control programme:

“Control on residues of veterinary medicinal products and contaminants in live animals and food of animal origin”

Ref. no. 2020/98037

Oslo, Norway, 25.05.2020

Contents

1. Introduction

According to the announcement in Doffin and TED databases, the Norwegian Food Safety Authority (NFSA) invite tenderers to an open tender procedure for entering into a framework agreement for purchases of laboratory services to our national surveillance and control program «Control on residues of veterinary medicinal products and contaminants in live animals and food of animal origin". Aquaculture is exempt from the residue program.

1.1. About the Norwegian Food Safety Authority

The Norwegian Food Safety Authority (NFSA) is a governmental, nationwide administrative body, whose mission is to:

- Ensure safe food and drinking water
- Promote healthy plants, fish and animals
- Promote animal welfare and respect for animals and fish
- Promote health, quality and consumer interests
- Ensure environmentally friendly production.

The NFSA has 1300 employees and comprises of two administrative levels: One head office and 5 regions with 32 local departments (70 office sites) throughout the country.

See our website http://www.mattilsynet.no/ for more information.

1.2. Contact person

The NFSA's contact person for this procurement is:

Name: Gunhild Jørgensen
E-mail address: contact via www.mercell.com

All contact between NFSA and the suppliers shall take place in the communication module in the NFSA's digital system, www.mercell.com

There shall be no contact or communication about this tender competition with NFSA other than through the abovementioned contact person.

1.3. Purpose

Residue monitoring program is one of many monitoring programs that the NFSA runs every year.

Council Directive 96/23/EC requires Norway, represented by the NFSA (according to European Economic Agreement, EEA), to draft a national residue control plan for the groups of substances detailed in Appendix 3 Tender form and price offer. These plans must comply with the sampling requirements in Annex IV of the directive. This directive also illustrates the sampling frequencies and the groups of substances, which have to be monitored for each food commodity. Commission Decision 97/747/EC provide further rules for certain animal products: milk, eggs, honey, rabbits and game meat.

The NFSA controls through targeted sampling the levels of certain organochlorines, pyrethroids, carbamates, organophosphates, heavy metals, mycotoxins, dyes, veterinary drugs and banned substances in live animals and animal products. Samples that contain levels above the Maximum Residue Limit (MRL) of the substances in the aforementioned groups of substances, or finding of a prohibited substance, are subjected for further investigations and actions in accordance with the current residue legislation.

According to a National Residue Control Plan (NRCP), the authority inspectors collect the samples.

The NRCP is prepared yearly by the Head office of the NFSA, and then being forwarded to the regional/local offices to make a monthly sampling schedule for the whole region throughout the whole year. On the basis of the NRCP, every region has to establish monthly plans to their districts during the first week of January every year. However, some samples are subjected to seasonal sampling (e.g. honey samples), and this is usually taken into account in the regional plans.

The number of samples included in the NRCP is determined on the base of animal production volume in Norway. The number of import samples varies according to the amount of imported goods each year. See Appendix 3 for more information about the approximate sample numbers each year, see also point 1.4 below.

The results of the residue-monitoring program in terrestrial animals 2018 are reported. Click the link below to download the report (in Norwegian and Summary in English):

https://www.mattilsynet.no/mat_og_vann/uonskede_stofferimaten/legemiddelrester_i_mat/rapport_fremmedstoffprogrammet_2018.35715/binary/Rapport%20fremmedstoffprogrammet%202018

The NFSA needs to sign a framework agreement for purchase of laboratory services, which are more closely specified in Appendix 3 – Tender form and Price offer. The NFSA is imposed to have a national reference laboratory (NRL) and we prefer that this function is also included in the tender. See point 1.3.3 below and Appendix 2.

Please note that aquaculture is not part of this tender.

1.3.1 The content and scope of the procurement

We refer to Appendix 3 - Tender form and price offer.

The wider the scope of analysis within the same group of substance, the higher evaluation score the offer will get. In Appendix 3, the tenderers must fill in all the analytes their methods could cover (column D). However, in the evaluation of tenders the NFSA will take into account whether the extent of the offered analyses scope cover the currently used veterinary medicinal products and the relevant contaminants.

For Dioxin and PCBs:
Appendix 2a shows the compounds and congeners, which are included in dioxin-tests of kidney fat. This also shows the reporting form for dioxins and PCBs.

The matrix of dioxin-test could be changed according to our risk analysis during the contract period.

1.3.2 The matrix and sampling procedure

In Appendix 3 Tender form and price offer, there are some groups of substances and analytes, which have defined matrices in accordance with Regulation 97/747/EC. For the other groups, you find the matrices that we currently use in 2020. However, the tenderers are invited to suggest the matrices that might be newly recommended by EURL or those the tenderer/supplier has already validated methods for. Such suggestions shall be written under column N (suggested Matrix) in Appendix 3. The NFSA will then decide which matrices will be chosen in this context.

Sampling carries out by inspectors of the NFSA in accordance with commission decision 98/179 EC of 23 February 1998 and the national residue control plan (NRCP). Sample registration and quality control (size, volume, label, and packaging) will take place at the local offices of the NFSA. The sampler keeps the samples under freezing conditions until they are transported fortnightly to the contracted supplier. In this context, we would like to stress that the NFSA will send one sample in a sufficient amount, which enables the laboratory to carry out the analytical procedures for both screening and confirmatory analyses.

1.3.3 Information

The NFSA goes through all analytes/substances every second year to make relevant audits of the selected matrices and substances. Risk assessment in EU and our own experience on control of residues constitutes the core of such audits. This means that some analytes that, are included in the NRCP could be substituted with new ones.

According to the article 100 in Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017, Norway is imposed to have a national reference laboratory (NRL) for all residue groups. The NRL may be situated in another Member State or in a third country that is a Contracting Party to the Agreement on the European Economic Area. The NFSA prefer that the contracted laboratory should serve as NRL, see Appendix 2 – Buyer's requirement specifications.

1.4. Scope and estimated number of samples

According to the change in the yearly production volume of animal products, the total number of samples could fluctuate/change from the numbers mentioned in Appendix 3. Our experience from previous years indicates that the fluctuation in the total number of samples would be approximately +/- 5 %.

Under occasional and certain emergency circumstances (inquiries from the EU or suspected cases etc.), the NFSA reserves the right to send more samples (approximately 30 % of the NRCP) than those scheduled in the yearly NRCP (see Appendix 3 and Appendix 2 requirement no 6).

The NRCP contains the total and divided number of samples within each group. The supplier will, as soon as the contract is signed and latest by 31st of December 2020 receive the NRCP of 2021. For the subsequent years, we will usually send the NRCP by 31 October.

From experience, the NRCP (including import samples) could annually consist of 4200-4500 samples, and several tests can be made on the same sample, see Appendix 3.
All samples in the NRCP have to be taken regardless of multi-group methods that some suppliers have developed to cover two or more EU substance groups. Such multi-group methods are appreciated to expand the monitoring spectrum, but they have no help to diminish the planned sample numbers. It will be considered as an advantage in the evaluation of the tenders for multi-group methods if the price is the same as single group method.

1.5. Publishing of results

The analytical results are property of the NFSA, and they can only be published by the laboratory with the consent of the NFSA.

1.6. General conditions

The supplier shall implement and follow all the EU legislation, recommendations and amending of legislation concerning control on residues in terrestrial animals. The residue regulations are now under revision, and both the substance groups and number of samples

are subjected to changes. Such changes could enter into force in 2022. The supplier must be able to comply with these changes immediately when they are entered into force.

In this context, we would like to keep special attention on the following:

- Council directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.
- Regulation (EC) No 470/2009.The residue limits of pharmacologically active substances in foodstuffs of animal origin.
- Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.
- Commission decision (98/179/EC) of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
- Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012
- Commission Recommendation of 16 November 2006 on the monitoring of background levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs.
- Commission Regulation (EU) No 1067/2013 of 30 October 2013 amending Regulation (EC) No 1881/2006 as regards maximum levels of the contaminant dioxins, dioxin-like PCBs and non-dioxin-like PCBs in liver of terrestrial animals
- Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results.
- Guidelines for the validation of screening methods for residue of veterinary medicines 20.01.2010 (This guideline document supplements Commission Decision 2002/657/EC regarding the validation of screening methods). https://ec.europa.eu/food/sites/food/files/safety/docs/cs_vet-med-residues_guideline_validation_screening_en.pdf
- Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed. https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en
- REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0625
- Guidelines for reporting data on residues of veterinary medicinal products: http://www.efsa.europa.eu/en/supporting/pub/783e

1.7. Progress plan

Date/week	Activity
27.05.2020	Announcement in Doffin and TED
26.06.2020	Deadline for requests for clarification regarding the tender documents
06.07.2020 at 12:00 noon	**Deadline for tenders**
August/September	Assessment of qualifications and tenders, and selection*

01.10.2020	Notification of decision*
12.10.2020	Waiting period for signing of contract*
15.10.2020	Signing of contract*
01.01.2021	Commencement of contract*

*All dates marked with an asterisk * are provisional and not binding.

2. Tender conditions

2.1. Procurement procedure

The procurement will be carried out as an open tender procedure in accordance with the Public Procurement Act of 17th June 2016 no. 73 and regulations about public procurements.

By using the open tender procedure, all interested parties have the opportunity to submit a tender. Negotiation is not permitted, and we therefore urge the tenderers to give their best offer. Tenderers are expected to be fully aware of the abovementioned regulations.

2.2. Wages and working conditions

Suppliers must accept the requirements regarding current wages and working conditions as described in the Buyers standard contract clauses 10.14 and 11.16, see Appendix 4 Standard contract for purchase of services.

2.3. Confidential information

The NFSA is under duty of confidentiality according to Public administration act ("forvaltningslovens") § 13. This regards details about technical devices, work methods and business conditions that are important for competitive reasons to keep confidential. The NFSA is responsible for the confidentiality of these details/information.

2.4. Validity date

The supplier is committed to their offer until 31.12.2020.

2.5. Language

All communication and documentation concerning the conditions of tender shall be in English.

2.6. Changes of tender the documentations

The NFSA reserves the right to make minor changes in the Conditions of tender and the attachments. The deadline to do changes is ten (10) days ahead of the deadline for submitting tenders.

All changes will be distributed automatically to the suppliers that have registered their interest for the tender competition in www.mercell.com

2.7. Questions and additional information

All communication during the process shall take place through the Mercell-portal, www.mercell.com

Any questions must be submitted through www.mercell.com The questions and answers will be distributed automatically to all suppliers that are registered in www.mercell.com The name of the part submitting the questions will be kept anonymous.

The deadline for questions and additional information is specified in point 1.7 above.

2.8. Contract

The NFSA will sign a contract with only one supplier.

NFSA's own standard contract will be used. The contract will be regulated by the attached draft framework agreement including price and payment terms, see Appendix 4 Standard contract for purchase of services.

The framework contract will be for a term of two (2) years, starting from 1 January 2021, with an option to renew it twice for the subsequent years 2023 and 2024 in separate option requests on the basis of the same contract. The contract will be for a maximum four (4) years if NFSA chooses to use the renewing options. The contract will expire automatically at the end of the term without prior notice.

2.9. Reservations

It is not possible to make significant reservations in respect of any terms of the Conditions of tender or the standard contract. Tenders which include significant reservations, which makes it difficult to compare with other tenders, will be rejected. Any reservations must be precise, unambiguous and specified in the Letter of tender (Appendix 1) so that the NFSA can assess and calculate the effect of the deviation.

2.10. Economical liability

The tenderer shall cover all costs related to the completion of documentation to participate in the tender. The same applies for expenses related to any meetings, presentations, visits or other related costs.

NFSA reserves the right to visit the contracted laboratory, and will cover its own costs related to such visits. The contracted laboratory should also expect inspection visits of ESA (EFTA surveillance authority). ESA will cover its own costs related to such inspections.

2.11. Use of subcontractor

The NFSA prefer to have one supplier which could carry out the analysis duty for all groups of the residue-monitoring program. However, the supplier could use subcontractors.

If the supplier intends to use a subcontractor, this must be stated in the Letter of tender. The tenderer shall specify the name of the subcontractor, as well as information on the subcontracted analysis and to what extent the subcontractor will be used.

However, the main supplier is responsible for ensuring that any subcontractor meet the same requirements (performance criteria) as they themselves are required to meet. The main supplier will be responsible for the completion of all objectives in the contract and is also responsible for the reporting of the results and invoicing. For more information about payment terms and invoicing, see Appendix 4 Standard contract for purchase of services (the two last pages).

3. The European Single Procurement Document (ESPD)

3.1. About ESPD

As a preliminary documentation to prove that they fulfil the exclusion and selection criteria of the tender, the suppliers must fill in a self-declaration form, the European Single Procurement Document (ESPD), and submit it to the Buyer together with the tender. The actual documents will only have to be provided by the winner of the tender before the contract is signed.

4. Qualification requirements

Suppliers that wish to participate in the tender competition must deliver documentation of the qualification requirements given in point 4.1 below.

The qualification requirements are minimum requirements that are connected to the capability of the supplier to deliver the actual delivery of the contract content. All the requirements must be fulfilled if the supplier should be qualified to participate in the tender competition.

The supplier must fill in the self-declaration form (ESPD) as described in point 3 above. After the deadline, the Buyer will carry out a qualification of the participants that have delivered a tender. The qualification will be done in accordance with the requirements in points 4.1 – 4.4 below. The suppliers that are not considered qualified will be rejected in accordance with Public procurement regulations § 20-12, and informed as soon as possible. Only tenders submitted by suppliers meeting the qualification requirements will be assessed.

Regarding BREXIT, and in order to fulfill the requirements in Control regulation 2017/625, the suppliers/tenderers in the UK themselves must check up on their legal eligibility to compete with other suppliers within the EU/EEA. Moreover, the tenderer shall be committed to a procurement contract with a minimum two and maximum four years.

4.1. Tax and/or VAT obligations

Requirements	**Documentations (re. ESPD scheme)**
The supplier must not be in default of their tax &/or VAT obligations.	Norwegian companies shall submit • Certificate for paid tax and value added tax (VAT). The certificate must not be more than 6 months old from the tender deadline. • Foreign suppliers shall submit similar certificates from the equivalent relevant authorities and they must be no more than 6 months old. In the event that the authorities in the applicable country do not produce such certificates, the supplier must produce a declaration confirming that all taxes/duties due have been paid. This declaration must be signed by the finance director.

4.2. Legal requirements

Requirements	**Documentations**
The supplier shall be a lawfully established business.	• Norwegian companies: Certificate of registration. • Foreign companies: Evidence that the company is registered in the relevant trade or company register, as required by the law in the country where the supplier is established.

4.3. Financial requirements

Requirements	**Documentations**
The supplier shall have the financial capability to perform the assignment/contract	• Credit assessment from a recognized rating agency, based on the most recent accounts and include credit rating, evaluation and historical ratings. Assessment should not be older than six (6)

throughout the whole term, including options.	months from the tender deadline. Credit ratings shall not be less than the equivalent of “creditworthy”.

4.4. Technical/professional requirements

Requirements	Documentations
Good experience of similar projects.	A summary of maximum 5 most important relevant assignments during the last 3 years, including the type of assignment, the name of the consignee, value and date.
Good ability to perform.	A short description of the company including: • Core skills relating to the contract • Description of the organisation • A summary of the average annual number of employees for the last three years.
In accordance with the provisions of Regulation (EC) No 2017/625, the laboratory must be accredited by a recognised accreditation body operating in accordance with ISO Guide 58. The laboratory must be accredited following the ISO/IEC 17025 standard. The accreditation shall include the analytical method(s) for substance groups, analytes, and matrices mentioned in Appendix 3, “Tender form and price offer”.	1) The supplier must document the laboratory’s compliance with the requirements of ISO/IEC 17025. The accreditation document must be attached. 2) If the supplier intends to use subcontractors, valid accreditation documents for the subcontractors must be enclosed.

5. Criteria for award of contract

The supplier will be chosen following an assessment of the best relation between price and quality in terms of the following award criteria:

Criterion	Weight
Delivery performance including NRL function	20 %
Quality	20 %
Price	60 %

5.1. Additional information regarding criteria

The description below is not comprehensive. Other factors that would naturally be considered under these criteria may also be subject to evaluation.

5.1.1. Delivery performance including NRL function

The NFSA emphasizes in this context on the requirements that are stated in Appendix 2 – Buyer's requirement specifications.

References from other customers will also be evaluated, ref Appendix 2b – Declaration from Reference.

5.1.2. Quality

The quality criterion means how well the offered laboratory services match our requirement specifications, as described in this document and its appendices, especially Appendix 2 – Buyer's requirement Specifications and Appendix 3 - Tender form and Price offer.

The evaluation of the laboratory services will be based on the accuracy and sensitivity of the used methods seen in relation to the current EU legislation governing the performance characteristics of the methods used in official control on residues (validation, accreditation, comparative laboratory tests and proficiency tests, etc.) See Appendix 2 – Buyer's requirement specification and Appendix 3 - Tender form and Price offer.

References from other customers will also be evaluated, ref Appendix 2b – Declaration from Reference.

5.1.3. Price

The supplier must fill in all prices in Appendix 3 - Tender form and Price offer.

The offer shall clearly indicate the price of analysis of each group or analyte and matrix. All prices shall be stated in € EURO excluding VAT. The price criteria will mainly be evaluated from the given prices and on a total cost basis.

If the contracted supplier uses a subcontractor, the NFSA will not compensate or pay for the transport costs for forwarding the samples from the supplier to the subcontractor. However, the NFSA can send the samples directly to the subcontractor if the transportation fee does not exceed the costs of sending the samples to the contracted supplier.

The remuneration of analysis:

The price of the analysis shall include the following:

a. The analysis process (from receiving the sample to reporting the result) and the interpretation of the results.
b. The immediate reporting of compliant and non-compliant results including the original or inscribed copies of certificate.
c. The final electronic report of all results in accordance with EFSA requirement (SSD2) in XLM format. Guidelines for reporting data on residues of veterinary medicinal products: http://www.efsa.europa.eu/en/supporting/pub/783e
d. All the necessary contacts with the NFSA and its NRLs.

6. Tender requirements and deadline for delivery

6.1. Tender setup

Tender participants must:

a) Complete the details in Appendix 1 – Letter of Tender including a binding signature.

b) Answer all requirements listed in Appendix 2 – Buyer's requirement specifications and provide the necessary documentation for this.

c) The tender shall also include a description of at least two relevant projects plus a declaration of description from the consignee. Complete the details in Appendix 2b – Declaration from Reference. NFSA shall be allowed to contact the references.

d) Complete Appendix 3 - Tender form and price offer with information and price per analysis.

e) Attach a list of potential subcontractors, see point 2.11 above.

It is *not* possible to submit a tender for part(s) of the contract. Tenders that clearly differ from the described requirements will not be considered.

The Buyer reserves the right to cancel the tender in case of justifiable basis.

6.2. Deadline for delivery of tender

The tender must be delivered electronically in the Mercell-portal, www.mercell.com before the deadline, 06.07.2020 12.00 noon. The system does not allow delivery of tender after the deadline.

Suppliers who are not users of Mercell, or have questions regarding the functionality of the tool, e.g how to deliver tenders, can contact Mercell Support, tel +47 21 01 88 60 or e-mail support@mercell.com.

Suppliers can do changes in their tender until the deadline for tenders. The last delivered tender will be considered as the final tender.

7. **Appendices**

Appendix 1: Letter of Tender
Appendix 2: The Buyer's requirement specifications
Appendix 2a: Dioxin – Buyer's requirement specifications
Appendix 2b: Declaration from reference
Appendix 3: Tender form and price offer
Appendix 4: Standard Contract for purchase of services, including appendix regarding total price and payment terms