22 March 2017

Anti-Fraud Office

Implementation of the EMA Anti-Fraud Strategy: the Fraud Reporting Process

1. Introduction

One of the action points of the approved EMA's Anti-Fraud Strategy[1] is to develop internal processes on how to report alleged fraud instances inside the Agency. In order to do so, a very simple reporting mechanism has been developed on the basis of the EMA's guidelines on whistleblowing[2] and of the guidance provided by the European Anti-Fraud Office (OLAF)[3].

2. Reporting procedures

In general, EMA staff members are expected to report a possible fraudulent behaviour of which they are aware to their immediate superior or to the Executive Director (Article 22a of the Staff Regulations).

However, if they are concerned that this may endanger their position, they may consider reporting directly to the Chair of the Management Board. Alternatively, staff may also address their concerns directly to the OLAF[4].

As an option of last resort, staff may address their concerns to another institution (e.g. President of the Commission or of the Court of Auditors or of the Council or of the European Parliament, or to the European Ombudsman), as provided for in Article 22b of the Staff Regulations[5].

[1] The adopted Anti-Fraud Strategy is available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500179569.pdf

[2] For further reference, see EMA guidelines on whistleblowing of 11th December 2014 (EMA/182359/2014), available at http://emeaplus.corp.eudra.org/EMEAPlus_Documents/Staff_matters/Entitlements/Administrative%20Procedures/Rights%20and%20Obligations/Whistleblowing/7_ESB_EMA%20Guidelines%20-%20whistleblowing.pdf

[3] This reporting process was drawn taking into due account the contents of the "Train the trainers" course held in Brussels on the 30th of June 2015 by the European Anti-Fraud Office, as well as the EMA guidelines on whistleblowing adopted on 11th December 2014 (EMA/182359/2014).

[4] There are no rules on how to transmit information in relation to fraud to OLAF. OLAF may be notified through the Fraud Notification System, or by any other means that the staff member considers appropriate. The OLAF Fraud Notification System (https://fns.olaf.europa.eu/) allows any informant to report suspected cases of fraud and corruption via the OLAF website. Information is submitted via a web-based questionnaire and allows the platform allows the informant to remain anonymous, whilst enabling a secure information exchange with OLAF investigators. The system is available in English, French, German and Dutch and any language can be used to report fraud.

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A template for transmission of information concerning allegedly fraudulent behaviour is provided for in Annex I and will be also published on the EMA public website. Individuals outside the EMA organization may use it to inform the Agency about possible fraudulent behaviours by addressing the report to the Anti-Fraud Office directly at afo@ema.europa.eu. The identity of this individual will be protected according to the EMA guidelines on whistleblowing. An acknowledgement of receipt will be sent to the sender.

Prior to reporting, a staff member may seek informal guidance and support from the Anti-Fraud Officer, HR or Audit. The identity of the staff member will be treated in confidence by these advisory functions. Once the staff member has reported a suspicion of an alleged fraudulent behaviour to his/her hierarchy, the latter will inform the Anti-Fraud Office (AFO) at afo@ema.europa.eu with no delay. An acknowledgement of receipt will be sent to the sender and to the staff member (if identified in the email).

In all cases, including when there is no reasonable ground to transmit a report to the OLAF, the AFO will perform an initial assessment of the facts in order to check whether a fraudulent behaviour is *prima facie* likely to have occurred. The relevant Head/s of Division and other advisory functions may be consulted during the assessment phase on a need-be basis. If this is the case, the AFO will prepare a note to the Executive Director in order to transmit a report to the OLAF for appropriate follow-up and investigation activities. As to possible disciplinary aspects, the AFO will liaise with the Human Resources Department.

The AFO will provide feedback to the staff member and to his/her hierarchical superior/s who reported the facts within a reasonable period of time.

For any other procedural aspects, the EMA guidelines on whistleblowing (EMA/182359/2014) shall be applicable to the extent feasible.

For any other clarifications on the fraud reporting process at the Agency, please address your queries to: Anti-Fraud Office, afo@ema.europa.eu.

[5] For further reference, see EMA guidelines on whistleblowing of 11th December 2014 (EMA/182359/2014).

Annex I

TEMPLATE FOR TRANSMISSION OF AN ALLEGEDLY FRAUDULENT BEHAVIOUR

Subject: Transmission of information

I hereby inform you about suspicions of

☐ fraud committed within the Agency

☐ fraud committed by an external party *[specify: grant beneficiary, contractor, tenderer, etc.]*

The facts came to my attention

☐ through another EMA staff member on *… [date].*

☐ through an EMA staff member who delivered the initial information under art. 22a of the Staff Regulations or similar provisions on *… [date].*

☐ through a complaint/letter sent by *… [name of entity, person, …]* on *… [date].*

☐ in the framework of an audit carried out by *… [name] on … [date].*

☐ other: *[explain and indicate date].*

Description of the suspected irregularity and its context:

[This section should contain the following information if possible/relevant (please note that the following list is not exhaustive):

- *all relevant circumstances of the case and description of facts, including e.g.:*
  - *identification of the contract/procurement or recruitment procedure;*
  - *references and dates of call for proposals/call for tender/etc;*
  - *name and contact information of the suspected entities/persons;*
  - *amounts involved;*
  - *relations between the reporting person and the suspected entities/persons;*
  - *risk that further operations are concerned*

- *reasons for suspicions of fraud or irregularity;*
- *precautionary measures taken;*
- *information on possible urgency situations (e.g. payments to be done)]*

I would be grateful if you could assess this information and inform me on which actions the Agency has taken with regard thereto.

[IF AVAILABLE] Please find enclosed documents relevant for the allegations.

[DATE]

[NAME OF THE REPORTING PERSON]

Data Protection Notice

1. DESCRIPTION OF THE PROCESSING OPERATION

This reporting template is made available to the public and to EMA staff as a template that may be used to report to EMA alleged fraud instances inside the Agency. All messages received are recorded by the EMA's Anti-Fraud Office and some of them may be further communicated to the European Anti-Fraud Office (OLAF).

The legal basis for this processing operation is Regulation 883/2013; Financial Regulations applicable to the budget of EMA (EMA/MB/783566/2013); EMA's Anti-Fraud Strategy (EMA/591051/2014) and related Action Plan.

2. WHAT PERSONAL INFORMATION DO WE COLLECT, FOR WHAT PURPOSE, AND THROUGH WHICH TECHNICAL MEANS?

EMA collects information supplied by users of the reporting template. If the user chooses to provide his/her name and will therefore be informed on which actions the EMA has taken with regards to his/her reporting, EMA collects the further information transmitted in all subsequent communications between EMA and the user.

The information the EMA obtains from the reporting template is only used with the objective of detecting alleged fraud instances, and of transmitting without delay any information relating to possible cases of fraud, corruption or any other illegal activity affecting the financial interests of the Union to OLAF. The confidentiality of this information and the data are protected in conformity with Regulation 883/2013 and Regulation 45/2001.

3. WHO HAS ACCESS TO YOUR INFORMATION AND TO WHOM IS IT DISCLOSED?

The Anti-Fraud Office has access to the information submitted through the template, which may communicate them to other EMA's functions to establish whether there is a need to involve the European Anti-Fraud Office (OLAF).

In addition, information may be passed to the relevant services in the European Anti-Fraud Office (OLAF).

4. HOW DO WE PROTECT AND SAFEGUARD YOUR INFORMATION?

In order to protect the personal data of users as well as the content of the messages, a number of technical and organisational measures have been put in place. Concerning unauthorised access to equipment and data, the EMA secure premises, protected by access control measures, host all hardware; network firewalls protect the logic perimeter of the EMA IT infrastructure; and the main computer systems holding the data are security hardened. Administrative measures include restricted access to the information.

5. HOW LONG DO WE KEEP YOUR DATA?

With regards to cases which will not be notified to OLAF and for which no further action is needed, the retention period by EMA will be 12 months.

With regards to the cases which will be notified to OLAF, the EMA aligns its conservation period with those of OLAF's policy on the retention of personal data. Therefore, your data will be kept for a period of 15, 8 or 5 years depending on the case type. Data in a case with follow-up will be kept for 15 years, Data in a case without follow-up for 8 years and data in case that has been dismissed for 5 years.

Improper and pointless messages will be deleted immediately.

6. HOW CAN YOU VERIFY, MODIFY OR DELETE YOUR INFORMATION?

You have the right to access the personal data we hold regarding you and to correct and complete them. Upon request and within 3 months from its receipt, you may obtain a copy of your personal data undergoing processing. Any request for access, rectification, blocking and/or erasing your personal data should be directed to the EMA's Data Controller, the Anti-Fraud Officer (afo@ema.europa.eu).

Exemptions under Article 20 (1) (a) and (b) of Regulation 45/2001 may apply.

7. RIGHT OF RECOURSE

You have the right to have recourse to the European Data Protection Supervisor (edps@edps.europa.eu) if you consider that your rights under Regulation 45/2001 have been infringed as a result of the processing of your personal data by EMA.

You may also contact the EMA's Data Protection Officer at dataprotection@ema.europa.eu to inform him or her of any issues related to the processing of your data.