EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Anti-Fraud Strategy

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1. General background

1.1. The EMA context

The European Medicines Agency (EMA) is a EU Agency responsible for coordination of the scientific evaluation and supervision of medicinal products for the benefit of public and animal health, as laid down by the provisions of Regulation (EC) No 726/2004[1], which replaced its founding regulation (Council Regulation (EEC) 2309/93).

EMA coordinates the scientific resources made available by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human and veterinary use. To perform this mission, the Agency and its scientific committees evaluate applications for marketing authorisations; facilitate the development of new medicinal products through provision of scientific advices as well as access to medicines; monitor the safety of medicines across their life cycle and provide reliable information on human and veterinary medicines to patients and healthcare professionals. EMA has also important responsibilities for organising and maintaining a number of databases, which are then made available to the European Commission and Member States, including those concerning the reporting of side effects of drugs (EudraVigilance), manufacturing and import licences (EudraGMDP), and the performance of clinical trials in the European Union (EudraCT).

EMA has recently assumed additional responsibilities under the new legislation on medical devices (Regulation (EU) No 2017/745 on medical devices[2] and Regulation (EU) 2017/746 on in vitro diagnostic medical devices[3]). In particular, EMA will have some consultation task, for example on medical devices incorporating ancillary substances; on a subset of the devices that are composed of substances or combinations of substances intended to be introduced into the human body or applied on skin; on borderline products; on companion diagnostics.

Since 2019 EMA has contributed on discussions on implementing and delegated acts aimed at the implementation of the new Veterinary Medicines Regulation[4], and will also be responsible for leading the implementation of the IT systems required by such Regulation. Finally, if the European Commission's proposal for a Regulation on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices[5] were substantially confirmed until the completion of the legislative process, the new Regulation would reinforce the Agency's role, with the formalisation and strengthening of structures which were deployed in the COVID-19 crisis.

For the performance of all its activities, the Agency is financed primarily by the fees that it charges to pharmaceutical companies for scientific evaluation procedures and services. These fees account for around 90% of EMA's budget. The Agency implements its budget in line with the Financial Regulation applicable to EU Agencies[6] and related implementations, and in accordance with the principles of sound

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.04.2004, p.1.
[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 05.05.2017, p.1.
[3] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 05.05.2017, p.176.
[4] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 07.01.2019, p. 43.
[5] Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, dated 11.11.2020, ref. COM(2020)725 final.
[6] Regulation (EU, Euratom) 2018/1046 of the European Parliament and the Council laying down the essential financial rules for bodies which are set up by the Union under the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community and which have legal personality and receive contributions charged to the Union budget, OJ L 193, 30.07.2018, p.1.

financial management (Article 317 TFEU) and with the provision of Article 325 TFEU, which stipulates that the EU and the Member States shall counter fraud and any other illegal activities affecting the financial interests of the Union. These articles provide an explicit legal basis for operations by the EU and its bodies and agencies to combat fraud and other unlawful activities. In this light, the Agency is committed to ensuring that the framework, the policies, the rules and the procedures in place enable the effective prevention and detection of fraud.

1.2. The EMA Anti-Fraud Strategy

On 24 June 2011, the European Commission adopted its anti-fraud strategy, aiming at improving the prevention and detection of fraud, the conditions for investigation of fraud, and at achieving adequate reparation and deterrence[7]. The European Commission has also subsequently developed a Common Approach on EU decentralised agencies[8], which requires a set of anti-fraud measures to be put in place, with the declared aim of improving their efficiency, transparency and accountability.

As an agency of the European Union, EMA is responsible for the management of the operational and administrative resources allocated to it to implement EU policies or to contribute to the smooth functioning of the institutions in a cost-effective way and reducing administrative burden as far as possible. As all other agencies, EMA is responsible for taking the necessary measures to provide reasonable assurance of achieving prevention and detection of fraud and irregularities.

Taking into consideration the priorities set by the European Commission within the framework of the Common Approach on EU decentralised agencies, the need to pursue the European Commission's main objectives for its implementation ("more balanced governance, improved efficiency and accountability and greater coherence") and the helpful guidance provided by the European Anti-Fraud Office (OLAF)[9], in December 2014 the European Medicines Agency approved its Anti-Fraud Strategy and the related action plan for the years 2015–2016[10], whose objective was to improve prevention, detection and the conditions for investigation of fraud, and to pursue adequate deterrence and reparation. In December 2016 the Management Board approved four additional actions for 2017.

The Anti-Fraud Strategy and Action Plan are in line with the provisions of Article 69 of Regulation (EC) No 726/2004 establishing the Agency, which calls upon EMA to combat fraud, corruption and other unlawful activities. The Anti-Fraud Strategy is thus integrated into the broader legal framework setting the tasks of EMA. The Anti-Fraud Strategy is also part of the Agency's internal controls system[11] and meets the requirements of Article 32 of the then Framework Financial Regulation[12] (now Article 36 of

[7] Communication from the Commission to the European Parliament, the Council, the European and Social Committee, and the Committee of the Regions and the Court of Auditors on the Commission anti-fraud strategy, COM(2011)376 final, 24.6.2011, available at: http://ec.europa.eu/anti_fraud/documents/preventing-fraud-documents/ec_antifraud_strategy_en.pdf

[8] Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies, available at: https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

[9] European Anti-Fraud Office, Methodology and guidance for anti-fraud strategies for EU decentralised agencies, Ref. Ares(2013)3560341, 25.11.2013, as well as the last update of the same Methodology dated 23.02.2016, ref. Ares(2016)931345.

[10] Doc. ref. EMA/591051/2014, adopted on 18.12.2014, published on the EMA public website at: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500179569.pdf

[11] See the document "Internal Control Standards and Underlying Frameworks. Strengthening Control Effectiveness", adopted by the Management Board on 20.04.2016, doc. ref. EMA/MB/602884/2015.

[12] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002, OJ L 298, 26.10.2012, p. 1. This Regulation is no longer into force since 31.12.2018, as it has been replaced by Regulation (EU, Euratom) 2018/1046 (see footnote 6).

Regulation (EU, Euratom) 2018/1046), which refer *inter alia* to the need for preventing and detecting irregularities[13] and fraud[14].

The updated OLAF's Methodology and guidance for anti-fraud strategies for EU decentralised agencies points out that "the anti-fraud strategy is part of risk management, but given the importance and complexity of the issue, fraud should be addressed in a dedicated, comprehensive process, which runs on top of the annual risk management exercise, though closely interlinked with it"[15]. Therefore, despite it being part of the internal control system, the EMA Anti-Fraud Strategy must be deemed as a separate, additional tool to further strengthen the internal control systems.

Since its inception, the Agency had already successfully developed a number of procedures and policies designed to mitigate identified risks, including major fraud risks, namely:

- a Code of conduct;
- a declaration of interests (DoIs) policy for committees' members, experts, Management Board's members and staff members;
- a transparency policy, whereby CVs and DoIs are published to enable public scrutiny;
- breach-of-trust policies for Management Board members and experts;
- a comprehensive auditing system, whereby the Agency is subject to annual audits by four independent audit teams: European Court of Auditors, external auditors auditing the Agency's annual accounts, internal audit service of the European Commission, and the internal audit capability of the Agency;
- ex ante and ex post controls, other controls and supervision mechanisms;
- a whistleblowing policy for staff and procedures for reporting improprieties;
- a policy on handling of information from external sources disclosing alleged improprieties concerning EMA's activities;
- annual risk assessments, including a fraud risk assessment;
- annual reviews of sensitive functions.

[13] Article 1(2) of Regulation No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests (OJ L 312, 23.12.1995, p.1) defines 'irregularity' as "any infringement of a provision of Community law resulting from an act or omission by an economic operator, which has, or would have, the effect of prejudicing the general budget of the Communities or budgets managed by them, either by reducing or losing revenue accruing from own resources collected directly on behalf of the Communities, or by an unjustified item of expenditure."

[14] Article 1(1) of the Convention on the protection of the European Communities' financial interests (OJ C 316, 27.11.1995, p.48) defines 'fraud' as "(a) in respect of expenditure, any intentional act or omission relating to: - the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds from the general budget of the European Union or budgets managed by, or on behalf of, the European Union; - non-disclosure of information in violation of a specific obligation, with the same effect; - the misapplication of such funds for purposes other than those for which they were originally granted; (b) in respect of revenue, any intentional act or omission relation to: - the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the illegal diminution of the resources of the general budget of the European Communities or budgets managed by, or on behalf of, the European Communities, - non-disclosure of information in violation of a specific obligation, with the same effect, - misapplication of a legally obtained benefit, with the same effect.". See also Section 4 of the present document for the definition of fraud adopted for the purpose of the EMA Anti-Fraud Strategy.

[15] European Anti-Fraud Office, Methodology and guidance for anti-fraud strategies for EU decentralised agencies, doc. ref. Ares(2016)931345, dated 23.02.2016, p. 5.

2. Guiding principles of the EMA Anti-Fraud Strategy

Ethics, integrity and transparency are key drivers of EMA's actions in performing its public health mission. EMA staff, members of EMA committees and working groups, scientific experts, members of the Management Board and all external contractors must pursue the highest standards of ethics and integrity in the exercise of their duties.

Fraud has the potential to jeopardize EMA core values (excellence, commitment, reliability, respect, accountability), which must be preserved in the performance of EMA public health mission. In this regard, a fraud-proof environment is functional to the fulfilment of EMA's strategic objectives as laid down in its Multiannual Work Programme and in the EU Medicines Agencies Network Strategy.

The Agency does not tolerate fraud, impropriety or dishonesty and will report, without delay, any instance of suspected fraud to OLAF, which is exclusively competent to investigate these cases[16]. In all such cases, EMA will cooperate fully with OLAF and all other EU authorities and institutions.

Further to OLAF's recommendations, EMA will take all actions and adopt all measures as appropriate, against anyone defrauding or attempting to defraud EMA and/or other EU assets and resources, or otherwise damaging EMA's reputation.

3. The implementation of the EMA Anti-Fraud Strategy over the last three years, leading to its second revision

According to the action plan annexed to the revised Anti-Fraud Strategy approved in December 2017, eight actions were to be performed from 2018 to 2020. Five additional actions have been performed on an annual basis. All the actions have been implemented within the assigned deadlines[17], and the recurrent ones (fraud risk assessment, assessment of the adequacy of controls, etc.) were performed on an annual basis. No additional actions were needed based on the continuous monitoring of the measures in place.

It is worth recalling the particular context in which the implementation of the action plan for 2018-2020 took place. Over the last three years, EMA staff members have faced a further sharp increase in workload and have been subject to professional and personal challenges due to the Agency's relocation to Amsterdam in 2019 and its preparation in the preceding years. Furthermore, EMA has faced in 2020 a sharp increase in workload due to the COVID-19 pandemic, that has generated more activities (e.g. assessment of dozens therapeutics and vaccines candidates). The Agency has not relaxed its anti-fraud commitment and efforts despite the persistent business continuity mode in which it is still operating.

In the last three years, the Agency continued its close and proactive cooperation with the European Anti-Fraud Office (OLAF), which is mandated by law to carry out internal investigations within EU Agencies[18]. The cooperation and information exchange with OLAF is enshrined both in Regulation (EU, Euratom) No 883/2013 and in the Decision of the European Medicines Agency of 1 June 1999

[16] See Commission Decision of 28 April 1999 establishing the European Anti-Fraud office (OLAF), OJ No L 136 of 31.5.1999, p.20, available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999D0352&from=EN
The investigations are conducted in accordance with Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999, OJ L 248, 18.9.2013, p.1.

[17] The action related to the update of the compulsory anti-fraud e-learning training course incurred into technical difficulties due to the code used to write the program, which could not be modified by EMA nor by an external provider. Actions have been put in place with a new provider to amend the course in 2021.

[18] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF), OJ L 248, 18.09.2013, p. 1.

concerning the terms and conditions for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the Community's interests[19]. In 2020 the cooperation with the Office has also concerned counterfeited medicinal products. Over the last three years the Agency has spontaneously reported to OLAF one suspected fraud (in December 2020), on which the decision on whether to open an investigation is still pending. Furthermore, an interaction with OLAF is also foreseen by the EMA Policy 0072 on the handling of information from external sources disclosing alleged improprieties concerning the Agency's activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products[20]. The EMA Anti-Fraud Strategy is expressly mentioned as complementing such Policy, without prejudice to OLAF's competence to carry out investigations where necessary or requested by EMA.

In the last three years the Agency has also exchanged best practices with the other EU Agencies on anti-fraud matters, for example through the Anti-Fraud Working Group within the Inter Agency Legal Network (IALN), which EMA chairs and whose aim is to enhance harmonised and standardised approaches to anti-fraud strategies among EU decentralised Agencies. The establishment of this working group has been praised by the Committee on Budgetary Control of the European Parliament in March 2017[21]. This is a public recognition of the right direction of travel taken by the Agency in relation to anti-fraud matters.

According to paragraph 8 of the EMA Anti-Fraud Strategy ("*Review and monitoring*"), the latter and its action plan shall be reviewed and updated every three years.

The present second revision takes into account the lessons learnt in the course of the implementation of the Anti-Fraud Strategy over the past three years, the latest fraud trends, the developments in the legislative framework (such as the establishment of the European Public Prosecutor's Office), any guidance received from OLAF[22] as well as the Agency's new needs with regard to fraud-related matters which have emerged from the annual fraud risk assessments. In this second revision, the Agency has also taken into account the new European Commission's Anti-Fraud Strategy[23], adopted in April 2019 and which had been qualified as "major initiative" within the meaning of the Better Regulation Guidelines[24].

An evaluation of the actions implemented since 2015 within the EMA Anti-Fraud Strategy concluded that most of the actions are still relevant and effective as measures to protect the Agency's against fraud. These actions however need to adapt to an evolving situation (new fraud trends, development of IT tools, etc.). EMA devoted significant efforts during the past years to fraud prevention, mainly through raising-awareness activities, and to the development of instruments for fraud detection, for example through the elaboration of internal reporting procedures and whistleblowing policies. EMA believes that it is crucial to maintain this high level of awareness among staff and non-staff (e.g. contractors) because prevention is the most cost-efficient way to create a fraud-proof environment.

In cooperation with the relevant organisation entities, the Executive Director has set the objectives for the further 3-year period, together with an updated action plan. As in the previous action plan, the

[19] Adopted by the Management Board on 01.06.1999, doc. ref. EMEA/D/15007/99/EN.
[20] Adopted on 17.03.2017, doc. ref. EMA/283205/2013.
[21] Committee on Budgetary Control, European Parliament, "Report on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2015: performance, financial management and control", dated 31.03.2017, doc. ref. 2016/2206(DEC), page 11, point 46, available at the address http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A8-2017-0149+0+DOC+PDF+V0//EN
[22] A revised methodology from OLAF was in preparation in the last months of 2020 and it is expected to be finalised and published in 2021.
[23] Communication from the Commission to the European Parliament, the Council, the European Social and Economic Committee, the Committee of the Regions and the Court of Auditors: "Commission Anti-Fraud Strategy: enhanced action to protect the EU budget", dated 29.04.2019, doc. ref. COM(2019)196 final, available at https://ec.europa.eu/anti-fraud/sites/antifraud/files/2019_commission_anti_fraud_strategy_en.pdf
[24] Commission Staff Working Document, "Better Regulation Guidelines", 07.07.2017, doc. ref. SWD (2017) 350.

actions planned to reach the revised objectives for the years 2021-2023 are linked to key performance indicators and will be implemented by a set due date.

4. Definition of fraud for the purposes of EMA Anti-Fraud Strategy

In December 2014, when the first EMA Anti-Fraud Strategy was adopted, it was decided that, for the purposes of the Anti-Fraud Strategy, the concept of fraud encompasses both internal and external misbehaviour (i.e. misbehaviour committed by staff members or persons anyhow linked to the Agency and by external parties) and relies on the assumption that the reputational impact of a misbehaviour might be equally important to, or even more important, than the financial damage itself.

The definition of fraud for the purpose of the Anti-Fraud Strategy covers in particular, but not only, any infringement of the financial interests of the EU as defined by the Convention on the protection of the European Communities' financial interests ('PIF Convention') [25], the Council Regulation on the protection of the European Communities' financial interests[26] and Directive (EU) 2017/1371 on the fight against fraud to the Union's financial interests by means for criminal law[27].

It also covers misbehaviour that may not have a direct effect on the EU's financial interests, but has anyhow a reputational impact on the Agency or on the EU as a whole, such as some cases of forgery (in CVs for example), concealment of material facts, breaches of IT systems, cyber fraud, transmission of confidential information and conflicts of interests that have not been declared intentionally. Favouritism and collusion are also included in the definition of fraud for the purposes of this Anti-Fraud Strategy.

The Agency deems appropriate to maintain in this revision of the Anti-Fraud Strategy this wide definition of fraud for the purpose of the application of this document. This wide definition is shared with the other EU Agencies and also reflected in their Anti-Fraud Strategies, and serves the purpose of preventing and detecting the highest possible number of illegal behaviours and keeping high the attention of staff members also on instances likely to create a reputational damage.

5. Fraud risk-assessment

In order to specifically focus on the risk of fraud and in line with the last OLAF's Guidance and Methodology [28], every year the Agency carries out a specific fraud risk-assessment with the participation of middle and senior management. This integrates the Anti-Fraud Strategy in the overall EMA risk assessment exercise by ensuring a dedicated area running on top of the annual risk management process - although closely interlinked within it. In accordance with Principle 8 of the

[25] Council Act of 26 July 1995 drawing up the Convention for the protection of the European Communities' financial interests, OJ C 316, 27.11.95, p.48. This Convention has been replaced by Directive (EU) for the Member States bound by it, with effect from 06.07.2019.
[26] Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities' financial interests, OJ L 312, 23.12.1995, p.1.
[27] Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law, OJ L 198, 28.07.2017, p. 29.
[28] European Anti-Fraud Office, Methodology and guidance for DG's Anti-Fraud Strategies, ref. Ares(2016)931345, dated 23.02.2016, p. 5. A revised methodology was in preparation in the last months of 2020 and it is expected to be finalised and published in 2021.

revised EMA Internal Control Framework, the Agency considers the potential for fraud in assessing risks to the achievement of its objectives[29].

The objective of such fraud risk-assessment is to document the key fraud risks and assess their impact after consideration of the mitigating measures in place. As a result of this fraud risk assessment, a list of prioritised risks was presented to the Executive Director to enable her to define the objectives for the next three years.

The outcome of the internal fraud risk assessment carried over in the last three years indicated that, considering the organisational context and the control mechanisms in place, the fraud risk is sufficiently mitigated at EMA. However, there are some areas that would require EMA to remain vigilant, for example cybersecurity. The remaining areas of risk also justify the need for continuous raising-awareness activities, as well as regular training on whistleblowing and internal reporting channels.

6. Objectives and actions

The strategic objectives of the Anti-Fraud Strategy are driven by the Agency's priorities and values. The reputation of the Agency and the public trust in the highest standards of professionalism, ethics and integrity that EMA follows when issuing recommendations on the quality, safety and efficacy of medicines is a key driver of EMA's actions. For this reason, the Agency needs to set certain objectives to counter fraud at all levels of the organisation and thus reinforce the public trust in its activities.

These objectives aim at encompassing all stages of the anti-fraud cycle: prevention, detection, investigation, recovery and sanction. Whilst prevention should remain one of the most important objectives of the revised Anti-Fraud Strategy, it is deemed appropriate to focus the efforts also on strengthening measures for detection of suspicious behaviours, in particular by encouraging internal reporting of any possible case of suspected irregularity.

In order to address the major risks identified in the fraud-risk assessments conducted over the last years, the following strategic objectives were agreed and endorsed by the Executive Director:

1. Maintain and enhance an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation (also among non-staff members).
2. Strengthen measures for detection of suspicious behaviours, including through maintaining an efficient system for internal reporting and handling of suspected irregularities.
3. Implement all actions necessary for fraud risk mitigation, also identified through internal and external audits.

[29] Principle 8 of the Internal Control Framework reads as follows: "The risk identification and assessment procedures (see principle 7) consider possible incentives, pressures, opportunities and attitudes which may lead to any type of fraud, notably fraudulent reporting, loss of assets, disclosure of sensitive information and corruption. The Agency sets up and implements measures to counter fraud and any illegal activities affecting the financial interests of the EU, through putting in place a sound anti-fraud strategy to improve the prevention, detection and conditions for investigating fraud, and to set out reparation and deterrence measures, with proportionate and dissuasive sanctions".

Objective 1

Maintain and enhance an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation (also among non-staff members)

Building a culture of fraud prevention is one of the most important objectives of the EMA Anti-Fraud Strategy since its first adoption and one that will be kept in the current revision. EMA believes that the keys to fraud prevention are awareness and training, and that fraud deterrence is facilitated by a widespread common understanding and sharing of the ethical values and relevant rules underlining any activity of the Agency.

This objective encompasses the need to constantly communicate the rules and ethical values of the EU public service to each member of staff, and also to non-staff members (e.g. contractors working for the Agency). This communication shall also stress the crucial link between a fraud-proof environment and the reputation and public health mission of the Agency. This is also the reason why it is deemed appropriate to reflect the implementation of the Anti-Fraud Strategy in the Annual Activity Report and in other strategic documents.

The development of an entirely in-house made compulsory anti-fraud e-learning training course for all staff members back in 2015 served the purpose of promoting the values of ethics and integrity amongst staff members. This training course needs now to be updated, also in light of the most recent OLAF trends and indications and of legislative developments.

Actions to reach objective 1[30]

- Maintain a regular communication to both staff and non-staff members on anti-fraud related matters, including the potential impact of fraud on the organisation
- Update the contents of the compulsory anti-fraud e-learning training course in line with recent fraud trends and best practices in other EU institutions and Agencies
- Include information on the implementation of the Anti-Fraud Strategy in the Annual Activity Reports and other strategic documents, as appropriate
- Targeted awareness raising sessions on anti-fraud matters and ethics as required at Division, Task Force or Department level

Objective 2

Strengthen measures for detection of suspicious behaviours, including through maintaining an efficient system for internal reporting and handling of suspected irregularities

This objective aims at reinforcing fraud prevention across the organisation, in particular through the provision of clear guidance to staff members on how to report suspected irregularities, i.e. how to use the whistleblowing channels without any fear of retaliation. Following instances of internal reporting, administrative enquiries can be opened when required or appropriate, as well as new actions can be added to the Action Plan in order to address some specific ethical needs.

[30] For the details of these actions, such as the responsible entity and the timeline for implementation, please refer to the Annex: Action plan.

One of the areas identified as crucial for the detection of fraud is cybersecurity. Therefore, an action is scheduled to enhance EMA's attention and defence against cybersecurity crimes.

Actions to reach objective 2[31]

- Strengthen staff's awareness of internal reporting and whistleblowing procedures
- Additional actions possibly needed based on the continuous monitoring of ethical behaviours and on the annual fraud risk assessment
- Administrative enquiries where required or appropriate
- Joint action with Information Security Office and IM Division to prevent cybersecurity fraud or circumvention of the Agency's security policy

Objective 3

Implement all actions necessary for fraud risk mitigation, also identified through internal and external audits

This objective aims at substantiating the remaining level of risks after the current mitigating measures have been applied. This is performed mainly through the annual fraud risk assessment, which allows the Agency to focus its fraud-mitigating efforts on those areas where the risks scores turned out higher[32], for example by identifying additional actions which might be required or desirable. The need for such additional actions can also be identified through internal and external audits.

In implementing all actions necessary for fraud risk mitigation, the Agency will also cooperate with, and learn from the experience of, other organisations, such as OLAF, the European Commission and other Agencies in countering internal and/or external fraud.

Actions to reach objective 3[33]

- Carry out annual, fraud-specific risk assessments and perform related audits with a specific aim to identify areas of vulnerability to fraud
- Assess the adequacy and effectiveness of the associated systems of internal controls, also through monitoring and audit activities
- Assess the necessity of specific fraud risk assessments in respect of possible conflict of interest of scientific experts
- Additional actions possibly needed based on the continuous monitoring of ethical behaviours and on the annual fraud risk assessment

7. Roles and responsibilities

The risk of fraud cannot be dealt with in isolation. Addressing and properly mitigating the risk of fraud is a key aspect of sound anti-fraud management.

[31] For the details of these actions, such as the responsible entity and the timeline for implementation, please refer to the Annex: Action plan.
[32] For example, based on the assessment of risk and the assurance map, audits are planned in 2021 on the review of Agency's operational procedures and measures taken in response to COVID-19, and on data governance and management.
[33] For the details of these actions, such as the responsible entity and the timeline for implementation, please refer to the Annex: Action plan.

Whilst it is essential that all EMA staff members have a clear understanding of the Agency's Anti-Fraud Strategy and of its action plan, some individuals and Agency's entities have specific leadership roles or responsibilities, and these are identified below.

In addition to the internal roles and responsibilities, it bears noting the major role played also by the European Anti-Fraud Office (OLAF), the Union body which investigates fraud against the EU budget, corruption and serious misconduct within the European institutions, agencies and bodies. Since 20 November 2017, when the Regulation establishing the European Public Prosecutor's Office under enhanced cooperation entered into force[34], another important external actor in the fight against fraud is the European Public Prosecutor's Office (EPPO).

7.1. The Management Board

The Management Board is responsible for the adoption of this Anti-Fraud Strategy and related action plan.

7.2. Executive Director

The Executive Director, with her 'tone from the top', promotes the anti-fraud culture across the Agency, sets anti-fraud objectives and puts in place effective arrangements for combating fraud.

7.3. Heads of Division and Heads of Task Force

The Heads of Division and Task Force are responsible for promoting the anti-fraud culture within their Divisions and Task Forces, checking staff awareness and ensuring that all suspected or reported cases of potential fraud are immediately reported to the Anti-Fraud Office, cooperating with all other functions involved in the implementation of the Anti-Fraud Strategy, including through the use of ex ante and ex post controls where required.

7.4. All managers

The primary responsibility for the prevention and detection of fraud rests with managers throughout the organisation. They are the so called 'first line controls'. They have the responsibility to manage the risk of fraud and will be supported and trained so that this task is fulfilled effectively.

7.5. Anti-Fraud Office

The Anti-Fraud Office[35] established within the Legal Department is responsible for identifying and preventing the risks of breach of legal provisions and ethical behaviour rules which may entail liabilities or reputational loss for the Agency. The Anti-Fraud Office coordinates the implementation of the Anti-Fraud Strategy and the follow-up actions, reports regularly to the Executive Director on such implementation and acts as a contact point for OLAF and EPPO for the strategy-related issues and for all fraud-related issues.

The Anti-Fraud Office provides guidance on managing fraud risk and design of additional controls, it develops training materials for all staff, in close collaboration with competent experts and entities within and outside the Agency.

[34] Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO'), OJ L 283, 31.10.2017, p. 1.
[35] Following the internal reorganisation effective from 01.08.2020, the full denomination of this office is 'General Affairs and Anti-Fraud Office'.

7.6. Quality and Risk Management Office

The Quality and Risk Management Office will coordinate the annual anti-fraud risk assessment and will regularly follow up on the implementation of agreed actions to further mitigate significant risks.

7.7. Head of Finance Department

The Head of Finance Department is responsible for ensuring that financial systems incorporate strong measures to reduce the risk of fraud and detect potential fraud cases at an early stage.

7.8. Head of Audit

The Head of Audit is responsible to perform regular risk-based *ad hoc* audits and consider the effectiveness of the anti-fraud arrangements.

7.9. Head of Staff Relations and Support Department

The Head of Staff Relations and Support Department contributes to promoting staff awareness about the anti-fraud principles and strategy; it applies sanctions commensurate to the breach by the relevant staff member, as decided by the Executive Director in accordance with the reports and recommendations drawn up by OLAF following an OLAF investigation[36].

7.10. Staff members

All staff members comply with the Agency's anti-fraud principles and strategy; forward any reasonable concerns with regard to fraud to their reporting officer and/or senior management, in accordance with the existing guidelines, for example, on internal whistleblowing.

7.11. Delegates/experts, partners, suppliers, contractors and consultants

All delegates/experts, partners, suppliers, contractors and consultants comply with the Agency's anti-fraud principles and strategy.

8. Review and monitoring

The Anti-Fraud Office will ensure that the Agency's approach to managing the risk of fraud is kept up to date with developments in best practices and with legislative requirements. The Anti-Fraud Strategy and its action plan will be reviewed every 3 years. The next revision will take place in December 2023.

The implementation of the Agency's Anti-Fraud Strategy, policy and procedures will be subject to periodic review on the basis of an evaluation of the impact of the strategy, measured using some key performance indicators (among which, for example, the number of cases notified to OLAF, the number of notified cases dismissed by OLAF, the number of internal reporting about suspicious behaviours received).

[36] See article 11 of Regulation No 883/2013, in particular paragraph 4: "*Reports and recommendations drawn up following an internal investigation and any relevant related document shall be sent to the institution, body, office or agency concerned. That institution, body, office, or agency shall take such action, in particular of a disciplinary or legal nature, as the results of the internal investigation warrant, and shall report thereon to the Office, within a time-limit laid down in the recommendations accompanying the report, and, in addition, at the request of the Office*".

9. Annex

Action plan for the years 2021–2023

Strategic Objective 1 - Maintain and enhance an anti-fraud culture underpinned by high levels of awareness, integrity, impartiality and transparency within the organisation (also among non-staff members)		
Action	**Responsible**	**Due date**
Maintain a regular communication to all staff on anti-fraud related matters, including the potential impact of fraud on the organisation	Anti-Fraud Office in cooperation with Internal Corporate Relations Office	Recurrent action
Update the contents of the compulsory anti-fraud e-learning training course in line with recent fraud trends and best practices in other EU institutions and Agencies	Anti-Fraud Office in cooperation with Staff Relations and Support Department (Competency Development Office)	31.12.2021
Include information on the implementation of the Anti-Fraud Strategy in the Annual Activity Reports and other strategic documents, as appropriate	Anti-Fraud Office in cooperation with Strategic Planning and Budget Office	Recurrent action
Targeted awareness raising sessions on anti-fraud matters and ethics as required at Division, Task Force or Department level	Anti-Fraud Office in cooperation with Staff Relations and Support Department	Recurrent action
Strategic Objective 2 - Strengthen measures for detection of suspicious behaviours, including through maintaining an efficient system for internal reporting and handling of suspected irregularities		
Strengthen staff's awareness of internal reporting and whistleblowing procedures	Anti-Fraud Office in cooperation with Staff Relations and Support Department	31.03.2022
Additional actions possibly needed based on the continuous monitoring of ethical behaviours and on the annual fraud risk assessment	Executive Director	Recurrent action
Administrative enquiries where required or appropriate	Executive Director	As needed
Joint action with Information Security Office and IM Division to prevent cybersecurity fraud or circumvention of the Agency's security policy	Information Security and IM Division in cooperation with Anti-Fraud Office	31.12.2021
Strategic Objective 3 - Implement all actions necessary for fraud risk mitigation, also identified through internal and external audits		
Carry out annual, fraud-specific risk assessments and perform related audits with a specific aim to identify areas of vulnerability to fraud	Quality & Risk Management Office and Audit, in cooperation with Anti-Fraud Office	Recurrent action, by 31.12 each year
Assess the adequacy and effectiveness of the associated systems of internal controls, also through monitoring and audit activities	Quality & Risk Management Office in cooperation with Anti-Fraud Office	Recurrent action
Assess the necessity of specific fraud risk assessments in respect of possible conflict of interest of scientific experts	Deputy Executive Director in cooperation with the relevant organizational entities and with the Legal Department	30.06.2022

Additional actions possibly needed based on the continuous monitoring of ethical behaviours and on the annual fraud risk assessment	Executive Director	As needed