

# **2018 Discharge of the EU decentralised agencies**

## **Answers to the written questions**

**Hearing on 4 December 2019**

**II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES**

# EASA

## Replies to written questions

# DISCHARGE 2018

## II. EP QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

### European Union Aviation Safety Agency (EASA)

#### 1. What kind of mechanisms to prevent conflict of interest do the agency, which collects fees from its clients, disposes?

EASA has in place a comprehensive set of measures concerning the prevention and mitigation of Conflict of Interest (Col). This includes in particular the adoption of a “Code of Conduct for the staff of EASA”, including a dedicated “Policy on impartiality and independence: prevention and mitigations of conflict of interest” and “Policy on Gifts and Hospitality”.

The main measures and actions contained therein are (1) the requirement for all EASA staff (incl. TAs, CAs, SNEs, interims, trainees, consultants) to complete a Declaration of Interest (DoI) and set up of a formal assessment process, (2) the establishment of an Ethical Committee to assess completed ADol submitted to it and to support the Executive Director on any matters related to the EASA Code of Conduct and (3) the establishment of a mandatory training on the Code of Conduct and its Annexes.

Similar Codes of Conduct have been established for the EASA Board of Appeal, the EASA Management Board (system of Public Declarations of Interest and Specific Declarations of Interest, set up of Assessment Committee) and a dedicated code for External Experts supporting EASA.

It should also be noted that in addition, several EASA processes contain specific elements that contribute to the prevention and mitigation of Col. For example in the specific context of issuing certificates this includes the signature of declarations of interest, supervision of the decision making process by management, four-eyes principle in decision making, and identification of sensitive functions and linked to staff mobility requirements.

Finally, it should be noted that EASA has established an “Anti-Fraud Strategy” and “Anti-Fraud” Officer.

Summary of main controls in place:

- Declaration of Interest process
- Establishment Ethical Committee
- Conflicts of Interest situations register
- Collegiality - "4 eyes principle" - and transparency in decision making (no single point of decisions)
- Sensitive functions policy
- Gifts and Hospitality policy
- Outside activities and post-employment

- Enforcement measures
- Mandatory training on Code of Conduct and Col
- Anti-Fraud Strategy

The Agency was requested to report to the discharge authority on the comprehensive review of its current system for prevention and mitigation of conflict of interest in 2018/2019. In the meantime the Agency has been subject to an IAS Audit on Ethics, Fraud Prevention and Conflict of Interest in EASA. The IAS Final Audit Report was received in May 2019, with an overall positive conclusion on the management and control systems in place in the area of ethics, fraud prevention and conflict of interest. Following receipt of the IAS Report, the Agency has reviewed the IAS recommendations and has established an action plan in this respect. Most notably, the Agency plans to perform by 31/03/2020 a review of the existing Col framework for EASA staff/Board of Appeal members, including the related Declaration of Interest (DoI) process, as well as a review of the Public Declaration of Interest (PDol) process for the Management Board members and to update the related Agency policies and procedures in line with the audit recommendations.

**2. Which are the measures implemented by EASA in 2018 to make the agency's expenses more efficient?**

The Agency launched coordinated initiatives to improve efficiency. LEAP (Lean Efficiency Agility Programme), as well as a number of individual improvement measures were programmed for 2018. That led to simplifications of processes and reduction of overhead. Such improvements will continue through the efficiency project starting in 2020.

**3. Which were the biggest personnel problems that EASA encountered in 2018? And how they have been solved?**

EASA continuously struggles with an increased scope of activities and a constraint budget and resources. In 2018, the new Basic Regulation entered into force with a considerable amount of new tasks, without the corresponding increase in budget and resources. This forced EASA to de-prioritise some of the tasks and to rely more heavily on outsourcing and to strive for increased efficiency.

**4. Which were the deficiencies of EASA in 2018? Which of these have been solved and which of them still persist today?**

The aviation sector is growing and new technologies and innovative products are entering the market. In addition, with the entry into force of the new Basic Regulation in 2018, EASA's competences were enlarged. Despite the increase in workload, the budget and resources remained constraint. This resulted in a major challenge for EASA to fulfil all its tasks and objectives in 2018. In addition to the efficiency measures explained under Question 2, EASA had to postpone or deprioritise certain activities during 2018 in coordination with the EASA stakeholders.

**5. Which steps does EASA consider that should be followed and what measures should be implemented to ensure better money management and to have more efficient expenses in favour of the agency?**

The potential for efficiency gains was analysed having in mind the need to support industry. At the same time, it was identified the need to reorganise the work so as to free up capacity to tackle new responsibilities assigned to EASA by the legislator in different domains like cybersecurity, drones, environment and research.

As part of the transformation programme, specific measures include in particular a progressive introduction of automation, digitalisation, process simplification as well as re-organisation of the outsourcing strategy.

EASA will begin its transformation programme in 2020 with the ambition to reach at least 8% efficiency gain by 2023.

**6. Which was the focus of the unforeseen expenses that EASA incurred in 2018?**

EASA does not reserve a specific contingency budget for unforeseen expenditure. However, spending is closely monitored during the year. Variations from the planning assumptions are addressed by freeing up capacity to meet the unforeseen high priorities. During 2018 the Agency brought forward some high priority projects, such as:

- Operational studies on environmental protection in line with requirements of the Agency's Basic Regulation
- Modernisation of IT systems
- Brexit
- Digitalisation

**7. Which were the agency's biggest achievements in 2018?**

The work programme was implemented as planned. Most important achievements are described in the Executive Summary of the EASA Consolidated Annual Activity Report (pages 4-5).

<https://www.easa.europa.eu/sites/default/files/dfu/EASA%20MB%20Decision%2004-2019%20Annex%20AAR%202018.pdf>

**8. Which other European agencies EASA collaborated with in 2018 and which were the results of these collaborations?**

EASA is establishing cooperation frameworks with other EU Agencies like EMSA and FRONTEX in the drones domain in view of supporting their drones operations by sharing information on the new EU-EASA regulatory framework.

EASA has also cooperated with the Computer Emergency Response Team for the EU Institutions, bodies and agencies (CERT-EU) as regards cybersecurity in the aviation domain by supporting the operations of the European Centre for Cyber Security in Aviation (ECCSA) after its roll out in 2017. In particular, the EASA support includes the provision of cybersecurity threat tools, specific deliverables, threat intelligence information tailored to the aviation sector as well as cyber-threats bulletins.

EASA is also cooperating with the European Railways Agency (ERA) in the domain of safety data analysis.

Furthermore, EASA is providing technical advice to the SESAR Joint Undertaking and Clean Sky Joint Technology Initiative for the validation of their air traffic management products.

EASA and the European Environment Agency (EEA) jointly produce every 3 years an European Aviation Environmental Report providing an overview of the environmental challenges of aviation in the EU. Please see also EASA reply to horizontal Question 3.

EASA is also supporting the European Chemicals Agency (ECHA) among others in the establishment of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) list.

# EBA

Replies to written questions

## 2018 discharge – Individual questions

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- 1. To what extent is the transfer of EBA Executive Director Farkas as Association for Financial Markets in Europe (AFME) Chief Executive in line with Article 16 of the European Union Staff Regulations, which stipulates that after resigning, EU officials are banned from lobbying staff of their former institution for a period of 12 months? How are you going to prevent future cases of conflicts of interest?**

The EBA's Board of Supervisors, as appointing authority for Adam Farkas, has adopted measures to ensure that Article 16 of the Staff Regulations is complied with by Adam Farkas.

The measures taken after leaving the service are in the present case the following.

- The Staff Member shall not, for 24 months after leaving the service of the EBA, engage in lobbying or advocacy of the EBA or its staff on matters for which he was responsible during the last three years of service.
- The Staff Member shall not, for 24 months after leaving the service of the EBA, have professional contacts with EBA staff on behalf of AFME.
- The Staff Member shall for 18 months after leaving the service of the EBA refrain from assisting AFME members, and otherwise contributing to AFME's activities on topics directly linked to work carried out by him during his last three years of service. This includes in particular: the EU impact and implementation of the finalised Basel III standards; prudential policies relating to the fundamental review of the trading book, non-performing loans and securitisation; the EBA stress test; ML/TF risks in the prudential supervisory process; and secure customer authentication and API implementation under the Payment Services Directive 2. In case of doubt, the Staff Member shall contact the EBA.
- The Staff Member shall not, without authorisation, disclose information received in the line of duty unless that information has already been made public or is accessible to the public (Article 17(1) Staff Regulations). The Staff Member shall not exploit insights of a confidential nature in policy, strategy or internal processes that the Staff Member has acquired in the line of duty and that have not been made public or is otherwise accessible to the public.



Article 16 of the Staff Regulations and Article 21(6) of the Commission Decision on occupational activities after leaving the service<sup>1</sup> require the EBA, in principle, to prohibit Mr Farkas from engagement in lobbying or advocacy vis-à-vis EBA staff for his future employer on matters for which Mr Farkas was responsible during the last three years in the service.

Since Article 16 of the Staff Regulations imposes a notification requirement for 24 months after leaving the service, 24 months is in practice the longest period for which such restrictions are applied. The EBA therefore exceeded the requirement of the Staff Regulations and Commission Decision and imposed this restriction for 24 months rather than the 12 months provided for in the Commission Decision.

The EBA went further and applied the restriction in Article 21(3)(a) of the Commission Decision, by requiring Mr Farkas to refrain from assisting AFME members, and otherwise contributing to AFME's activities on topics directly linked to work carried out by him during his last three years of service. Taking into account that Mr Farkas was not involved in preparation of EBA regulatory or supervisory policies following the tendering of his resignation on 2 August 2019, the EBA imposed this restriction for 18 months, effectively ensuring a 'cooling off' period of a total of 24 months.

Article 21(3) of the Commission Decision requires the Board of Supervisors to "define an appropriate balance between the need to ensure integrity through temporary prohibitions and restrictions and the need to respect the former staff member's fundamental right to engage in work and to pursue a freely chosen or accepted occupation".

While recognising the substantial conflict with the legitimate interests of the EBA, taking into account the factors set out in Article 21(2) of the Commission Decision, the EBA considers that it has achieved the balance required through imposing the significant restrictions described.

The EBA has adopted policies to manage conflicts of interest of its staff and its members of the Board of Supervisors. The EBA staff receive training regarding the EBA's policies in this area.

The primary responsibility for ensuring compliance with conflicts of interest obligations rests with staff members, and therefore with Mr Farkas in the present case. We also consider that it will not be in the interests of Mr Farkas and AFME to breach the requirements given the reputational risks to which this would give rise. Nevertheless, the EBA recognises the risks to its own reputation and where we identify potential breaches of the requirements, we will actively pursue any those concerns. EBA staff have also been informed of the restrictions imposed on Mr Farkas and have been

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<sup>1</sup> Commission Decision of 29.6.2018 on outside activities and assignments and on occupational activities after leaving the Service (C(2018) 4048 final)

instructed to report professional contacts by Mr Farkas on behalf of AFME through their line management. EBA staff will be reminded of this obligation through the regular ethics training provided.

While conflicts of interest cannot always be prevented, the adopted conflict of interest policies therefore aim at identifying and managing any actual or potential conflict of interest, while the significant restrictions imposed on Mr Farkas within the current legal framework, together with our plans for monitoring the restrictions, demonstrate the seriousness with which the EBA takes these matters and our concern for ensuring that the EBA continues to be seen to be acting with integrity and that the interests of the EBA and of the EU are protected.

**2. Have you performed an analysis on how working conditions are in line with national and European labour law as suggested by the ECA, and if applicable, what corrective measures will you implement?**

The EBA used interim administrative staff in London. In its tender for the supply of interim workers for general administration, in drafting the technical specifications, the EBA used the basic salaries of EU contract agents to determine the estimated contract volume. In this tender, the following was stated:

*During and throughout implementation of the Framework Contract, the contractor will be fully responsible for ensuring that when they provide interim workers to the EBA, the employment of the interim worker by the EBA complies in full with all current UK law relating to the employment of interim workers.*

The framework contract also stated that: *The contractor acknowledges and agrees to accept the 'Swedish derogation model' to the AWR. Under the Swedish derogation, the temporary worker will not be employed by the contracting authority, but by the contractor. The Contractor is responsible for ensuring compliance with this requirement. The contractor is responsible for organising compliance with national law on employment of temporary workers. The contracting authority does not provide advice or legal assistance in this regard.*

Furthermore, tenderers were also required to sign a declaration where the following was stated for one of the mandatory technical requirements: *Compliance with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU.*

On moving to Paris in 2019, the EBA analysed the French legislation on the use of administrative interim staff and concluded that it would not be efficient to do so. The EBA has therefore now eliminated the risk identified by the Court in this regard.

The EBA now uses consultancy for services in the field of facility management and ICT. Tenderers once again are required to comply with the minimum requirement of complying with applicable environmental, social and labour law obligations established by Union law, national legislation, collective agreements or the international environmental, social and labour conventions listed in Annex X to Directive 2014/24/EU and this is also stated in the provision of services on the contract implemented between the contractor and the Authority.

However, the EBA will request proof from their contractors for these services, throughout the duration of the contract, that they are fulfilling their obligations in this regard to mitigate any risks.

# ECHA

## Replies to written questions

Helsinki, 6 November 2019

R0/lm

CONT Secretariat  
European Parliament

By e-mail: [CONT-secretariat@europarl.europa.eu](mailto:CONT-secretariat@europarl.europa.eu)

**Subject: 2018 Discharge of the EU Decentralised Agencies: Reply to the individual question addressed to the European Chemicals Agency (ECHA)**

*What kind of mechanisms to prevent conflict of interests does the agency, which collects fees from its clients, dispose of?*

The REACH Regulation and the Fee Regulation foresee that industry pays a fee to ECHA for the registrations of chemical substances and applications for authorisation, among others. The fees are set by the European Commission, not by ECHA. The purpose of the fee is to cover the costs of the handling of the registration or application and in particular on the scientific work to provide the opinions. It is linked with the "polluter pays" principle enshrined in EU law. The fee is paid upfront, irrespective of the outcome of the scientific assessment. Thus the payment of the fee does not have an effect on the independence of the Agency's work and in particular on the independence of the members of ECHA's scientific committees and ECHA's staff who are working on the opinions. Furthermore, the committee members and ECHA staff involved in the opinion making are assessed to ensure that they do not have a conflict of interest.

ECHA's Conflict of Interest Prevention policies cover the whole lifespan of the employment of staff at ECHA, from the selection and recruitment phases, throughout the whole period of collaboration and continuing even during the period after the employment has ended.

To safeguard its independence, the external experts who participate in the scientific committees, Management Board and Enforcement Forum are screened against five targeted eligibility (exclusion) criteria before appointment:

- No current employment or positions in scientific or governing bodies of companies with an interest in the field of activity of ECHA;
- No employment or active membership in an interest group with an interest in the field of activity of ECHA;
- No current contractual engagements with companies or interest groups in the field of activity of ECHA;
- No current significant investments in chemical companies manufacturing, importing or supplying substances or mixtures;
- No employment, positions in governing bodies or active membership in the previous two years in companies or interest groups with an interest in the field of activity of ECHA, if such position would lead to a potential conflict of interest of a general nature that would potentially lead to multiple exclusions of the individual from the meetings of the Committee or from rapporteurship.

These same eligibility criteria are also used during the selection process for other sensitive positions such as that of member of the Board of Appeal or Executive Director.

Once appointed, ECHA obliges anyone taking up a position in ECHA to complete a detailed declaration of interests before they can start to work for the Agency. The scope of such declarations is very wide and covers all private interests held, including those of their close family members (spouse, partner and/or dependent children). This includes, but is not limited to, previous employment, consultancy, legal representation or advice, membership of a governing body, scientific advisory body or equivalent, other membership or affiliation, research funding, financial investments, intellectual property, etc.

The declarations of ECHA middle and senior management as well as those of the members of all ECHA bodies (Management Board, Committees, Forum, Board of Appeal) are published on ECHA's website for transparency reasons and public scrutiny.

The declarations are updated annually (or earlier if changes occur during the year) and reviewed by the supervisor of the staff member or by the Chair of the relevant scientific committee to detect any potential issues. After that, they form the basis for specific conflict of interest checks before each Committee meeting or every time a task is assigned. As a general principle, Committee members cannot vote and staff members are not assigned tasks related to organisations or substances in which they have recent or current interests.

Additionally, there are specific restrictions to outside activities, gifts and hospitality and restrictions even after the employment at ECHA has ended: for a period of two years all subsequent employment needs the authorisation of the Executive Director and conditions can be imposed. Confidentiality duties continue to apply as well.

# EIGE

Replies to written questions

## ***EIGE***

Question:

Have you performed an analysis on how working conditions are in line with national and European labour law as suggested by the ECA, and if applicable, what corrective measures will you implement?

Answer:

EIGE carried out thorough analysis of the tasks of statutory staff and the staff of the temporary agency workers, which underlined that they are hardly comparable. The main difference is ensuing from the Financial Regulations stipulating that the tasks of financial actors can only be executed by the staff covered by the Staff Regulations.

EIGE's contract with the temporary workers agency places a requirement on this agency for full compliance with the Lithuanian law and specifically refer to the Lithuanian social legislation in force with respect to the interim agents. This indeed includes also the transposition of the Directive 2008/104/EC of the European Parliament and of the Council into the Lithuanian law.

The matter of compliance is currently subject to an ongoing court case, in which EIGE participates as a third party. At present, the case is dealt with by the Lithuanian Supreme Court, which was also requested to consult the European Court of Justice. One of the principal questions to be examined are the analysis as to what extent the positions of the interim and EIGE statutory staff are comparable. Given that all positions / job functions of staff directly employed by EIGE include tasks that can be executed by the staff covered by the Staff Regulations only and exclusively, it is to be examined whether these positions can be considered the same job / the same job function within the meaning of Art 5 (1) of the Directive 2008/104.

EIGE will act on the basis of the final court ruling when in effect and will proceed with the corrective measures accordingly.

EIGE points out that the matter of the interim workers is very complex in particular due to the various ways of transposition of the Directive 2008/104 into national laws and partially also due to the diverse interpretation and terminology used. EIGE therefore highly welcome the intention of the ECA to establish an interinstitutional group to deal with this matter.



# EIOPA

Replies to written questions



EIOPA REGULAR USE

EIOPA-19/577  
11 11 2019

**Reply of the Executive Director to the Discharge Authority to the individual questions received in the light of the discharge in respect of the implementation of the budget for the financial year 2018 (2018/2203(DEC))**

**Question 1**

The number of staff at EIOPA has reduced from 151 in 2017 to 146 in 2018. In terms of ensuring the efficiency of the agency and ensuring that it is fully able to carry out its mandate, is the use of an increased number of interim workers the most efficient use of the agency's budget?

**EIOPA's reply**

Over the past years, the fulfilment rate of EIOPA's establishment plan has been always close to 100%. For 2018, at the end of the year, some positions were not filled due to turnover of staff and a number of unsuccessful recruitment campaigns. EIOPA does not see the usage of interim workers as an efficient solution to structurally solve capacity gaps. The Authority aims to limit the engagement of interim staff to cases of a temporary need for expertise or skills not available in the agency (e.g. specific IT skills) or to cover short-term staff absences in the administrative and support areas (e.g. the reception).

**Question 2**

Have you performed an analysis on how working conditions are in line with national and European labour law as suggested by the ECA, and if applicable, what corrective measures will you implement?

**EIOPA'S reply**

Compliance with the respective European and national labour law framework, and more in particular the German law implementing Directive 2008/104/EC (i.e. the Arbeitnehmerüberlassungsgesetz, AÜG), is of utmost importance to EIOPA.

Based on the advice of ECA, as well as further to an analysis of the implementation modalities of the respective laws, internal correctives measures have been put in place such as the update of procurement documents, equal treatment regarding the access to facilities, working hours, rest periods and public holidays.

# EMA

Replies to written questions

EMA/610290/2019  
11 November 2019  
European Medicines Agency

## EMA reply to questionnaire from European Parliament

2018 Discharge of the EU decentralised Agencies

CONT Hearing on Agencies discharge for Financial Year 2018 (4 December 2019)

### II. Questions to be answered by individual Agencies

15. What is the current state of play of the EMA's movement to its new seat? What difficulties related to Brexit have been already solved and what difficulties still remain to be solved?

Construction of the permanent EMA building is progressing with more than 500 persons working 24/7 on site at peak moments. Prerequisites for the handover from CGREA to EMA on 15 November 2019 are completion of the building on time without defects preventing a safe and secure occupancy, with an agreed plan for the management of defects, particularly an agreed prioritisation approach towards any defects that may adversely affect EMA's business continuity, which should be resolved before EMA takes responsibility for the building as of 6 January 2020. Another important prerequisite is the timely finalisation and sign-off of a number of legal documents: Lease Agreement and annexes including Service Level Agreement and annexes and Delivery Report Part I with annexes. Several levels of quality assurance are in place at the building consortium BC-EMA, CGREA and EMA. In addition, the Municipality of Amsterdam will control whether the new premises are built in accordance with the building permit they issued and with NL legislation and regulation, and the Municipality Fire Inspector will control the fire safety and approve the notification of occupancy. EMA will conduct a quality assessment with the involvement of an external consultant to determine whether the building complies with the agreed contractual baseline and whether its quality and safety are sufficiently verified and validated. In addition, an audit will run in parallel, involving an external company performing an audit of the lease arrangements.

EMA has continued to monitor and track submissions of Brexit-related changes for all affected Centrally Authorised Products (CAPs) under the assumption that the UK would become a third country. The Agency continues to work with MAHs to address any outstanding issues, and should their plans change indicating that they are no longer in a position to implement the necessary changes before the withdrawal date in order to ensure alignment with EU legislation, will subject the relevant CAPs to a criticality assessment. An EU Executive Brexit Steering Group on availability of medicines has been set-up and will operate in a no-deal scenario providing urgent and coordinated action within the network in case of a crisis situation that increases the risk of supply shortage. The Steering Group is

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An agency of the European Union



composed of European Commission, Member States and EMA representatives in the human and veterinary medicines field and reports to the Pharmaceutical Committee, the EMA Management Board and HMA.

The most recent staff retention figures continue to confirm previous trends of a 20-25% staff loss. The proportion of staff resigning of total staff leaving has increased to ca. 80 %. Selection procedures of new staff are now processed within ca. 3 months, as efficiency gains and staff reallocation under the Agency's business continuity arrangements have been introduced. Although the Agency has built up impressive reserve lists, these are mostly generic, and single specialised profiles will have to be filled through dedicated selection procedures. Although new staff will join EMA in coming months, there will be limited resources for engaging in additional activities beyond the current level of Brexit Business Continuity Plan (BCP) activities until after the Agency has moved to the permanent EMA building.

The Agency will also be setting up a contractual framework and will manage sub-lease of its premises in the UK, potentially as a 3rd country, which were sublet following the decision to take this matter out of the EU-UK negotiations.

16. What kind of mechanisms to prevent conflict of interest does the agency, which collects fees from their clients, dispose?

It should be emphasised that applicants to the EMA pay fees for the initiation of a scientific assessment procedure, i.e. the time and resources spent by the experts of the Agency and of the national competent authorities of the Member States, but not for its outcome. This means that a company pays at the time of submission of an application to EMA; then the Agency carries out an independent assessment. At the end of the assessment, the Agency gives a recommendation on whether or not a marketing authorisation should be granted. If the Agency does not recommend a medicine for a marketing authorisation, the company still has to pay. Using an analogy of a driving test, one needs to pay to take a driving test but there is no guarantee of passing the test.

In addition, it should be emphasised that EMA, since its establishment, has put in place several layers throughout its scientific evaluation processes to ensure robust and independent scientific reviews. Firstly, the Agency has three policies on the handling of competing interests (for management board, experts, staff), with ex ante and ex posts controls on the implementation of such rules, including an annual report on independence (see more details about these policies on the EMA webpage for handling competing interests: <https://www.ema.europa.eu/en/about-us/how-we-work/handling-competing-interests>). Secondly, the Agency has a system of peer-review of its scientific opinions, whereby each product is separately assessed by a rapporteur and a co-rapporteur and then subject to committee discussion and vote between 28 Member States. Thirdly, the Agency makes public declarations of interests, assessment reports, agenda and meeting minutes, allowing public scrutiny on how the EMA works and reaches its decisions (transparency).

It is also worthwhile to point out that a regulatory system based on fees is a conscious political choice of the EU legislator: as a marketing authorisation brings considerable economic advantages to the applicant (i.e. access to the EU single market) it is fair that the cost for the scientific assessment and post-authorisation monitoring of its medicinal product is shared by the applicant and not borne exclusively by taxpayers' money (system based only on public funded regulators), otherwise the applicant would benefit twice, i.e. first from accessing the EU market where it can make a profit and secondly for not paying any regulatory costs for accessing it.



In addition, processing and collecting the fees involves a significant administrative burden and requires a detailed knowledge of both fee regulations applicable to the Agency of the scientific characteristics of the product. Transferring these executive tasks and workload to the Commission would not generate improved effectiveness or efficiency in this process. The Commission already currently makes proposals for the Agency's establishment plan with no regard to the actual workload and staffing needs of the Agency. This has resulted in a critical situation where the Agency's workload and fee income from scientific activities has grown by over 30% over the past years whilst in the same period its number of temporary agents working on these activities were reduced by the Commission by 10%, causing significant issues for the Agency in delivering its mandate. Transferring to the Commission funds paid by applicants for work carried out by the Agency would reduce effectiveness of such fund management since, as shown in the EC's approach to establishment plans, a short-term focus on cost reduction rather than a strategic focus on added-value would be applied to the EMA, which would strongly jeopardise the functioning of the Agency going forward.

Finally, it is important to consider that, over the past decades, several national medicines agencies have moved from a central government funding to a fee-based income model, which has allowed them to manage their resources much more effectively and subsequently increase the performance of their public health activities. Equally, other leading international regulators (US FDA, Health Canada, the Therapeutics and Goods Administration of Australia) are directly funded by applicant fees enabling them to provide public health activities.



# EMCDDA

Replies to written questions



## **2018 Discharge of the EU decentralised Agencies**

### **WRITTEN QUESTIONS TO THE AGENCIES**

**Hearing on 4 December 2019**

#### ***II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES***

##### **EMCDDA**

17. Have you performed an analysis on how working conditions are in line with national and European labour law as suggested by the ECA, and if applicable, what corrective measures will you implement?

##### **EMCDDA's REPLY:**

The working conditions of the EMCDDA staff are in line with the applicable provisions of the relevant EU legislation (namely Staff Regulations and CEOs for officials, temporary and contracts agents. The EMCDDA relies on a reduced use of services of interim workers via temporary-work agency (currently 3 compared to 111 members of the EMCDDA staff).

The contracts for the engagement of these workers have been concluded and implemented in accordance with the applicable rules, i.e. the relevant EU financial rules (for the procurement and contracting of the services of the relevant temporary-work agency) and the relevant national legislation (for the contracts in place between this agency and the referred interim workers for the execution of the required services to the benefit of the EMCDDA). This legislation is in line with the EU Directive concerning the matter at stake, this Directive being not directly applicable to the contracts in question. Pursuant to this legislation, the temporary-work agency contracted is the entity required/obliged to comply with the conditions laid down by this legislation for the form and the content of the contract of employment for temporary work to be concluded with each interim worker. The contract concluded between the EMCDDA and the temporary-work agency explicitly refers to the obligation of the latter to comply with all these conditions and requirements.

Without prejudice to the residual use of interim workers, the EMCDDA has assessed and clarified the tasks that may be carried out on a temporary basis by means of the services of these workers, in order to further ensure the consistency of these tasks with the corresponding remuneration levels and minimise and prevent any risk relating to the compliance with the relevant legal framework. This does not put in question that the agency contracted to provide services for temporary work is, and will remain, the main entity responsible for this compliance.

# EMSA

Replies to written questions

Lisbon, 11 November 2019

## **REPLY OF THE EUROPEAN MARITIME SAFETY AGENCY (EMSA) TO THE QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES (HEARING 04/12/2019)**

### **18. Which are the measures implemented by EMSA in 2018 to make the agency's expenses more efficient?**

As regards the control over the Agency's expenses, the Agency's Single Programming Document includes for each single activity a clear link to its legal basis and strategic context through references to the relevant articles of the EMSA Founding Regulation and to the relevant objectives of the EMSA 5-year Strategy. This demonstrates the consistency of the annual activities with the tasks assigned by the legislator and the strategic outlook adopted by the Administrative Board. Furthermore, the allocation of budget and staff to each activity clarifies relative impact on resources and allows for a better and continuous control of the Agency's expenses.

The simplified and side-by-side representation of planned and actual output and the related achievements as well as expenses for each activity allows for an accurate and continuous comparison of objectives, results and expenses.

It should be noted that the last evaluation of the Agency (May 2017) concluded that by operating at EU level, EMSA is providing significant added value in all its areas of activities and for all its stakeholders. EMSA has become an important and respected player in the maritime community, offering world-class services that made the EU maritime sector safer and more secure. The agency's efficiency has increased, demonstrated by a lower share of overhead expenditure, the accomplished new tasks without additional resources and also due to the performance management system used by the Agency, which sets multiannual objectives and quarterly KPI indicators as one element in the periodic monitoring of the implementation of the annual work programmes. The cost effectiveness of the Agency's activities is assessed positively: A number of activities provide high value for money compared to alternative models of provision at the national or regional level.

EMSA's activities also contribute to reducing the administrative burden for Member States and to improving Member States' efficiency in implementing their legal obligations. None of EMSA's activities have been assessed as redundant, and EMSA's work is generally assessed as being complementary to that of the Member States. As a result, the evaluation concludes that EMSA's services and products are cost-effective and that EMSA provides value for money within the context of the EU maritime sector and within all areas of work. The full evaluation report is available on the agency's website:

<http://emsa.europa.eu/who-are-we/admin-board/evaluation-activities.html>

### **19. Which were the biggest personnel problems that EMSA encountered in 2018? And how have they been solved?**

One of the biggest personnel problems the Agency is facing concerns the recruitment of female staff in operational posts. This is a general concern that affects the maritime / transport sector. This issue also affects recruitments in the area of ICT.

In 2018, an 'Action Plan for Gender Balance at EMSA' was prepared where three main goals were identified: Promotion of values of non-discrimination by gender, equal opportunities in attracting and recruiting staff and retaining women. In order to achieve these goals, actions were agreed. One of these actions was for EMSA to participate in specific outside activities. This was accomplished by the signature of the "Declaration on equal opportunities for women and men in the transport sector" by the Agency's Executive Director on 12/11/2018. As a consequence, EMSA's name is published among the signatories of the declaration in the European Commission website Women in Transport – EU Platform for Change.

**20. Which were the deficiencies of EMSA in 2018? Which of these have been solved and which of them still persist today?**

EMSA did not suffer from major deficiencies during the course of 2018. During the course of 2018, IAS performed an audit on Visits and Inspections with focus on QMS at EMSA and issued 4 recommendations to improve operations. None of these recommendations were of critical nature. Actions to address the areas for improvement for 3 of these 4 recommendations have already been implemented whilst the action for the remaining audit recommendation is being implemented according to schedule.

Likewise, the recommendation issued by the Court of Auditors related to the accounts for 2018 has been solved.

**21. Which steps does EMSA consider that should be followed and what measures should be implemented to ensure better money management and to have more efficient expenses in favour of the agency?**

EMSA believes that a detailed allocation of budget and staff to each of its activities allows for a better, more efficient and continuous control of the Agency's expenses. The Agency has already implemented this measure. As regards procurement, the Agency is actively participating in the interinstitutional procurement as party or leading Agency. This also leads to a reduction of efforts and resources. EMSA also actively searches for and implements synergies with the neighbouring Agency, EMCDDA.

**22. Which was the focus of the unforeseen expenses that EMSA incurred in 2018?**

EMSA did not incur any unforeseen expenses during 2018.

**23. Which were the agency's biggest achievements in 2018?**

The implementation of the Agency's working program and related achievements are fully outlined in the Agency's Consolidated Annual Activity Report (CAAR). The Agency's Consolidated Annual Activity Report for 2018 is made available to the EU Citizen and published on the Agency's website.

The key strategic achievements in each work area in 2018 are outlined below.

## *1. Standards, rules and implementation*

*EMSA shall be a leading technical partner in cooperation with Member States for the development and implementation of EU safety standards and regulations in the maritime sector.*

The contribution of the Agency to the development and implementation of EU standards and regulations in the maritime sector is delivered through a programme of visits and inspections, corresponding reports and cumulative horizontal analyses. By implementing the Methodology for Visits to Member States, as adopted by the EMSA Administrative Board in 2015, the Agency succeeded to enhance the potential for reducing the administrative burden to Member States, developing and sharing best-practices and lessons learnt, and strengthening the flow and exchange of information. The integration of the cost-efficiency assessment into the horizontal analyses maximised the value added to both Member States and the Commission of EMSA visits.

In addition, the Quality Management System for Visits and Inspections, which in 2018 was extended to cover Horizontal Analyses Activities and Maritime Security Inspections, aims to guarantee high standards in terms of the reliability of information and provides a framework for continual improvement.

The technical work carried out in relation to Passenger Ship Safety, Marine Equipment, Fire Safety confirmed the leading role of the Agency for issues related to Ship Safety in support of the Commission and the Member States at EU and IMO level.

Safety analyses of data from EMCIP confirmed their added value as a tool to identify safety issues and possible improvements towards enhanced safety culture.

## *2. Monitoring, surveillance and information sharing*

*EMSA shall aim to become a major provider of reliable and efficient information services for the benefit of the EU maritime cluster and, where appropriate, for the use of other communities.*

The process of enriching and tailoring the maritime picture made available by EMSA to its key stakeholders continued in 2018, with the integration of new data and functionalities, and EMSA's Integrated Maritime Services were delivered to more users exercising an ever wider range of maritime functions. More functionalities have been added and the development of Automated Behaviour Monitoring algorithms were stepped up together with interested Member States and EU Agencies. Efforts to support the digitalisation of maritime transport continued with amongst others the deployment of SafeSeaNet version 4, the development of the central databases and pilot projects in the field of the National Single Window and the eManifest.

The operational services under the Copernicus Maritime Surveillance Services, executed on behalf of the Commission, saw a significant growth. All earth observation contracts were retendered, providing a stable and robust basis to deliver higher quality and variety of services in the years to come.

While the deployment of RPAS services was delayed, due to the pioneering nature of civilian maritime RPAS and resulting technical and logistical issues, at the end of 2018 four services were offered in four countries in parallel. The portfolio of RPAS services was completed by another round of public procurement, adding more capacity in the field of long range RPAS and vertical take-off and landing. These services are adding unique data that the Agency can make available across its systems and for different users, from supporting the implementation of standards and rules in the environmental field and contributing to pollution prevention, to

enriching the maritime picture for a range of functions in law enforcement, border and fisheries control, search and rescue and pollution response.

The integrated maritime picture, Automated Behaviour Monitoring, and surveillance services based on satellite imagery and RPAS were shared with Frontex and EFCA with the required customization in the framework of coast guard cooperation and specific bilateral service level agreements. Integrated Maritime Services were also developed in 2018 for EUNAVFOR, MAOC-N and a new cooperation agreement was signed with EUROPOL for similar services.

In the context of the ongoing discussions on digitalisation and the effects of more enhanced use of existing EU-wide digital maritime systems and services, EMSA is working on a number of initiatives with a view to increase efficiency, synergy and burden reduction both on administrations and on industry, in particular for ship related certificates, using THETIS as the platform to store relevant information, so as to make them available to Member States in their capacity both as Flag and Port States. Work started on a pilot basis on the possible support to Flag States for eCertificates.

### *3. Environmental challenges and response*

*EMSA shall aim to become the main EU resource to support Member States' efforts for mitigating shipping-related environmental risks and responding to environmental accidents in the maritime and offshore sector.*

As the developer and provider of tools and services to directly support Member State environmental enforcement effort and the expert support to the Commission at the IMO, EMSA is poised for a lead role in this sector in the future, supporting Member State efforts to implement EU and International maritime environmental legislation.

Regulation (EU) 2015/757 is the first of several steps in the EU's efforts to include the maritime transport sector in its overall policy to reduce greenhouse gas emissions. From 1 January 2018, companies are monitoring and reporting, to an accredited verifier, data on each ship's CO<sub>2</sub> emissions (over 5000 gross tonnes, irrespective of its Flag State) and other relevant information allowing for the determination of ships' efficiency or for the further analysis of the drivers for the development of emissions, while preserving the confidentiality of commercial or industrial information. THETIS-MRV, which is a purpose-built monitoring, reporting and verification web-based system developed and hosted by EMSA, supports the aforementioned activities within the context of cost-efficient services based on the use of existing infrastructure and supporting arrangements, as well as proven concepts and expertise.

With almost 300 LNG fuelled ships confirmed, 70% of which operating in Europe, and LNG fuel capacities currently exceeding several thousands of cubic meters per ship (up to 18,600 cubic meters in the 9 confirmed CMA-CGM mega container carriers), the LNG bunkering market will witness a significant change in paradigm with a need to develop higher capacity and throughput for LNG bunkering systems and operations. The EMSA Guidance on LNG Bunkering for Port Authorities and Administrations, published in early 2018, established EMSA as one of the leading partners in the challenging activity to develop adequate control measures in ports for a fast-developing market. EMSA has provided state of the art guidance to Member States administrations, port authorities and competent bodies for the national LNG fuel frameworks on how to develop adequate control measures for LNG bunkering operations in the context of specific ports regulatory exercise.

In the field of response, the Agency is enriching its portfolio of services, besides maintaining and renewing its existing network of oil recovery vessels, by continuing to build the Equipment Assistance Service which saw a

new depot in the Adriatic Sea becoming operational and the successful completion of the procurement procedure for another one in the northern Baltic Sea. EMSA also added to this service which makes specialised stand-alone equipment available to Vessels of Opportunity some dispersants and dispersant spraying devices thereby diversifying the options available for topping up national and regional oil pollution response capacities. The new HAZMAT (hazardous materials) database became operational and is directly accessible by Member States, which can also use the MAR-CIS database (datasheets of chemicals). In addition, the MAR-ICE network is available 24/7 for obtaining information on chemicals accidentally released in the marine environment. Information on the EMSA response capacity is automatically available in the EU civil protection mechanism system CECIS, an interface has been developed and installed for this purpose.

The Remotely Piloted Aircrafts Systems (RPAS) portfolio for pollution surveillance and support to response operations was completed in 2018 and new RPAS were contracted to support vessel's emissions monitoring campaigns.

#### *4. Information, knowledge and training*

*EMSA shall aim to become one of the foremost knowledge providers within the maritime cluster.*

Continuity for capacity building activities in neighbouring countries around the Mediterranean and the Black and Caspian seas is assured until 2021 through SAFEMED IV and BCSEA. These activities aim to contribute to the approximation of standards in maritime safety, security and increasingly also pollution prevention and response. This is a crucial element in the overall success of the EU's vision for its seas.

EMSA offers to Member States, candidate and potential candidate countries and neighbouring countries sharing EU sea basins an increasingly innovative, collaborative, and flexible capacity building service that can be specialised and tailor-made and relies increasingly on e-learning. The growing body of tools and guidance reflects evolving policy priorities and related stakeholder needs.

Following the interest expressed by third countries, access to tools in support of Port State Control activities in different regions of the world was authorised by the EMSA Administrative Board, thus confirming the potential for exporting the Agency's knowledge and, by extension, EU standards and solutions beyond the European geographical dimension.

## **B) Operational Achievements**

In each of the strategic areas, key stakeholders benefitted from EMSA products and services.

#### *1. Standards, Rules and Implementation*

All EU ship-safety initiatives and relevant negotiations at IMO were supported by EMSA technical assistance, while the combined effort of EMSA and Member States in the programme of visits and inspections – all those planned for 2018 were carried out - has fed into Commission initiatives to assess and fine-tune maritime safety EU legislation in order to improve the efficiency and effectiveness of measures in place. In addition, the horizontal analyses performed have provided essential feedback for the improvement of the relevant EU legislation in the area. Special emphasis was given to passenger ship safety and notably the work on fire safety, with the study FIRESAFE II completed.



EMSA also delivered the 3<sup>rd</sup> Implementing Regulation for Marine Equipment Directive, which provides the industry with the latest changes and updates of the relevant standards used for the certification of marine equipment on board EU flagged ships.

The development of the new EMCIP was concluded, with an enhanced and more user-friendly database available for the accident investigative bodies of the Member States. A safety analysis of data on accidents involving ro-ro vessels was delivered, thus identifying safety issues of horizontal nature.

## *2. Monitoring, Surveillance and information sharing*

The process of data integration and incorporating new data sources and functionalities, such as enhancing Automated Behaviour Monitoring, combining fishing vessel positions and search and rescue data, and providing a mobile application that is actively used by Member States, continued to add value for a growing number of end-users showing increasing interest in tailor-made services. Brought together and delivered under the heading Integrated Maritime Services, the Agency's systems are a pivotal part of Member State monitoring, information and surveillance systems, and benefit a steadily expanding list of other EU agencies and bodies where synergies with EMSA have been identified. Progress was made with the rolling-out of the SafeSeaNet Ecosystem Graphical User Interface (SEG) which is gradually replacing old single interfaces, offering a common and combined view of maritime information provided by several back-end systems operated by the Agency. In 2018 the Agency started offering online access through the SEG to long term storage of maritime information allowing for a more in-depth analysis by surveillance authorities of maritime patterns of vessels of interest.

Extending the possibilities of the original THETIS information system, EMSA started the development of a purpose-built dedicated voluntary module for Member States to report security inspections under Regulation 725/2004. In addition, in 2018 THETIS-EU was further enhanced enabling Member States to submit the annual reports on the implementation of the Sulphur Directive, using data already available in the system as retrieved from inspection reports, thus reducing the associated administrative burden for national competent authorities.

EMSA has developed an enhanced webservice to facilitate communication of all dates of issue, dates of expiry and date of (re) survey of all statutory certificates as issued by the RO's on behalf of flag States, to all classed ships, as a first step towards digitalisation and better use of eCertificates. A full refresh of 400.000 statutory certificates takes place every day covering all the ships classed with the ROs. Information on new ships entering into service, changes of flag (leading to renewal of statutory certificates) and changes of class implying certificate changes are immediately processed as a consequence of the requirement to update information submitted to THETIS within 72 hours after changes in the respective RO systems. By way of Proof of Concept, the same technical arrangement has been made available for those Flag States that issue statutory certificates themselves through a pilot project with the Danish Maritime Authority.

RuleCheck is a decision-support tool, developed and maintained by EMSA. It contains all applicable maritime legislation such as IMO Conventions, Codes, Resolutions and Circulars, ILO Conventions and guidelines, relevant EU Regulations and Directives as well as the respective manuals and Instructions of the Paris, Black Sea and Mediterranean Memoranda of Understanding on Port State Control. While originally developed for the Paris MoU Port State Control authorities, today approximately 1000 users from about 50 countries (Med MoU, BS MoU, Carib MoU, Indian Ocean MoU, Flag State Administrations from Member States and ENP beneficiary countries, as well as Accident Investigation Bodies from the Member States) are granted access rights. Providing access to RuleCheck beyond the EU contributes to harmonised implementation of



international conventions, global harmonisation of PSC practices, and adequate access to the up-to-date regulations for inspectors worldwide. At the same time supports approximation with best practices applied in the EU, increases the visibility of the EU, showing the added value of a tool enhanced for and used by the EU Member States and its competent authorities.

### *3. Environmental challenges and response*

Services for the prevention of, preparedness and response to, pollution caused by ships as well as response to marine pollution caused by oil and gas installations have become more adaptable and flexible in order to increasingly reflect regional capacity, requirements and risk. In this regard the development of the Equipment Assistance Services ready for mobilisation in the North, Baltic and Adriatic seas, together with a regular training program for Member States constitute a real added value, highly appreciated, as can be testified by the increasing number of requests for equipment sets during national or regional exercises. Extensive support was given regarding the ship accident north of Corsica, for which an EMSA oil recovery vessel was mobilised and satellite imagery were provided for detection of oil pollution at sea and later regarding polluted beaches. For this type of pollution incident close to shore, the use of optical images for detection of pollution close to the beach was tested with success. In addition, satellite images were provided for assessing and monitoring several maritime accidents throughout the year. Dispersant from the stockpile in Malta was also made available at the request of the Bulgarian authorities during the lightering of the “MOPANG” wreck. The signature of a memorandum of understanding between EMSA, the International Oil Pollution Compensation Funds and the International Group of Protection and indemnity Associations by which the hire rates of EMSA antipollution assets have been agreed gives certainty to Member States that the costs they will claim for the use of EMSA assets will be accepted

Support was provided to the Commission and the Member States in the ongoing discussions leading to the IMO's Green House Gases Strategy and in the revision of the PRF Directive. Alternative fuels and LNG were the subject of workshops, training and guidance. The Guidance on LNG Bunkering to Port Authorities and Administrations published at the beginning of 2018, is the result of close cooperation with the European Commission, Member States and industry within the context of the European Sustainable Shipping Forum. It aims to support port authorities and administrations backing the use of LNG as a ship fuel, as part of a joint effort to increase safety and sustainability.

A process has been established between DG ENV and EMSA through which the Agency provides information (situational awareness) on selected ships allegedly in imminent breach of the Waste Shipment Regulation (Regulation (EC) No 1013/2006). Information includes, for each ship of interest, the track of the last seven days, the last port of call and departure date and destination and estimated arrival date. The information is provided in the form of a table including a map with print screen of the ship's track.

EMSA using data drawn from MARINFO provided reliable statistics to the European Commission and the maritime Industry on the calculation of the recycling needs of the EU shipping fleet for the years 2013 to 2017.

### *4. Information, knowledge and training*

Member State demand for training, e-learning or ad-hoc technical assistance from EMSA attests to the Agency's added value in this area, as does the Commission's increasing reliance on EMSA for the implementation, in the maritime safety field, of EU policies regarding candidate and potential candidate countries, and neighbouring countries, channelled through the IPA (Instrument for Pre-Accession Assistance), Mediterranean, and Black and Caspian Sea projects.

Within the context of the SAFEMED IV and Black and Caspian Sea Projects and in addition to the assistance offered to beneficiaries to align their national standards and practices with those of the European Union, with the aim of promoting a harmonised approach in the field of maritime safety, security and pollution preparedness/response a new action was established in 2018 in relation to the IMO Member State Audit Scheme (IMSAS). The activity entails pre audit actions where beneficiaries through a mock audit are guided how to better improve the implementation of the international instruments and post audit activities through which support is provided for the preparation and implementation of the corrective action plan.

#### **24. Which other European agencies EMSA collaborated with in 2018 and which were the results of these collaborations?**

EMSA is closely cooperating with Frontex and EFCA in the framework of the interagency cooperation on coast guard functions.

This cooperation agreement mandates Frontex, EFCA and EMSA to cooperate in 5 areas in order to provide more efficient and cost-effective support to the MS authorities carrying out coast guard functions. More in particular, the cooperation agreement focusses on (1) improving information sharing, (2) enhance Surveillance and communication services (3) enable Capacity building (4) develop a common Risk Analysis and (5) Capacity sharing.

As a result (non-exhaustive list) common European Coast Guard Events were organised and there are now bilateral Memoranda of Understanding (MoUs) and Service Level Agreements (SLAs) signed between the agencies covering different subjects, such as information sharing or procurement procedures. As an example, the Service Level Agreement (SLA) between EMSA and EFCA was amended to extend the scope of the information services exchanged and to foresee the equipment of the EFCA inspection vessel with pollution response equipment and dispersants by EMSA. Another example concerns the provision of RPAS services by EMSA to Frontex and EFCA (e.g. EMSA provided mid-size fixed wing RPAS services over Portuguese waters to FRONTEX with a payload configuration composed of optical and infrared cameras, a maritime radar, AIS and distress signal receiver. This aircraft was equipped with satellite communications which allows beyond radio line of sight operations).

EMSA also concluded an administrative arrangement “Working Arrangement establishing cooperative relationships between the European Maritime Safety Agency (EMSA) and the European Union Agency for Law Enforcement Cooperation (EUROPOL)”. This arrangement resulted in the provision of EMSA’s Integrated Maritime Services (IMS) to Europol staff.

The Agency also cooperates with other Agencies such as EMCDDA and EFCA in the administrative areas. This has resulted in a number of synergies with EMCDDA and a Service Level Agreement regarding the back-up services in the area of Accounting (with EFCA). In 2018 EMSA was the leading agency in the successful interinstitutional call for tender for provision of services for the assessment of candidates to managerial functions, acting on its own behalf and 12 other Agencies.

# ERA

Replies to written questions

## ERA

1. Which are the measures implemented by ERA in 2018 to make the agency's expenses more efficient?
  - A. *The agency underwent a reorganisation to implement a matrix structure and to build the Agency work on the basis of either projects or services. This allows more effective and responsive redeployment of resources with shifting priorities. In addition it meant that all of the Agency work would be carried out within clearly defined resources and with clear deliverables. The Agency also changed the way budgets were monitored so that each project or service had its own budget line, supporting a more effective monitoring. Finally in 2018 the resource distribution for SPDs was built bottom-up across the Agency based on historical cost data allowing a greater scrutiny of how costs were generated and supporting a stronger test of the added value. This system was introduced in 2018 but will have a clearer impact from 2019 onwards.*
2. Which were the biggest personnel problems that ERA encountered in 2018? And how have they been solved?
  - A. *Reorganising the entire Agency in a short period of time was challenging for all the staff and whilst outputs were maintained the scale of the changes and the speed created some unhappiness among some of the staff. This has in part been addressed by recognising that the structural changes have been done but the wider cultural transformation will take longer and allow for greater staff involvement. The Agency also faced a related financial challenge since it had been given an additional 12 posts, to be funded from work that generated fees and charges. However to do the work which was to start in 2019 the Agency needed to recruit in 2018, thereby generating the costs but without any revenue from the future work. A growing problem is the mixture of types of posts, TA and CA, where staff do similar work but where the CA staff are paid much less and have fewer career prospects. This creates tensions within the teams.*
3. Which were the deficiencies of ERA in 2018? Which of these have been solved and which of them still persist today?
  - A. *There was and remains a resource gap between the Establishment plan and budget and the tasks allocated to the Agency. In the new regulation the Agency gained a much wider range of tasks that require significant resources. These are all clearly new obligations for which there was no provision, with the exception of the Vehicle Authorisation and Safety Certification where 12 posts were added to the establishment plan but to be paid from generated revenue. These 12 posts do not cover the needs of the new tasks. During the year the Commission found some additional budget to support the development of a mandatory new IT tool (OSS) but only for the year 2018 and this cost will continue into future years.*
4. Which steps does ERA consider that should be followed and what measures should be implemented to ensure better money management and to have more efficient expenses in favour of the agency?

- A. *The Agency considers that the new system of budgets clearly allocated to projects or services with devolved budget responsibility is the right approach. Earlier adoption of the Budget would support better planning and hence reduced carryover. Additionally where new tasks are to be allocated to the Agency they should be accompanied by an impact assessment that addresses how the financial consequences should be managed.*
5. Which was the focus of the unforeseen expenses that ERA incurred in 2018?
- A. *In 2018 the new tasks (Monitoring National Safety Authorities, Monitoring Notified Bodies, revision of the IT registers managed by the Agency, the development of a new IT tool (OSS) ) were never accounted for in the MFF and hence these substantial new costs had to be absorbed within the existing budget.*
6. Which were the agency's biggest achievements in 2018?

- A. *The EU Agency for Railways in 2018 was on the verge of implementing one of the biggest changes in European Rail History, namely the creation, for the first time, of a system that would see a European wide authorisation scheme for new trains and a single operating certificate for train operators. As set out in the new Agency Regulation (EU) No. 796/2016 the work was scheduled to start in June 2019 but this required significant preparatory work in 2018, including the training of Agency and national authority staff as well as establishing contact with industry projects that would be caught up in the migration. A key success story of 2018 has been the way the preparatory work has been carried out, giving confidence to sector and national stakeholders.*

*In addition to this new authority role the new Agency regulation saw the introduction of the first mandatory monitoring scheme of national safety authorities by the Agency. In 2018 the Agency successfully piloted the scheme, paving the way to introduction of the monitoring scheme in 2019.*

*A major barrier to the creation of a single European railway area is the huge number of national rules that have been developed over the decades on national railway networks. These technical and safety rules increase the costs of new trains that have to comply with a complex arrangement of national requirements and hinder international operation of trains. In 2018 the Agency has made significant progress in reducing these rules so that for national rules affecting the authorisation of new trains the Agency programme has seen a reduction from over 14000 rules to a little over 3000 by the end of 2018, with further progress expected in 2019.*

*Safety leadership and positive safety cultures are recognised as key to safe operations in a wide range of industries and in 2018 the Agency triggered work to bring this thinking into Railways. The Safety Culture and safety leadership work has seen early significant successes in 2018 with CEOs of major rail companies signing a public pledge to work on this area. This culminated in a successful conference in Dubrovnik on safety culture that brought together key industry players and created a momentum around this work.*

7. Which other European agencies ERA collaborated with in 2018 and which were the results of these collaborations?

- A. In addition to the systematic coordination meetings the Agency invited an expert from EASA to join a team from the Management Board that carried out a review of the Agency's preparedness for its new authority role. This because EASA had previously been through such a transformation. The support and feedback from EASA was very helpful.*

*ERA is sharing its accounting Officer's services with ESMA. ERA has signed an SLA with ESMA and both agencies meet the requirement in terms of obligations stemming from the Financial Regulation.*

*ERA welcomed an HR Officer from EASO for a couple of weeks to bring expertise in the domain of Competency framework. The Colleague from EASO helped ERA analysing the required competencies for operational functions and roles.*

# ESMA

Replies to written questions

**To: European Parliament  
CONT Committee**

**2018 Discharge of the EU decentralised Agencies**

**WRITTEN QUESTIONS TO THE AGENCIES, Hearing on 4/12/2019**

**ESMA (European Securities and Markets Authority)  
questions and answers**

Dear Members of Parliament,

Please find below ESMA's replies to your questions:

**1. How would an eventual reduction in available budget due to a modification of the rules concerning fee collection from Credit Rating Agencies and Trade Repositories affect the running of ESMA and its ability to fully carry out its mandate?**

The audit report of the European Court of Auditors (ECA) refers to possible unintended effects of the current Regulation which bases the fees charged to Credit Rating Agencies (CRAs) on the revenues of the CRAs as legal entities, but not as a group or group of related entities (paragraph 3.13.6 of page 134 in ECA audit report). It should be noted that,

- With regard to possible impact of rule modification on ESMA's budget, it should be noted that any modification to the way the individual fees charged to CRAs are calculated and allocated across the CRAs would not in itself affect the total ESMA's revenue needed for performing its supervisory activity (i.e. ESMA supervisory budget). Specifically, ESMA's supervisory budget is approved by ESMA Board of Supervisors (BoS) during the annual activity-based budgetary procedure. The revenues of the supervised entities play no role in the establishment of ESMA's budget (including the supervisory budget), whereas those revenues are taken into account only to allocate the supervisory budget appropriately across the supervised CRAs.
- On the other hand, while a modification in the rule underpinning the calculation of the supervisory fees will inherently have an impact on how those fees will be allocated across CRAs, it is worth noting that such effect is likely to be limited. This is because ESMA's supervisory fees are already almost entirely paid by the largest CRAs (approx. 95% of all CRA fees). Moreover those largest CRAs have all established a similar



corporate structure at group level in the EU. Therefore any change in the calculation rule is expected to have a similar impact across those largest CRAs

- Finally, Trade Repositories (TRs) are not affected by this issue.

ESMA will continue the discussion with the Commission in order to avoid any loopholes, simplify and harmonise all current fee calculation and collection processes both for the supervised entities and for ESMA, while ensuring predictability and transparency.

**2. What measures will be put in place following the ECA analysis of a potential risk of confusion between the procurement of IT services and interim workers, in order to ensure that Directive 2008/104/EC is fully respected? How will the methodology be improved?**

In terms of measures put in place to avoid a potential risk of confusion between IT consultancy services and interim workers, ESMA clearly has separated both services by setting up two distinctive framework contracts. In 2018, tenderers responding to the IT consultancy services clearly understood the type of services requested under the IT consultancy services tender, given the fact that all nine tenderers offered genuine IT consultancy services, while not a single tenderer offered temporary agency worker services. Today, ESMA has two completely independent framework contracts in place.

In order to ensure that the implementation of Directive 2008/104/EC is respected, ESMA has taken external legal advice from a local firm specialised in French Labour Law to assess ESMA contracts and practices. This Law firm confirmed that ESMA's IT consultancy contract does not fall under the French implementation of Directive 2008/104/EC, on temporary agency work. Nevertheless, this legal firm also proposed some improvements to ESMA's internal methodology in relation, not to interim workers, but to EU seconded workers at ESMA. To this end, ESMA has drawn internal working instructions for documenting all processes and requirements for intra-muros external resources at ESMA.

**3. What kind of mechanisms to prevent conflict of interest does the agency, which collects fees from their clients, disposes?**

ESMA collects fees for the registration and supervision of CRAs and TRs in line with the Commission's delegated Regulations (EU No. 272/2012 for CRAs and EU No. 1003/2013 for TRs). In this respect, collection of fees is not from clients, but supervised entities. These regulations define the modalities for the collection of fees and set out the rules of determining the amounts of fees to be paid. In order to implement those regulations and prevent conflict of interest, the agency has set up in addition an ESMA's Policy on Conflict of interests and ethics and a Supervision and Registration handbook.

Regarding the possible conflict of interests in terms of enforcement decisions and the fact that the supervised entities would potentially pay fines related to ESMA's supervisory measures, it should be noted that fines do not go into ESMA's budget but are transferred systematically to the general budget of the European Union. In addition, there is a clear independence requirement and internal separation between enforcement and supervision, so the investigative officer is not involved in the direct or indirect supervision or registration process of the supervised entity concerned. This independence requirement is effectively implemented through ESMA's internal procedures/guidelines and an internal organisation structure respecting these requirements.

ESMA's fees are collected to cover the costs of direct supervision of the financial entities it supervises and the fees collected are used only for that purpose. There are internal procedures detailing the entire process and principles to be followed by ESMA for the management of the supervisory fees for TRs and CRAs. Amongst other factors, the role of budget setting and fee collection is separated from the role of direct supervision, with different teams in charge of each activity and rigorous approval processes. In addition, ESMA applies an Activity Based Management methodology, recently audited by the Internal Audit Service (IAS) of the European Commission, and has implemented Activity Based Budgeting (ABB) and Activity Based Costing (ABC) to support and explain the global level of fees.

# FRONTEX

Replies to written questions

## Point 35. FRONTEX

*How many return operations did Frontex coordinate and how much financial assistance did it provide with in 2018? How did Frontex implement and report on its monitoring to these operations? How many cases of serious incidents were reported and what measures have been recommended and undertaken by Frontex to avoid such incidents?*

### How many return operations did Frontex coordinate and how much financial assistance did it provide with in 2018?

In 2018 Frontex coordinated a total of 1427 return operations, out of which 345 were return operations by charter flight and 1082 were return operations by scheduled flights. All return operations were financed by Frontex. In regards of scheduled flights the financial assistance provided by Frontex was 2,717,367.48 EUR, while the assistance concerning return operations by charter flights was 46,153,907.35 EUR in 2018.

	Number of return operations	Financial assistance by Frontex
Return operation by charter flights	345	46,153,907.35 EUR
By scheduled flights	1082	2,717,367.48 EUR

### How did Frontex implement and report on its monitoring to these operations?

Pursuant to Section 6 of Art. 8 of Directive 2008/115/EC, Member States shall provide for an effective forced-return monitoring system.

Pursuant to Article 28(6) of Regulation 2016/1624 every return operation shall be monitored in accordance with Article 8(6) of Directive 2008/115/EC. The monitoring of forced-return operations shall be carried out by the forced-return monitor on the basis of objective and transparent criteria and shall cover the whole return operation from the pre-departure phase until the hand-over of the returnees in the third country of return. The forced-return monitor shall submit a report on each forced-return operation to the executive director, the fundamental rights officer and to the competent national authorities of all the Member States involved in the given operation. If necessary, appropriate follow-up shall be ensured by the executive director and competent national authorities respectively.

According to Article 28(3) of Regulation 2016/1624 on the European Border and Coast Guard, the Agency may provide the necessary assistance and, either at the request of the participating Member States or on the basis of its own proposal, ensure the coordination or the organisation of return operations for which the means of transport and forced-return escorts are provided by a third country of return ('collecting return operations'). The participating Member States and the Agency shall ensure that the respect for fundamental rights, the principle of non-refoulement, and the proportionate use of means of constraints are guaranteed during the entire return operation. At least one Member State representative, and

one forced-return monitor from the pool established under Article 29 or from the national monitoring system of the participating Member State, shall be present throughout the entire return operation until arrival at the third country of return.

Article 29(1) of Regulation 2016/1624 states that the Agency shall, after consulting the fundamental rights officer, constitute a pool of forced-return monitors from competent bodies who carry out forced-return monitoring activities in accordance with Article 8(6) of Directive 2008/115/EC and who have been trained in accordance with Article 36 of this Regulation.

According to Article 29(4) of Regulation 2016/1624 the Agency shall make the forced-return monitors available upon request to participating Member States to monitor, on their behalf, the correct implementation of the return operation and return interventions throughout their duration.

In 2018 a total of 319 monitors were deployed to monitor return operations by charter flights. At least one monitor was present on board of 231 out of all 345 Frontex-coordinated return operations by charter flights. In accordance with Article 28 of the European Border and Coast Guard Regulation, the Agency ensured that monitors are present on all collecting return operations flights in 2018.

Every six months Fundamental Rights Officer (FRO) issues her observations on the conduct of return operations coordinated or organised by Frontex, mainly based on the recommendations and observations included in the received monitoring reports. Subsequently, the FRO Observations, together with the Executive Director Evaluation Report on return operations, are submitted to the Management Board.

### **How many cases of serious incidents were reported and what measures have been recommended and undertaken by Frontex to avoid such incidents?**

The Agency has developed a standard operating procedure for the complaint mechanism as required by Article 72(1) of Regulation 2016/1624 which is used during implementation of return operations coordinated or organised by Frontex, providing further safeguards to the returnees. The process of reporting serious incidents was also updated and is used in all return operations supported by the Agency.

In 2018 there were a total of 3 serious incidents in return operations coordinated by Frontex, of which 1 occurred on a chartered flight, while 2 on return operations by scheduled flight.

The incident regarding the return operation by charter flight occurred in a Joint Return Operation to Nigeria and Gambia organised by Austria where two escort officers were injured by a Gambian returnee.

One incident regarding a return operation by scheduled flight took place in before the departure of a flight and two officers from the Federal Police of Germany were slightly injured by a returnee. The other incident regarding a return operation by scheduled flight took place during the boarding phase where 3 police officers from

the Federal Police of Belgium and 1 returnee was slightly injured. Frontex personnel were not present at the above mentioned 2 return operations.

Frontex organized debriefings with the involved authorities, in order to discuss the risk assessment made on the individual returnees and on the whole return operation.