2017 Discharge of the EU decentralised agencies

Answers to the written questions

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

ACER

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

ACER

1. ACER moved the REMIT data recovery site to the same location where the original data is stored. The Agency considers this the only possible solution, due to insufficient financial resources. Within the constraints of the current resources, what kind of a business continuity plan would the Agency implement in case of any unexpected event?

ACER reply:

The Agency was indeed forced to merge the data recovery site of the Agency's REMIT Information Systems (ARIS) with the ARIS primary site for budgetary reasons in the course of 2017, as the Agency was not provided with the appropriate resources and did not receive the requested REMIT IT budget, neither in 2017 nor in 2018. This is why the Agency can currently not ensure business continuity for its REMIT IT operations and would be forced to shut down its REMIT operations in case of a disaster. This applies in case of both natural disasters (such as floods, hurricanes, tornadoes or earthquakes) and man-made disasters (such as hazardous material spills, infrastructure failure, bio-terrorism, and disastrous IT bugs or failed change implementations). For 2019 the Agency has requested REMIT IT budget of EUR 3.5m, in order to overcome the current shortcomings and to possibly re-establish an ARIS disaster recovery site in the course of 2019. The requested REMIT IT budget is foreseen in the Commission proposal for the EU budget for the year 2019, but put into question by the Council. The Agency trusts in the European Parliament's support to receive the appropriate resources in 2019 to overcome the current predicament.

BEREC

Replies to written questions

Body of European Regulators for Electronic Communications
BEREC OFFICE

2017 Discharge of the EU Decentralised Agencies
WRITTEN QUESTIONS TO THE AGENCIES
Hearing on 3 December 2018

QUESTIONS TO BE ANSWERED BY THE BEREC OFFICE	**THE BEREC OFFICE ANSWER**
BEREC Office paid translation worth of €106.432,50 (i.e. 2,5% of its 2017 budget) to CdT[1] in March 2017, which the ECA considered not justified. The Office, however, considers these payments necessary and duly justified, as their purpose was to establish a large bank of reserve lists for potential recruitments in order to proactively react to the trend of high staff turnover. Is BEREC Office implementing an action plan to mitigate its business continuity against the risks of high staff turnover, and to fight the original reasons causing the turnover?	The BEREC Office is the smallest Agency of the EU with only 14 establishment plan posts but with administrative requirements as for any other body of the EU. This has reflected in very demanding requirements to the job holders, who in multiple cases have to perform three or more different assignments. Key job profiles are missing from the establishment plan, such as internal control coordinator, local security officer, quality manager, local informatics security officer and others, which makes the day-to-day operation of the Agency even more challenging. This situation has been further aggravated by the highest possible cuts of staff at the Agency (12.5%) and the assignment of additional tasks to BEREC via the Telecom Single Market Regulation without adjusting the BEREC Office resources. These factors, in combination with other external factors, such as: low correction coefficient, the living conditions in Latvia, the lack of European School, difficulties in accessing health care and others, which makes Riga a less attractive working place, have led to a high staff turnover. The risk of loss of knowledge and reduced efficiency due to high staff turnover has been identified both by the BEREC Office and the auditors. Therefore in the Annual and Multiannual Programming of the BEREC Office Activities 2017-2019 the

[1] Translation Centre For the Bodies of the European Union

QUESTIONS TO BE ANSWERED BY THE BEREC OFFICE	**THE BEREC OFFICE ANSWER**
	Management Committee requested the BEREC Office to ensure the establishment of reserve lists for minimum 75% of the job profiles at the Agency an indicator with which the BEREC Office has complied. To further mitigate the consequences of the high staff turnover, the Agency developed and implemented a structured handover procedure for the outgoing staff, and started the gradual enhancement of the backup system to avoid the loss of know how. Furthermore, the BEREC Office implements an action plan adopted in 2015, which has the objective to mitigate the risk of high staff turnover and to ensure business continuity. According to the plan, the BEREC Office works towards a long term prospective to retain staff in the organization. To improve the living conditions in Latvia the BEREC Office regularly discusses with the Latvian Authorities the measures, which should be undertaken to improve the implementation of the Seat Agreement. However, some of the measures which the Latvian Authorities have been requested to implement will require legislative changes in the national laws and bylaw and cannot be implemented immediately. Other measures, such as the establishment of European schooling for the BEREC Office staff pupils require long-term commitments (political and financial) from the side of the host country and are also associated with high level of uncertainty. Therefore in parallel with the work carried out with the Latvian Authorities the BEREC Office has started work to retain the staff by implementing the following measures, which are within its direct remit: - To ensure business continuity for critical tasks in the event of staff turnover and to reduce the administrative and technical workload for the staff, some highly specialised or ancillary and technical tasks have been partially or fully externalised (e.g. accounting officer function (to DG Budget), internal control coordinator (to ENISA), procurement of digital products and services (to DG DIGIT), IT security (to EU-CERT), medical services for the staff (to DG HR Medical Service), salary calculation and establishment of individual rights (to the PMO), secretarial, logistical and ICT support – to external companies).

QUESTIONS TO BE ANSWERED BY THE BEREC OFFICE	**THE BEREC OFFICE ANSWER**
	- To make the jobs at the BEREC Office more attractive the Agency adopted a policy on duration of contracts and on internal mobility for temporary agents; the Agency is studying the possibilities for establishing similar policies for the contract agents. - The BEREC Office adopted new, more favourable rule on learning and development and on the implementation of telework. - Since March 2018 the BEREC Office implements an action plan on measures of a social nature, including via a framework contract with a service provide who is tasked with the development and the implementation of a programme on wellbeing of the staff. - Until the establishment of European School as a temporary measure the BEREC Office supports financially the tuition fees for the international schools in Latvia and has the intention to use a similar approach for kindergartens and nurseries. The BEREC Office will continue its effort with the Latvian Authorities to improve the living and working conditions in Riga, especially in the framework of the new BEREC Regulation, which has been recently agreed.

CDT

Replies to written questions

The Director

Luxembourg, 26 October 2018

Ref: MK/GK/cl-096/2018

2017 Discharge of the EU decentralised agencies

CONT QUESTION TO CDT

The amount of EU Agencies using in-house services for translation is relatively high. This is causing duplication of services, and the Centre's capacity is not used to the greatest extent possible. Could the CdT provide the Discharge Authority with the results of the external evaluation on the appropriateness of the Centre's business model?

REPLY FROM THE TRANSLATION CENTRE

The European Court of Auditors commented as follows in its report on the Translation Centre's annual accounts for the financial year 2017:

"The Centre's task is to provide the EU agencies and bodies with the translation services necessary for their activities in addition to doing so for the EU institutions which may call on its services. The founding Regulations of most of the agencies and bodies require them to use the Centre's translation services. Several of them (counting for more than half of the Centre's revenue) make increasing use of in house and other alternative solutions. However, this means that the Centre's capacity is not used to the greatest possible extent, that there is a duplication of systems development and running costs at European level and that the Centre's business model and continuity could be at risk."

In accordance with a decision of the Centre's management board, the Centre commissioned in 2017 a Study on the Translation Centre as the Linguistic Shared Service Provider for the EU Agencies and Bodies. Following a negotiated procedure, a contract was concluded for this purpose with the Centre for Strategy & Evaluation Services (CSES).

The Study concluded that the rationale for the Centre as the linguistic shared service provider for the EU agencies, bodies and offices remains fundamentally valid. Nevertheless, the Study identified that the Centre needed to become more effective, efficient and relevant to its clients while at the same time putting the Centre onto a more sustainable footing. The Study contains 35 recommendations, including a recommendation with regard to a subsidy being provided to the Centre in order to enable it to continue to balance its budget. The executive summary of the Study is annexed to this note.

Annex: Executive summary of the Study on the Translation Centre as the Linguistic Shared Service Provider for the EU Agencies and Bodies

CEDEFOP

Replies to written questions

CORRIGENDUM

Cedefop's reply to the CONT Members' individual questions intended for the CONT hearing on the decentralised Agencies' 2017 discharge, addressed to Cedefop:

CEDEFOP

Why is the position of the Cedefop director vacant? Since when is this position vacant? How long will that position be vacant?

Cedefop's reply:

The mandate of the former Director was not renewed by conclusion of Cedefop's Governing Board on 6 October 2017 and consequent decision of the European Commission of 4 December 2017. The former Director resigned as of 30 May 2018, a few months earlier than the formal end of his mandate (15 October 2018). To ensure business continuity the Deputy Director was appointed Acting Director as of 1 June 2018 by decision of Governing Board decision of 21 April 2018. A selection procedure for the recruitment of new Director is ongoing and the new Director is expected to take up duties in Q2/2019.

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EASO

Replies to written questions

Valletta Harbour, 30 October 2018

EASO's replies to written questions on the 2017 Discharge on the EU decentralised Agencies

1. **EASO received an adverse opinion from the Court on its payments for financial year 2017. Could EASO please provide further clarification on its internal investigations into the non-compliances identified by the ECA? The Discharge Authority would appreciate in particular additional detailed information on the chronological order of corrective actions taken by EASO, including reporting any suspected fraud to OLAF, and the consequent effects on the personnel involved in the irregularities.**

The ECA report, received in July 2018, provided a clean audit opinion on the reliability of the Agency's accounts as well as a clean opinion on the legality and regularity of the revenue underlying the accounts. It did, however, provide an adverse audit opinion on the legality and regularity of the payments. The audit report was accepted by the Agency and the weaknesses identified by the Court of Auditors are being taken very seriously, and corrective measures are being put in place.

In its report, the Court also recognises the extremely difficult situation for the Agency during the reference period, with an unprecedented expansion of its tasks required to provide the necessary support to Member States, and in contributing to the implementation of EU-level initiatives, including relocation and the implementation of the EU-TR statement, the budget increase, the exponential increase in payments as well as the increase in procurement procedures (both in number and complexity).

EASO is taking several measures to address the shortcomings identified by the Court, in particular (non-exhaustive list):

- With regard to the systemic nature of non-compliance in EASO, the Agency - under new leadership – has started to take the necessary steps to ensure that compliance is front and centre in the culture and conduct of all its activities. A thorough self-assessment of the Agency's internal controls was carried out, and corrective actions are being finalised by EASO's Management Team. The conclusions of the self assessment and the corrective actions will be presented to the Management Board (MB) for its consideration in November 2018 and will be reflected in the Consolidated Annual Activity Report 2017. The first and more urgent corrective action will be to propose a new internal control framework to the MB, the appointment of an internal control coordinator and to put the procedure in place for a continuous assessment of the effective and efficient functioning of all internal control systems and report the outcome to the MB.

- EASO is also putting in place the necessary structures and systems to ensure that legality and regularity are systematised and assured (and that reporting is similarly accurate and comprehensive). By a decision of the ED a.i. a procedure was introduced to improve awareness and understanding of finance, internal control, fraud prevention, procurement

and budgetary matters by all staff, in particular through training, guidance information and support activities. For example:

- Dedicated training sessions on internal control and fraud prevention were delivered to all staff;
- An administrative circular was adopted on 11 June 2018 to increase awareness on the "procedure for staff informing of irregularities or mismanagement to the Commission Financial Irregularities Panel (FIP), and anonymous reporting to OLAF";
- A finance and procurement manual documenting the main processes, roles and responsibilities is almost finalised and will be made available by the end of 2018.

- The current HR situation represents one of the greatest challenges facing the Agency in overcoming the weaknesses identified in ECA's observations, as those can be seen as largely symptomatic of the lack of resources to operate in a structured and regular fashion. To this end, EASO has been taking immediate mitigating measures in order to strengthen recruitment and retain staff. A detail outline on measures undertaken in recruitment can be found in the replies hereunder.

- ECA correctly illustrates the challenges and speedy growth experienced by EASO in absolute numbers of financial transactions and procurement procedures. These numbers are stark in themselves, but in fact, do not adequately reflect the pressures in finance and procurement. These numbers do not take account of other associated facts and activities swelling the pressure on procurement.

- The ECA report importantly recognises the fact that EASO is one of few 'multi-location' Agencies. This characteristic is fundamental in understanding the relatively high burden on administrative support as well as the highly complex environment for implementing functioning internal control structures. It should also be noted that EASO is unusually reliant on contractors as a result of its operational activities, geographical spread and (as correctly identified by ECA) the limitations on deployment of MS Experts. This is a multiplication factor on the tasks associated with procurement and finance (including decentralised financial actors), as Operational Bases in Greece, Italy and Cyprus, as well as hotspots in Greece and Italy require their own cross section of contracts (lease agreements, cleaning, security, water, as well as critical contracts such as interim and interpretation services). Again, human resources will be key, and EASO (in recognition of the multiplication factor of being 'multi-location) is currently assessing the possibility to allocate the resources necessary to provide adequacy, quality as well as assurance of legality and regularity to the full procurement and financial cycles.

- EASO recognises and accepts the need for an internal legal capability. A vacancy for Senior Legal Officer has been published in August 2018. In addition, it is accepted without reservation that legal support shall always be strictly in the interest of the Agency, and not individual persons (although not mutually exclusive). EASO recognises that the engagement of external legal services have not been adequately controlled. As stated in the ECA report, internal inquiries continue into this matter and the results will be communicated to ECA.

- The referenced irregular contracts for interim services and travel agency services have been replaced by EASO during 2017 (as reported on previous occasions to Parliament). The rectification of this situation was initiated immediately after ECA identified their irregularity in their audit of 2016 (which took place in 2017).

2. The Court has shown serious concern towards the human resources situation at EASO. The Court considers that this puts EASO's operational continuity at risk, and creates weaknesses inter alia to its internal audit services, legal service etc. The Discharge Authority is aware of EASO's plans to prioritise recruitments for the most important services and to actively seek to normalise its operations and avoid any irregularities in recruitment. Could EASO please provide more information on its recruitment action plan and its state of play?

Rebuilding the Agency's internal capacity and restoring a normal working environment and conditions for all staff is a key priority. The targeted deliverables set out in EASO's Governance Action Plan[1], are further defined in a recruitment plan for the Agency, which is developed on the basis of a thorough needs-assessment conducted in June and July 2018 by the new EASO management team.

Between August 2018 and January 2019, 29 new vacancy notices will be published resulting in up to 70 staff members, which would bring the total number of staff to around 270 (90% implementation of the established plan 2018 in 6 months). The recruitment process prioritises the filling of key positions, including the head of department of operations, head of human resources, the head of finance and procurement, heads of sectors, and the position of a senior legal officer.

The recruitment procedure and the probation confirmation process have also been revised. Following extensive internal consultations, the recruitment procedure has been amended. The revision sees the removal of excessive involvement by the Executive Director in the recruitment procedure from the composition of the selection panel to the selection of the candidates. It also ensures stronger safeguards in terms of fairness and transparency.

3. The Court noted that EASO has been insufficiently able to mitigate the risks caused by the migration crisis, and that hence unexpected situations might endanger EASO's operational capacity. Considering in particular the upcoming enhancement of EASO's mandate, has the Office initiated any further action plans to prepare itself for any unexpected workload that may occur?

In 2018, EASO has been transitioning towards implementing a project management approach to operations. This approach is being fully implemented in the development of the Operating Plans for 2019. This involves a validated needs-assessment methodology that results in the completion of a comprehensive and prioritised needs analysis. These feed into a results matrix and multi annual plan from which draft costed operating plans are developed for extensive internal and external consultation.

Monitoring and evaluation frameworks have been established to ensure that there are effective review mechanisms in place to adjust plans within the project management cycle. An evaluation of existing operating plans is planned by a monitoring and evaluation team supported by external consultants at the end of this year.

[1] EASO Governance Action Plan, published on 17 September 2018.

EASO also prepares different budget scenarios in view of any potential reduction or escalation of operations in Italy, Cyprus and Greece and other countries, and for possible involvement in the setting up and running of the asylum procedure in the controlled centres foreseen under the new EUAA Proposal.

The Agency is also reviewing its current contracting and deployment management arrangements to ensure that the Agency can enhance its flexibility and contingency planning capabilities. The Agency is discussing these scenarios with the European Commission, and within the framework of the overall discussions on the financial and human resource allocation for the whole Agency.

4. The Court noted that EASO has inadequate documentation of its procurements, recruitments etc. Could EASO please explain how it will revise its work methods and documentation systems in order to become more transparent and accountable in this regard?

In line with EASO's Governance Action Plan, measures have been foreseen in order to improve the Agency's internal working methods and documentation systems. To this end, a revision of the framework for the classification and registration of documents is foreseen by the end of 2018. Moreover, an Electronic Records and Document Management System (ERDMS) is gradually being rolled-out throughout the Agency, and is currently in its final stages of implementation. This system supports content organization, classification and collaboration between staff members, and enables records management functionalities (based on EASO's retention policies), leading to more transparency and user accountability.

The current reinforcement of administrative staffing will also help mitigate the risk of non-compliance in the execution of internal processes in HR and finance and procurement-related areas.

5. The ECA drew attention to the fact that the human resources situation at the Office has deteriorated exponentially. The Office currently does not have the administrative capacity to fill the high number of vacancies. For the Office's management, out of 10 head of unit posts, 4 were vacant and out of 27 head of sector posts, 18 were vacant. How does EASO deal with this understaffing? Has the HR situation also an impact on other weaknesses stated by the ECA?

The current HR situation represents one of the greatest challenges facing the Agency in overcoming the weaknesses identified in ECA's observations, as those can be seen as largely symptomatic of the lack of resources to operate in a structured and regular fashion. In 2016 / 2017, the HR situation had negatively impacted EASO's internal control capacity, and the capacity to conduct internal verification of administrative workflows. Remedial measures have been introduced, with others in the pipeline, in order to address these shortcomings (vide reply to question 1).

As further elaborated in replies to questions 2 and 14, the Agency is working to address these challenges by prioritising efforts on recruitment, as set out in EASO's Governance Action Plan and recruitment plan. This applies equally to key managerial posts – including, in finance, procurement, and human resources – and non-managerial posts.

Building up human resources is now key in directing efforts towards overcoming systemic, structural, and internal control shortcomings, as well as drafting better policies, procedures and processes. The recruitment plan is designed on the basis of a comprehensive needs assessment, with priority assigned

to the filling of key positions in administration and core business areas. All key management positions will be filled by Q2 2019. A revised approach to the planning of resources is also being implemented in view of the adoption of the SPD 2019-2021.

Finally the Agency will seek to phase out gradually interim occupying stable functions in the agency to have those positions filled by staff during 2019. .

6. The Annual Report discusses the fact that the Agency has a high labour turnover since 2014. Such a situation creates a considerable risk to the achievement of the objectives. What is EASO's plan to ensure that employees stay in the Agency for a longer period? How did EASO make sure that the labour turnover is not affecting the achievement of objectives?

The staff turnover at EASO has decreased considerably since 2014. As per EASO's earlier reports to the EP, the highest recorded turnover was in 2015 (19%), which dropped to 17% in 2016, and now stands at 8.76%.

EASO's recruitment policy is being coupled with increased focus on training and other measures targeting the retention of staff. A staff engagement plan was presented on 2 July 2018, which sets out several actions and measures aimed at the better integration of staff, and the retention of employees. Whilst it has to be acknowledged that the correction coefficient plays a role due to its mismatch with the evolution of the cost of living in Malta, EASO recognises that more needs to be done to improve staff satisfaction. To this end, flexible ways of working are being explored, internal communication is being improved and all staff meetings / events are being given more attention. Some of these targeted measures include: the introduction of smart working systems, such as telework/part-time work; better workflows to improve efficiency; regular management team meetings, including more all staff meetings; and the introduction of exit interviews (ongoing), intended to gather feedback and draw lessons learnt from staff prior to their departure from the Agency.

EASO is currently also engaging with the host country to improve certain measures relating to schooling and transport services, amongst others, and has recently signed an agreement with the lessor to extend EASO's premises to better accommodate for the increase in staff, and improve working conditions (vide reply to question 13).

7. Since 2016, the Office has been facing an unprecedented expansion of tasks and activities to provide Member States with operational and technical assistance in the context of the migration crisis. How was EASO dealing with this pressure in 2017? Was the increase of staff from 125 to 200 enough to fulfil the new tasks?

EASO has taken significant steps in providing Member States with the necessary support in the context of the migration crisis, in particular to IT and EL, but also in CY and BG. The budget of the Agency has also increased exponentially since 2016, as the Agency took on more tasks and activities.

The increase in staff from 125 to 200 was clearly not enough and thus efforts are being made by the Agency to recover the shortage in recruitment during the second semester of 2018, to reach the 297 staff target identified in EASO's establishment plan for 2018.

EASO also welcomes the additional financial resources that will be available for the Agency, as proposed by the Commission on 12 September.

The Agency would undoubtedly need the necessary administrative staff (finance, procurement, etc) to execute the additional budget foreseen in full compliance with sound financial management principles and procurement rules that will be available for the Agency, considering that the work generated from these activities (including provision of services and infrastructures) is very much human resource intensive.

Certainly, besides additional administrative staff, the Agency could also need the necessary operational staff. For a long time, EASO has relied on the deployment of interim staff in its operations, as is the case in Italy and Greece, due to the rapid increase in tasks and lack of resources. With the new responsibilities, the Agency would want to engage more staff in its operations which will undoubtedly require an increase in the current staff level. EASO sees more EU added value in this approach.

8. An investigation by the OLAF was launched in October 2017. Some staff members in key managerial positions had to leave the agency or have resorted to taking time off. In your Governance Action Plan you stated that all key management positions will be filled by 2019, based on a recruitment plan. In its Human Resource Plan EASO states that there will be 297 new staff members. How will they be trained if not all the posts for the mid management have been fulfilled?

The figure of 297 staff members is reflected in EASO's establishment plan for 2018. As of 26 October 2018, 209 people are employed with the Agency, with the aim to increase this number to 270 (positions occupied or offered) by the start of 2019.

Filling in all management positions is a priority of the recruitment plan, and a vast majority of these posts will be filled by Q1 2019. At present, some key management posts are being filled on a temporary basis by existing staff of the Agency.

All new staff members are subject to an induction course and on-the-job training delivered by their respective units.

9. In the Governance Action Plan, it became clear that there was a lack of transparency in procedures and processes across the board in the Agency and that this created a situation of mistrust and uncertainty among staff members. What kind of procedures and processes are involved? Moreover, EASO states that staff were very often not aware of decisions taken by the Management Team. What measures have been taken in order to diminish the mistrust?

As reported in EASO's Governance Action Plan, measures have already been introduced in order to restore trust amongst staff, and increase transparency. The staff engagement plan, presented in July 2018, had provided an important platform for staff members to voice their opinion on the workplace and other aspects of their job. A number of immediate actions were introduced on the basis of feedback received, with other actions to follow in the medium term.

Regular and minuted staff meetings are held in most units and departments. Since June this year, two all staff meetings have been held, in addition to regular core business briefings focusing on developments in key activities of the Agency. Thematic meetings and brown bag lunches have been

intensified since June this year. Other actions (non-exhaustive) include: increasing the number of staff "away days" / team-building activities, and the introduction of exit interviews, intended to gather feedback and draw lessons learnt from staff prior to their departure from the Agency. The system is currently being tested and will be mainstreamed by end 2018.

Training is also being provided to all staff on Fraud prevention, together with ethics and integrity (to be finalised by Q4 2018). By the end of 2018, EASO plans to have in place a policy on whistleblowing, which is being developed in line with Commission guidelines. All procedures initiated against staff members have also been reassessed, with most of them being withdrawn. Others are being addressed at the appropriate level.

Meetings have also been renewed with representatives of the staff committee in an attempt to re-establish a dialogue and a functional relationship with the staff committee. Increased attention to the role played by the staff committee has been given since June 2018. An expression of interest for the election of a new staff committee was communicated to all staff in October 2018. Elections will be held later this year. The Staff Committee is regularly consulted on new / revised policies / relevant decisions of the Agency. Representatives of the staff committee are also invited to participate in recruitment selection committees.

Restoring transparency and involving relevant staff, including Heads of Units and sectors, is considered an essential recovery process of the Agency. As an immediate measure, Management Team meetings were opened to include heads of units, in addition to heads of departments. Thematic management team meetings are also being held to address specific themes that require focused attention. Extended Management Team meetings, involving also heads of sectors (including Athens and Rome) started to be held on a monthly basis since September 2018. The outcome of Management Team (MT) meetings are communicated to all staff. Furthermore, all internal documents concerning policies and procedures are published in the intranet and staff notified accordingly.

10. In the Governance Action Plan EASO states that it should promote its communication better with the sub offices in Rome, Athens and Cyprus. Which measures have been taken to improve the communication between EASO and the sub offices?

Continuous efforts are made to ensure proper communication channels with colleagues in the field. This is achieved, for example, through weekly VCs, including on quality-related issues between Head Quarters and EASO's regional offices.

Focal points will also be identified in the finance, procurement, HR, and ICT sectors to support training in EASO's regional offices.

11. EASO has relied for a long time on interims to fill important fixed positions. What is the process to replace interims with fixed staff? Could you provide us more information regarding the process to gradually replace interims with fixed staff? Could you provide us the recruitment plan?

Following a thorough needs assessment carried out by the Agency over the summer of 2018, several positions that are currently occupied by interims have been integrated in the recruitment plan. The aim is to have several key positions currently occupied by interims gradually filled by staff by Q1 2019.

12. EASO's policy on the prevention and management of conf lict of interests has been in place since November 2013. The Agency is currently in the process of updating this policy. Based on which criteria will the conflicts of interest's policy be revised? Does the Agency also take as example other Agencies, such as the ECHA?

Indeed, EASO is in the process of updating its policy on the prevention and management of conflict of interests, which will be concluded during the course of 2018. A benchmarking process has been initiated.

The draft policy has sought inspiration from other Agencies, and own lessons-learnt from past experiences.

13. Up to 100 staff will be relocated to new office spaces. What is the reason that this action will only start in 2019? Does this delay affect the operationality of the Agency?

On 9 October 2018, EASO signed a lease agreement with the Maltese authorities which will see the office space more than triple in size. EASO is now in the process of refurbishing and adapting the new premises to its requirements, including the installation of workstations, as well as the updating of its various systems. The aim is to have the first additional 96 workstations and 5 meeting rooms available by Q2 2019.

The delay in moving to the new premises had no adverse bearing on the operations of the Agency. It will, however, help to improve the working conditions of staff, and facilitate the accommodation of additional staff, which are expected as a result of the ongoing recruitment process.

Once the renovations are completed, the Agency's Headquarters will be able to accommodate up to 440 workstations and up to 20 meeting rooms. The increase in human resources will see staffing rise from approximately 220 current employees to around 500 by the end of 2020. The increased requirements, including for office space and meeting rooms, is a result of the expansion of EASO's support activities for the asylum systems of EU Member States, and the anticipated strengthening of its mandate under the new EUAA.

14. In your Governance Action Plan you state that key positions in finance, procurement, and human resources but also in core business areas were not published. What is the reason for this? Can you guarantee that this will not happen again in the future?

Prior to June 2018, several management positions – including, in finance, procurement, and human resources – but also in core business, were left vacant. The investigation by OLAF into the Agency also led to a slowdown in recruitment. Interim measures, including on recruitment, were instituted by EASO's Management Board (MB) with regard to the then Executive Director. These measures are still in force today and the Agency regularly reports to the MB on these matters, and seeks the endorsement of the Chair of the MB for HR-related matters.

As detailed in reply to question 2 above, the Agency has embarked on an ambitious, yet realistic recruitment plan for 2018, intended to restore and strengthen its internal capacity. The recruitment plan is designed on the basis of a comprehensive needs assessment, with priority assigned to the filling of key positions in administration and core business areas. All key management positions will be filled by Q2 2019. A revised approach to the planning of resources is also being implemented in view of the adoption of the SPD 2019-2021.

EASO's recruitment policy is being coupled with increased investment in training and measures targeting the retention of staff, in order to mitigate the incidence of poor performance and high turnover. Efforts are also being made to ensure that procedures for continuity of service (handover arrangements, backup procedures, etc.) are reinforced through training, are made readily available (in particular to new staff) and are applied into practice.

EBA

Replies to written questions

19. EBA is highly affected by Brexit, both physically and financially. As the Agency is soon moving to Paris, and its direct contributions from Member States are expected to potentially decrease in the future, its organisation and personnel have to be prepared for significant changes. Has EBA thoroughly prepared its staff and administration for the move, and is EBA ready to mitigate any operational or financial risks that may follow after Brexit?

Measures adopted by EBA in order to facilitate and ensure smooth relocation of the EBA staff members to Paris:

- Specific arrangements to support staff in relocation to Paris have been agreed:
    - Relocation transition period (29 March 2019 until 31 August 2019) defined with special support measures;
    - Financial and organizational support to relocation: Installation allowances, removal company services to EBA staff, special leave, and administrative support (earlier renewals of employment contracts).

Events/activities organised (in close cooperation with Choose Paris Region) in preparation for relocation:

- information sessions for EBA staff on living in France/Paris, schooling in Paris, housing in Paris;
- discovery trips to Paris for EBA staff and one family member;
- individual consultations provided by CPR advisers to staff members (2 advisers are permanently present and available to EBA staff in the EBA premises);
- presentation on European School to be established in Paris in 2019;
- French language training to EBA staff;
- French language training to spouses (in cooperation with CPR and financed by French government);
- Liaison with French authorities (Protocol and Customs) regarding registration of staff and visa requirements for non-EU spouses.

The EBA is taking a number of actions to mitigate the operational risks arising from relocation. These include: implementing systems and procedures to support teleworking; implementing a workflow system to replace the existing paper-based workflows with electronic workflows; reviewing all existing contracts for services and supplies to identify those that can continue to be used in Paris and those that must be re-procured; liaising closely with ESMA on budget and procurement planning.

Regarding financial risks, possible reduced contributions after UK departure would be more than offset by drop in salary weighting cost. The EBA can also confirm that the UK Headquarters Agreement continues to apply to the EBA for a reasonable period required for our transfer and disposal of our premises. Under the proposed Withdrawal Agreement, the Commission would give notice of termination of the HQA, but even without the Withdrawal Agreement the HQA should ensure that our privileges and immunities remain in place.

20. Following the withdrawal from the United Kingdom of the European Union, the European Council decided to move EBA to Paris, France. What kind of actions have been undertaken to prepare the re-location? Are there any information on the potential costs of the re-location and regarding the impact on the rental agreement in London? Out of the total amount of staff based in London, how many will be pursuing their contracts in Paris?

Actions undertaken to prepare relocation can be listed as follows:

- EBA Paris Building: the EBA submitted the notification to the Budgetary Authority and subsequently run a market prospecting in order to identify the shortlist of premises for the selection process in line with Financial Regulation. The EBA Paris Building was selected and approved in July 2018 by the European Parliament and the European Council. The lease agreement was then signed at the end of the same month with a subsequent condition requiring the adoption of the amendment of the EBA's Founding Regulation by 30th September 2018 (to change the legal seat of EBA). The lease agreement signed envisaged that the necessary fit out works would have been completed by March 2019, and the EBA would have been able to relocate by 29th March 2019. However, due to the delay in the adoption of the legislation to change the EBA's seat, the subsequent condition of the contract was not met; Subsequently, EBA concluded a further amendment of the lease to retain the exclusivity on the office space until 31st October 2018 by extending the deadline for the subsequent condition by one month; This delay however resulted in a contractual delay of the completion of the fit out works, and thus, a delay in the EBA's ability to relocate to the new premises beyond 29th March 2019; The seat change legislation was finally adopted by the European Parliament on 25th October 2018, and thus the subsequent condition was met. This as a consequence means that the lease for the Paris offices is in force, but the relocation is delayed.

- Tender procedures were launched to support the market prospecting (property advisors services), fit out consultants, removal services while more are in the pipeline (cleaning services, catering services, office supplies) to ensure the on time delivery of services and supplies striving to a smooth transition from London to Paris;

- The EBA relocation team has been established to organise and monitor milestones and tasks related to the relocation project;

- Logistical support provided to organise and reimburse discovery trips and informal sessions in current premises.

- Ongoing meetings with external consultants (furniture, conference rooms, Audio-visual equipment), and EBA staff organised to finalise the design development for the EBA Paris Building before the kick off of fit out works.

Regarding the potential costs of relocation, the EBA maintains a rolling projection of all of the costs expected to be driven by the relocation. This projection has, in turn, driven the EBA's request for an amending budget in 2018 and is being incorporated into the 2019 budget and 2020 Single Programming Document (SPD).

The EBA's rental agreement for the offices in London includes a break clause negotiated in 2013 that can be activated so as to terminate the lease after six years in case the seat of EBA is removed from London, in December 2020. Until that time, the EBA will remain liable for rent and charges on the London office. The EBA is exploring the possibilities available to it to reduce or eliminate these costs.

The number of staff relocating to Paris is not known at this stage of preparations for relocation. The process is not completed yet. It is foreseen that by the end of November the EBA will launch a staff survey in order to get better orientation in the number of staff intending to relocate with the EBA. The EBA published 12 vacancy notices to establish reserve lists for the most typical positions in order to be able replace resignations in the context of relocation of the EBA to Paris.

ECDC

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

ECDC

21. The number of staff of ECDC increased over 7% from 2016 to 2017 according to the ECA annual report, although the budget stagnated at 58 mio €. Why was there a significant increase of staff in the Agency? How did the Agency finance the new employees? In which sectors did the Agency have to make cuts to engage 19 new people? Is the Agency in need of higher funding to fulfil its objectives?

Response:

ECDC has a turnover of circa 6-7 % per year (which is equivalent to 17-19 staff members per year). In previous years, the Centre had a backlog in filling the vacant posts in its Establishment plan. Through increased recruitment efforts, the Centre managed to reduce this backlog in 2017, reducing the vacancy rate considerably. In 2017, ECDC also had a higher budget execution, which can be partly attributed to the lower vacancy rate.

ECHA

Replies to written questions

ECHA

26 October 2018

DISCHARGE 2017 – replies to CONT Secretariat

No	Question	Reply
22	The amount of the fees ECHA receives from companies requesting the registration of chemicals as required under the REACH regulation are dependent on the size of the companies. The Agency has found that the self-declarations they provide are too often inaccurate, and results ultimately to a large amount of fee corrections. ECHA has done tremendous work in this regard, but is still too dependent on the Member States verifications. Since ECHA has already discussed the problem with the Commission, has the Agency come to a conclusion on how to address the situation?	ECHA is the sole actor who performs the verification of the SME company sizes that the registrants self-declare; in other words, the Member States are not involved in the SME size verifications, as their focus is understood to be rather on the protection of human health and environment. Currently, ECHA is performing c. 400 SME size verifications annually, ranked primarily based on the financial significance of the dossiers (that is, the largest quantity of registrations within the highest tonnage bands). In the future, the Agency will increasingly perform SME size verifications based on the cost-benefit principle.
23	According to the ECA, fees are charged based on information provided by the companies. Ex-post verifications by the Agency identified the need for considerable fee corrections, with the total amount of corrections being unknown at the end of 2017. The Court states that 55 % of the companies who claimed to be of a micro, small or medium size (16 % of all companies) had categorised their size incorrectly resulting in lower fees. Which definition of SMEs is ECHAs using? Is there a way to avoid self-declarations made by applicants? Is there a way for ECHA to put pressure on Member States' national enforcement authorities for the verification of volumes declared by the companies?	ECHA uses the Commission Recommendation 2003/361/EC on the EU SME definition, which is referred to in the REACH regulation and the related Fee Regulation. Currently, this Recommendation is under review by the Commission. Due to the lose number of SME registrations arriving, most notably around the registration deadlines, it has not been possible to perform the SME size verification before issuing the invoice, to respect the legal processing deadlines. Therefore, the invoiced fee amounts are based on the self-declared company size and ECHA performs the verification only afterwards. With respect to the verification of the volumes declared by the REACH registrants, in 2019, ECHA's Enforcement Forum is starting an enforcement project (REF-7), within which – among other verifications - inspectors will check whether the tonnage band in the registration dossier corresponds to the real tonnage of the substance manufactured or imported.

		In addition, in 2018, ECHA informed the enforcement authorities about a number of cases where the registration tonnage band does not correspond to the reported substance quantities. Inspectors will investigate these during the inspections under the REF-7 project.
24	Manufacturers could apply for the registration of their substances until 31 May 2018. It is often assumed that after this deadline the workload for ECHA would diminish. However, according to the Agency, the authorisation procedures will actually take up all the available resources. Can ECHA provide more detailed information on this change in activities and the necessary resources?	The core mandate and specific tasks of ECHA, as laid down in the four regulations that it implements, will continue to be the backbone of its future activities. As a result, the majority of human and financial resources will continue to be consumed to ensure that the registration, evaluation, restriction, authorisation and classification processes under REACH and CLP deliver the impact that the legislator has attributed to them. While the 2018 registration deadline was the final regulatory deadline of the REACH registration for phase-in substances, it should be noted that ECHA's registration activity is expected to remain at a high level during the period of this strategy. In addition, the implementation of the recommendations of the Commission's 2018 REACH Review provides clear guidance for ECHA's future direction, including an increased focus on the level of compliance of registration dossiers, enhancement of ECHA's evaluation, restriction and authorisation processes, and the expectation that ECHA would become a reference for the sustainable management of chemicals. Similarly, the processes under BPR and PIC remain significant contributors to manage risks and achieve a higher level of safety to human health and the environment. In parallel, ECHA has undertaken a strategic analysis of its future direction and has identified certain existing activity areas that are expected to grow and a number of potential new tasks that ECHA may assume, at the request of the Commission and/or legislator, during the time-frame of its Strategic Plan 2019-2023.

EFSA

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

EFSA

25. The glyphosate scandal has raised attention on the monitoring and control system of the EU law in protecting citizens from any form of abuse. Endocrine disruptors, glyphosate, and other cases show how science can be exploited for political purposes. How the EFSA could guarantee the impartiality of EFSA's experts? Could EFSA explain its policy to identify clear-cut criteria to avoid any conflict of interests in all of its expertise?

Measures in place to guarantee the impartiality of experts

The measures EFSA has put in place to guarantee the impartiality of experts are set out in detail in the Authority's Independence Policy and accompanying implementing rules.

In June 2017, EFSA's Management Board adopted an updated version of the Independence Policy, providing a clear framework for the way in which the Authority manages the interests of its scientific experts and others with whom it works in the course of its activities.

The new Policy builds on EFSA's experience of managing interests over the last 15 years as well as on input received from stakeholders, the European Parliament and the general public. It is designed to strike the appropriate balance between attracting the best experts to work with EFSA while protecting it against undue influence.

Underpinning the Independence Policy is a set of rules that detail how EFSA will implement the Policy in practice and that provide guidance to scientific experts and others on how to declare relevant interests and how they will be assessed by EFSA to prevent conflicts.

The rules also outline the enforcement measures EFSA will take in case the rules are breached and how transparency will be ensured throughout the process.

Basic principles of EFSA's approach to independence in place since 2012

- Prior to working with EFSA, all experts must submit Declarations of Interest (DoIs) that are assessed and published on our website.
- DoIs must be updated by experts at least once a year and every time a declared interest changes.

- DoIs are checked to identify whether or not a conflict exists in relation to an expert's professional activities and financial interests.
- No participation in EFSA scientific groups under any circumstances for experts employed by industry.
- Annual compliance and veracity checks carried out by EFSA on a sample of experts' DoIs.
- Regular external evaluations or audits carried out by the European Court of Auditors and the Internal Audit Service of the European Commission.

What's new with EFSA's 2017 Independence Policy

- Two-year "cooling-off" periods from any scientific EFSA activity for experts employed by industry or NGOs.
- Two-year "cooling-off" periods for a wide range of other professional interests if they overlap with the type of work the expert will carry out for EFSA.
- Requirements for experts to declare the financial impact of their interests on their total earnings.
- Proportionate restrictions depending on an expert's financial declaration, up to a two year "cooling-off" period from any scientific EFSA activity.
- No participation in EFSA scientific groups under any circumstances for experts with financial investments linked to business operators directly or indirectly impacted by EFSA's outputs.
- Publication of a register of activities of Management Board members after they fulfil their mandate with EFSA.
- Publication of the list of EFSA's partner organisations, such as national and international authorities, universities or research institutes.
- Requirements for pesticide experts from national authorities in the Member States to be subject to the same transparency measures and DoI rules as experts on EFSA's Scientific Panels.

How EFSA enforces its Independence Policy

If an expert omits information from his or her Declaration of Interest that would have resulted in a conflict, this is considered as a breach of EFSA's rules. Depending on the nature and severity of the breach of rules, the following measures may be taken by EFSA:

- Issue a reprimand letter to the expert.
- Suspend the expert from the scientific group in question for a period of between 6 months to 1 year, without dismissal from the group.

- Dismiss the expert from the scientific group in question, which may or may not be combined with a decision to ban the expert from taking part in future activities with EFSA for a period of between 1 to 10 years.

Furthermore, if an expert is suspended or dismissed from a scientific group, EFSA will perform a review of any scientific outputs to which that expert contributed to determine the extent to which the expert influenced the final, published output. The outcome of this review is reported to EFSA's Executive Director and to the Audit Committee of EFSA's Management Board.

Regarding glyphosate, it is important to highlight that the assessment was carried out by EFSA staff alongside public officials from Member State competent authorities appointed by their national governments **and not** by members of EFSA's Scientific Panels.

26. In 2017, the Commission's Internal Audit Service issued an audit report on "The process for Evaluation of Regulated Products: Assessment Phase in Pesticides Authorisation". The Authority is preparing an action plan to address any potential areas for improvement. What is the state of play of this action plan?

EFSA's Audit Committee assists EFSA's Management Board by ensuring that audit recommendations are taken into account and receive appropriate follow-up. In the case of the Commission's Internal Audit Service (IAS) 2017 audit on the evaluation of Regulated Products and the assessment phase in pesticides authorisation[1], the state of play of actions plans on 28 May 2018, as reflected in the latest follow-up report (two reports a year, presented every 6 months), shows that out of four recommendations issued, one has been fully implemented and relates to the selection of external experts and clarification of mutual commitments and management of expectations between experts and EFSA, while the three remaining ones have been partly implemented as follows:

- *Improvement of internal rules on Declaration of interest*: following the adoption by EFSA's Management Board of its new Independence Policy (see above under question 25), EFSA established a process creating a working group composed of members of its Advisory Forum to map independence standards implemented by the national competent authorities sitting in the advisory forum. The outcome is expected to be fed in a process aimed at the development of standard memoranda of understanding that will set out the basic principles ensuring the independence of scientific experts. This process is ongoing and on track with the drafting of a Memorandum of Understanding to be submitted to EFSA's Advisory Forum for discussion or endorsement by the end of 2018.

[1] The scope of this audit deals with the preparation of the EFSA's reporting activities on pesticides residues and does not directly relate to the assessment phase of the peer-review of active substances under the EU pesticides authorisation process.

- *Improvement of the preparation of EFSA's Annual Report on Pesticides Residues*:

  - EFSA did improve its resources allocation by separating responsibilities and assignments among scientific officers for the preparation of the annual report on pesticides residues on the one hand and, for the provision of support to the European Commission in the preparation of the evaluation's work of the Joint FAO/WHO Meeting on Pesticide Residues under the Codex Committee on Pesticide Residues (CCPR) on the other hand.
  - EFSA has updated the process charter and prepared an annual project plan that provided all details, including deadlines for milestones and assigned tasks and responsibilities, as agreed by all relevant units in-house.
  - To improve the management of the increased number of ad-hoc requests by the European Commission, EFSA requested the latter to send formal mandates for their ad-hoc requests and decided to include in the above-mentioned detailed project plan a process for keeping track of all ad-hoc requests to be constantly kept updated with an indication of the type of request, of the responsible scientific officer and his/her back-ups, together with the deadline dates.

- *Improvement of the monitoring process for the preparation of EFSA's Annual Report on Pesticides Residues*:

  - EFSA has implemented a performance corporate monitoring tool for reporting, which ensures information consistency among units and departments.
  - EFSA is currently reviewing the governance of its Risk Assessment Workflow (RAW) and reinforcing quality checks. This among others includes an update of the RAW guidance, which would aim at improving the process for controlling the quality of data to be entered and maintained in the RAW. This process should be fully implemented by June 2019.
  - By December 2018, EFSA should have a tool in place for producing a single data view and corporate reports for planning and monitoring purposes.

27. EFSA is dealing with new additional tasks such as the increased workload related to plant health, pesticides and novel foods. On short term this will mean that an adequate level of financial appropriations to deal with these new additional tasks is needed. How is EFSA dealing with that future challenges?

EFSA is continuously seeking efficiencies within its working practices, by exploring cooperation and shared services with Member States, other EU Agencies and EU

institutions, to reallocate resources to new tasks. While some short term benefits are feasible (e.g. tasking grants with Member State competent Authorities, production of light versus full risk assessments where relevant and in agreement with EC DG SANTE) these measures have a rather medium to long term impact.

EFSA has requested additional resources to cover the short term gap for new tasks and increased workload to the budgetary authorities. This request has only partially been granted for the 2019 budget (6 half FTEs out of the requested 25 CA posts).

To cover the remaining gap, EFSA is reprioritising its portfolio of activities in close collaboration with its European Commission partner DG SANTE, with an aim to minimise the impacts to the achievement of expected results. In doing so, it has strengthened the implementation of flexible resource management across different areas of work; a concrete example of this is the prioritisation of the coverage of the new tasks in the area of novel foods dossiers to the expense of work in preparedness for risk assessment (guidance development) and general risk assessment advice (i.e. renegotiation of deadlines).

28. In June 2017, EFSAs Management Board adopted a new Independence Policy. According to the new policy, EFSA will be reinforced with external experts from Member States. How will you ensure their independence?

For the first time since 2008, EFSA renewed all 10 of its scientific panels and its Scientific Committee simultaneously in July 2018. It has selected over 170 top scientific experts to take over the work of EFSA's scientific panels. More than 1,000 scientists applied following a call for experts held in the summer of 2017. The 170-plus nominees were chosen after an exhaustive selection process and thorough screening of their declarations of interest, using objective and transparent criteria, with a new recruitment e-solution, the newly established comprehensive library of scientific competences and a new IT tool to process the declarations of interest, in full alignment with the new Independence Policy and related implementing rules (*see details on the policy under question 25 above*). These high calibre scientific experts play a leading role in providing independent scientific advice to protect EU consumers, animals and the environment.

New panels are composed of experts coming from 24 countries and from a wide array of scientific disciplines. Over one-third of these experts have never been on an EFSA panel before. EU Member States provide the largest share of incoming experts, with 17% affiliated to national risk assessment bodies and 29% to other government or public research institutes. European universities provide another 44% underlining our continuing strong ties to the academic world. The remainder includes self-employed and retired scientists whose extensive experience and expertise help to ensure the continuity of EFSA's panel system and the consistency of EFSA's scientific advice.

Activities carried out within public institutions as part of Public Interest Duties (i.e. without risk management tasks), including teaching or research, do not constitute a conflict of interest under EFSA's rules on independence. Activities with public

institutions, which are unrelated to Public Interest Duties are assessed and validated according to the rules on independence. Finally, risk management functions that are ongoing, or terminated in the two year prior to the submission of a declaration of interest, and which are performed with public institutions on the same subject discussed in the EFSA scientific groups are considered as a conflict of interest.

EIT

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

EIT

29. *The Court emphasised that EIT is not encouraging the KICs to find own sources of financing, but instead it has increased reimbursement rates before the end of the eligibility period allowing the KICs to receive extra money for the same amount of previously approved eligible costs, and also retroactively added activities not foreseen in the initial business plans. Could EIT please provide the Discharge Authority an explanation on their policy to make significant changes for KICs contracts in the middle of their eligibility periods, and why does it not consider the goal of encouraging the KICS to find own sources of financing worth reaching for?*

First, it is important to clarify an apparent misunderstanding in that KICs did not *"receive extra money for the same amount of previously approved eligible costs"*. Both the amount of eligible costs and the EIT grant decreased significantly for the 2016 grant agreements compared to the costs planned in the original Business Plans and compared to the EIT grant that had been awarded. The five KICs planned to incur eligible costs in amount of 353,3 million euro in 2016 but the final approved eligible costs amounted to 300 million euro only. Likewise, the EIT awarded 274,9 million euro grant for the implementation of the 2016 Business Plans but the final grant amount paid was 241,8 million euro. Therefore, the EIT wishes to reiterate that no additional grant was paid to the KICs as a result of the implementation and amendments of the 2016 EIT-KIC grant agreements.

As regards additional *activities added to the 2016 Business Plans*, the EIT wishes to underline that in the course of the process of amending the 2016 grant agreements, the conditions for amendments laid down in the EU Financial Regulation, the Horizon 2020 legal basis and in the EIT-KIC Framework Partnership Agreements were fully complied with by the EIT. This has not been questioned in the audit report of the European Court of Auditors either. It is important to recall that innovative actions are dynamic and fast-reacting in nature and cannot be linearly planned. Certain innovation projects or plans may turn out to have less potential than expected and have to be cancelled, while new opportunities may arise during the implementation of an annual Business Plan.

Therefore, and due to the nature of the KIC Business Plans, which consist of hundreds of activities/projects to be implemented in a given year, and due to the nature of the KICs as partnerships, each of them having several hundreds of partners, the possibility to amend grant agreements is a key element in the annual grant cycle to ensure the operational flexibility required by the EIT Regulation, while respecting the provisions of the EU Financial Regulation and the Horizon 2020 legal framework.

Finally, as regards the practice of accepting new projects in amended KIC Business Plans, it is also important to note that the European Court of Auditors presented it as a positive feature of the EIT model, which effectively addresses the challenges of planning and managing a dynamic portfolio of innovation activities, in its Special Report 4/2016 published in April 2016 as follows: "*The draft business plan for the coming year must be submitted to the EIT at the latest at the end of September of the year N-1. In order for the KIC to meet this deadline, KIC partners must identify and cost all innovation activities they wish to carry out in the following year by the end of the second quarter. The KIC partners therefore have to anticipate at least 6 months in advance the exact innovation activities they will carry out in the following calendar year. Under the innovation project action lines, an additional period of 3 months is needed to launch a competitive call for project proposals. Nevertheless, the KICs can amend the business plans during the year in order to include new innovation projects, which is formalised by way of an amendment to the annual grant agreement.*"

As regards encouraging KICs to find own sources of financing and incentivising them to become financially sustainable, the EIT can report significant progress over the last couple of years. First, it is important to recall that financial sustainability of KICs is a unique ambition of the EIT-KIC model and it is one of the most challenging aspects of the EIT's mission. While this was a distant objective for KICs in the past, they have made this ambitious and unique goal one of their main strategic objectives following the adoption of the Principles on KICs' Financial Sustainability by the EIT Governing Board in March 2015. As a result, 2016 was the first full-year cycle when KICs implemented their Financial Sustainability strategies in line with the principles. Further to the principles, the EIT not only provided guidance to KICs but introduced a dedicated template for KICs to report on the achievement of financial sustainability targets. A dedicated annex to the 2017 Business Plans was for the first time introduced in 2016, where KICs are required to explain revenue forecasts across a range of activities (e.g. ROI and equity, Education, Services & Consulting, Alternative Funding Sources). The EIT Governing Board monitors the implementation of the KICs' financial sustainability strategies closely and provides strategic recommendations where necessary. Some of the Innovation Communities already provide significant co-funding to finance their activities and generate substantial revenues compared

to their budget. For example, EIT Digital provided 26% co-funding (or 23 million euro) to finance their KIC added-value activities in 2016, in addition to reporting more than 200 million euro of KIC complementary activities carried out and financed by their Partner organisations. Another example is EIT Health that collected over 6 million euro in revenues in their first year of operations, a substantial sum compared to the total EIT funding received (ca. 19 million euro).

30. *The Court noted that the business continuity and disaster recovery plan of EIT is severely outdated. Could the EIT please provide the Discharge Authority a state of play on the update of its business continuity plan, which has fortunately been announced to be adopted in 2018?*

The EIT has concluded its business impact analysis in 2018. Both the Business Continuity Plan and the Disaster Recovery Plan are currently being finalised and their adoption is planned by the end of November 2018.

EMA

Replies to written questions

EMA/740104/2018
31 October 2018
European Medicines Agency

EMA reply to questionnaire from European Parliament

2017 Discharge of the EU decentralised Agencies

CONT Hearing on Agencies discharge for Financial Year 2017 (3 December 2018)

II. Questions to be answered by individual Agencies

31. EMA experienced high dependency on external consultants in the establishment of new IT systems for the implementation of two regulations directing the Agency's work, which was to result in additional costs and decreased control over EMA's own projects. The Agency has taken several measures to improve the situation, but the results are expected to be seen only in the coming years. Could the Agency please provide the Discharge Authority an update on the issue in hand?

EMA operates at the heart of the European medicines regulatory network ('the Network'), a unique collaborative model between over fifty European national regulatory authorities for both human and veterinary medicines, EMA and the European Commission. In this collaborative model, EMA provides essential information services – so called Telematics services - for the Network. For example: IT systems for the implementation of new regulations such as the Pharmacovigilance and the Clinical Trials Regulations.

To meet this demand in the area of Telematics, EMA has to outsource a significant part of its IT services. To maintain control over, and thereby reduce dependency on external consultants, EMA has taken the following steps:

1. Transition from a strategy of contracting consultants on a time and means basis to a strategy of sourcing services via outcome-based contracts. Improvement: the proportion of the IT budget for outcome-based contracts between 2017 and 2018 has increased from about 60% to 70% (for reference, this proportion was 15% in 2016).

2. Complement outcome-based contracts with staff augmentation using consultants (T&M, Time and Means contracting) under close supervision by EMA staff. In this instance, EMA staff maintains control over strategy, policy, governance and quality assurance and uses T&M consultants only to augment its delivery/execution capacity. In 2017 the proportion of T&M consultants compared to staff had reduced to 50% and this proportion will be further reduced by the end of 2018. EMA's goal is that the % of T&M consultants versus EMA Staff in IT will be comparable to the average % found across national/international government organisations (benchmark currently at 32%).

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32. EMA is highly affected by Brexit, both physically and financially. Particularly the lease contract with no exit clause, and the corresponding €465 millions of contingent liabilities, puts the Agency in a rather difficult situation. Has EMA kept itself updated on the discussions regarding the lease contract, and has it thoroughly prepared its organisation for the upcoming move to Amsterdam? Is EMA ready to mitigate any operational or financial risks that may follow after Brexit?

The Agency has disclosed in the notes to its 2017 financial statements EUR 465 mln as maximum contingent liability in relation to the current premises in London. The net financial impact, if any, will depend on termination negotiations with the UK government. Legal action against the Agency has been undertaken by the landlord of the building. The outcome of this legal action will only be known in 2019.

In order to address the challenges presented by Brexit and impending relocation of the agency, an internal Operations and Relocation Preparedness (ORP) task force has been established to plan and prepare the Agency for the upcoming changes brought about by Brexit and its relocation. This work also ensures that the Agency takes all the necessary steps to maintain continuity of its business operations both during and after this period. Detailed account of the work undertaken is provided under Question 33.

33. Following the withdrawal from the United Kingdom of the European Union, the European Council decided to move EMA to Amsterdam, Netherlands. What kind of actions have been undertaken to prepare the re-location? Are there any information on the potential costs of the re-location in total and regarding the impact on the rental agreement in London? Out of the total amount of staff based in London, how many will be pursuing their contracts in Amsterdam?

The UK's decision to leave the European Union (EU) following the 2016 referendum has significant implications for EMA. Not only will the Agency leave London and, following the 20 November 2017 seat decision, move its seat to Amsterdam, but it also has to continue complying with its legal role and performing its activities on time and to the same high level of quality, and this in light of both the loss of the UK expertise and anticipated staff loss.

The physical relocation presents a number of challenges – including making sure the new premises are available on time and fit-for-purpose, transferring and maintaining operational IT systems, ensuring the necessary procurements are run and services are provided, as well as the logistics of the actual move of the organisation and staff with minimum disruption to the Agency's day-to-day activities. It is important in this respect that the new host Member State will fully comply with its commitments as stated in the offer to host EMA. It should also be emphasised that the Agency will have to move twice in 2019; first in Q1 2019 from its current premises in London to a temporary building (the Spark building) in Amsterdam Sloterdijk, and in Q4 2019 from the Spark building to the final premises, currently still under construction.

More significantly, the Agency and the wider EU regulatory network will have to address the challenge of maintaining the Agency's scientific operations when faced with the departure of UK experts and some inevitable loss of EMA staff.

In order to address the challenges presented by Brexit, in June 2016 EMA established an internal Operations and Relocation Preparedness (ORP) task force to plan and prepare for the upcoming

changes, and to ensure that the Agency takes all the necessary steps to maintain continuity of its business operations both during and after this period of change.

The work of the ORP task force is organised into 2 areas of activities:

- EMA Brexit preparedness and implementation.
- EMA-Dutch Authorities collaboration for relocation to Amsterdam.

Each area of activity is divided into various work streams.

EMA Brexit preparedness and implementation

Work streams include:

- Scientific committees procedures and inspections, which focus on the preparedness of the scientific committees and working parties, in particular with respect to how the scientific assessment and monitoring of medicines will be shared between the Member States in view of the UK's withdrawal from the EU. It also includes the necessary activities to be undertaken to enable an undisrupted supply of medicines.
- Brexit preparedness business continuity plan (BCP) which has been developed to address a situation where a "business as usual" scenario is no longer possible. The BCP covers prioritisation of EMA activities in order to free up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss.
- Staff relocation and support, which encompasses the work to address HR-related aspects of the EMA preparedness and its implementation.
- Communication activities, covering both internal and external communication to EMA's staff, its key stakeholders and the wider public.

EMA-Dutch Authorities collaboration for relocation to Amsterdam

The Agency and the Dutch Authorities have put in place a dedicated joint governance structure to steer and oversee the relocation to Amsterdam project, with plans to progress activities within 5 work streams as follows:

- The new permanent building
- The temporary building
- Staff relocation
- Financial and legal aspects
- External communication
- Removal and logistics.

To reinforce good governance of a highly complex and time pressured situation for the Agency, a joint EMA and Netherlands Task Force was put in place that meets regularly to ensure that the progress at the work stream level is on target and to address any issues that require escalation. There is also a Steering Committee with representation by the Executive Director and at Ministerial level on behalf of the Netherlands.

During 2016-2018 the Agency has undertaken considerable work to address the Brexit impact on the Agency's operations, including but not limited to:

- Completing an initial impact assessment, identifying also the key risks that the Agency would be facing in this environment
- Preparing the Agency's requirements for the new location, including infrastructure requirements, technical specifications for the new premises, and other factors critical to operations of the Agency, and sharing this information with the interested Member States as well as the EU Institutions
- Hosting Member State visits to EMA and EMA site visits to candidate host countries upon request from a candidate host Member State
- Undertaking further analyses of the impact of the decision for the Agency to relocate to the Netherlands
- Liaising with representatives from the new host city of Amsterdam and the government of the Netherlands following the Council decision of the new EMA seat on 20 November 2017
- Preparing for the relocation of the Agency's data centres to Hamburg
- Reviewing current contracts for goods and services and preparing a procurement plan to ensure the necessary contracts are in place at the time of the Agency's move to the Netherlands
- Conducting several staff surveys, to gauge the potential staff losses in view of their impact on the Agency's operations and assess potential remedial actions
- Developing a dedicated Brexit recruitment and selection strategy to address the potential staff loss, including a job and competency mapping to support succession planning
- Developing and implementing a dedicated EMA Brexit preparedness BCP, to address situations where a "business as usual" scenario is no longer possible. More details on the business continuity plan are available below:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/07/news_detail_002789.jsp&mid=WC0b01ac058004d5c1

- Putting in place supporting measures to maximise staff retention and to facilitate the relocation of staff to Amsterdam in addition to the support provided by the Dutch Authorities

- Working with the Member States to address the workload issues arising from the loss of UK expertise and agreeing on the re-distribution. Conducting surveys with the Member States to establish the capacity and training needs
- Issuing communications and preparing guidance for pharmaceutical industry, to ensure companies have the correct information and take the necessary steps to be able to operate in the EU 27, ensuring continued availability of their medicines to EU citizens.

Taking into account the latest EMA staff survey performed in June 2018, conducted to inform the Agency's recruitment strategy to compensate for staff loss, as well as further direct feedback from staff, the end of September 2018 status on staff intention to relocate indicates that a relocation of EMA to the Netherlands could result, in a best-case scenario, in EMA losing some 24% of its total workforce. Although this would allow the Agency to stay operational throughout the transition period, nevertheless

there will be important disruption to the daily work. Consequently, the actual staff loss will need to be closely monitored to ensure continuity of operations, also because it is possible that some specific functions experience significant staff attrition while the overall staff loss at the Agency level may remain manageable.

The status now in 2018 is that some 85 EMA staff relocated in August and September 2018 to the Netherlands. Arrangements have been put in place to enable the continuity of their functions through teleworking. These staff are settling in and their positive reports are encouraging for the other staff.

EMA reports regularly on the progress of the relocation through a tracking tool that is published on its corporate website and can be accessed from the following link:

https://www.ema.europa.eu/documents/other/ema-tracking-tool-relocation-amsterdam-main-milestones_en-0.pdf

EMA undertook an analysis of the unforeseen costs which could have been incurred in 2017 or beyond. EMA faced additional expenses and resource needs related to preparatory activities which were required in order to plan for the relocation and to ensure business continuity. By way of example, it has been necessary to develop a project plan for the relocation of the EMA data centres. Significant IT and infrastructure budget investments are needed in the relocation preparatory phase for a physical relocation in 2019, together with preparatory staff missions. A procurement plan was developed for replacement procurement and additional procurement requirements, e.g. relocation consultancy, data centre relocation, legal expertise in the new host country.

A provision of EUR 14 mln has been made as the estimated maximum cost the Agency might incur for restoring the premises to their original state at the end of the existing lease contract.

A provision for EUR 18 mln has been recognised at the reporting date of 31.12.2017 to reflect the best estimate of the cost the Agency might incur for relocating staff to Amsterdam, the Netherlands.

34. In the course of last year's audit, the Court did an analysis of EMAs management of consulting services. Since there was no increase in the Agency's staff establishment plan that could enable it to build-up the necessary expertise in-house, the Agency used consulting firms to address the tasks. Would it be more productive for the Agency and all stakeholders to have a higher budget for staff to keep necessary expertise in-house? Is it even possible for EMA to lower the costs of external consulting services, regarding the complexity of their projects?

Indeed, the European Court of Auditors noted that significant new tasks (e.g. in the area of Clinical Trials, development of other pan European IT systems) were assigned to the Agency without increase in establishment plan that could enable it to build-up the necessary expertise in-house. This increases the Agency's dependence on external expertise in specific areas. The Agency has introduced a number of developments as outlined in question 31. As noted by the Parliament, restrictions in the establishment plan however limit the Agency's possibilities to fully address in this period the need to have sufficient internal business and IT expertise in order to reduce dependency in specific areas on outside parties. Given the significant role of the Agency to implement legislation, which among other requirements necessitates the establishment of complex pan-EU network systems, adequate resourcing of the establishment plan would create benefits for EMA stakeholders, Member State authorities and EU citizens by improving EMA's capacity to implement such important pan-European projects. To achieve this, the Agency has proposed headcount neutral changes to its establishment plan as outlined under question 35.

35. EMA is experiencing significant staff loss while at the same time requiring additional resources to prepare for its relocation to Amsterdam and to deal with growing workload in product-related activities. It is important that the Agency restores its full capacity as soon as possible to be able to address the increasing complexity of upcoming innovation in the pharmaceutical sector. What additional support has the Agency received from the European Commission and the Council in this regard? What strategy has the Agency put in place to address the staff loss issue and to attract talented people with the right expertise for the future?

Time-limited contract agents to manage knowledge loss and workload

As indicated under question 33, relocation of EMA could result, in a best-case scenario, in EMA losing some 24% of its total workforce and a real risk of losing significantly more than that number, and therefore the Agency faces a risk of an extensive loss of scientific, technical, and managerial knowledge.

The Agency requested for 40 exceptional time-limited contract agents to mitigate the impact of the loss of experienced staff, and the risk to business continuity during the transfer, as they will be the 'shuttles' of essential knowledge to be retained between the staff that will be leaving EMA and those that will eventually replace them. Failure to apply this mechanism puts the Agency at further risk of business continuity.

In addition, the Agency already engaged a large number of staff to prepare for relocation activities. An estimate for 2018 was 86 FTEs and this figure is being reached with all parts of the Agency affected by Brexit preparedness and relocation-triggered work. Support with additional contract agent resources is needed to manage relocation workload. To address this pressure, the Agency has already launched Phase 3 reduction of activities which took effect from 1 October 2018.

With a longer term perspective in mind outlined below under this question, the support of these time-limited contract agents is also important to enable the Agency to replace its establishment plan vacancies in a planned and orderly way with the scientific and technical skills needed for the future of the Agency.

The time-limited contract agent approach is cost neutral since savings will be made through forecast large attrition of staff across function groups, including temporary agents and since these resource will be fee financed.

Exchange with the Commission to grant the 40 time-limited contract agents continues.

Restoring capacity to address the increasing complexity of upcoming innovation

It is important to emphasise that the EMA is approaching its staffing and competency development needs in a long term strategic way to support the evolving business model needed to respond more effectively to a growing workload within an increasingly complex scientific and technological environment, legislative changes and workforce reductions, which necessitate IT investment.

The Agency anticipates that advances in regulatory science, increasing complexity of products, fast paced innovation require new expertise to meet today's public and animal health needs and to be prepared for the challenges and opportunities of tomorrow.

Additionally, advances in information technology in areas like process automation provide opportunities for efficiency through automating high-volume repeatable tasks, modernising technical workflows thus enabling to shift workforce to value adding activities. These changes require expertise in developing and implementing new IT solutions and managing resulting contracts.

Comprehensive work has been carried out to understand job structure focussing on jobs needed for the short and mid-term future that would benefit public health, the Agency's legal obligations, competitiveness and innovation in Europe. This work informed what jobs need to be recruited at which entry grade for each of the function groups AD, AST and CA.

The Agency and its Management Board have therefore requested the Commission and Budgetary authority to make a headcount neutral change to its establishment plan by moving 74 AST posts to AD posts to reflect legislative, scientific and technological development referred to above.

In this context, the Agency has to use the Brexit timing to adjust the Agency's establishment plan to take into account the above developments. The Agency regrets that the Commission however reduced significantly this request, which will not be sufficient to address aspects outlined above including under questions 34. The Agency welcomes nevertheless the fact that the Commission has accepted at least some headcount neutral conversion from AST to AD posts in 2019. It is essential that this gradual shift continues through the full 2019-2021 programming and budgetary cycle, so that the Agency can attract and develop staff with the competencies needed to fulfil our mandate effectively and efficiently while facing significant developments in regulatory science and information technology.

Staff retention and recruitment strategy

To reduce estimated staff loss, the Agency has put in place staff retention measures. These measures, whether available under the Staff Regulations or as additional provisions put in place for a transitional period or provided as services by the Dutch Authorities, have the purpose to support staff retention by facilitating the relocation of staff to Amsterdam. The Agency believes that these measures are providing tangible impact of staff retention and will be able to see its full impact closer to the relocation period.

In addition, the Agency analysed and identified critical areas at risk of staff departures and knowledge loss, and mobilised its resources to launch a large number of carefully planned selection procedures. 25 have been launched so far with over 4000 applicants. Specific selection procedures are carried out within 2.5 - 3 months period between publication and conclusion of a reserve list.

36. A new EU regulation on veterinary medicines, which will be adopted in 2018 and become applicable across the EU in 2021, is introducing a number of important initiatives at the EU level related to the fight against Antimicrobial Resistance (AMR). Has the Agency been allocated sufficient resources to implement all the new tasks set out in the new veterinary regulation, in particular in the area of AMR?

The new EU regulation on veterinary medicines sets out a significant number of new tasks and projects for EMA which will need to be implemented by the end of 2021. The Agency will be asked by the Commission to help develop several delegating and implementing acts as well as to develop and

maintain a number of EU-wide databases and IT systems that are foreseen in the regulation, and which will be critical tools for the EU regulatory network as a whole to achieve the overall objectives of reducing administrative burden and safeguarding animal and public health. In particular in the area of AMR, the Agency will have a key role in e.g. developing new processes for the collection and analysis of data on the sales and use of antimicrobials, and for the selection of antimicrobials that should be reserved for human use only. The final legal text has changed quite significantly compared to the original EC legal proposal in terms of new tasks and responsibilities allocated to the Agency. However, no additional resources have been allocated to the Agency by the EC to support the implementation of those important new tasks. The original EC's financial statement that accompanied the original legal proposal, had, already at that time, not reflected EMA's estimated required staffing and financial resource needs. We have therefore asked the EC to revise the legislative financial statement to adequately reflect the budgetary and staffing needs for EMA, in line with the co-legislators' expectations in the area of AMR and veterinary medicines in general. This has not yet happened and also the EC's draft 2019 union budget contribution and establishment plan proposal for EMA has not reflected any additional resources for the implementation of the new veterinary medicines legislation.

37. Due to the Brexit the EMA will relocate from London to Amsterdam in 2019. In its Final programming document 2018-2020, the EMA expects to retain 80% of its staff; however, in reality 70% of the staff will be retained after the relocation. Additionally, because of legal problems (British and Dutch employment laws differ) employees with temporary contracts are not able to move to the Netherlands as well. How will the EMA fill up these vacancies? What will happen to the staff that is left behind?

Loss of workforce due to the end of temporary worker placements under UK labour law has been integrated and is being addressed under the overall resourcing and business continuity planning of EMA, outlined under questions 33. A procurement procedure for temporary workers under Dutch labour law is currently being examined and prepared; the Agency believes however that the use of such temporary workers in the Netherlands will be very limited. Placement of temporary workers under UK law has been restricted to 28 February 2019.

38. Approvals of marketing authorisation applications are based on three criteria: efficacy, quality and safety. The European Parliament stated in its discharge 2016 resolution (P8_TA-PROV(2018)0150) that a fourth requirement should be added, 'Added Therapeutic Value (ATV)', comparing a medicine with the best available drug instead to placebos. Did the Management Board discuss the addition of this fourth criterion? Was the addition of the criterion mentioned in discussions with the European Commission or representatives of the Commission?

EMA has noted this request from the European Parliament. However, EMA's benefit-risk assessment can currently only be performed on the basis of Quality, Safety and Efficacy, as per the criteria that are laid down in Regulation 726/2004, which also confirms in its recitals that: *"(13) In the interest of public health, authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations."*

As the scope of EMA's benefit/risk assessment is defined in EU legislation, it is not possible for EMA to discuss the possible addition of an additional 'fourth' criterion with its Management Board or the European Commission outside of a legislative procedure.

However, it should be noted that benefit-risk assessments performed by regulators are made with reference to a comparison, which includes existing treatments (where available), in order to contextualise the results. For further information see CHMP Reflection paper on benefit-risk assessment methods in the context of the evaluation of marketing authorisation applications of medicinal products for human use. This will ensure that already at time of marketing authorisation relevant "comparative efficacy" assessments are conducted for the purpose of the benefit-risk assessments.

39. The dependence on fees from the pharmaceutical industry is still high (89,34% in 2016 and 87,96% in 2017). How does the Agency view in this respect the danger of conflicts of interests for the EMA relying on fees from their clients since they have a commercial interest in having the medicine approved by the Agency? Would it be a solution if fees were collected by the Commission, so that EMA would remain fully funded from the EU budget?

EMA's funding model, consisting of industry fees and a general contribution from the EU budget, is set out in various (financial) regulations governing the operation of the Agency[1].

We would like to emphasise that pharmaceutical companies pay for a procedure but not for the outcome of a procedure. This means that a company pays at the time of submission of an application to EMA; the Agency then 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. You can liken this to a driving test. You need to pay to take a driving test, but there is no guarantee that you will pass the test. EMA has one of the most advanced and robust systems in place to check for potential conflicts of interest and this is independent from the fact whether industry fees are charged or not.

With regard to the proposal to have fees collected by the Commission we highlight that, in line with the Joint Statement of the European Parliament, the Council of the EU and the European Commission of 19 July 2012 on decentralised agencies, for bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level that avoids a deficit or a significant accumulation of surplus, and should be based on the Agency's workload and related costs, and on the costs of the work carried out by the national competent authorities of the Member States. The fees should be transparent, fair and proportionate to the work carried out. Therefore, regardless of how the fees are collected, there is a direct and inextricable link between the level of the fees collected and the funding requirements of the Agency. If the European Commission was the collector of the fees to simply pass them in any case back on to the Agency, this would simply introduce an unnecessary administrative step.

In addition, processing and collecting the fees involves a detailed knowledge of both fee regulations applicable to the Agency. This includes a complex validation process to establish the appropriate fee levels for each individual submission, based on its scientific characteristics. The validation process therefore relies on scientific and regulatory experts with relevant technical expertise within specialised business areas and financial functions. Transferring these executive tasks and workload to the Commission would not generate improved effectiveness or efficiency in this process.

[1] See also **Replies to written questions by the individual agencies**, page 56, http://www.europarl.europa.eu/cmsdata/135941/2016%20Discharge%20-%20EU%20Agencies%20-%20Individual%20answers%20assembled.pdf

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Furthermore, should EMA become completely dependent on the Commission in terms of its funding and resource management, and if the industry fees would no longer be earmarked as budget for the Agency, this could be detrimental to the operation of the Agency. The Commission already currently makes proposals for the Agency's establishment plan. Such establishment plan proposals do not reflect actual workload and evolution of new tasks and ensuing staffing needs of the Agency. This has resulted in a critical situation where the Agency's workload and fee income has grown by over 50% over the past years whilst in the same period its number of temporary agents was reduced by 10%.

The Agency sought in the past to mitigate the risk of establishment plan cuts to its legislative obligations by relying on short term or low paid contracts – which is a suboptimal and unsustainable situation for an agency dealing with innovation, public health and pan-European IT systems, as well as large quantities of confidential and sensitive information. The Agency was not in a position to build-up the necessary expertise in the areas of business and IT development in line with new tasks and therefore had to rely on consulting companies. 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 establishment plan approaches, a short-term focus on cost reduction rather than a strategic focus on added-value will prevail, which would strongly jeopardise the functioning of the Agency going forward.

Finally, we wish to highlight 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 increased the performance of their public health activities. Equally, other leading international regulators (US FDA, Health Canada, TGA) are directly funded by applicant fees enabling to provide public health activities attuned to changing needs[2].

[2] See also **Replies to the standard written questions to the Agencies**, August 2018, page 222-223, http://www.europarl.europa.eu/cmsdata/152180/Discharge%202017%20standardised%20questions%20report%20.pdf

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EMCDDA

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

EMCDDA

40. In its audit report of January 2016, the Commission's Internal Audit Service (IAS) highlighted a strong need to improve the Centre's management of IT projects. The Centre and the IAS agreed on a plan to take corrective action. In the Annual Report 2017, EMCDDA marked the status as "ongoing". What is the state of play of the implementation of the plan to take corrective action?

EMCDDA's REPLY:

- In January 2018, the design and adoption of the 2025 ICT multi-annual strategy was accomplished and the respective recommendation promptly closed by the IAS.

- In early 2018, a first version of the EMCDDA Enterprise Architecture Management Framework was issued. Following substantial progresses made throughout 2018, the final adoption of this Framework is expected for December 2018. The corresponding recommendation will be then sent to the IAS for review.

- During the past two years the EMCDDA had in place a Project Management approach based on the PRINCE PM methodology. After further evaluation, the EMCDDA opted for the PM2 methodology (applied in EC), since deemed as better fitting its core business needs. The substantial progresses made on this matter will allow the EMCDDA to send before the end of 2018 the two relevant recommendations to the IAS for review.

- The follow-up to the two last IAS recommendations concerning the definition of adequate requirements management process and system development methodology is expected to be implemented by mid-2019.

ESMA

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

ESMA

41. ESMA will potentially be greatly affected by Brexit, as its most significant supervised entities are located in the UK. In addition to monitoring the situation actively, has the Authority made any concrete preparations to mitigate the potential operational and financial risks that may follow?

ESMA's REPLY (26 October 2018)**:**

As the UK plays an important role in EU financial markets, preparing for Brexit is one of the current main priorities of ESMA. In the context of Brexit preparations, ESMA aims at (1) ensuring consistent regulatory and supervisory standards to the relocation of activities, entities and functions from the UK to the EU27, in this sense, ESMA is monitoring that CRAs and TRs post-Brexit set-up will meet minimum substance standards; and (2) preparing for the risk that, when the UK leaves by the end of March 2019, no agreement is in place regarding its withdrawal, a so-called "no-deal scenario", among others, ESMA is assessing compliance with the CRA Regulation and EMIR of a number of applications of registration and is doing its endeavouring to ensure that there is no disruption in the use of credit ratings for regulatory purposes and EMIR reporting.

EU-LISA

Replies to written questions

2017 Discharge of the EU decentralised Agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 3 December 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

EU-LISA

42. The Court considered that the Agency might experience risks of over-reliance and dependency on external contractors in its large IT projects, particularly when considered together with its small number of staff in key operational units. Under constraints of the current resources, how is EU-LISA addressing the issue, is the Agency planning to implement an action plan in this regard?

At present, eu-LISA does not have sufficient statutory staff available to deliver its entire mandate on its own. To compensate the gap between available and necessary human resources Agency needs to use external contractors and service providers. The Agency has been highlighting this issue continuously. It was also acknowledged by the Management Board of eu-LISA. Nevertheless, eu-LISA has not received additional human resources in the past years. As long as eu-LISA has no control over allocation of additional human resources to it (subject of approval of the Budgetary authority), the Agency is not in position to prepare an action plan to address the observation of the Court.

At the same time Agency takes measures to optimize use of available human resources, in particular:

- *Agency is currently finalizing its sourcing strategy which will provide guidance and a clear cut between internal capabilities necessary and capabilities that can be sourced externally;*
- *Agency initiated a transformation program that aims to implement a new organizational structure, organizing operational activities in more horizontal and streamlined way;*
- *As part of transformation program Agency intend to revise also its operational model and relevant internal processes to reinforce efficiency of its core operations.*

It should be also noted that with entry into force of revised establishing Regulation of eu-LISA as well as of the respective legal proposal related to ETIAS, interoperability etc. agency will be reinforced with additional staff (172 people in total). While most of them will be allocated to the core operational activities of eu-LISA they will still not be sufficient to remove necessity of external contractors and services providers. It should be also reminded that corporate functions (i.e. HR, Finance & Budget, Procurement, corporate IT etc.) will continue to be understaffed, creating operational difficulties and risks for the Agency.

FRONTEX

Replies to written questions

FRONTEX
EUROPEAN BORDER AND COAST GUARD AGENCY

Ref: CGO/BFCS/SAKL/16110/2018

2017 Discharge of the EU decentralised agencies

WRITTEN QUESTIONS TO THE AGENCIES
Hearing on 3 December 2018

Frontex replies

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FRONTEX

1. **The Court considers that FRONTEX is too reliable on cooperating countries' proof of expenditure, and that the info the Agency receives is often insufficient. Since FRONTEX has done some restructuring in order to mitigate any risks involved, could the Agency please inform the Discharge Authority about the state of play of the issue in hand?**

   In 2018 Frontex introduced a new financing scheme for its operational activities. One of major aspects of the scheme is the extended use of unit costs in case of deployment of human resources. In accordance with the legal framework in force, unit costs were established on the basis of statistical data or similar objective means. In 2018, 35% of grants awarded by Frontex are reimbursed primarily on the basis of unit costs. Consequently, Frontex is in the process of amending its ex-ante policy to include the extended use of unit costs. The main changes introduced in the ex-ante policy will include:

   1. Ex-ante check of a sample established at the level of 10% of the total value of the claim. Frontex believes that such a sample gives sufficient assurance in case of unit costs which are predefined and only the number of units claimed needs to be checked.
   2. In case of an error rate above 20%, which indicates a systemic error, an ex-ante control mission will be carried out.
   3. In case of an error rate below 20%, the grant beneficiary will be requested to correct the claim and then a second ex-ante check will be carried out.
   4. If the error rate is still identified during the second ex-ante check, the error rate is to be applied to the whole claim and the beneficiary included in the rolling ex-post control plan.

   At the same time, Frontex will continue to request 50% of supporting documents proving the costs incurred for the deployment of assets where the reimbursement is based on real costs actually incurred.

   In 2018 the focus of ex-post controls was, due to the introduction of the new financing scheme, on checking unit costs established by the beneficiaries.

   The ED Decision on ex-ante and ex-post controls of 22/11/2016 is applied at present. The new policy related to ex-post controls only is being drafted and internally coordinated. The document will be forwarded to the executive management for adoption by the end of December 2018.

2. **According to the Court, FRONTEX is still missing a comprehensive business continuity plan. When and how is the Agency planning to address this issue and adopt a new business continuity plan putting further consideration to the enhanced mandate and the new structure of the Agency?**

   Regarding business continuity, the following elements are worth mentioning:

   - Crisis communication encompassing business continuity: processes have been drafted, exercises have been held. More detailed business continuity processes are under development;

   - Event Response Policy is in place with a detailed Event Response Plan and a Concept of Operations (CONOP) to respond to any kind of event from a crisis, serious incident or an incident.

   - disaster recovery: Frontex IT systems are safeguarded on a disaster recovery site at Eu Lisa in Strasbourg.

   - an appropriate alternative office facility is currently being identified, also in the light of ETIAS and its potential implications of being a critical infrastructure to secure business continuity.

3. **In response to the migration crisis faced by the Union, the mandate of the Agency was considerably extended in 2016. The Agency's budget 2017 was again 21 % higher than the one of the previous year. In addition, the staff increased from 365 to 526 employees. How is the Agency dealing with those issues?**

   Regarding the increase in budget and how the agency is dealing with this issue, please refer to the next answer.

   In terms of staff increase, at the end of 2017 one third of Frontex staff were newcomers (who joined the Agency less than 12 months ago). Such a rapid staff increase puts additional demands on the existing staff to recruit, train and make proper use of additional manpower. In June 2017 a new organizational structure of Frontex was adopted by the Management Board to better address the issue of new and enhanced missions

and tasks of Frontex and to properly absorb the influx of newcomers. The preparations for the implementation of the new organigram were made from summer 2017 to January 2018. The new organigram entered into force on 1 February 2018.

4. **If we additionally take into account that, following the extension of its mandate, Frontex' staff will be doubled from 2016 to 2020. How is Frontex dealing with the increasing staff numbers? How does Frontex cope with the extension of the mandate in general?**

A new Frontex organisational structure encompassing the projections of staff increase by 2020 was adopted in 2017 by the Management Board. The Management Board is informed on progress at each meeting and is reported annually on the implementation of the organisational structure. Resource allocation is subject to an annual detailed staff needs estimates encompassing justification for each activity area and entity. It is followed by several rounds of discussions between the managers and the executive director who decides on the staff allocation for the next year. Staff recruitment progress is monitored monthly between HR and the executive director who determines the priorities for the next period. The Frontex internal structure is adjusted accordingly to detail further the breakdown of entities by activity areas to cover the extended mandate in a rapidly changing environment. The Cabinet of the Executive Director has also developed an internal communication policy and an internal change management policy.

5. **The contributions to agencies from the EU general budget is EUR 2,5 billion. One of the agencies with the highest increase in its budget in 2017 was Frontex. Please specify how Frontex absorbed this increase in its budget, and insofar as the budget is used for additional staff, how the training of new staff has progressed**

The budget of Frontex increased by 20% between 2016 and 2017. The final commitment implementation (End of December 2017) amounted to EUR 274m, representing a decrease of EUR 28m in comparison to the initial budget. It appeared during the course of the year that part of the budget could not be absorbed by the agency. Although staff increased in the course of 2017, the initial recruitment objective could not be reached; moreover, return operations proved to be over-estimated with regard to real developments and the financial reserve had to be kept until the end of the year, leading to cancellations of the concerned appropriations.

However, if comparing final implementation 2016 with final implementation 2017, Frontex was able to absorb EUR 46 m more in 2017 compared to 2016.

Part of this increase covers the salaries of the growing number of staff as well as the increase in administrative expenditures necessary to cover the costs of additional rented premises to accommodate the new staff. Finally, the main increase concerned Operational expenditures (EUR +33m), and mainly Return expenditures. A significant increase in the number of return operations and returnees has been achieved in 2017: the number of return operations in 2017 amounted to 341, compared to 232 in 2016. The number of readmission operations also increased to 50 compared to 35 in 2016. In total, the Agency supported Member States in returning 14 200 irregular migrants in 2017, which represents close to 10% of the total number of irregular migrants that were effectively returned by EU Member States to third countries.

The final use of appropriations for 2017 will be known at the end of 2018, once the final payments which have been carried over from 2017 will be known.

Regarding the training, the training offer for Frontex' staff is developed in line with learning needs based on extended mandate, new tasks and new organisational structure, which affects trainings needs of all staff members. Frontex implements cost effective internal trainings (including training delivered to newcomers) as well as training activities provided by external experts.

The training budget of the agency between 2016 and 2017 increased by approx. 60%, whereas in terms of number of participants taking part in trainings there is an increase by about 140%.

In 2016, with a budget of approx. EUR 369,000, the number of staff trained was 115, and number of training records (participants) was 137.

In 2017, with budget of approx. EUR 587,000, the number of staff trained was 275, and the number of training records (participants) was 440.

Please note that some staff members took part in more than one training, and for that reason the total number of participants is higher and refers to the number of records.

GSA

Replies to written questions

European
Global Navigation
Satellite Systems
Agency

THE GSA'S REPLY TO THE EUROPEAN PARLIAMENT'S WRITTEN QUESTIONS IN THE FRAME OF THE 2017 DISCHARGE OF THE EU DECENTRALISED AGENCIES

Question 48

Could the GSA please provide the Discharge Authority an update on its Galileo Security Monitoring Centre's move from the United Kingdom (UK) to Spain, and the situation of the Galileo ground station located in UK territory, and any financial implications these changes have or are expected to cause?

The GSA's reply

The Galileo Security Monitoring Centre Back-up site shall be relocated from the United Kingdom to Spain, 25 km Southeast from Madrid, as per the Commission Implementing Decision (EU) 2018/115.

All Galileo assets in the United Kingdom have been shut down since 12 October. The assets will be moved within approximately a month after two conditions are met:

1. A Hosting Agreement between the European Commission, the GSA and Spain is signed, and
2. The technical and security acceptance of the site's early configuration is adopted. The move is expected before the end of 2018.

The Agency has started discussions with the United Kingdom regarding the early contract termination of the current Galileo Security Monitoring Centre Back-up site, and the GSA is still awaiting for an reply from the United Kingdom to attend a bilateral meeting on the termination of the lease agreement and its financial modalities (2.6 million euro have already been requested from delegated tasks budget to the European Commission).
The European Commission has already delegated a budget of 1.2 million euro for priority technical and project management relocation review actions, performed by the GSA regarding Spain's Early Configuration building. As soon as the first move is implemented, further needs are anticipated to finance issues that might appear during the installation of the equipment, and further technical and project management review actions are expected to be launched for the Final Configuration design review until the finalisation of the acceptance and relocation of such Galileo assets.