2016 Discharge of the EU decentralised agencies

Answers to the written questions

Hearing on 22 January 2018

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

BEREC

Replies to written questions

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Riga, 08 January 2018

Sent by e-mail only

Subject: Submission of BEREC Office reply on the individual questions

Reference: Email dated 30/11/2017 received from the Coordination of Agencies regarding CONT questionnaire for the decentralised agencies 2016 discharge (hearing 22 Jan 2018)

Dear Secretariat of the CONT Committee,

In what regards the 2016 Discharge of the EU decentralised agencies, section Written questions to the agencies, please find below the BEREC Office replies to the questions received:

1. The European Court of Auditors has identified high staff turnover as a risk to the implementation of the work programme. The average employment period in the office was 2,58 years. Did the mitigation techniques introduced by the management deliver the intended results?

Answer the BEREC Office:

The reasons at the base of the turnover are mainly of external origin and have been grouped as follows:

A – Not realistic correction coefficient
The correction coefficient applied to the remuneration of active staff serving in Riga is low and for some aspects not realistic. The purchase of goods and services at a level which can be compared to Brussels does not show a significant price difference.
The BEREC Office has no influence in the calculation of the correction coefficient and may only raise the issue of the calculation in all the relevant meetings.

B – Living conditions in Latvia.
The staff of the BEREC Office seems to be not satisfied by the living conditions in Latvia. For example, the BEREC Office staff experiences difficulties in the access to Latvian private markets (banks, telecommunications, real estate). The modalities of car registration are burdensome. There is no support to the spouses of staff in the access to job market. There is no European schooling yet. Some aspects of the dissatisfaction have been brought to the

attention of the Latvian Authorities, as they derive directly or indirectly by a restricted interpretation of the Seat Agreement.
In July 2017 the BEREC Office formally approached the local authorities in order to have a better implementation of the Seat Agreement and to improve the quality of life of staff and bilateral discussions with several Ministries have been initialised. The results of such negotiations are expected gradually in short or mid-term, but some issues, like European schooling, might be solved only in long term.

C – Working conditions at the BEREC Office.

The BEREC Office is struggling to ensure proper working conditions to the staff. The main issues identified are:
- Heavy workload
Being the smallest decentralised agency with 14 establishment plan posts and resources for 13 external staff FTEs, the BEREC Office experiences difficulties to hire individuals with specific profiles. Consequently, the staff is expected to perform multi-tasking, sometimes with duties the staff member is not confident in. The selection of appropriate candidates for such posts is challenging as the establishment plan provides the lowest grades available for hiring.
Amongst the mitigation techniques, the management makes every efforts to offer training opportunities to staff and quick career advancement through reclassifications where applicable. Externalisation of certain activities is also considered but not always relevant.
- Limitation of the space in the premises and quality of the offices
The current offices are state owned and are rented from the organisation responsible for the management of state properties. Based on experiences of the first years' operation, improvement is needed in the overall office space, in the number of meeting rooms, toilets, service spaces (like canteen or recreational spaces) and parking places. All offices will need proper illumination, insulation and air ventillation.
Negotiations were initiated with the property management organisation but solutions might be found only in relation to the revised founding regulation.

Results of mitigation techniques

The results of the activities put in place by the BEREC Office in order to reduce the turnover can be properly assessed only in a multiannual prospective. In 2017 no temporary agents left the Agency and 1 contract agent and 1 SNE resigned (overall 7.4% of the staff). A certain stability in the organisational has been achieved, which seems to be encouraging, although it also has to be noted that there are high expectations that difficulties will be addressed in, and during the implementation of, the revised founding regulation.

2. The BEREC Regulation is currently under review and the Commission proposal includes a specific provision on periodical external performance evaluations. What is the current state of play of the negotiations, and when is the revised regulation expected to enter into force?

Answer by the BEREC Office:

a. The periodical review

The Commission's proposal[1] indeed foresees that the proposed new agency will be reviewed and evaluated periodically. In this respect, Article 38 of the proposal indicates that not later than five years from the day of entry into force of the regulation, and every five years thereafter, the Commission shall perform an evaluation.

b. The current state of play of the negotiations

The legislative proposal is considered by the legislators in an ordinary procedure, currently awaiting for Parliament 1st reading opinion. The lead ITRE committee report was adopted on 16/10/2017[2] and the Council adopted a general approach on 04/12/2017.

c. Expected entry into force of the new Regulation

According to Article 41 of the Commission's proposal, the regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.
The political agreement on the regulation might take place during the first half of 2018. The regulation would then be translated and checked by the lawyer-linguists and the publication and entry into force could happen during the second half of 2018.

I remain at your disposal in case of any further need for additional information.

Yours sincerely,

e-signed

László IGNECZI
Administrative Manager **of the BEREC Office**

[1] COM(2016) 591 final 2016/0286 (COD); 14.9.2016
[2] http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&mode=XML&reference=A8-2017-0305&language=EN

CEDEFOP

Replies to written questions

Cedefop's reply to the CONT Members' individual questions intended for the CONT hearing on the decentralised Agencies' 2016 discharge, addressed to Cedefop:

CEDEFOP

CEDEFOP has one legal adviser since 2007 for investigating of the past irregularities between 2011 and 2005. Following one prolongation, the contract will lapse in 2017. Will CEDEFOP extend her work contract for another five years? Could you provide the Parliament with background information of the decision of prolonging or not prolonging the contract?

Cedefop's reply:

Following an OLAF investigation in 2005-2006, five former and current Cedefop staff members were indicted to stand trial before the Court of Appeals of Thessaloniki. Since 2008, Cedefop joined the criminal proceedings as joint plaintiff ("partie civile"). In line with usual practice in EU institutions regarding proceedings before national courts, the case is followed on Cedefop's behalf by an externally contracted lawyer qualified to represent Cedefop at the Greek bar.

In accordance with his prerogative to engage and dismiss staff; as laid down in Article 7(4) of the Cedefop Founding Regulation, the Director has decided not to renew the temporary contract of the internal legal adviser, which expired on 15 November 2017. This decision does not affect Cedefop's involvement in the legal proceedings related to the OLAF case, which will continue to be followed by the external lawyer.

In the context of the continuing pressure on resources and with a view to making efficiency gains and reinforcing the agency's capacity to deliver on its core missions, Cedefop has launched a revision of administrative services, including legal advice. This approach is in line with the recommendations of the 2012 Joint Statement of Parliament, the Council and the Commission on decentralised agencies (the "Common Approach"), as well as the (draft) recommendations of the Inter-Institutional Working Group on resources of decentralised agencies. This responds also to similar calls of the European Parliament, including in its Resolution of 27 April 2017 "on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2015: performance, financial management and control" (2016/2206(DEC)), highlighting "the benefits of sharing services, which enable consistent application of administrative implementing rules and procedures that concern human resources and finance issues, as well as the potential efficiency gains of

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sharing services between the agencies, in particular when considering the budget and staff reductions that the agencies are facing".

The main aim of the revision of Cedefop's legal advice function was therefore to explore the feasibility of alternative ways to provide legal services in order to make efficiency gains while upholding the required standards for legality and regularity. As requested by the Cedefop Governing Board, the risk assessment and cost-benefit analysis underpinning the proposed alternative scenario were reviewed by an external auditor (Deloitte). The external auditor concluded that "under the alternative scenario, it is estimated that Cedefop will transfer important resources to operational departments in order to support the fulfilment of its mission, vision and mandate (as stated in its programming document) without compromising ethics, compliance, efficiency or independence".

CEPOL

Replies to written questions

CEPOL

4. In the report of the European Court of Auditors on the annual account of CEPOL for 2016, the Court indicated that the staff turnover is very high. There is also mentioned that recruiting staff from other Member is not easy because of the low payments. Which measures are planned by CEPOL for the upcoming years to avoid the high number of staff turnover and to increase the number of staff from Member States other than the host state?

The staff regulations do not provide CEPOL (or other agencies) with ready-made tools to address the high number of staff turn-over and to increase the number of staff from Member States other than the host state. The recently implemented staff engagement survey shows that grading not matching other EU agencies and remuneration not reflecting cost of living in Budapest are most mentioned by staff as areas for improvements. Unfortunately, neither of these are in the hands of the Agency to change with immediate effect.

With regards to staff turn-over, CEPOL is paying already the costs for the schooling in international schools for the children of the staff of the Agency. Beside this CEPOL has not identified measures that are aligned with the Staff Regulations and Implementing Rules thereof that would improve staff retention. Many leaving colleagues cite that their wish to leave is not or limited impacted by the working environment but mainly by better opportunities elsewhere. The positive working environment is evidenced in the outcome of the 2017 Staff Engagement Survey which shows that 74% of staff has an overall favourable opinion of CEPOL (compared to 66% in 2015 when the relocation from UK to HU was still fresh).

Measures to increase the number of staff from Member States other than the host state are also difficult to implement. Although remuneration is low compared to other EU Agencies and generally not sufficiently attractive to allow for the recruitment of staff from the broadest possible geographical basis among the Member States, it has been noticed that host state nationals agree to the offered remuneration and even willing to accept employment offers in lower grades than they have in other EU Agencies. Although offering positions at increasingly higher grades – a policy which CEPOL is implementing, provided there is sufficient room in the establishment plan – would attract more non-Hungarian nationals, it simultaneously makes it more attractive for Hungarians as well. CEPOL aims to adopt appropriate measures in a transparent way in case a significant imbalance between nationalities of staff members develops.

EASA

Replies to written questions

EASA

5. Similarly to previous years the Agency has accumulated a surplus from industry fees. While the surplus of the previous years was spent on refurbishment and removal cost for the Agency's relocation to a new building, what will happen to this year's surplus? When and how do you intend to amend your Financial and Fees and charges regulations?

EASA's reply:

In fact, the 2016 budget result on the Fees and charges was negative, reducing the accumulated surplus by €7.7Mio. While in the past part of the accumulated surplus was indeed used on refurbishment and removal costs (as agreed with the Management Board and European Parliament), for its long term strategy, the Agency plans to utilise part of the fees and charges accumulated surplus to finance some important certification related development projects.

In parallel, the Agency has launched a review of its Fees and charges regulation.

6. How does EASA view the results of the pilot project as fee-funded agency? Does this project affect the independency of the Agency? How does EASA respond to the fees from the industry? Does it influence EASA?

EASA's reply:

The pilot project substantially preserved the staffing level ensuring the possibility to respond to a growing market without disruptions. With this project the Agency made evident the efficiency efforts realised without impact on safety. The industry welcomed and supported the exercise without any interference on the activities performed by the Agency. The project to review the Fees and Charges scheme has just started.

7. Every European designed and manufactured aircraft requires EASA certification. How is EASA's procedure on issuing certificates? As manufacturers are closely involved, how does this procedure improve the Agency's independence?

EASA's reply:

With regard to issuing certificates for European designed and manufactured aircraft, EASA applies the certification procedure set forth in Regulation (EU) No 748/2012. This Regulation, which spells out obligations and privileges for design and production organisations, has further been implemented by a decision of the EASA Management Board (Decision 12/2007 on general principles related to the certification procedures to be applied by the Agency for issuing of certificates for products, parts and appliances) and internal procedures, work instructions and a user guide (Certification Handbook).
Through the Regulation and procedures, manufacturers are involved in the process and have certain obligations to support EASA's procedure on issuing certificates. However, ultimately, it is for the Agency alone to take the decision whether or not a certificate can be issued.
To ensure that the Agency remains unbiased by any undue influence, the Agency has set up a comprehensive set of measures to ensure impartiality and independence, including prevention and mitigation of conflict of interest. In the specific context of issuing certificates this includes the signature of declarations of interest, supervision of the decision making process by management, four-eye principle in decision making, and identification of sensitive functions and linked to staff mobility requirements.

8. In 2016, EASA developed quality indicators on initial airworthiness, continued airworthiness, organisational approval and certification standards and bilateral aviation safety agreements. These indicators seem to focus on customer friendliness and efficiency but less so on quality indicators relating to the assurance of safety. How does EASA measure this type of quality?

EASA's reply:

The quality of safety related indicators are measured in the EASA Annual Safety Review. These above mentioned indicators complement the comprehensive safety indicators contained in this Annual Safety Review.

EASO

Replies to written questions

Valletta Harbour, 13.12.2017

CONT questionnaire for the decentralized Agencies 2016 discharge (hearing 22 Jan 2018 pm) Questions and Answers

Question: EASO's Activity Report discusses the fact that the Agency had to deliver more than originally planned for 2016. How did EASO deal with this pressure? Also, the Agency had to respond immediately. How did EASO ensure quickly that its new staff possess the needed requirements?

EASO Answer:

The year 2016 saw the signing of the EU-Turkey Statement on 18 March that gave EASO a mandate to support the implementation of several measures in Greece, in particular the admissibility procedure.

Moreover, numerous Justice and Home Affairs Council conclusions called upon the Agency to rapidly scale up its activities on the operational front to support Member States, notably Greece and Italy, in dealing with unprecedented and continued pressure on their asylum procedure.

EASO's presence in the hotspots in Greece, supported by experts from the EU+ countries, required complex logistical planning and rapid delivery for field operations to kick off and become effective.

The new tasks assigned to EASO through the EU-Turkey Statement, for operations in Greece, and subsequent Council Conclusions, targeting operations in Greece and Italy, required reprioritisation of the planned activities due to the increased focus on operational support.

The challenges faced by EASO in dealing with the additional and unplanned tasks were namely related to the need for rapid and effective intervention in the absence of immediately available financial, human and contractual resources.

Four budget amendments were required during 2016 to increase EASO's revenue from €19 million to €53 million, eventually allowing EASO to provide the level of support that was requested. Nevertheless, the agreement of additional budget from the EU General Budget proved to be a resource-demanding and time-consuming process that, to some extent, limited and hindered the urgent interventions. During 2016, the Executive Director had to effect 20 budget transfers across EASO budget titles and chapters to compensate for budget shortfalls and to accommodate the exponentially increasing budgetary needs in the hotspots, particularly following the EU-Turkey Statement.

EASO did its utmost to respond rapidly within the limitations of its small initial budget, whilst awaiting additional financial resources. As the Agency has acquired experience in running successful operations in the Member States, the immediate access to sufficient funding remains a constraint and a hurdle to be overcome in delivering support, as and when requested.

In 2016, EASO's statutory staff complement did not increase in spite of the sudden increase in workload. The Agency met the needs of the Member States whose asylum and reception systems were under disproportionate pressure by bringing on board external resources, including more than 650 Member State and individual experts and interpreters, as well as interim staff, in order to complement EASO staff

numbers. Other Agency staff provided the logistical and infrastructural support to the asylum support teams operating in the hotspots. EASO acknowledges the effort and commitment of its staff and external resources that ensured the delivery of support in challenging circumstances.

The requests for rapid and effective intervention meant that EASO had to procure certain goods and services for which no contracts were in place at the time due to the specificity of the requests – for instance, for containers and mobile offices, interim case-workers, etc.

The Agency reiterates its full commitment to its obligations under the EASO Financial Regulation and the procurement rules. However, the requirements have at times slowed down the response to specific or urgent needs of Member States. Due to the exceptional circumstances, in some cases, the Agency had to resort to "exceptions procedures" (as allowed by the regulations) to procure urgently required goods and services, whilst ensuring the expected level of assurance. Consequently, EASO has been mitigating this constraint by anticipating insofar as possible Member State needs and establishing the required framework contracts.

EASO expert and support staff that had to intervene rapidly in the circumstances had been recruited on the basis of their experience, qualifications and skills.

This continues to be the case as it is a requirement of EASO's staff and recruitment policies. The staff that were deployed to the hotspots had always the required experience and profiles to deal with the situation on the ground.

Support was provided from Headquarters by staff that travelled on longer mission to the hotspots to identify and address the needs. As the situation evolved, EASO opened two operational offices in Athens and in Rome from where operations were overseen and supported, and a closer contact point established with the host Member States' authorities.

Moreover, the Agency responded rapidly to the evolving situation by developing and delivering specific tailor-made, intensive induction training (for up to eight weeks) for deployed experts in the context of the EU-Turkey Statement.

At the time, EASO already had an established Training Curriculum in place that was adapted to the emerging needs. The induction training is mandatory for experts, interpreters, cultural mediators and interim caseworkers and support staff that have not been previously trained.

Question: EASO has created its Early Warning and Preparedness System (EPS) obliging EU Member States to provide monthly data to gather information about the situation in the countries. Where can the information thus collected be found? If it is not public, why not?

EASO Answer:

In the context of the Early Warning and Preparedness System, Member States exchange provisional, non-validated data, on a voluntary basis (there is no obligation).

Since this is national data collected by Member States, the Member States are the data owners, and thus decide on the dissemination of the data.

As data is collected on indicators with different levels of sensitivity in Member States, a detailed dissemination guide has been developed, outlining which data (and related analytical reporting) are public, limited or limited-sensitive, as well as the access level for different types of stakeholders.

Aggregated data (EU-level) on applications, decisions and pending cases are publicly available on the EASO website, with breakdowns per nationality.

Question: Following the Special Report of the Court of Auditors on the hotspots, Parliament considered that co-ordination between the different actors (European Commission, EASO, Europol, FRONTEX, national authorities and other international organisations should be improved. What is the current state of play in this respect? Has the link between the hotspots and the following procedures in the host country or other EU Member States been improved or is there still a problem in this respect leading to situations in which asylum seekers and migrants find themselves in limbo?

EASO Answer:

With respect to the coordination mechanisms described in the European Court of Auditors' Special Report, the coordination networks currently existing at the local and national level continue to be fully operational.

Their efficiency has been considered as an added value for all EU Agencies operating in the hotspots, and by the European Commission. As a result, the coordination system, and, in particular, the EURTF, has been mentioned among the best practices to be included in the hotspot approach in the Commission Staff Working Document 669 on the 'Best Practices on the implementation the Hotspot Approach', released on 15th November 2017.

This mechanism has been proved particularly effective in the case of EURTF Piraeus, due to the centrality of the geographical location and to the Headquarters of the main institutions concerned.

This has resulted in increased leverage on the national systems acquired by the EU Agencies, which has allowed them to streamline political priorities within the country with operational aspects.

In the case of Greece, the coordination mechanisms have increased their efficiency on matters strictly related to the implementation of the asylum procedure also thanks to the formalization of the Joint Action Plan on the Operationalization of the EU-TR Statement.

The added value of this process has been directly reflected in the functioning of the different coordination networks at the national level. By identifying key actions and milestones to be performed by each of the involved stakeholders and to be properly monitored in due course, the Action Plan has represented a solid base for the work of the EURTF and similar mechanisms, facilitating their monitoring and coordinating role.

Since January 2017, periodic updates on the state of progress of the Joint Action Plan are discussed in the coordination meetings chaired by SRSS, where shortcomings, potential risks and feasible solutions are discussed in real time.

Concerning the situation of migrants just disembarked, or asylum seekers already registered by the national authorities, EASO has done considerable efforts in order to step up its presence on the territory in both, Italy and Greece, in order to maximize reach out of all Third Country Nationals, irrespective of which stage they are within the national procedure.

Some of the existing efforts, which have shown already tangible results, have been considered by the European Commission as best practices, to be replicated whenever a hotspot is to be set up in a frontline Member State (European Commission Staff Working Document 669 of 15th November 2017).

In Italy, EASO has Asylum Support Teams deployed in 7 locations, for provision of information, in 10 fixed locations for registration of applications for international protection, and Roving Teams travelling across Italy, which guarantees coverage to 45 "Questure", supporting in the registration of applications for international protection.

This operational set-up ensures full reach-out of the migrants and asylum-seekers, even once they have been transferred to the reception centers located around the territory.

The efforts of the Asylum Support Teams, which are mainly meant at providing information face-to-face, are further complemented by information provided through a dedicated hotline, where asylum experts, supported by interpreters, are answering to individual queries. The hotline receives about 70 calls per week.

Moreover, in order to reach out to all potentially eligible migrants, in particular Eritrean Migrants, in order to complete their registration by 26th September 2017, EASO increased the outreach of the Roving Teams travelling across Italy and of the Mobile Teams, based in Catania, and covering the whole territory of Sicily.

This was further complemented by an awareness raising campaign carried out on social media, in Tigrinyia, in order to promote the Relocation Programme among Eritreans, and encourage them to register.

In Greece, the efficiency of the asylum border procedure has been considerably increased during the first six months of 2017, following the Joint Action Plan on the Operationalization of the EU-TR Statement.

The main impact has been observed in the reduction of the length of the asylum procedure, as well as increased transparency and accessibility to information for migrants and asylum seekers, through targeted actions.

Moreover, other outputs which have contributed to an overall improvement as increased efficiency of the asylum procedure have been:

- **Continuation of a stable amount of experts deployed per island;** improved communication to Member States on profiles and needs on long-term basis, including through the development of a section dedicated to Greece Operations on the IDS Platform;

- **The increase of the overall workforce of EASO and Greek Asylum Service, from 100 to 200 caseworkers in total**, allowed a significant increment in the number of cases processed at first instance. As of early December 2017, 8.557 interviews were carried out by EASO experts and interim caseworkers (which represents more than 68% of the total number of interviews conducted in Greece under the border procedure);

- **A train-the-trainer pilot project for lead interpreters in Athens**, which is an ad hoc operational training for interpreters involved in the asylum procedure, was gradually rolled out by EASO in all the 5 hotspots: 16 training sessions were delivered by trainer-interpreters, in small groups, involving EASO Field Coordinators, interpreters and selected caseworkers;

- Continued **actions to guarantee the overall quality of the asylum procedure**, including bi-weekly review and Quality Guidance developed by EASO HQ, establishment of Helpdesk for deployed experts in Athens, manned by MS experts and supported by EASO HQ, creation of a COI Query System for Hotspots;

- **Communication and information on the asylum procedure**, rights and obligations of Third Country nationals arriving irregularly in Greece, by way of a dedicated information booth operational in Lesvos, Chios and Samos (in cooperation with the European Commission); in the main two islands the information booth can serve on average 300 cases per week; and

- **Support to the set-up of an entry-exit system in the hotspots**, to monitor effective migrants' presence and access to services delivered in the reception centers.

EBA

Replies to written questions

EBA Response to

2016 Discharge of the EU decentralised agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 22 January 2018

I. HORIZONTAL QUESTIONS TO BE ANSWERED BY THE AGENCIES' NETWORK

II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

EBA

12. What kind of actions have been undertaken so far in order to prepare for the re-location following the withdrawal of the UK from the EU? Could you provide us with a calculation of all the potential costs and budgetary effects and implications for contractual arrangements regarding the re-location? Could you provide further information about the stakeholders of the re-location?

Following the UK Government's decision that the UK should leave the EU, the EBA has put in place a project team for the relocation. This team has prepared a high-level plan for the relocation, which incorporates an impact assessment, risk mitigation and scenario planning. This is a living document that is updated on a regular basis and is reported on to the EBA's Management Board (MB). Early on in the process the EBA began working together with the EMA on relocation matters of shared interest. The EBA also presented the MB with a note on the eight offers received and provided input to the Commission on the offers.

Now that the Council decision was taken on 20 November 2017, [see Council press release http://www.consilium.europa.eu/en/press/press-releases/2017/11/20/european-banking-authority-to-be-relocated-to-city-country/] that the EBA will move to Paris, the EBA is in a position to update its cost estimates, including procurement implications, based on what is known from the French offer. These will be presented to the EBA's Board of Supervisors in December 2017.

The EBA will liaise with the French Government and the Commission to prepare the building file which will be submitted to the DG Budget, European Commission and the European Parliament and Council for approval.

13. Due to the Brexit, EBA has to relocate. As EBA has employees who are same-sex couples the problem occurs that not every Member State recognises this right. What is the Agency's response to this? How does EBA protect its employees by relocation to one of these Member States?

The EBA will follow the Council decision on relocation. As for the employees who are same sex couples, the EBA follows and will continue to follow the Staff Regulations as all other EU agencies do in this respect.

14. The EBA website mentions that the EBA published the result of the 2016 EU-wide stress test of 51 banks, covering around 70% of banking assets in each jurisdiction and across the EU[1]. However, in 2014, 123 banks were tested[2]. What is the reason for the decreased number of banks? What are the risks of not testing all banks? On the basis of which criteria have these banks been selected? Are the remaining banks tested differently?

The EU-wide stress test exercise is carried out on a sample of banks covering broadly 70% of the banking sector in the euro area, each non-euro area EU Member State and Norway, as expressed in terms of total consolidated assets as of end 2016.

Since the EU-wide stress test is run at the highest level of consolidation, lower representativeness is accepted for countries with a wide presence of subsidiaries of non-domestic EU banks. To be included in the sample, banks have to have a minimum of EUR 30 bn. in assets. The criteria chosen are designed to keep the focus on a broad coverage of EU banking assets and to capture the largest banks. In particular, the EUR 30 bn. materiality threshold is consistent with the criterion used for inclusion in the sample of banks reporting supervisory reporting data to the EBA, as well as with the SSM definition of a significant institution.

Competent authorities could, at their discretion, request to include additional institutions in their jurisdiction provided that they have a minimum of EUR 100 bn. in assets. Banks subject to mandatory restructuring plans agreed by the European Commission could be included in the sample by competent authorities if they were assessed to be near the completion of the plans. Banks under restructuring are subject to the same methodology and assumptions as other banks in the sample.

This algorithm was applied for the 2016 stress test and also for the selection of banks for the 2018 stress test.

The reason for the decreased number of banks from 2014 to 2016 was that following a wide ranging exercise in 2014, the EBA decided to focus on a more homogeneous sample of large banks, to ensure greater comparability while ensuring a significant coverage of EU banking assets. However, this does not mean that other banks are not assessed. Smaller banks not included in the EU-wide stress test are tested by their relevant competent authorities as part of the SREP process.

[1] https://www.eba.europa.eu/-/eba-publishes-2016-eu-wide-stress-test-results
[2] https://www.eba.europa.eu/risk-analysis-and-data/eu-wide-stress-testing/2014/results

15. Furthermore, the European Central Bank (ECB) carries out a separate stress test of another 56 banks under its supervision using the same methodology[3]. However, the results of these tests are not published. What is the role of the EBA in publishing the results of these tests in order to improve the ECB's transparency?

The EBA welcomes the application of the common methodology for the EU-wide stress test also for other banks. This is done not only by the ECB but also by a number of other competent authorities. The implementation of these stress tests, including the publication of results, remains under the sole responsibility of the relevant competent authority. The EBA only provides technical and methodological support to some authorities on a case-by-case basis at their request, e.g. by providing specific data templates.

16. The curricula vitae of the Board of Supervisors and Management Board members are not published on the EBA website. Will the curricula vitae be published in order to improve transparency, and if so, when?

The CVs of members of the Board of Supervisors and Management Board are published since the entry into force of the Conflicts of Interest policy in 2014. Please check the relevant sites of the EBA's website: http://www.eba.europa.eu/about-us/organisation/management-board/declaration-of-interests

17. The meeting minutes of the Board of Supervisors are being published on the EBA website only two or three months after a meeting takes place. Could these minutes be published directly after the meeting?

The meeting minutes of the Board of Supervisors (BoS) are published when they are formally approved by the BoS, which normally occurs at the subsequent BoS meeting. The EBA has introduced this year a fast-track process whereby the minutes are approved by written procedure before the subsequent meeting of the BoS. It is important to note that we give BoS members the opportunity to provide comments on draft minutes before they are submitted for formal approval, thus reducing the risk that a request for approval of minutes be rejected by members and then the whole process (comments and approval) need to recommence, which would invariably delay even further their publication. The EBA acknowledges the importance that the publication of meeting minutes have for the transparency of its decision-making procedures, and it also ensures that they reflect the discussions by BoS members by giving them the opportunity to comment before they are approved and published.

18. On 26 October 2015, the Banking Stakeholder Group had a discussion on whistleblowing[4]. The Danish Financial Supervisory Authority has implemented an encrypted website where individuals can easily report in complete anonymity. When will the EBA establish a secure channel for whistle-blowers and in which way will the anonymity and protection of whistle-blowers be ensured?

[3] https://www.bankingsupervision.europa.eu/about/ssmexplained/html/stress_test_FAQ.en.html
[4] http://www.eba.europa.eu/documents/10180/1313669/EBA+BSG+2015+083+-+Draft+Minutes-+26+October+Meeting.pdf

The EBA has established internal whistleblowing procedures that protect both, the whistle blower and the person concerned. OLAF, the European Anti-Fraud Office, has whistle blower channels in place that can be used by externals also with regard to issues that may involve the EBA.

Article 71 of Directive 2013/36/EU requires competent authorities to establish whistleblowing procedures and sets out the protection mechanisms that have to be put in place. Considering the existence of external whistleblowing channels at OLAF and at competent authorities, and its resource constraints, the EBA is currently not planning to establish EBA specific external whistle blower channels.

ECHA

Replies to written questions

DISCHARGE 2016 – ECHA

No	Question	Answer
1	*Despite the fact that chemical companies are obliged to present a dossier to ECHA on each chemical substance that they want to launch, the chemical GenX has been found in Dutch drinking water. Is this due to national implementation errors or did ECHA allow for this chemical to be used and dumped in open waters by the industry?*	The substance GenX has indeed been registered at ECHA under the REACH Regulation. The Regulation is based on the principle that the burden of proof lies with industry to demonstrate that the substances they manufacture and place on the market can be used safely and do not cause harm to humans or the environment. At the stage of registration, the Agency performs a completeness check of the dossier which investigates whether the relevant information that should be available according to the tonnage produced is present and whether a chemical safety assessment has been provided. An assessment of the content of the dossier can be done for specific substances under the dossier and substance evaluation processes by ECHA or the Member States. These evaluation processes are in particular used to obtain missing data or to request additional information to clarify a specific concern (e.g. information on persistency or endocrine disrupting properties). In the specific case of GenX, the substance has been identified to be of potential concern for the environment and is currently being evaluated by Germany and the Netherlands. These concerns stem largely from the fact that GenX has been introduced as an alternative for PFOA (perfluorooctanoic acid), a substance for which the Commission has recently adopted a restriction under REACH on its use based on an opinion by ECHA. The results of the ongoing substance evaluation are expected to lead to a request for further information from the Registrants in March 2018. GenX is manufactured and used at a specific site in the city of Dordrecht in the Netherlands. The local or provincial authorities in the Netherlands are responsible for issuing the discharge permits for such sites as well as for the monitoring and enforcement of the conditions laid down in these national permits. It is our understanding that the local authorities in the Netherlands have had extensive contact with the national authorities responsible for the REACH regulation on this matter. ECHA has no specific information as to how the substance has entered the groundwater in the

		Netherlands. We understand this is being further investigated by the Dutch authorities. We also expect that ground water pollution may be an element of investigation in the substance evaluation by Germany and the Netherlands.
2	*During the event organised by the European Ombudsman on 18 October 2017, the Deputy Executive Director of ECHA stated that it was not wrong to rely on research undertaken by industry itself, since it was also in industry's interest to provide correct testing results. Is this ECHA's declared policy and how does it deal with the inherent conflict of interest in industry's research, since they have a commercial interest in having the chemical approved by the Agency? To what extent does the Agency seek the advice of independent stakeholders when examining industry's research?*	All EU chemicals legislation is based on the principle that it is up to industry to conduct the studies required by the law, and that are needed for the safety assessment of those chemicals. To ensure that the studies are reliable and reproducible, companies must carry out the studies according to internationally accepted test guidelines and following the principles of good laboratory practice (GLP). Test guidelines define at detailed level the parameters and conditions that have to be followed in testing, and GLP ensures that the conduct and reporting of the studies is done correctly and prevents the likelihood of manipulating the test results. In the regulatory processes ECHA and Member States authorities verify that these provisions have been followed. In addition, Member States are responsible for monitoring the compliance with the GLP by conducting study audits in laboratories. In addition to the industry studies ECHA always uses in its assessment additional studies from published scientific literature, whenever such studies are available, which unfortunately is not the case for the vast majority of industrial chemicals and biocides ECHA is dealing with. In addition, under REACH, CLP, and Biocidal Products Regulation ECHA conducts public consultations that allow third parties to review the scientific basis and justification for the proposed action. This applies under REACH for: testing proposal examination, identification of substances of very high concern, recommendation for inclusion of substances into authorisation list (Annex XIV), opinion forming on authorisation applications and restriction proposals. Under CLP public consultation applies for the opinion forming on proposals for harmonised classification and labelling. Under BPR public

		consultations are carried out for identification of potential candidates for substitution. One of the key principles of REACH is the reversal of burden of proof, i.e. that it is for industry to demonstrate that the chemicals can be used safely, instead of authorities to proof that there is a risk and that risk management may be needed. ECHA is of the view, that to implement this principle in full, industry should even more than today integrate the safety considerations in their product research and development activities, to enable chemicals and products to be 'safe by design'. This type of an approach would be supporting also the ambitions on circular economy and non-toxic environment. This, however, does not eliminate the need for ECHA and other authorities to intervene if there are risks identified despite the industry activities, or if indeed there would be doubt about compliance with the quality control rules related to the industry funded studies.
3	*Despite the fact that the World Health Organization (WHO) and other research calls glyphosate possible carcinogenic, ECHA approved it. How did ECHA come to the conclusion that glyphosate is not damaging? The Monsanto Papers show how Monsanto has manipulated science around glyphosate for several decades by ghost-writing, withholding research and influencing regulators. Can ECHA ensure that the Monsanto Papers are not influenced by Monsanto in the rating of glyphosate, and if so, can the Agency explain how? Is this conclusion supported by public and published studies?*[1]	**Background** ECHA is responsible for managing the harmonised classification and labelling (CLH) process for hazardous chemical substances. Active substances in plant protection products (PPP) are normally subject to harmonised classification and labelling. As part of the procedure for the renewal of glyphosate approval under the PPP legislation, a harmonised classification and labelling proposal was prepared by the German Federal Institute for Occupational Safety and Health (BAuA) and submitted to ECHA in May 2016. The CLH process for an active substance is triggered when a proposal for harmonised classification of that chemical substance is submitted by a Member State competent authority (MSCA) to ECHA. Based on the content of BAuA's proposal, ECHA's Risk Assessment Committee (RAC) assessed glyphosate's hazardousness in several areas,

[1] https://www.euractiv.com/section/agriculture-food/news/european-farmers-say-glyphosate-deadlock-shows-mistrust-in-eu-bodies

		including carcinogenicity, against the criteria in the CLP regulation. ECHA organised a 45-day public consultation on the German proposal during the summer 2016. RAC considered extensive scientific data that is publicly available and also non-public studies provided by the industry. Additionally RAC considered all information received during the public consultation. After examining all the relevant scientific studies, and by using weight of evidence approach, the independent scientist from all EU Member States agreed by consensus that glyphosate does not warrant to be classified as carcinogenic under the CLP regulation**.** Therefore, RAC suggested to maintain the harmonised classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects. The Risk Assessment Committee's opinion, ECHA's replies to NGOs as well as lot of other information regarding ECHA's work on glyphosate is available on ECHA's website here. **Why is there a difference of opinion on carcinogenicity of glyphosate between ECHA and IARC?** The criteria which need to be met for the classification of substances for their hazardous properties are provided in the CLP Regulation, which is also the implementation of the UN Globally Harmonised System of classification and labelling of chemical substances in the EU. ECHA plays a central role in the implementation of the CLP Regulation. This includes processing proposals for harmonised classification and labelling (CLH proposals) which are submitted to ECHA in the form of dossiers on chemical substances. A committee of ECHA (RAC) adopts an opinion on such proposals for classification and submits these to the Commission. ECHA focuses on adopting an independent opinion on what should be the

		harmonised classification and labelling of glyphosate, as it does with all substances for which Member States or industry submit proposals. Different conclusions on classification can potentially be drawn, because the scientific evidence may be interpreted or weighted differently between different groups of scientists, in particular in this case where not the same datasets were used in the evaluation. When conducting their assessments, regulatory agencies rely to a substantial extent on data from toxicological studies that are **not available in the public domain**, but also use relevant data from the public domain. There is a legal requirement on industry to ensure the safe use of chemical substances that they place on the market. The burden of proof for the safety of an active substance/pesticide lies with the company that seeks to place the product on the market. Industry therefore is obliged to conduct toxicology studies to identify the hazardous properties of these substances. The studies are paid for by the industry. The studies are conducted under conditions ensuring that public bodies can extract the relevant information without bias from the study sponsors. To that end, industry has to follow strict guidelines, which are laid down in EU legislation guidance documents. The studies must be performed in accordance with agreed methodology and quality requirements (OECD or equivalent technical guidelines and good laboratory practice). This is the same system used, for example, with medicines. The complete study reports from these studies are available to relevant regulatory authorities for their evaluation. The complete study reports from these studies are not normally publicly available, but summaries of such studies may be available. In addition to their studies, the companies must also submit any relevant public scientific information on the substance. Relevant results of the studies included in the CLH process are publicly available from the links to ECHA's website provided above.

		To conclude, IARC based its conclusion on glyphosate on data that was publicly available at the time of their work while ECHA looked at wider scientific data, as requested by the regulation. **Can ECHA ensure that the Monsanto Papers are not influenced by Monsanto in the rating of glyphosate, and if so, can the Agency explain how?** ECHA has responded to this question in an open letter sent to the European Commission on 22 August 2017. In short, based on the careful assessment of the information contained in the released additional "Monsanto papers", ECHA can confirm that they did not have any impact on the overall hazard assessment as presented in the RAC's opinion on the proposed harmonised classification and labelling (CLH) of glyphosate. As mentioned above, the CLH process is concerned exclusively with the assessment of hazardous properties of a substance, not risks associated with its use. Much of the information released in the so called Monsanto Papers is mainly related to risk assessment of the glyphosate – not hazards. Therefore they have not been relevant for ECHA's work. You may find ECHA's open answer on this matter here.
4	*In the Annual Activity Report 2016[2], ECHA states that 46% of the expenditure of ECHA are covered by collected fees and charges. These fees include for the first time a high proportion of fees from authorisation applications. What is the effect of this on the independence of the Agency's work in making decisions regarding the authorisations of applications? Why is this for the first time defined as a high proportion? How did this development occur?*	ECHA received a high number of applications for authorisation in 2016 and in consequence, the fee income increased substantially. This development was expected as the latest application date for authorisation of several substances of very high concern, particularly hexavalent chromium, was in 2016 and 2017.

[2] pages 5 and 9

		For clarity, ECHA does not make decisions on applications. ECHA provides scientific opinions on the applications and sends these to the Commission for decision. The REACH Regulation and the Fee Regulation foresee that each applicant pays a fee to ECHA for the applications. The purpose of the fee is to cover the costs of the handling of the application and in particular on the scientific work to provide the opinions. This takes all in all about 14 months. The fee is paid upfront, irrespective of the outcome of the scientific assessment. Thus the payment of the fee does not have an effect on the independence of the Agency's work and in particular on the independence of the members of ECHA's scientific committees and ECHA's staff who are working on the opinions. Furthermore, the committee members and ECHA staff involved in the applications for authorisation are assessed to ensure that they do not have a conflict of interest.
5	*During 2016, ECHA conducted two evaluations[3], one of the main recommendation in response to the evaluation was ensuring a clear strategy and effective/efficient governance, and implementation and better communication of objectives to staff. How and when will the recommendations be implemented?*	The legal basis of the ex-ante and ex-post evaluations is stipulated in ECHA Financial Regulation (MB/WP/03/2014) and Implementing rules (MB/55/2014, Chapter 7, Art.29). ECHA's evaluation framework and approach, established in 2015 and presented to the 40th Management Board on 16-17 December 2015, is based on the Better Regulation guidelines of the Commission as well as on the benchmarking performed with other agencies. In 2016, ECHA performed an ex-post evaluation of ECHA's Chemical Safety Assessment (CSA) programme / Exchange Network of Exposure Scenarios (ENES). The interim ex-post evaluation of the CSA programme /ENES, performed by internal and external evaluators, is an evidence based-judgement of the extent to which the programme has been effective,

[3] Annual Activity Report, page 23

		efficient (incl. economical), relevant, coherent and achieved EU added-value. The main findings, recommendations and follow up are listed below: • The main recommendations of the internal evaluators refer to reshaping the scope and focus of the CSA programme and ENES, implementation of existing tools, ensuring a clear strategy and effective/efficient governance and implementation, better communication of objectives to staff, and stakeholders' support in benefiting from the programme's tools and products. • The external evaluators recommend that implementation and consolidation work should be carried out to maximise the take up and use of ENES products, for which ENES needs to produce a communication plan to promote the ENES/CSR roadmap. The second ex-ante evaluation concerns ECHA's future building project, which was approved by the budgetary authority in November 2017.

EFSA

Replies to written questions

2016 Discharge of the EU decentralised agencies

WRITTEN QUESTIONS TO THE AGENCIES

Hearing on 22 January 2018

Specific questions to EFSA with EFSA's answers

EFSA

1. What is the state of implementation of the action plan following the IAS governance audit? Can all actions be implemented by the end of the year as announced in the Authority's reply to the European Court of Auditors?

   All action plans following the IAS IT Governance audit are considered completed by EFSA (i.e. status ready for review). The next step is for the IAS to perform a follow-up audit.

2. In 2012 the Court of Auditors reported conflicts of interest concerning EFSA Management Board members. What actions have been taken to clear the conflicts of interest? What are the improvements achieved in this respect so far?

   EFSA's Management Board represents the highest level of governance for the organisation. Its Members are appointed by the Council of the European Union – after consulting the European Parliament – from a shortlist drawn up by the European Commission following an open call for expressions of interest.

   In 2012, EFSA's Management Board adopted a voluntary Code of Conduct in which applicable independence standards are set out. This Code actually implements a system by which its members shall undertake to act independently in the public interest and should make Declarations of Commitment and Declarations of Interests (DoIs) indicating either the absence of or any direct or indirect interests, which might be considered prejudicial to their independence.

   The Code was last reviewed following an adoption by the Board on 12 December 2017 in order to align its rules to the new revised Independence policy adopted in June 2017. All DoIs of Board members are first assessed by EFSA and then collegially validated by the Board itself. DoIs shall be submitted on an annual basis in writing and shall be immediately updated whenever relevant new declarable interests emerge or a change in relation to any already declared interest occurs.

   Board Members shall declare at each meeting of the Board any interests which might be considered prejudicial to their independence in relation to the items on the agenda. If an identified conflict with one of the members substantially affecting the work of the Board or EFSA's reputation is not resolved, the Board, acting on a two-thirds majority, may ask for his or her replacement.

   Since its establishment, EFSA has complied with the legal requirement of making publicly available the declarations of interest of the members of its Management Board. Further, the 2017 policy on independence prescribes the establishment of

a register of activities concerning former Management Board members, in which the latter declare any new engagement overlapping with EFSA's remit for two years after the end of the engagement with EFSA.

All Management Board meetings are open to the public and can be followed on demand via webcast. All relevant documents are also posted on the website prior to meetings.

Finally, to be noted that since 2012 every time the Management Board has been renewed, each of the new members thereof has had to undergo a training session on ethics and integrity.

3. The glyphosate scandal of 2016 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 could EFSA guarantee the impartiality of the 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.

4. A study published in October, elaborated by the European Commission's JCR and two Dutch universities, found out that 45% of the European soil contains glyphosate residues - often in high concentrations - and that humans are exposed to contamination of these residues through inhalation or contact with dust. The study defines this as "worrying"[1].

   According to newspaper reports, a spokesman from EFSA said, on the same day, that a review of glyphosate evaluation by EFSA itself is possible if new scientific data emerge[2].

   The "worrying" situation in the study mentioned above is a new scientific evidence: did EFSA started the revision of its previous assessment, at least concerning the toxicological safety threshold, given that this threshold is compounded by high environmental contamination?

   In line with what the EFSA spokesperson said, the Authority has indeed assessed this specific study in detail in relation to its previous assessment of glyphosate.

   The conclusion is that the values presented in the study are in line with the current authorised uses of glyphosate, they are covered by EFSA estimations, and they do not indicate risks or concerns for humans or the environment, except for one concern already identified in the original EFSA assessment of glyphosate and addressed by the European Commission and Member States[3].

   The study reports measured environmental levels of glyphosate residues in soil and reports values from previous studies including the original EFSA assessment. The study does not present information on hazards or effects on human health or the environment. Therefore, the study does not affect the toxicological safety thresholds for humans and non-target organisms proposed by EFSA through the in depth peer-review of hundreds of studies.

[1] http://www.sciencedirect.com/science/article/pii/S0048969717327973
[2] https://www.euractiv.fr/section/agriculture-alimentation/news/eu-agencies-accused-of-cherry-picking-evidence-in-glyphosate-assessment/
[3] See pages 18 & 21 of the EFSA Conclusion 2015: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf

EFSA checked if the reported or modelled concentrations are covered by the EFSA risk assessment. In EFSA's view, the values reflect the expected environmental levels resulting from the use of glyphosate as a herbicide.

The reported concentrations in agricultural soils are in line with the predictions expected for the authorised agricultural uses and fully covered by the EFSA Acconclusion that did not detect concerns for soil organisms. The reported measurements in air do not represent health concerns and confirm that this is an insignificant source of human inhalatory exposure compared with the conservative EFSA risk estimations. The information presented for the aquatic compartment was already identified as a concern in the EFSA assessment, which triggered a decision by risk managers that was introduced by the European Commission already in 2016[4], well before the proposal for renewing the approval of glyphosate.

5. According to the recently published implementing rules to EFSA's new Independence policy, EFSA has again decided that it would only screen the interests of its external experts according to the mandate of the scientific panel they are asked to join, and not, as was repeatedly requested the European Parliament, according to EFSA's remit. This means that, for instance, an expert receiving significant research funding from the food industry on a slightly different but not unrelated topic could still be appointed on the panel at stake. Why did EFSA refuse to take the European Parliament's demand into account?[5]

Firstly, it is important to note that EFSA's new Independence Policy was adopted in June 2017 by the Authority's Management Board following a lengthy consultation process involving civil society, other interested parties and the general public.

Secondly, the premise in the question is not accurate. The way in which EFSA assesses an expert's interests depends on the type of interest in question.

For example, an expert's employment interests are assessed against **the entire remit** of EFSA. The rules stipulate that employment with industry or NGOs leads to a two-year cooling off period from **any EFSA scientific activity**.

Similarly, an expert with a current financial investment, meaning an economic stake in any entity with a **direct or indirect interest falling within EFSA's entire remit**, leads to the exclusion of the expert from **any EFSA scientific activity.**

For other professional interests (e.g. managerial role or membership of a scientific advisory body), under the new policy the expert has to declare the financial impact in percentage terms of these interests on their total earnings. E.g. "interest X represents 15% of my total earnings". This financial declaration has to **cover interests falling directly or indirectly within EFSA's remit**.

If the financial impact of one of these interests is more than 25% of the expert's total earnings, the interest is classified in the same way as EFSA classifies an

[4]See Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate

[5]*https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf*

employment interest, which leads to the expert being excluded from any EFSA scientific activity **regardless of the mandate of the scientific group**, with the applicable two year cooling off period.

If the financial impact of these interests is less than 25% of the expert's total earnings, the interest is assessed **against the mandate of the group**. Where there is an overlap between the interest and the mandate of the group, the expert is excluded from that group with the applicable two year cooling off period.

Regarding research funding, EFSA encourages professionals contributing to its work to pursue projects with the global research community in order for them to be at the forefront of scientific developments and innovation. EU-wide policies and policy papers encourage private-public partnership and collaboration[6]. As a decentralised agency of the EU responsible for assessing food safety risks, EFSA acknowledges the importance of close cooperation between these two spheres.

In line with the EU approach to research funding, EFSA considers that for experts contributing to its activities, the acceptable level of research directly funded by the private sector is 25% of the total budget of the expert and his/her research team, with relevance to the scientific group that the expert is taking part in. If the level of research funded by the private sector is more than 25%, the expert is ineligibile to join the EFSA scientific group in question and a two-year cooling off period is applied.

Overall, the new policy represents a significant strengthening of the rules in place, reinforcing what was already a robust and comprehensive system for guarding against conflicts of interest. The decision that EFSA's Management Board took was informed by the public and stakeholder consultation process mentioned above but, above all, by the need to strike the appropriate balance between attracting suitably qualified and experienced experts to work with EFSA while securing against undue influence.

6. The screening of EFSA's experts' Declarations of Interests' is based on the Agency's entire remit. How does this procedure work in practice?

Please see above response to question 21.

7. How does EFSA respond to attempts of the food industry to exert influence on its activities? To what extent does the Agency take the advice of independent stakeholders?

Independence is one of EFSA's key values. The Authority is committed to safeguarding the independence of its experts, methods and data from any undue external influence and to ensuring that it has the necessary mechanisms in place to achieve this.

[6] 8 See e.g. Europe 2020 Strategy, COM(2010) and Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Public-private partnerships in Horizon 2020: a powerful tool to deliver on innovation and growth in Europe, COM/2013/0494 final.

The central pillar of EFSA's independence is its Management Board, itself an independent body whose members are appointed by the Council of the European Union and who are required to act in the public interest.

In addition, the Authority applies a robust set of measures and working practices to safeguard the independence of its scientific work and avoid conflicts of interest. These are all brought together and explained in EFSA's Independence Policy, the principles of which are described above in response to Q.21.

Good risk assessment practices: EFSA has developed a comprehensive body of good risk assessment practices to guide the work of its Scientific Committee and panels. EFSA's Scientific Committee has also adopted a set of recommendations on transparency in risk assessment to ensure maximum transparency of its work.

All the final scientific opinions adopted by the Scientific Committee and scientific panels are the outcome of collective deliberations and decisions, with each member having an equal say. No single expert can unduly influence the decisions of the panel and minority views are recorded.

Selection of scientific experts: Members of the Scientific Committee, scientific panels and their working groups, as well as other external experts contributing to the work of EFSA, are selected according to their scientific competence and expertise using objective, transparent criteria. During the selection process, interests declared by applicants are scrutinised to ensure the prevention of conflicts of interest.

In addition, independent external evaluators review the assessment of applications for scientific panel membership to ensure that the selection process is coherent.

Declarations of interest: all experts of the Scientific Committee, scientific panels and working groups are required to sign a declaration of commitment, including a commitment to act independently, and to provide an annual declaration of interests (ADoI) for each EFSA group of which they are a member. All of the ADoIs are published on the EFSA website.

An ADoI contains details of current activities and those completed in the last five years. Experts are also required to declare in advance their specific interests for each agenda point of a meeting in writing, through a specific declaration of interests (SDoI), and any additional interests orally at the beginning of the meeting.

Preventing conflicts of interest: EFSA systematically checks the information provided by an expert in the DoI and assesses whether a declared interest constitutes a conflict in line with the Independence Policy described in the response to Q.21 above. For ADoIs, the process is coordinated and validated by EFSA's Legal and Assurance Services.

EFSA staff: EFSA staff act in the public interest and are subject to several obligations under EU staff regulations, including that of acting with independence and integrity and of avoiding conflicts of interest. EFSA requires staff to fill out an ADoI and ensures that staff members are not assigned to projects where potential

conflicts of interests have been identified. The ADoIs of EFSA's senior managers are published online. Training on conflicts of interest has been compulsory since 2010 for every EFSA staff member. Moreover, to facilitate a correct discharge of these duties, in 2017 EFSA organised an additional ad hoc training session on ethics and integrity for all staff members in which it specifically trained staff members on best practices for declaring interests.

Stakeholder engagement: regarding taking advice of "independent stakeholders", EFSA understands this question to mean input into the scientific process from stakeholders other than industry. These stakeholders may have an intellectual or ideological position in relation to EFSA's work but are less likely to have a direct financial interest in the same way that industry does.

The framework EFSA has in place to involve and interact with stakeholders in relation to its activities is set out in the Authority's Stakeholder Engagement Approach, endorsed by EFSA's Management Board in 2016. The Stakeholder Engagement Approach describes the numerous mechanisms in place for interacting with stakeholders, which include: yearly roundtable meetings with NGOs and industry stakeholders, discussion groups on specific areas of EFSA's work (e.g. emerging risks, GMOs), targeted consultation groups (e.g. endocrine disruptors), scientific colloquia, and information sessions.

Participation to these activities are open to all stakeholders registered with EFSA, which at the time of writing extends to over 100 representative organisations covering NGOs and advocacy groups, consumer organisations, practitioners associations, academia, industry, primary producers, and distributors. The full list of registered stakeholders is available on EFSA's website alongside a list of current stakeholder activities.

One of the fundamental principles of the Stakeholder Engagement Approach is the concept of balanced representation. This means that all stakeholders should have equal access to information from EFSA and to opportunities to engage with the Authority. In practice, this is managed through the way in which EFSA organises its stakeholder activities.

For example, in 2017 EFSA launched a call for stakeholders to take part in a targeted consultation group on the joint guidance it is preparing with ECHA on endocrine disruptors. Consumer organisations, advocacy groups and NGOs were afforded the same number of places in the group as industry participants. The call for interest and the minutes of the selection process were published on EFSA's website in the interests of transparency.

In addition to the activities related to the Stakeholder Engagement Approach, EFSA continues to offer public consultations on a significant proportion of the scientific outputs that it produces. All EFSA Guidance documents are put out for public consultation as well as scientific opinions on high-profile or sensitive scientific issues. This gives all stakeholders the opportunity to provide comments on draft scientific documents before they are adopted by EFSA's scientific panels. The comments made during the public consultation and the manner in which EFSA incorporates them are reported transparently in a public consultation report, which is published alongside the final scientific output.

Furthermore, EFSA frequently launches call for data to ensure it has the largest possible evidence base upon which to base its scientific advice. A notable recent example was the call for data to support its work on the re-assessment of neonicotinoids, which resulted in EFSA receiving many hundreds of responses and datasets from a wide variety of stakeholders, including NGOs and the bee-keeping community. EFSA is due to publish its updated assessments of neonicotinoids in February 2018.

8. 46% of all EFSA scientists are still in financial conflict of interest situations with the agribusiness and food industries. According to a report from Corporate European Observatory[7], declarations of interest show that 26.5% of experts received money in the past five years from companies whose products are regulated by EFSA. More than 30% have indirect financial conflicts of interest in that they belong to an organisation which has received more than 20% of its funding from such companies in the past five years. What is EFSA's appraisal of this report and what follow-up action will it take?

EFSA strongly rejects the statement that 46% of all EFSA scientists have a conflict of interest with industry. The figures and percentages that CEO put forward in its report are misleading and based on an arbitrary interpretation of financial interests that EFSA does not agree with.

For example, CEO considers that experts employed by or affiliated with several well-respected scientific organisations across Europe, such as Wageningen University or Fraunhofer Institute, result in a conflict of interest. They also cite the mere participation of an expert at an industry-sponsored event as a reason to ban scientists from EFSA's activities.

The financial interests of all experts working on EFSA's Panels have been assessed carefully according to the strict independence rules the Authority has in place and they were not found to have interests that were incompatible with membership of EFSA's Scientific Panels.

It is also worth noting that this report was published prior to the adoption of EFSA's new Independence Policy. As already mentioned above in response to Q.23, the new policy represents a further strengthening of the rules in place, reinforcing what was already a robust and comprehensive system for guarding against conflicts of interest.

9. Despite the fact that the WHO and other research calls glyphosate possible carcinogenic, EFSA approved it. How did EFSA come to the conclusion that glyphosate is not damaging? The Monsanto Papers show how Monsanto has manipulated science around glyphosate for several decades by ghost-writing, withholding research and influencing regulators. Can EFSA ensure that the Monsanto Papers are not influenced by Monsanto in the rating of glyphosate, and if

[7]https://corporateeurope.org/efsa/2017/06/recruitment-errors

so, can the Agency explain how? Is this conclusion supported by public and published studies?[8]

EFSA did not "approve" glyphosate. This was the role of the national risk managers (Member State representatives) on the basis of a proposal submitted to them by the European Commission. EFSA's advice, alongside that of the European Chemicals Agency, was the scientific basis upon which the decision to re-authorise glyphosate was taken.

It is not accurate to say that the WHO has called glyphosate carcinogenic. It was the International Agency for Research on Cancer, an independent agency of the WHO, that reached this conclusion. Another body of the WHO, the Joint WHO/FAO Meeting on Pesticide Residues, reached the conclusion that glyphosate is unlikely to cause cancer in people via dietary exposure, the same conclusion as EFSA.

EFSA did not come to the conclusion that glyphosate is not damaging. EFSA provided a proposal for non-classification of glyphosate on the basis that it considers glyphosate to be unlikely to be carcinogenic to humans.

This proposal was supported by pesticide risk assessment experts that took part in the peer review of glyphosate in 27 out of 28 Member States. It has also subsequently been supported by the European Chemicals Agency, the Joint WHO/FAO Meeting on Pesticide Residues, and other regulatory bodies from the USA, Canada, New Zealand, Australia, Japan and Switzerland.

The main reasons that explain the scientific divergence on the carcinogenicity of glyphosate between EFSA and the International Agency for Research on Cancer (IARC) are as follows:

- EFSA is required to follow the system for classification and risk assessment set out in EU law; IARC uses a different system. This has an impact on the evidence EFSA assesses compared to IARC, the scope of the assessments, the methodologies used, and the criteria followed for cancer classification.
- For example, EFSA's assessment focussed on glyphosate as a single active substance, as it is required to do so by EU legislation on pesticides; IARC on the other hand also gave weight to studies on glyphosate-based formulations. In the EU regulatory system, the evaluation of the safety of pesticide formulations takes place in a second step and is done by Member States at a national level.
- EFSA's assessment was more comprehensive than IARC's: it considered all studies in the IARC report as well as regulatory studies which, under the EU pesticides legislation, must be submitted by industry when they make an authorisation application. In other words, the EU review was based on a different and more comprehensive evidence base than the one considered by IARC.

It should also be noted that glyphosate is not the first time the EU has classified an active substance differently to IARC. In some cases the EU classification was

[8] *https://www.reuters.com/investigates/special-report/who-iarc-glyphosate/?utm_campaign=Storylift+-+EG8-X1LZ&utm_source=Storylift&utm_medium=EG8-X1LZ&utm_content=A*

"stricter" than the IARC classification; in some cases not. For example, in an analysis by EFSA from February 2016 there are 17 active substances with an EU classification that have also been assessed by IARC. Of these 17, there are 11 where the EU classification is more conservative than the classification provided by IARC. These past differences have not led to a public health crisis or to a lessening of the standards the EU has in place for the safe use of pesticides.

Regarding the so-called "Monsanto papers", EFSA has published detailed statements (here and here) to address concerns about ghost-writing and the assessment of published literature in the EU review process. EFSA's statements on these issues can be summarised as follows:

Ghost-writing: EFSA is the first to defend the integrity of the scientific process and if the allegations of ghost-writing are true this would constitute a grave breach of scientific and ethical principles. The allegation was serious enough for EFSA to investigate its significance in relation to the EU assessment of glyphosate. Following this investigation, EFSA confirmed that there are no grounds to suggest that industry improperly influenced the EU assessment of glyphosate. This is because:

i. The authors of the two review papers in question[9] clearly indicate that they were either paid by industry or that they received access to data from industry to produce their papers. In other words, their provenance was evident to EFSA from the Declarations of Interest and Acknowledgements in the papers themselves.

ii. The weight of the two review papers in question was very limited in the overall assessment of glyphosate. This is because EU experts rely primarily on the findings of original safety studies and the underlying raw data, not review papers, to produce their conclusions.

iii. The review papers represented only two of approximately 700 scientific references on mammalian toxicology in the glyphosate assessment.

Assessment of public/published literature in the EU review process

The EFSA Conclusion on glyphosate was based on an assessment by EFSA and Member State experts of both regulatory safety studies (i.e. those that industry are required by legislation to submit) and studies published in the open scientific literature.

The status of a study – e.g. industry-sponsored or from the open literature – is irrelevant to the assessment. What is important is how well the study is designed, carried out and reported.

After carefully weighing the relevance and reliability of all available studies, EFSA concluded that glyphosate as a single active substance is unlikely to be carcinogenic or genotoxic.

[9]Kier and Kirkland 2013: https://www.ncbi.nlm.nih.gov/pubmed/23480780; Williams et al. 2000: https://www.ncbi.nlm.nih.gov/pubmed/10854122

However, based on the findings of published studies from the open literature, EFSA recommended that the toxicity of glyphosate-based formulations and in particular their genotoxic potential should be further considered and assessed.

10. According to this internal document of the US Environmental Protection Agency, published within the so-called "Monsanto Papers", EFSA would have decided to disagree IARC's assessment of glyphosate as soon as May 2015, more than two months before the publication of the actual detail of the IARC Monograph. IARC confirmed they only sent the data to EFSA at the time of publication. Is this true, and if so, what is the agency's justification for judging a piece of scientific evidence without seeing it?[10]

    EFSA did not arrive at an assessment of the IARC Monograph prior to receiving it. Although the full IARC Monograph was published in July 2015, IARC published the main findings of their assessment in March 2015, highlighting that it considered glyphosate as a probable carcinogen. In March 2015, the EU assessment of glyphosate was nearing an end and it was already clear to EFSA and Member State experts that glyphosate was unlikely to be carcinogenic to humans. This is reported in the background documents available on EFSA's website, in particular the minutes of a Member State expert meeting held in February 2015 in which the carcinogenic potential of glyphosate was discussed. In other words, EFSA already knew in May 2015 that the EU assessment of the carcinogenicity of glyphosate was likely to diverge with that of IARC.

    EFSA can confirm that there was no pre-judgement of the IARC monograph. This becomes immediately evident if you consider the Addendum in the Renewal Assessment Report prepared by the Rapporteur Member State (Germany) and commented on by Member States and EFSA, which contains a full scientific assessment of the IARC monograph and is published on EFSA's website. The assessment contained within the Addendum was carried out once the IARC published its assessment in full in July 2015. This assessment was fully integrated in the final EFSA Conclusion on glyphosate.

11. How is the assessment procedure of EFSA by reviewing glyphosate? Both EFSA and ECHA are involved in this situation. Did the Agency collaborate with ECHA? Is the same assessment procedure used for other reviews?[11]

    ECHA manages the law on classification and labelling of chemical substances and mixtures (Regulation (EC) No 1272/2008, known as the "CLP Regulation"). This law regulates the way in which substances are assessed and labelled, based on the hazardous properties they may have.

    For certain substances, such as pesticide active substances, Member States may submit a proposal to ECHA for a classification to be applied uniformly at EU level (a so-called "harmonised classification").

[10] *https://usrtk.org/wp-content/uploads/2017/10/EPA-cooperation-with-EFSA.pdf*
https://usrtk.org/pesticides/mdl-monsanto-glyphosate-cancer-case-key-documents-analysis/
[11] *https://www.euractiv.com/section/agriculture-food/news/european-farmers-say-glyphosate-deadlock-shows-mistrust-in-eu-bodies/*

In 2015 when EFSA drafted its conclusion on glyphosate, such a harmonised classification was not available under the CLP regulation. In this situation, the Regulation for Plant Protection Products (Regulation (EC) 1107/2009) foresees that EFSA propose a classification in its conclusion on the active substance, according to the criteria of the CLP Regulation.

In June 2017 ECHA published its opinion on the harmonized classification of glyphosate under the CLP Regulation, and joined EFSA in stating that there is no evidence to link glyphosate to cancer in humans, based on available information. ECHA's assessment was broadly based on the same evidence as that used by EFSA.

However, the experts that carried out the assessment were different. In the case of EFSA, the assessment was carried out by a network of approximately 70 experts from Member State organisations appointed by their national governments, alongside scientists from EFSA. In the case of ECHA, the assessment was carried out by members of its Committee for Risk Assessment (RAC), a group of approximately 50 experts nominated by Member States.

EFSA and ECHA reached the same conclusion regarding the carcinogenicity of glyphosate based on assessments that were independent of each other using different experts in different settings.

It should be noted that for EFSA the classification of an active substance is the first step in a wider assessment that also takes into account the risk and the extent to which people and the environment are exposed to the substance. These risks are considered on a case-by-case basis by EFSA in line with the requirements of the EU's Plant Protection Regulation. In this respect, ECHA does not have a role in producing assessments on the risks of active substances in pesticides.

Regarding the assessment of other pesticides, the same process is applied by EFSA and Member States for the assessment of all pesticide active substances. The process is based on the Plant Protection Regulation mentioned above that came into effect in 2009 after co-adoption by the European Parliament and the Council.

The European Commission is currently developing legislation to align the Plant Protection and CLP processes such that an ECHA opinion for harmonised classification can be concluded during the evaluation timeline for the authorisation of an active substance.

Glyphosate is one of several hundreds of active substances that have been assessed by EFSA and Member States in recent years. It is the same system that has led to dozens of harmful pesticides being withdrawn from the market in the EU.

It is also worth noting that since EFSA published the EU assessment of glyphosate, it has carried out 47 other assessments of pesticide active substances. Of these, 10 were classified for carcinogenicity and three for reprotoxicity.

EIGE

Replies to written questions

Vilnius, 08. 01. 2018
EIGE/VL/rs D/2018/ 5

Bart Staes
Discharge Rapporteur
European Parliament
Wiertzstraat 60,
B-1047 Brussels,
Belgium

Sent by email: CONT-secretariat@europarl.europa.eu

Subject: **EIGE's answer on CONT questionnaire for the decentralised agencies 2016 discharge**

Dear Mr Staes,

Please, find the answers of the European Institute for Gender Equality (EIGE) to the questions presented in the CONT questionnaire for the decentralised agencies 2016 discharge.

Question:

17. Why the call for tender for a framework contract on the maintenance and update of its gender statistics was split into two lots? According to the European Court of Auditors, two separate framework contracts were signed with the same tenderer.

EIGE's response:

The contracting authority decided to split the FWC into two Lots based on the similar purpose but different character of the services required with the aim of attracting more interest among economic operators in the open procurement procedure.

Lot 1 entails the overall management of the Gender Statistics Database: its structure, content, technical maintenance and specific communication activities and covers mainly the data mining of existing gender sensitive statistics and data produced by national and international data providers. The services facilitate the integration of data, metadata and statistics used for several areas across EIGE's work, including EIGE's Gender Equality Index, BPfA reports, gender-based violence and other relevant research.

On the other hand, Lot 2 entails services ensuring collection and processing of data (the whole production cycle) the Institute has been assigned to produce in one specific area, namely Women and Men in decision-making. The work on this data collection was initiated by the European

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Commission and transferred to EIGE in 2015, following the request from DG Justice to integrate the collection, storage and dissemination of this data set into EIGE's Gender Statistics database. The nature of the services significantly differs from the services under Lot 1 as the task requires tailor made data collection instruments, methodologies and expertise in the area of women and men in decision-making.

Within the open tendering procedure, three economic operators submitted offers for both lots. Based on the preannounced award criteria and after a thorough evaluation of the offers executed by the appointed Evaluation Committee consisting of in-house and external experts, the same economic operator was chosen as the most economically advantageous tender to be awarded the contract.

The above-mentioned procurement procedure is in full compliance with the provisions of Article 168 of the Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, as amended[1]. Furthermore, the decision to split FWC into two Lots was made in accordance to Commission's Vade-mecum on Public Procurement "good practices in Public Procurement, Part 2, 2.2.2. Lots[2]".

EIGE remains available for any other information or clarifications that you might need.

Yours faithfully,

V. Langbakk

Virginija Langbakk
Director

[1] Lots (Article 118(4) of the Financial Regulation)
Whenever appropriate, technically feasible, and cost efficient, contracts shall be awarded in the form of separate lots within the same procedure.

[2] Contracts covering a set of supplies or services serving a similar purpose, whose combined value is such that few operators would be able to provide them all in their entirety, should be split into lots, so that any operator who is interested can tender for one or more lots (Art. 168 RAP).
Dividing a contract into lots increases competition and make it easier for small and medium-sized companies to participate. Indeed, in the case of very high-value contracts competition can only be achieved by splitting the contract, since only a small number of operators would be able to offer all the products or services requested, thus placing the contracting authority in a position of dependence.
Splitting into lots is also appropriate when a contract for a single global purchase is made up of a variety of products or services offered by companies operating in different sectors of the economy (for example, information and communication activities often include managing a website, producing videos, publishing written material, etc.). In such cases, a company which is highly efficient within its own sector but is not able to provide all the products or services would be unfairly prevented from competing.

EMA

Replies to written questions

EMA/795218/2017
European Medicines Agency

EMA reply to questionnaire from European Parliament

CONT Hearing on Agencies discharge for Financial Year 2016 (22 January 2018)

II. Questions to be answered by individual Agencies.

18. What kind of actions have been undertaken so far in order to prepare for the re-location regarding the withdrawal of the UK from the EU? Could you provide us with a calculation of all the potential costs and budgetary effects and implications for contractual arrangements regarding the re-location? Could you provide further information on the stakeholders of the re-location?

In order to address the challenges presented by Brexit, in June 2016 EMA established internally an Operations and Relocation Preparedness (ORP) task force to plan and prepare for the upcoming change, 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 4 work streams:

- **Relocation preparedness**, which includes activities enabling the scientific experts from the Network to continue attending scientific meetings at EMA, retaining staff, including a smooth relocation of staff and their families as well as working with the Netherlands on the timely availability of the new premises and the required facilities, including telecommunication.
- **Operational and financial preparedness**, which focuses 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. This work stream also elaborates on the Agency's Brexit preparedness business continuity plan (BCP) which covers prioritisation and delivery of EMA activities in order to free-up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss.
- **Human resource-related matters**. This work stream 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.

The task force is supported by ORP subgroups devoted to specific activities and deliverables within these 4 work streams.

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Preparations to date

During 2016-2017 the Agency has undertaken considerable work to prepare for the relocation, including but not limited to:

- Completing an impact assessment, identifying also the key risks that the Agency would be facing in this environment;
- Preparing 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;
- Member State visits to EMA and EMA site visits to candidate host countries upon request from a Member State;
- Conducting several staff surveys, to gauge the potential staff losses in view of their impact on 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;
- 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 new host Member State, including those for staff support during the transition;
- Developing support measures to maximise staff retention;
- Working with the Member States to address the workload issues arising from the loss of UK expertise;
- 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;
- Developing a dedicated EMA Brexit preparedness BCP, to address situations where a "business as usual" scenario is no longer possible;
- Beginning preparation for relocation of the Agency's data centres;
- Beginning liaison 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.

A calculation of all potential costs and budgetary effects and implications for contractual arrangements is outlined in the table below, as presented to EMA to the European Parliament Committee on Budgets on 11 July 2017, totalling €582.5 million. However, it is not possible at this time to reasonably estimate final actual costs, which are subject to discussion with the new Host Member State, subject to clarification of liability for remaining obligations under the current lease contract, and also bearing in mind that determining final responsibility for bearing the costs of relocating the Agency forms part of the EU/UK withdrawal negotiations.

Remaining obligations under the lease contract	448.0 million
Potential Operations and Relocation Preparedness costs – outbound from UK	42.1 million
Potential Operations and Relocation Preparedness costs – inbound to new location	92.4 million

19. The European Medicines Agency set up a taskforce to ensure preparedness in this respect. What is the outcome of the assessment of this taskforce?

The Task Force referred to in our answer to Q18 above was established immediately following the referendum result in 2016. It carried out an impact assessment across all the Agency's activities to examine the impact of the withdrawal of the UK from the EU. This assessment demonstrated that the withdrawal of the UK from the EU would have a major impact on the Agency's operations. The Task Force set up work streams for specific subject areas and has taken action as follows:

Main aim of the Task Force: to ensure that the Agency remains operational and is able to deliver on its mission before and after relocation.

Public health: A mapping exercise was carried out to examine the workload undertaken by the UK in scientific assessment. The UK may no longer participate in the work of the Agency and the assessment work currently carried out by the UK will have to be distributed across other EU member states. The Task Force organised an information meeting of the 27 Member States, with a follow up meeting. Two working groups, human and veterinary, were set up to explore options for robust re-allocation of the workload on human and veterinary medicines across the network. Principles were proposed to the network that the National Competent Authorities have agreed and that provide a basis by which the workload relating to the evaluation and the monitoring of medicines will be redistributed. Steps have been taken to ensure capacity building across the network of 27 member states.

Actions were initiated to ensure that companies have the right information and take the necessary steps to be able to operate in the EU 27 and continue to make their medicines available to citizens.

Business continuity: Business continuity principles were approved:

- Ensure business continuity
- Maintain the same high standards of scientific assessment
- Continue compliance with legal timelines
- Ensure knowledge retention
- Assure easy implementation and medium and long-term sustainability

The Task Force categorised and prioritised all EMA activities according to their impact on public health and the Agency's ability to function. A dedicated 'Brexit' business continuity plan (BCP) was developed to free up the necessary resources to prepare for Brexit, including for the potential staff loss and the necessary changes to operations and procedures after withdrawal of the UK from the EU. EMA has launched its BCP to make sure that its core tasks are not impacted by the necessary preparations for the move and the revision of procedures and operations.

Relocation: Following the Council's decision on 20 November 2017, the Task Force is setting up further action plans to prepare for the move and to manage the changes in a proactive and efficient way. It

has established a joint governance structure to work in partnership with the new host MS, the Netherlands.

The Agency has provided technical input to E. Commission, with respect to the requirements for the future host city, on any area relevant to the Agency's activities. In line with the criteria established by the Council EMA provided a technical assessment on the proposed building(s) with indicated layout and facilities and the relocation plan. This assessment was requested by the Commission and was based solely on the information provided in the 19 MS offers

Procurement: contracts (194) were categorised for portability or tenders that will need to be done for the new location.

Staff: The Task Force conducted several surveys of the Agency's staff to understand their intentions to move with the Agency and the impact of the staff loss. It monitors the impact of eventual staff loss and will take action in line with the business continuity principles and the prioritisation of activities. The Task Force has looked into ways to support staff retention. Staff retention support measures are implemented in line with the Staff Regulations and in consultation with the E. Commission. The Staff Committee is represented on the Task Force for reasons of transparency and in order to achieve closer co-operation. Options to maintain recruitment of staff have been examined. An IT tool has been implemented in order to streamline the process, improve the experience for candidates and to ensure that the Agency has reserve lists in place for staff replacement reasons.

Communication: regular and relevant external communication has been assured to update external stakeholders and to inform them on specific issues of relevance to their interests regarding Brexit. Questions from the staff of the Agency were encouraged and replied to transparently to promote better information transmission. In addition, regular staff General Assemblies have been held to provide information and to enable staff to engage with the Director and the Task Force. Frequent internal reporting has ensured that the Agency has addressed the issues of concern and has been taking the required decisions in a timely manner.

20. The Report on Budgetary and Financial Management (page 2) displays that 5.49% of EMA's total revenue comes from EU budget (in 2015: 11.1%). However, the 'Detailed revenue overview, evaluation' (page 14) shows an EU budget decrease of 89.08% between 2015 and 2016. Can EMA explain this difference?[1]

The 5.49% of 2016 revenue represents EUR 16.76 million (of total revenue of EUR 305.10 million) and includes the general EU contribution (BL2000R, EUR 2.04 million), the Orphan Medicinal Products (OMP) fee reduction contribution (BL2010R, EUR 12.77 million and the EMA's surplus from 2014 which the EC returned in 2016 (BL7000R, EUR 1.95 million).

The **part** of this contribution which decreased by 89.08% (page 14) is the general EU contribution which decreased from EUR 18.67 million in 2015 to EUR 2.04 million in 2016. The **overall** EU contribution, i.e. the general, OMP fee reduction plus the returned surplus from year N-2, decreased from EUR 33.38 million to EUR 16.76 million, or by 49.8%.

[1] http://www.europarl.europa.eu/cmsdata/124860/Report%20on%20Budgetary%20and%20Financial%20management.pdf

This table provides the breakdown:

Chapter	Heading	2015 EUR	2016 EUR	Change EUR	Change %
10	Revenue from services rendered (Fees for the evaluation of medicines), 89.36%	251,490,172.82	272,588,211.46	21,098,038.64	8.39%
200	European Union contribution, 0.67%	18,668,607.31	2,037,869.78	-16,630,737.53	-89.08%
201	Special contribution for orphan medicines fee reductions, 4.19%	13,212,250.00	12,768,875.00	-443,375.00	-3.36%
30	Participation by third countries in EMA activities, 0.02%	554,457.69	56,245.22	-498,212.47	-89.86%
52	Revenue from administrative operations, 0.01%	107,548.90	72,541.06	-35,007.84	-32.55%
60	External assigned revenue for projects and programmes, 5.01%	17,558,760.53	15,276,321.70	-2,282,438.83	-13.00%
70	Correction of budgetary imbalances (Balance of outturn account of previous year), 0.64%	1,499,357.43	1,949,934.18	450,576.75	0.00%
90	Miscellaneous income, 0.11%	1,027,075.81	348,699.15	-678,376.66	-66.05%
Total		**304,118,230.49**	**305,098,697.55**	**980,467.06**	**0.32%**

21. How does EMA view its dependence on fees from the pharmaceutical industry (89.34%)[2]?

- We charge **pharmaceutical companies** fees for our scientific evaluation procedures and services; this makes up about 90% of our budget.
- We also receive a **general contribution from the EU** budget for our public health programmes. This general contribution is about one tenth of our budget.
- 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).*

[2] http://www.europarl.europa.eu/cmsdata/124860/Report%20on%20Budgetary%20and%20Financial%20management.pdf

- The actual funding model applied is set out in various (financial) regulations governing the operation of the Agency. The establishment and revision of these regulations is very much a matter for the legislators and the legislative process within which the EMA has no direct role.

22. Annually, EMA may transfer money from one title to another. However, for the 2016 budget the Agency transferred substantial amounts without any explanation. Can EMA explain its decision for making the following transfers?[3]

    a. Basic salary (€290,000);

    €40,000 was transferred to BL1410 (medical services), as part of transfer No. 06/2016, to cover the cost of a higher than planned number of staff medicals and €250,000 was transferred to BL1114 (basic salaries and allowances for contract agents) as part of transfer No. 09/2016, to cover higher than planned cost on contract agents. Availability on BL1100 (staff in active employment) came mainly from savings due to the weakening of Sterling compared to Euro throughout 2016.

    b. Studies & Consultants (€47,700);

    €47,700 was transferred to BL3105 (business IT development), as part of transfer 11/2016, to cover the cost of a number of fixed-price contracts related to IT projects put in place in 2016. Availability on 3030 (studies and consultants) was due to a number of projects requiring business consultancy resources being delayed in 2016.

    c. Subscriptions to specialised research (€186,200);

    €186,200 was transferred to BL 3105 (business IT development), as part of transfer 11/2016, to cover the cost of a number of fixed-price contracts related to IT projects put in place in 2016. Availability on BL3031 (scientific databases) came from a specific contract being delayed until 2017.

    d. Information & publication (€120,000).

    €70,000 was transferred to BL3105 (business IT development), as part of transfer 11/2016, to cover the cost of a number of fixed-price contracts related to IT projects put in place in 2016. €50,000 was transferred to BL3010 (evaluation of medicinal products), as part of transfer 12/2016 to cover the cost of rapporteur payments linked to scientific applications received. Availability on 3040 (information and publication) came mainly from the cancellation of a tender procedure for an electronic content management tool.

23. Since one year EMA publishes its clinical trials data. This shows EMA´s transparency. However, academics are required to provide personal details, such as Passport/ID Card number before gaining access to the data. The European Parliament has just adopted the ePrivacy Regulation, putting citizens back into control of their own personal data online. Why is it necessary for EMA to have these personal details, as visitors for 'general information purposes' do barely have to provide information?[4]

[3] http://www.europarl.europa.eu/cmsdata/124860/Report%20on%20Budgetary%20and%20Financial%20management.pdf

[4] https://clinicaldata.ema.europa.eu/web/cdp/termsofuse

In order to ensure the proper functioning of the platform on which access to clinical trial data is made available, the Agency has prepared, after consultation of all stakeholders involved, a minimum set of measures including terms and conditions for members of the public to register as users (Terms of Use).

Users who choose to be able to download, edit and print the published documents, rather than to have screen-only access, are asked to provide additional information concerning their identity including the details of an ID document. The main reason for this is to prevent abuse of the system or circumvention of the obligations assumed under the Terms of Use and ensure a reasonable degree of protection of third parties' rights under UK law. The Agency will review the Terms of Use on or before 30 March 2019, when UK law cannot be applied anymore to the Terms of Use due to the UK leaving the European Union.

In any event, the Agency collects the strict minimum of personal data that may be needed in the event of a breach of the Terms of Use and a request by a Court of law to disclose such data.

In addition, the ePrivacy regulation that is referred to in the question does not seem to be relevant for the clinical trial data website as it mainly concerns privacy protection for users of electronic communication services within the digital single market e.g. e-commerce activities and communications.

24. Pharmaceutical industry only publishes research that shows certain medicines are safe and effective. However, they will not publish clinical trial results that are less positive. How does EMA deal with this imbalance?

Evaluation of medicines

Firstly it should be clear that EMA and its scientific committees do not have to rely on published data for their assessments and regulatory actions (although they may use publications). Annex 1 Part 1, paragraph 7 of Directive 2001/83/EC requires MAHs to provide to EU regulators in their application dossier (to EMA for the centralised procedure and National Competent Authorities for national, mutual recognition or decentralised procedures) "(*7) All information, which is relevant to the evaluation of the medicinal product concerned, shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned pharmaco-toxicological or clinical test or trial relating to the medicinal product and/or completed trials concerning therapeutic indications not covered by the application*." This means that companies have to submit all available information to EMA, independent of whether this concerns published trial results or not.

Transparency of information on clinical trials

The Agency has actively contributed over the last years to an increased transparency in clinical trials in the EU, including publication of results, through implementation of legal requirements as well as by taking its own initiatives in this regard.

EMA's policy on publication of clinical data (Policy 0070)

The EMA's policy on publication of clinical data for medicinal products for human use (Policy 0070) was adopted in October 2014 (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf).

Under this policy, the Agency publishes the clinical data submitted by pharmaceutical companies to support their request for marketing authorisation via the centralised procedure, and which are assessed by the Committee for Human Medicinal Products (CHMP). Clinical data normally include:

- the clinical overview, providing a critical analysis of the clinical data in the submission package, including the conclusions and implications of the clinical data;
- the clinical summary, which provides a detailed factual summarisation of all the clinical information submitted;
- the study reports on the individual clinical studies, irrespective of where in the world those clinical trials are conducted;
- three appendices to the clinical study reports, namely the study protocol, the sample case report form used to record information on an individual patient, and documentation of the statistical methods used to analyse the data.

The policy allows the publication of the data after the EC decision on the marketing authorisation application (positive or negative). The same applies for withdrawn applications.

The EMA published its first clinical reports on Thursday 20 October 2016. On that day, the EMA became the first regulatory authority to give open access to all clinical data submitted by companies in support of their marketing authorisation applications. As of 20 October 2017 clinical reports on 50 medicines relating to 54 regulatory procedures including more than 3,000 documents have been published.

Current legal framework for clinical trials conducted in the EU

As of 21 July 2014, it became mandatory for sponsors to post clinical trial results in the European Clinical trials Database (EudraCT), managed by the European Medicines Agency (EMA). This date corresponded to the finalisation of the programming of the database as referred to in the European Commission guideline 2012/C 302/03 in application of the current clinical trials Directive 2001/20/EC and the Paediatric Regulation. Therefore, according to the current applicable legislation, sponsors are obliged to post results in EudraCT for interventional clinical trials conducted in EEA countries, as well as clinical trials conducted in third countries which are linked to European paediatric drug development. Sponsors have to post clinical trial results independently of the study outcome.

A subset of the data included in EudraCT is made available to the public in the European Union Clinical Trials Register (https://www.clinicaltrialsregister.eu/). The content and level of detail of these summary results is set out in the European Commission guideline and in its technical guidance. A typical set of summary results provides information on the objectives of a given study, explains how it was designed and gives its main results.

As of 20 December 2017, 9486 summary results are published in EU-CTR.

New Clinical Trial Regulation

The main objectives of the Clinical Trials Regulation (CTR) (Regulation EU No. 536/2014) include fostering innovation through simplification of the clinical trial authorisation process (in particular for multinational trials) and to increase transparency and availability of information on clinical trials and their results.

Under this Regulation the Agency shall, in collaboration with the member States and the Commission, set up and maintain a EU portal and a database.

The EU clinical trial portal and database will enable transparency of clinical trials, with at least one investigator site in the EU, from the point of their authorisation until the publication of their summary

results, and for those later included in a Marketing Authorisation application in the EU, the publication of the clinical study reports.

The Clinical Trial Regulation requires all information stored in the database to be publicly available, unless exempted under the Regulation to protect: personal data; commercially confidential information, in particular the marketing-authorisation status of the medicine, unless there is an overriding public interest; confidential communication between Member States in the preparation of their assessment; supervision of clinical trials by Member States.

More detailed information on the transparency rules which will be applicable, can be found in the "Appendix on disclosure rules to the Functional Specifications for the EUPD to be audited – EMA/42176/2014", which sets out the rules for the documents/data to be published and the timing for their publication, was adopted by the EMA MB on 2 October 2015. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/10/WC500195084.pdf.

25. Pharmaceutical companies are one of the stakeholders of EMA as they provide information. However, how does EMA respond when a pharmaceutical company exerts influence on its activities? To what extent does the Agency take the advice of independent stakeholders?

Interactions with pharmaceutical industry as stakeholder of the EMA are guided by a formal framework that rests on the principles of accountability, transparency and broad representation.

EMA routinely interacts with pharmaceutical companies through various channels

EMA also regularly discusses topics with industry representatives in the context of public health, including the implementation and operational impact of new legislation and scientific guidelines, procedural and/or organisational developments at EMA, including policies such as those on transparency and public access to information and the latest scientific advances in medicine.

The Corporate Stakeholders Department, set up in 2014, acts as a central contact point dedicated to consolidating, streamlining and coordinating EMA's relations and communication activities with pharmaceutical industry associations. The dedicated SME office, established in 2005, addresses the specific needs of smaller pharmaceutical companies, with the aim of promoting innovation and development of new human and veterinary medicines.

The framework for interaction with industry stakeholders formalises and structures interactions with pharmaceutical industry associations active in the human and veterinary medicines. The framework takes account of the general principles for stakeholder consultation outlined in the European Commission's staff working document on 'Better Regulation Guidelines', adopted in May 2015. EMA's Management Board endorsed the framework for interaction in October 2015. The framework is in line with EMA's overarching framework for stakeholder relations management, which the EMA Management Board adopted in June 2016.

In line with Good Administrative Behaviour practices, the EMA discusses internally any case where a pharmaceutical company exerts influence on its activities and decides on the appropriate mode of action. This can range from the application of the EMA code of conduct up to applying the Agency's anti-fraud strategy. The EMA is committed to ensuring that its staff, members of committees and all external contractors pursue the highest standards of honesty, propriety and integrity in the exercise of their duties and has a 'zero tolerance' approach to fraud.

Compliance with the Agency's policy on handling competing interests of scientific committees' members and experts continues to be pivotal to the Agency's accountability and governance for engagement with all of its stakeholders. The Agency takes care to ensure that its scientific experts do

not have any financial or other interests that could affect their impartiality. The policy allows the Agency to identify cases where the potential involvement of an expert as a member of a committee, working party, other group or in any other Agency activity needs to be restricted or excluded due to interests in the pharmaceutical industry.

The Agency screens each expert's declaration of interests (DoI) and assigns each DoI an interest level based on whether the expert has any interests, and whether these are direct or indirect. After assigning an interest level, the Agency uses the information provided to determine if an expert's involvement should be restricted or excluded in specific activities of the Agency, such as the evaluation of a particular medicine. It bases these decisions on the nature of the interests declared, the time since the interest occurred and the type of activity that the expert will be undertaking.

The current revised policy reflects a balanced approach to handling competing interests that aims to effectively restrict the involvement of experts with possible competing interests in the Agency's work while maintaining EMA's ability to access the best available expertise. Representatives of the pharmaceutical industry cannot be members of EMA's Management Board, be represented on any of EMA's seven scientific committees or their respective working parties.

26. Research has shown that unauthorised medicines are marketed within the EU. How is it possible that a pharmaceutical company could still market its product after a negative recommendation from EMA?[5]

Theoretically this could happen in two distinct scenarios:

- Following a negative Decision from a regulatory authority, a medicinal product is not covered by a marketing authorisation. However, the product might still be available at national level on a named-patient/compassionate use basis, in accordance with the relevant national legislation. Indeed the product might still be needed by individual patients and the medical doctor assisting the concerned patient would, under his/her responsibility, decide whether the relevant product would still be the right therapeutic choice for that individual, whether in the indication covered previously by the MA or in another indication that was never authorised;
- Following a decision from a regulatory authority to suspend or revoke a marketing authorisation, there may be a limited period (e.g. 6 months) to defer the entry into force of the decision or to allow a transitional time to switch patients to alternative treatments.

27. The pharmaceutical industry strives for short trials and fast market access. However, in 2014 EMA launched its pilot project 'Adaptive Pathways', trying to grant marketing authorisation of new medicines prior to the completion of the last test phase. This could result into risks for patients. Has the pilot project been evaluated yet? How does EMA view the potential health risks due to prior authorisation?[6]

The Agency would like to emphasise and reassure the discharge authority that the Adaptive Pathways (AP) concept does not change the standards for the evaluation of benefits and risks or the approach to 'uncertainty'.

[5] http://sargasso.nl/lange-arm-farmaceutische-industrie/

[6] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp&mid=WC0b01ac05807d58ce

The AP concept does not change the standards of regulatory approval or compromises patient safety. A marketing authorisation will only be granted if the balance of benefits and risks for a defined patient population is found to be positive; the same principles and legal tools apply to AP as for any other new medicine.

The aim of the AP concept is not to accelerate marketing authorisation, but rather to optimise the way medicines development will be planned to better meet the needs of patients with serious conditions for whom there may be no suitable treatments, and to ensure that patients can access approved medicines by generating an appropriate dataset.

This prospective approach is particularly emphasised as a necessary way to optimise the post-authorisation planning. Accordingly, good planning of post-authorisation data collection is seen as reinforcing, not weakening, the essential role of EMA in protecting patient's health.

The pilot was concluded at the end of 2017, following a public workshop, and a concluding report was published shortly thereafter (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/08/WC500211526.pdf).

The findings were that all of the proposals received for an Adaptive pathways discussion were in line with the current framework of scientific advice or parallel scientific advice with HTA bodies, including pharmacovigilance provisions.

28. Post-marketing studies are done by the pharmaceutical industry; however, the safety of a medicine could be jeopardised as data is treated as 'business secrets' and is, therefore, not transparent. This undermines the transparency of pharmacovigilance. Does EMA recognise this problem and does it have any recommendations in order to put health safety first?

EU Pharmacovigilance has high levels of transparency. This applies to post-authorisation safety studies and across the documents and data sources used in PV. Reports of suspected ADRs can be accessed in an anonymized form at http://www.adrreports.eu/ and clinical trials relevant to safety are more public than ever before (see: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000555.jsp&mid=WC0b01ac05809f363e).

Post-marketing studies may be conducted by the pharmaceutical industry, by regulators or by academic groups. The latter may initiate studies as part of their ongoing research interests, or following specific requests from regulators (http://www.encepp.eu/index.shtml). Regulators can themselves conduct some studies or engage academic networks to do so. In this light EMA has established the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP®)(http://www.encepp.eu/structure/index.shtml) which provide governance and scientific standards and guidelines for the conduct of safety studies by academic centres/networks or contract research organisations. In addition the Agency in conjunction with the EU Medicine Regulatory Network is exploring how real world data may be used in future, and this includes for safety studies.

With regard to industry studies, Directive 2010/84/EU (Article 22a) and Regulation (EU) No 1235/2010 (Article 10a) of 15 December 2010 allow national competent authorities and the Agency to impose an obligation on the marketing authorization holder to conduct a post-authorization safety study (PASS) if there are concerns about the risks of an authorized medicinal product. Regulators can also impose a post-authorization efficacy study (PAES) when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. Article 26(h) of the Regulation also impose an obligation on the Agency to make public the protocols and public abstracts of results of the post-authorization safety studies.

In annex III of the Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012, marketing authorization holders (MAHs) are required to provide in the final study report the date of the study registration in the electronic study register.

Recognising the importance of transparency for post-authorization studies conducted by pharmaceutical companies, the Agency introduced in Module VIII (Post-authorization safety studies) of the Good pharmacovigilance practice (GVP) recommendations to MAHs to register all PASS in the public European Union electronic Register of Post-Authorization Studies (EU PAS Register®). The same recommendation has been introduced for PAES in the Scientific guidance for post-authorization efficacy studies. In accordance with the legislation and the recommendations of the GVP, a procedure has been put in place at the Agency to ensure that all PASS imposed as a legal obligation are registered in the EU PAS Register and that the study protocol and the abstract of the study results are uploaded after finalization of the study.

The EU PAS Register is publicly accessible (http://www.encepp.eu/encepp_studies/indexRegister.shtml). As of 3 December 2017, a total of 1,206 studies have been registered, of which 115 are PASS imposed as an obligation by a regulatory authority to a MAH (the so-called RMP Category 1 and Category 2 studies) and 372 are PASS agreed between a regulatory authority and a MAH in the context of the risk management plan (RMP Category 3 studies).

The protocols and final study reports of the PASS imposed as a legal obligation are reviewed by the Pharmacovigilance Risk Assessment Committee (PRAC) and its assessment and conclusions are reflected in the PRAC Assessment report published on the Agency's website. PASS protocols and full study reports are also publicly available via the Agency's obligation to provide access to documents under Regulation (EC) No 1049/2001.

29. Both EMA and FDA (U.S. Food and Drug Administration) authorise marketing applications of medicines, resulting into a collaboration. However, this collaboration (cluster) is not as transparent as EMA's key aim states. Why is this cluster confidential?[7]

The EMA and FDA have currently more than 14 'clusters' on various topics (for example rare diseases, paediatrics, biosimilars). Some of the clusters include other regulators, such as from Japan, Canada, and Australia, with whom the EMA has a confidentiality arrangement. The main objective of clusters is to allow regulators' discussions, exchange of information and work towards scientific convergence, at a time when the data are still considered commercially confidential. EMA is mindful of the provisions of Article 39(3) of the TRIPS Agreement,[1] which provides that "*Members, when requiring, as a condition of approving the marketing of pharmaceutical* […] *products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use*" (emphasis added).

Based on Article 39(3) of the TRIPS Agreement, which binds all EU institutions and bodies, such data may be shared with other regulatory authorities in the interest of public health, as long as steps are taken to protect the data. To that end, a Confidentiality Arrangement has been concluded between EMA and FDA, enabling thereby the exchange of such data. However, the further disclosure of such data to third parties is precluded.[2]

[7] *http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/09/news_detail_002609.jsp&mid=WC0b01ac058004d5c1*

[1] Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO) (OJ 1994 L 336, p. 214).

[2] For more information on the Confidentiality Arrangement between EMA and FDA, see: http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000651.jsp&mid=WC0b01ac0580a51ff3 (last visited on 12 December 2017).

30. CHMP authorises medicines' application; however, the committee gives scientific advice to companies, helping them during the researches, which the CHMP has to judge itself as well. Moreover, the committee has to appeal against its own objections. How does EMA evaluate this procedure and potential conflicts of interests?[8]

In accordance with its legal mandate, the Agency through its scientific committees is responsible for the scientific evaluation of applications for marketing authorisation based on data, as well as the provision of advice on the prospective planning of evidence generation plans. This occurs in the context of strongly regulated processes to ensure objectivity and avoid bias. it is important that patients and the public are properly informed and can understand the benefits that these processes bring.

The objective of scientific advice (SA) is to support sponsors in creating a development program that is likely to generate adequate data for the regulatory benefit–risk assessment at the time of marketing authorization application (MAA). Thus the SA given should as far as possible reflect the evidentiary standards that the CHMP will apply by the time of MAA. This is important for the following reasons:

- Ensuring that the clinical trials in which patients take part are appropriately designed to provide robust and useful data as part of an optimised development plan hence avoiding exposing patients to useless or less useful clinical trials. It should be noted that in 67% of all SA procedures the development plan proposed by the company is deemed not acceptable by EMA experts.
- Helping developers (especially newer and smaller companies as well as academia) understand regulatory requirements and select the most appropriate regulatory pathway.
- Increasingly, providing a platform to include other parties involved in the access to patients, particularly HTA bodies and payers.
- Ultimately helping to provide patients with the timely access that they rightly demand to new, safe and effective medicines, with specific focus on areas of unmet medical needs where no treatments are available. Early dialogue with medicine developers through scientific advice increases the likelihood that a medicine will be developed in a way that generates the evidence we need to properly evaluate its benefits and risks.

The scientific evaluation of a new drug for marketing authorisation is later performed on the basis of an overall benefit–risk assessment that is established by the CHMP following the assessment of the relevant scientific data. In this context the data evaluation process is not bound by scientific advice recommendations on the methodology to generate such data. This is reflected by the fact that not all development programs that comply with SA concerning clinical trial design are successful (16% failure rate), and vice versa, 43% of the development programmes that do not comply with SA concerning clinical trial design are still successful in achieving a marketing authorisation.

The potential public perception of bias is a concern which the Agency has always taken extremely seriously. The Agency has strong links with civil society, embedded in its day-to-day functioning and its governing structure. Moreover all the SA responses are becoming accessible once Marketing

[8] *https://www.ftm.nl/artikelen/european-medicines-agency-is-te-afhankelijk-van-de-farmaceutische-industrie?share=1*

Authorisation of the product has been granted. Important also in this context the transparency provided through the publicly available assessment report for the new medicines following the scientific evaluation of the MAA, which provides information on the scientific advice received for the respective development.

On conflict of interest it is important to stress that the Agency has robust and rigorous assessment processes in place, which aims at avoiding plain reproduction of the initial advice into the final decision. No single person has the final say on a medicine's approval. Our Committees issue scientific recommendations based on extensive peer-review and discussions amongst approximately 30 committee members. The assessment is also supported by a wide range of independent experts, including patients, from around the EU.

31. The three requirements for marketing authorisation are safety, efficacy and quality. However, the latter does not cover quality of life. The majority of new medicines entering the market between 2009 and 2013 were approved without clear evidence of improvement of the quality of patients' lives. Even after a minimum of 3,3 years there was still no evidence. Why does quality of life not count as one of the requirements for marketing authorisation?[9]

When used as requirement of marketing authorisation the term quality refers to pharmaceutical quality of the medicine and therefore consists of the physiochemical characteristics of the product and its manufacturing. On the other hand when referring to "quality" in the context of quality of life, it needs to be clarifies that these aspects are part of the elements that compose the efficacy of medicine and therefore are part of the assessment of the benefit risk when appropriate. The benefit of the product on patient's lives is always considered in the context of the discussions on efficacy and constitutes an integral part of the benefit risk assessment. The agency has worked in this field in order to integrate quality of life measurements or patient reported outcomes in several guidelines on medicines development and currently has also a general Reflection paper on the regulatory guidance for the use of health related quality of life (HRQL) measures in the evaluation of medicinal products (EMEA/CHMP/EWP/139391/2004).

In relation to the paper published by the BMJ the EMA would like to emphasise that its evaluations of cancer medicines take into account a wide range of measures, including overall survival, quality of life measures, progression-free survival (where the cancer does not get worse over a certain period), response rate (where a patient's tumour may shrink) and duration of response. Although not all such measures are directly linked to increased longevity, they are, in many cases, important indicators of how patients might benefit from treatment. EMA regularly consults its cancer experts to make sure that these measures, when used a basis for approval, are meaningful for the patients concerned. Restricting approvals of cancer medicines to situations where there is indisputable evidence of improvement in overall survival or quality of life will not improve the outlook for cancer patients in the EU. On the contrary, such an approach may delay early access to effective medicines for patients in urgent need.

32. Due to the Brexit, EMA has to relocate. As EMA has employees who are same-sex couples the problem occurs that not every Member State recognises same-sex marriages or partnerships. What

[9] *http://www.bmj.com/content/bmj/359/bmj.j4530.full.pdf*
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000173.jsp&mid=WC0b01ac058002d89a

is the Agency's response to this? How does EMA protect its employees by relocation to one of these Member States?[10]

As an EU Agency the staff are employed under the Conditions of Employment of Other Servants of the European Union, CEOS. In CEOS article 1d it is clearly stated that the application of these Staff Regulations, any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age, or sexual orientation shall be prohibited. It further states that for the purpose of these Staff Regulations, non-married partnerships shall be treated as marriage provided that the couple produces a legal document recognising the registration as a stable non-marital partner by a Member State. It does not require the registration to be made in the Member State where the Agency has its seat, present or future. By this reassurance all staff members can be assured of equal treatment by EMA as an employer.

Should the Agency have relocated to a Member State where the societal structure would limit the freedom of its employees with constitutional ban or no recognition of same-sex marriage the Agency would have needed to seek reassurance from that Member State that discrimination would not occur of its staff for full participation as a full worthy citizen for themselves and their families in the new location of the Agency. Based on the decision by the Council of Europe on the 20th November 2017 to relocate EMA to the Netherlands this action shall not be needed.

33. EMA revised its "handling of declarations of interests of scientific committees' members and experts" policy. Stated in the discharge of 2015, the Agency was requested to provide Parliament with a summary of the impact assessment on the revised policy. Did EMA respond to this request and if so, how?[11]

The EMA provided the following reply to the Discharge Authority on measures taken in light of the European Parliament's recommends in the Discharge 2015.

The main change in the October 2016 revision of the Agency's policy on handling competing interests of scientific committees' members and experts consisted of increased restrictions applied in case of close family members of committees and working parties with interests in a pharmaceutical company. The implementation of this change resulted in 19 members and alternates of the human scientific committees (CHMP, PRAC, CAT, PDCO, COMP, HMPC – total number of members and alternates: 354) to become subject to more restrictions compared to the previous version of the policy. However, this had no major impact on the functioning of these committees.

In 2016, 7 experts (2 committee members, 4 working party members, 1 expert) informed the Agency on their intention to become an employee in a pharmaceutical company. In line with the revised policy, those members were immediately fully restricted from further involvement in any Agency activity.

34. Also, EMA was requested to create a report, outlining the pilot project 'Adaptive Pathways' and the measures to ensure it does not undermine the safety of medicines. Was this report published yet and if so, was it transmitted to Parliament as requested?[12]

[10] *https://euobserver.com/lgbti/139678*

[11] Discharge 2015: European Medicines Agency Annual Activity Report 2016, p. 98

[12] Discharge 2015: European Medicines Agency

The pilot project was concluded at the end of 2017, following a public workshop, and a concluding report was published shortly thereafter (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2016/08/WC500211526.pdf).

A link to this report was included in the “EMA report on the follow-up to the 2015 Discharge”, which was transmitted to the European Parliament in October 2017 (as per Art. 110(2) of the Framework Financial Regulation).

EMCDDA

Replies to written questions

EMCDDA

35. The Commission's Internal Audit Service highlighted a strong need to improve the Centre's management of IT systems. The IAS concluded in particular that the process to manage system requirements is inadequate. What is the state of play of the implementation of the plan to take corrective action?

EMCDDA's reply:

The measures aimed at aligning IT projects with the EMCDDA business needs, as foreseen in the action plan, reached an advanced stage of progress: by the end of 2017, the ICT 2020 strategy has been finalised; moreover, the Enterprise Architecture Framework has been defined in 2017, to be prepared for implementation in 2018 and integrated into the ICT strategy; finally, project management best practices have been and continue to be disseminated across the EMCDDA.

The agency's new project management methodology has been adopted in 2017. Tailoring and implementing such methodology to the agency's business needs is an endeavour to be completed by mid-2018. Automation of the respective processes will be made compatible with the new project management methodology throughout 2018.

Definition and adoption of a business requirements management process will be achieved by the end of 2018 and will build also on the implementation of the measures described in the paragraphs above. To be noted that the selected project management platform already foresees requirements management artefacts as part of the management process. Definition and adoption of a systems development methodology will be pursued along basically the same lines, it being expected that completion will also occur by the end of 2018.

ENISA

Replies to written questions

CONT questionnaire for the decentralised Agencies 2016 discharge

ENISA

Question:

According to the European court of Auditors, it is likely that costs could be reduced if all staff were centralised in one location. In 2016 and 2017 several staff members requested to move to Athens, due to the constraints of the Heraklion location. Do you expect further such requests? Did you take steps in order to initiate the amendment of the basic regulation, which provides that administrative staff should be based in Heraklion?

Answer:

Actually, only 9 staff members are remaining in Heraklion location. Some staff members already showed interest to be relocated to Athens for the year 2018.

During the negotiations for the Agency's new mandate, the Agency took the necessary steps to suggest the change of the location of the Headquarters of ENISA from Heraklion to Athens and therefore stop the Agency's presence in Heraklion.

The European Commission proposal for a new mandate COM(2017) 477 final underlined this point on the result of Ex-post evaluations, stating that regarding efficiency , one of the main challenges to the Agency's efficiency relates to ENISA's difficulties in recruiting and retaining highly qualified experts. The findings show that this can be explained by a combination of factors, including the general difficulties across the public sector to compete with the private sector when trying to hire highly specialised experts, the type of contracts (fixed term) that the Agency could mostly offer and the somewhat low level of attractiveness related to ENISA's location, for example linked to difficulties encountered by spouses to find work. A location split between Athens and Heraklion required additional efforts of coordination and generated additional costs, but the move to Athens in 2013 of the core operations department increased the Agency's operational efficiency.

The final decision on ENISA's location is based on the framework of Decision 2004/97/EC, Euratom, adopted at the meeting of the European Council on 13 December 2003. The representatives of the Member States decided that ENISA would have its seat in a town in Greece to be determined by the Greek Government. The Agency's host Member State should ensure the best possible conditions for the smooth and efficient operation of the Agency. It is imperative for the proper and efficient performance of its tasks, for staff recruitment and retention and to enhance the efficiency of networking activities that the Agency be based in an appropriate location, among other things providing appropriate transport connections and facilities for spouses and children accompanying members of staff of the Agency. The necessary arrangements should be laid down in agreement between the Agency and the host Member State concluded after obtaining the approval of the Management Board of the Agency.

Therefore, the proposal for the regulation of the European Parliament and of the Council on ENISA, the "EU Cybersecurity Agency" states in Chapter V General Provisions Article 41 on Headquarters Agreement and operating conditions:

1. The necessary arrangements concerning the accommodation to be provided for the Agency in the host Member State and the facilities to be made available by that Member State together with the specific rules applicable in the host Member State to the Executive Director, members of the Management Board, Agency staff and members of

their families shall be laid down in a Headquarters Agreement between the Agency and the Member State where the seat is located, concluded after obtaining the approval of the Management Board and no later than (2 years after the entry into force of this Regulation).

2. The Agency host Member State shall provide the best possible conditions to ensure the proper functioning of the Agency, including accessibility of the location, the existence of adequate education facilities for the children of staff members, appropriate access to the labour market, social security and medical care for both children and spouses

EUROJUST

Replies to written questions

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MEP Dr Ingeborg Grässle

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The Hague, 5 January 2018
01/2018/AD

2016 Discharge of the EU decentralised Agencies: Written Questions to the Agencies, Eurojust reply
Hearing on 22 January 2018

Dear Dr Grässle,

Eurojust would like to provide to the discharge authority with the following reply to the written question addressed to Eurojust:

Question:

" 37. Eurojust states in its Annual Activity Report 2016 that due to the rise of cross-border crime the demand for the Agency's assistance increased by 4%. How did the Agency deal with this increased demand, especially taking into account that Eurojust's pursuit for efficiency lead to a decrease of budgetary and human resources?"

Eurojust reply:

"In the year 2016 the number of cases grew by 4% from 2.214 to 2.306 requests for assistance by Eurojust. With regard to budgetary and human resources, Eurojust was able to absorb this increase in 2016. In the year 2017 the number of cases increased further to 2.550 cases, while at the same time the number of Eurojust Coordination Meetings and Coordination Centres related to these cases increased substantially, so that Eurojust is currently analysing if additional requirements in terms of budgetary and human resources would need to be brought to the attention of the budgetary authority for consideration."

Yours sincerely,

P.P.

Nick Panagiotopoulos
Administrative Director

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EUROPOL

Replies to written questions

The Hague, 9 January 2018
939599v4A

Discharge proceedings by the European Parliament (EP) on the implementation of the budget for the financial year 2016

Europol's answers to the specific questions by the Budgetary Control (CONT) Committee of the European Parliament:

1. *"In its Special Report on the hotspots, the European Court of Auditors calls for better co-operation between the European Commission, EASO, Europol, FRONTEX, National Authorities and other International Organisations in order to better co-ordinate their support to the hotspots. What steps have been taken by Europol in this respect?"*

Europol's answer:

- The field work of the audit activities in relation to the Special Report "EU Response to the refugee crisis: The 'hotspot' approach" of the European Court of Auditors (ECA), concerning which Europol was duly involved, took place in Q2-Q3 2016.
- In Q1 2016, Europol launched its on-the-spot support to the migration 'hotspot' related activities, operated by the competent authorities in Greece and in Italy, as well as other involved national authorities of EU Member States (MS) and EU agencies.

  Europol's main operational objectives were to support, in particular, (the):
  - Security of the EU's external borders, in particular by providing secondary security checks (including cross-checks against Europol's databases);
  - Operational cooperation between the concerned authorities, services and EU agencies (in particular with Frontex);
  - Acquisition and exchange of information, including from forensic support activities (for sharing resulting information with EU MS and relevant partners through Europol's capabilities and Member States' competent authorities);
  - Identification of and response to terrorist and criminal threats (including activities of suspicious individuals).

  The delivery of the operational objectives relied on the development of a 'Guest Officers' Concept and subsequent deployment from a pool of Seconded National Experts (SNEs) by EU MS (referred to as Europol 'Guest Officers' – GOs). For this purpose, a dedicated deployment management team was set up at Europol.

  Greece: Since March 2016, Europol staff was present in the EU Regional Task Force (RTF) in Piraeus/Greece, as well as in the migration hotspots on the islands of Lesvos, Samos, Chios, and Leros (and in Kos as of August 2016). Since September 2016, Europol provided support to the Greek authorities, with the additional frontline deployment of the Europol GOs.

  Italy: As of April 2016, Europol staff supported the Italian authorities in the EU RTF in Catania (Sicily)/Italy. In October 2016, two Italian SNEs were deployed from Europol to Catania, to help prepare forthcoming deployments of GOs in Italy and to further assist with the coordination of operational activities at the EU RTF. By the end of January 2017, Europol started deploying GOs to 2 Italian migration 'hotspots', namely Pozzallo and Trapani in Sicily. Additional deployments of GOs to Agrigento/Lampedusa and Taranto commenced at the end of March 2017.
- **On-the-spot coordination and operational cooperation** between **Europol**, the competent national authorities, as well as the **EU agencies (Frontex, EASO)** takes place on a **continuous basis** (e.g. meetings, exchange of information etc.).
- In line with Europol's operational plan for the support activities in migration 'hotspots', and as per the mandate endorsed by the Management Board of Europol in Q1 2017, the implementation of Europol's aforementioned operational objectives, in particular regarding the Europol 'Guest Officers' Concept, was reviewed in **Q2-Q3 2017** by a **dedicated evaluation** team, consisting of representatives from EU MS, the European Commission, the concerned internal Europol teams and the Internal Audit Capability (IAC) of Europol. Relevant stakeholders, including Frontex and EASO, were involved in the evaluation exercise.

  The aspect of coherence of the different stakeholders on-the-spot – as also referred to in the ECA's Special Report "EU Response to the refugee crisis: The 'hotspot' approach" – was as-

sessed during the evaluation. The findings of the **evaluation report** were presented to the Management Board of Europol in **December 2017**, which endorsed the related recommendations on the way forward.

The evaluation report concluded that *"... **good cooperation** exists **among all parties active at the hotspots**. Distinct roles are **clearly defined** and **complement each other**. **No duplications are perceived**. GOs add value to the activities of the hotspot by offering specific, specialised services not provided by other entities involved. ..."* (emphasis added in the quoted text).

In order to maintain the good level of cooperation, the evaluation report contains the recommendation for Europol GOs to organise training or awareness sessions with local authorities, Frontex and EASO about their role and (counter terrorism) related activities. In addition, with a view to exploiting opportunities for improvement, the evaluation report concludes that Europol (with the involvement of relevant actors) should carry out a review of the information exchange process between host states (Greece and Italy), Europol, Frontex, EASO and other EU MS to optimise the information flow further. The implementation of both aforementioned recommendations is ongoing.

2. *"As Europol outlines in its Annual Activity Report[1], the Agency had to adapt a new structure to the new Europol Strategy 2016-2020; this resulted into a reorganisation of the Operations Department. Could Europol comment on the outcome? Why was this reorganisation required? What happened with the employees during this reorganisation?"*

Europol's answer:

a) Context for changing Europol's core business organisational structure

Europol Strategy

Against the background of the developments in cybercrime, trends in serious organised crime, criminal activities associated with the migration flows towards the European Union, as well as the unprecedented terrorist threat impacting Europe, the Management Board of Europol approved a new **Europol Strategy 2016–2020**[2], shaping the **Europol Values** of **Service**, **Integrity**, **Accountability**, **Initiative** and **Teamwork** through 3 distinct **Goals**:

- Goal 1: Europol will be the EU criminal information hub, providing information sharing capabilities to law enforcement authorities in the Member States.
- Goal 2: Europol will provide the most effective operational support and expertise to Member States investigations by developing and employing a comprehensive portfolio of services.
- Goal 3: Europol will be an efficient organisation with effective governance arrangements and a positive reputation.

Ever-increasing demand for Europol's services

Europol's role as the EU criminal information hub and leading operational support centre across the EU Justice and Home Affairs area is characterised by the following exemplary figures:

- **66% increase** of the **volume of messages** exchanged by Member States, operational cooperation partners and Europol through **SIENA**[3] over the **last 3 years**[4], including an almost **twofold increase** of **new cases** initiated during 2015-2017[5].
- **A more than 4-times increase** of the **data objects in the Europol Information System (EIS)**, next to **more than 6 times** of **searches in the EIS**, over the **last 3 years**[6].
- A **doubling of the demand** for Europol's **support to operations** overall, and **on-the-spot (mobile office deployments)**[7] in the **last 3 years**[8], and in **2017**, **more than twice**

[1] Europol – Consolidated Annual Activity Report (CAAR) 2016, Europol file no. 877774v7A, page 38
Published on: https://www.europol.europa.eu/publications-documents/consolidated-annual-activity-reports
[2] Europol Strategy 2016 – 2020, Europol file no. 796794
Published on: https://www.europol.europa.eu/publications-documents/europol-strategy-2016-2020
[3] Secure Information Exchange Network Application: SIENA
[4] Considering the results by the end of 2014 as a baseline: 1,005,610 messages in SIENA by the end of 2017, 605,245 by the end of 2014 (+66% over 2015-2017, reported figures for 2014 and 2017 represent annual results)
[5] Considering the results by the end of 2014 as a baseline: 66,113 new cases initiated by the end of 2017, 34,472 by the end of 2014 (+92% over 2015-2017, reported figures for 2014 and 2017 represent annual results)
[6] Considering the results by the end of 2014 as a baseline: 1,062,236 data objects in the EIS by the end of 2017, 236,606 by the end of 2014; 2,478,825 searches in the EIS by the end of 2017, 390,914 by the end of 2014 (reported figures for 2014 and 2017 represent annual results)
[7] Considering the results by the end of 2014 as a baseline: 292 mobile office deployments by the end of Q3 2017, 146 by the end of 2014 (reported figures for 2014 and 2017 represent annual results)

as many operations were supported in the area of **counter terrorism**, compared with 2016[9].

b) Rationale and outcome of Europol's core business organisational structure in 2016

Against the background of Europol Strategy 2016-2020 and in light of the rapidly increasing demand for Europol's services, Europol strengthened its operational capabilities by redesigning its response to terrorism and serious and organised crime. While the European Cybercrime Centre (EC3) was stablished in 2013, the following changes to Europol's core business environment were launched in 2016:

- Launch of the **European Counter Terrorism Centre (ECTC)**, to support an enhanced response against counter terrorism related threats across EU Member States, including the **EU Internet Referral Unit (IRU)** to counter radicalisation online;
- Establishment of the **European Migrant Smuggling Centre (EMSC)**, combined with on-the-spot deployments in Greece and Italy, to support action against organised criminal activities and to perform secondary security checks within the framework of the 'Guest Officers' Concept and in coordination with the ECTC – please refer to the answer to Question 1, in addition);
- Introduction of a **24/7 Front Office** (as an Information Hub Centre and Operational Support Service capability), including enhanced information processing procedure, in particular to support live investigations across Member States (increase of on-the-spot deployments by Europol, requiring full– and real–time support delivery from Europol), Joint Action Days (JADs) and to process contributions to Europol's Analysis Projects (APs) more efficiently;
- Establishment of a **Horizontal Operational Services** capability, providing, inter alia, financial support services (Financial Intelligence Unit – FIU.Net), special tactics (e.g. EU Most Wanted List – with 42 high-profile fugitives being arrested[10]), financial (grant) support to operational activities in MS, a common service for the MS and third party Liaison community based at and seconded by Europol, the further development and management of the 'Guest Officers' Concept (deployment to migration hotspots in Greece and Italy), as well as common standards in analysis etc.);

c) Impact on staff

Relevant staff members were re-assigned within the core business area and respective job descriptions were adjusted where required. In Q3 2017, an **independent staff survey** was conducted, showing an overall significant improvement, compared with the results from the previous staff survey (from 2014). The **'sense of belonging to the organisation' received a 76% favourable rating** (+10%), followed by the aspect of 'accountability' at Europol, rated by 70% as favourable (+11%), and job satisfaction with 69% (+4%).

Europol's assessment, therefore, is that the changes to the core business structure complemented the positive effects noted in the 2017 staff survey.

3. *"An ineffective first-line information exchange is the outcome of an operational information backlog and not meeting the target response time to Member States' requests. How is this possible? What measures has Europol taken to reduce the response time?"*

Europol's answer:

Europol's performance reported in the Consolidated Annual Activity Report (CAAR) 2016 for the objective "Provide effective and immediate first-line information exchange"[11] should be considered in the context of the **substantial increase of the volume and demand for Europol's services** (please refer to the statistical information provided under Question 2 a) above), which was mitigated, only to a certain extent, by the overall staff increase of 12% in 2016[12].

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[8] Considering results by the end of 2014 as a baseline: 1,151 supported operations by the end of Q3 2017, 632 by the end of 2014 (reported figures for 2014 and 2017 represent annual results)

[9] 279 supported counter terrorism operations by the end of Q3 2017, 127 by the end of 2016

[10] EU Most Wanted website launched in 2016 (Christmas 2016 campaign etc.): 115 fugitives published, 41 high-profile fugitive arrests, including 13 arrests due to the launch of the website, with tips from citizens etc.). On 14 December 2017, Europol published a press release on the arrest of Romania's most wanted fugitive in Buenos Aires/Argentina, constituting the 42nd high-profile arrest that appeared on the EU Most Wanted Platform.

[11] Europol – Consolidated Annual Activity Report (CAAR) 2016, Europol file no. 877774v7A, pages 15, 20–22

[12] Europol – Consolidated Annual Activity Report (CAAR) 2016, Europol file no. 877774v7A, page 71

Europol provides effective first line information exchange, and is satisfied that the following **additional measures** have led to **significant improvements**, after the reporting period of the CAAR 2016:

- **Reduction** of the backlog of processing contributions in full in the Analysis Projects (APs) from **10,096 by the end of 2016** to, on average, **6,376 in 2017**, which is within the target of 6,500 messages for 2017 (it should be noted that the backlog of processing contributions in full in the APs does not affect the cross-matching of all information when being sent to Europol).
- The re-organisation of the core business structure, including the launch of the **24/7 Front Office** in Q4 2016, led to a **more efficient processing of operational information**. While the overall first-line response to MS' requests was given within 27.5 days by the end of 2016, this has been further reduced in 2017 to **11.3 days**, and **20.3 days on average across** the year **2017**[13].
- Introduction of a new data processing procedure, supported by a new case management tool, with a view to managing prioritised cases more efficiently. Europol's **24/7 Front Office** performs an **assessment of all incoming messages to Europol within 2 hours**, with all urgent messages, especially those with a short deadline, being identified and responded to accordingly.

[13] As per internal performance reporting by the end of Q3 2017

FRONTEX

Replies to written questions

FRONTEX
EUROPEAN BORDER AND COAST GUARD AGENCY

...../01/2018
Reg. No 135/2018
Ref:
<CGO>/<FCS>/<SAKL>/<2018>

2016 Discharge of the EU decentralised agencies

WRITTEN QUESTIONS TO THE AGENCIES
Hearing on 22 January 2018

Frontex replies

Frontex - European Border and Coast Guard Agency
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FRONTEX

1. **The ECA notes in paragraph 18 of its report that the Agency recruited 14 staff at higher grades than the Staff Regulations would allow in case of an external selection procedure. While understanding that Agency would like to attract qualified and experienced candidates, how can you explain this deviation from the rules? The situation is worrying, if we take into account that following the extension of its mandate the Agency's staff will more than double from 2016 to 2020 and a lot of new recruitment procedures have to be launched.**

Frontex took note of the remarks made by ECA. Indeed, in the previous years the recruitment for certain posts in the AST function group went beyond the AST4 level. The main reasons were the specific labour conditions, namely the constantly low correction coefficient in Poland (compared to the conditions in the majority of other EU countries) resulting in consequently lower interest of qualified candidates from among nationals of certain EU Member States and balancing the geographical distribution. The issue at stake was also the level of qualifications of potential candidates originating from law enforcement field which is very important for different Agency's activities. Usually, such candidates possess significant professional experience but lack the required education diplomas (at university level) and thus do not qualify for the function group AD. The AST4 level (maximum allowed by the Staff Regulations) did not seem to be sufficiently appealing for many qualified candidates to apply for a job in Frontex.

Looking at the last paragraph of Article 31.2 of Staff Regulations ('…To address specific needs of the institutions, labour market conditions prevailing in the Union may also be taken into account when recruiting officials…', Frontex took an inspiration to allocate higher grades in AST functions group. This was fully reflected in the establishment plans (being integral part of the budget) and was never questioned by the budgetary or other authorities of the EU.

Anyway, Frontex already took two steps in order to comply with the ECA recommendation (and the limits imposed by the Staff Regulation):

(1) Frontex has stopped publishing any external selection procedures at grades higher than AST4 already in March 2016.

(2) Since March 2017, Frontex is not appointing any external candidates for grades higher than AST4. The last such an appointment was made in February 2017.

Since that time, no job offers were made for candidates at levels higher than allowed by Article 31 of the Staff Regulations.

This approach is intended to continue while running recruitment processes and requesting new posts in future establishment plans. However, we shall stress that the issue of the low correction coefficient for Poland (the lowest one among all the EU Agencies) remains a significant problem for recruitment of new staff (and of retaining the current staff) and is in fact the major challenge on Frontex path to have more than 1000 qualified staff (with diverse geographical balance) at the end of 2020.

2. **Could you explain further on the relation between FRONTEX and the five joint operations at the sea borders? What are the operative goals and tasks of these operations? What actions are being undertaken as part of these operations? Do you cooperate with other players, such as NGOs and authorities from third countries, and with whom? How does the cooperation with EASO work?**

JO POSEIDON 2017 / TRITON 2017 / INDALO 2017 / HERA 2017

The operational aim of the JOs was to provide increased technical and operational assistance to the host MS regarding the control of the external borders coordinating the operational activities at the external sea borders to control irregular migration flows, to tackle cross border crime and to enhance European cooperation on coast guard functions.

The operational aim was implemented in full compliance with the relevant EU and international law, guaranteeing the protection of the fundamental rights in particular the access to international protection and the compliance with the principle of non refoulement and taking into account the recommendations of the Frontex Consultative Forum and the reports and observations of the Fundamental Rights Officer.

Operational goals:

- Enhance border security
- Technical and operational assistance in SAR

- Support MS on carrying out coast guard functions
- Enhance operational cooperation
- Support to migration management
- Enhance collection and exchange of information, including personal data
- Identify possible risks and threats
- Establish and exchange best practices

Operational tasks:

- Supporting SAR operations
- Border surveillance
- Border checks at border crossing points (POSEIDON)
- Preventing and detecting cross-border crime such as migrant smuggling, trafficking in human beings, terrorism and other crime
- Supporting screening, fingerprinting, registration and documents checks of migrants (POSEIDON/TRITON)
- Information gathering through the debriefing activities for risk analysis and combating cross-border crime purposes, including personal data
- Supporting the implementation of the Readmission activity (POSEIDON)
- Supporting the identification of special needs of children, unaccompanied minors, persons with disabilities, victims of trafficking in human beings, persons in need of medical assistance, persons in need of international protection, and other persons in a particularly vulnerable situation
- Refer and provide initial information to persons who are in need of, or wish to apply for, international protection
- Provide a clear and updated situational picture related to the JO
- Carry out daily and ad-hoc exchange of information between Frontex, all operational actors and external stakeholders involved
- Share experiences and exchange expertise
- Facilitate the cooperation with Union agencies, bodies or international organizations, and Third Countries.

Cooperation with Third countries:

JO POSEIDON
In the framework of the existing Working Arrangements (WA) between Frontex and respective Third countries (TC) and pursuant to legal framework, Frontex could invite border guard/police officers from TC to be deployed as observers (Georgia, Moldova and Ukraine in 2017) in the ICC/LCC, after the prior consultation and agreement of the hosting authorities.

The operational cooperation with Turkey included exchange of information through the respective operational coordination/ rescue centres.

Based on the role of the Frontex Liaison Officer (LO) in Ankara and in the frame of his mandate, LO received information from the Agency which can be shared with the Turkish Coast Guard in order to facilitate the latter's capacity to combat against smuggling of migrants within Turkish territorial waters. The type of information to be shared to Turkish authorities is a subject to prior consultation with the Host Ms.

In case Frontex LO received information from the Turkish authorities which was relevant for the implementation of the present JO, such information could be shared with the host MS with the view to increase the capacity to achieve the operational objectives, when agreed by respective Turkish authorities.

In addition, LO received general information related to the operational activities via regular reports and was immediately informed by the Agency for any abnormal event that might have consequences in the conduct of operational activities or may affect Frontex cooperation with the Turkish authorities.

JO INDALO/ HERA
A Moroccan Liaison Officer (LO) was regularly deployed within the ICC of the JO in the frame of bilateral agreement between Spain and Morocco.

JO HERA
LCC Dakar was established in the Spanish Embassy where representatives of both Spanish authorities Cuerpo Nacional de Policia (CNP) and Guardia Civil (GC) worked together.
In addition, the exchange of information between the Liaison Officers of Senegal, Mauritania, Morocco and RCC Las Palmas (Canaries Island) was done in the framework of bilateral cooperation between aforementioned Third Countries and Spain.

JO MINERVA 2017:

Operational goals:

- Enhance border security
- Enhance operational cooperation
- Enhance exchange of information
- Identify possible risks and threats
- Establish and exchange best practices
- Guarantee the protection and compliance with fundamental rights in activities encompassed by the JO

Operational tasks:

- Provide support to Spanish authorities by enhancing border checks at designated border crossing points in deploying First-line Officers, Advanced-Level Document Officers and Stolen Vehicles Detection Officers to:
    - carry out border checks on persons crossing the borders in the ports of Algeciras and Tarifa, including their means of transport and objects in their possession; and to carry out identity checks on persons in the port of Ceuta according to the Article 41 of the SBC;
    - carry out search for human beings hidden in any transportation means in the ports of Algeciras, Ceuta and Tarifa by deployed Dog Teams;
- Support debriefing activities in order to collect information for risk analysis purposes;
- Support debriefing activities by deploying Joint Debriefing Teams in order to collect information for risk analysis purposes including personal data in line with the Frontex legal mandate;
- Share experiences and exchange expertise as well as constantly update knowledge on the irregular migration trends in order to adopt countermeasures to tackle the phenomena;
- Collect and assess information in order to improve the detection of human smuggling and trafficking in human beings facilitation by individuals and/or criminal networks and assist wherever possible identification of facilitators;
- Provide with a clear and updated situational picture concerning the operational areas, modus operandi, main trends and possible rapid changes in this respect;
- Carry out daily and ad-hoc exchange of information between Frontex and all operational actors and structures involved;
- Facilitate cooperation with E.U. agencies and bodies or international organizations, and Third Countries;
- Support identification of persons in vulnerable situation including those in need of international protection or asylum;
- Referral of persons in vulnerable situation including those in need of international protection or asylum to the Officers of the host MS to be further directed to the competent national authorities for appropriate assistance;
- Share expertise and best practices related to strengthening the rights of persons in vulnerable situation in the performance of border guard tasks;
- Provide guidance through trainings, briefings, observations and recommendations on fundamental rights matters during operational activities, including information on the complaints mechanism.

JO FOCAL POINTS SEA 2017(mentioned to complete the number of operations at the sea border):

Operational goals:

- Enhance border security
- Enhance operational cooperation
- Enhance exchange of information
- Identify possible risks and threats
- Establish and exchange best practices

Operational tasks:

- Enhance border checks at designated border crossing points (BCP);
- Carry out search for human beings hidden in transportation means at designated ports;
- Detect networks of smuggling of goods (stolen vehicles, cigarettes, drugs etc.)
- Share experiences, best practice and exchange expertise as well as to constantly update knowledge on the irregular migration trends in order to adopt countermeasures to tackle the phenomena;

- Collect and assess information in order to improve the detection of human smuggling and trafficking in human beings facilitation by individuals and/or criminal networks and assist wherever possible identification of facilitators;
- Provide with a clear and updated situational picture concerning the operational areas, modus operandi, main trends and possible rapid changes in this respect;
- Carry out daily and ad-hoc exchange of information between Frontex and all operational actors and structures involved;
- Promote the inter-agency cooperation and cooperation with Union agencies and bodies or international organizations, and Third Countries;

Cooperation with Third Countries in JO Minerva and FP Sea:

In the framework of the existing Working Arrangements between Frontex and the competent authorities of relevant third countries and pursuant to legal framework, Frontex invited border guards/police officers from 3rd countries (Georgia and Ukraine in 2017), to be deployed as observers within the JO. They were deployed as observers in some of the activated BCPs, with the agreement of the host MS authorities.

The observers received appropriate training delivered by Frontex.

The observers, who have no executive powers and who are not authorized to take any measures, received appropriate operational briefing and debriefing delivered by Frontex.

Observers could not transmit to the deploying TC authorities' personal data to which they had access while acting as observer.

Note: For information on cooperation with EASO, please refer to the Frontex response to the question 3 (see after).

3. **In its Special Report on the hotspots, the European Court of Auditors calls for better co-operation between the European Commission, EASO, Europol, FRONTEX, National Authorities and other International Organisations in order to better co-ordinate their support to the hotspots. What steps have been taken by FRONTEX in this respect?**

Cooperation with other Union agencies and bodies or international organizations:

JO TRITON

Frontex, within the framework of JO Triton, has permanent cooperation structures established with the main stakeholders as EFCA, EMSA, EASO, EUNAVFOR Med Operation Sophia, UNHCR, IOM and Host MS Authorities. Frontex has also invited in the course of JO Triton 2017 3rd country observers to ICC Rome from Ukraine, Georgia, Albania, FYROM and Kosovo. The cooperation with the NGOs is limited, however during 2017, Frontex showed openness to cooperate by providing guidance in the usage of Maritime Incident Template, which aims to aid the second line activities (referral, identification of facilitators, identification of THB victims, claimed nationalities) by providing preliminary information of the incidents to the ITA authorities before arrival to the designated port of safety in Italy.

In the frame of Hotspot approach:

Frontex provides tailored and coordinated packages to support the frontline MS under migratory pressure.

The main objectives of this support package for the implementation of the Hotspot approach include, among others a) identification and registration of 100% of the migrants arriving at EU external borders, b) investigation and dismantling criminal people-smuggling networks, c) Referral of people in need of international protection.

For the operational coordination of implementation of the Hotspots in Italy, a European Union Regional Tasks Force (EURTF) have been established in Catania, Sicily.

As a flexible regional tool based on synergies and complementarities, the EURTF fostered stronger cooperation with all the stakeholders, to close monitor the implementation of the operational activities on spot and enhanced the EU presence in the operational area. A good example of such is the weekly meeting, chaired by COM, held in EURTF premises, which contributed to enhance cooperation and exchange of information.

In the EU Regional Task Force each EU Agency led its own business area (modules) while Frontex acted also as service provider for the others putting in place all necessary horizontal instruments.

Cooperation with EASO under JO Triton:

Frontex and EASO have established their cooperation in the area of asylum and migration management, exchanging information and best practices. The agencies have been strengthening the coordination of their activities in the operational area in close cooperation with the host Member States authorities to ensure prompt referral and effective access to asylum procedures in accordance with the Common European Asylum Acquis.
Frontex deployed Cultural Mediators could support EASO activities upon request and if available.
EASO contributed to the Operational briefings for Frontex deployed experts to maintain the awareness about EASO mandate and role at the hotspots as well as to present the Access to Asylum Procedure Tools developed jointly by EASO and Frontex in cooperation with FRA and UNHCR.
It should be noted that all these components of the migration process were an integral part of the practical implementation of the Hotspot approach, which is a prerequisite of the relocation process of asylum seekers.

JO POSEIDON

During the JO the cooperation with the European Asylum Support Office (EASO), the European Fisheries Control Agency (EFCA), the European Maritime Safety Agency (EMSA), the European Police Office (EUROPOL), the European Agency for the Operational Management of Large-scale IT Systems (eu-LISA), the International Criminal Police Organization (Interpol), the Fundamental Rights Agency (FRA), the European Union Judicial Cooperation Unit (EUROJUST), the International Organisation for Migration (IOM), the North Atlantic Treaty Organization (NATO) and the United Nations High Commissioner for Refugees (UNHCR) may be established and maintained.

In the frame of Hotspot approach:

In Greece, Frontex premises (FLO/ EURTF Piraeus) are used as a seat for the EURTF structure. There the mention EU Agencies, national authorities and other relevant organizations coordinate their activities and exchange information in a daily communication as well as in regular EURTF meetings hosted by Frontex and chaired by COM. Frontex has actively participated, contributed and initiated, through FLO/ EURTF and nominated coordinating staff, to different coordination documents such as hotspot SOPs, security documents, EURTF mandate and rules for procedures for the EURTFs as well as in general coordination of the activities in the hotspots.

Necessary steps have been taken to ensure the effective cooperation between the key Agencies (Frontex, EASO, and EUROPOL) with whom the cooperation stands as:

- Cooperation with EASO (see after)
- Cooperation with EUROPOL; Europol officers deployed to hotspots with the availability to check SIS2 and Europol databases, Europol contributes to brief Frontex Team Members on their activities and on FTF common indicators, referral of suspected persons identified during surveillance, identification, debriefing or registration activities (according to indicators) by Frontex via nominated Hellenic Police POC to Europol for secondary security checks (as guided in the joint advice document for practical daily cooperation).

Cooperation with EASO under JO Poseidon:

EASO contributed in the framework of EURTF Piraeus for the issues related to the hotspot approach; the Agency contributed to the operational briefings for the participants of the JO Poseidon at the central and local levels, “Access to asylum procedure toolkit” (guide, booklets, leaflets, posters) elaborated by EASO & Frontex supported by FRA & UNHCR is available on Frontex website http://frontex.europa.eu/publications/ and disseminated in hard copies to the participants of the JO on the islands, Frontex deployed interpreters may support EASO activities at the hotspots, if requested by EASO.

JO INDALO/ HERA

National agencies involved in Coast Guard Functions activities (SASEMAR, DAVA, Spanish Air Force and Navy) take part regularly in JCB of the ICC.

The cooperation with EMSA and EFCA were achieved via exchange of operational information (e.g. Fishing sighting forms)

In the frame of promoting protection of fundamental rights, NGOs, such as UNHCR took part in the operational briefings on regular basis when there are some rotations of experts/ assets.

JO MINERVA/FP SEA

In the frame of JO, cooperation with International Criminal Police Organization (INTERPOL), European Police Office (EUROPOL), and United Nations High Commissioner for Refugees (UNHCR), Fundamental Rights Agency (FRA) and European Asylum Support Office (EASO) was established.

Cooperation with EASO under JO Minerva/FP Sea:

Frontex and EASO cooperated in the area of asylum and migration management, exchanging information and best practices on the functioning of their experts' database, sharing their respective training activities and their reports. The Agencies planned to strengthen their cooperation in operational areas, including training on nationality establishment and best practices and methods to better identify persons in need of international protection.

With regard to these JOs, Frontex and EASO strengthened the coordination of their activities in the operational area in close cooperation with the Host MS authorities in order to ensure prompt referral and effective access to asylum procedures in accordance with the Common European Asylum Acquis.

GSA

Replies to written questions

GSA

1. **On 15 December 2016 the Agency signed a Framework Contract on the exploitation of the Galileo satellite system during the period 2017 to 2027, amounting to 1,5 billion euro. The contract was awarded following a public procurement procedure. One of the tenderers involved, EUTELSAT has launched legal proceedings against the Agency at the European Court of Justice, challenging the outcome of the procurement procedure. When is the ruling of the ECJ expected? Have you put aside appropriations for the eventuality of losing the case?**

   Ruling is expected in 2019. We have not put aside appropriations because, according to our legal analysis – confirmed by external law firm –, the probability of losing – let alone paying substantial damages is not high for the moment. In addition, any damages would in principle be paid from delegated budget which includes a management reserve which could be used for this purpose.