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

Budget and financial management

1. The Court of Auditors noted in its Special Report 12/2016 on the Agencies’ use of grants that most Agencies have not adequately addressed alternative funding options and consequently grants have not always been the best way to achieve their objectives. Before launching grants, do agencies have an ex-ante assessment system in place to explore whether grants are the most effective funding tool?

Furthermore, the Court has also found that the audited agencies have not adequately measured the effectiveness of their grants. What steps did the agencies take in order to strengthen their verification systems for grant project implementation? Did agencies establish performance monitoring and reporting systems based on result and impact-oriented key performance indicators, as well as ex-post evaluation results?

Brexit

2. The withdrawal from the United Kingdom of the European Union will cause implications for several agencies. Some agencies are financed by the European Union and/or by direct contributions of the Member States or by relevant economic actors. The European Court of Auditor points out that the revenue of these agencies could decline as soon as the payments of the United Kingdom will stop. How much will the agencies’ revenue decrease in the future, respectively? Could each agency please provide the Parliament with the exact amount of this future lack of payments and how they want to work with a potential reduced budget?

Commitments and carryovers

3. After the consultation from June 2017 to establish the EU Agencies Network position on carryovers and the EUAN proposal (that the Court reports the cancelled carryovers that exceed 5 % of the total budget to the Discharge Authority), what are the steps taken by the Agencies to reduce the cancelled carryovers?

4. Cancelled carry-overs seem to indicate a lack of prudent budgetary management and might signal lack of good planning. They could be more problematic than carry-overs themselves. Could Agencies provide the amounts of cancelled carry-overs by budgetary title and the justification for them?
Conflicts of interest and transparency

5. Could the agencies ensure easy access to the declarations of absence of conflicts of interests and the CVs of their respective management and senior management board members?

6. According to the report “EU Agencies Network report to the European Parliament on the follow-up to the 2015 budgetary discharge”, published in October 2017, only 60% of the agencies check at least once a year the factual correctness of the declarations of interest submitted by experts, the management board and staff. For the agencies that do not check the factual correctness at least once a year, do those agencies plan on checking?

Performance

7. What measures did the agencies take in order to ensure the explanation in layman’s terms and user-friendliness of the performance reports?

Other comments

8. How much each agency spent on promotional materials and publications in 2016? Could the agencies name the target group to which they send their promotional materials and publications?

9. Accountability of the agencies depends to a large extent on their visibility to the citizens in Europe. Which initiatives have the agencies taken to enhance their visibility? Can citizens directly or indirectly get involved in and thus contribute to the work of the agencies?

10. Each of the agencies is evaluated every five years. This evaluation includes the assessment of an agency’s accountability. Can the Network explain which criteria for accountability are used for these evaluations and summarise the results of these evaluations in this respect?

11. In the case of EASA a pilot project was started promoting fee-funded agencies. What is the Network’s appraisal of this project? Should it guide other agencies as well to rely more heavily on fees for their resources?

12. How does the Network view in this respect the danger of conflicts of interests for agencies relying on fees from their clients? Would it be a solution to follow the example of the position of testing institutions in the case of type approval of motor vehicles, following Dieselgate? In their case, Parliament considered that it would be better to collect the fees centrally, instead of the testing institutions collecting these. Would it be a solution if fees of agencies were collected by the Commission, so that agencies would remain fully funded from the EU budget?

13. EU institutions and bodies are major consumers. By using their purchase power (translation services, IT services, etc) to choose environmentally friendly goods, the agencies can make an important contribution to sustainability or Green Public
Procurement. The GPP is a voluntary tool. Do agencies include additional green criteria in tender specifications? Have the agencies developed any circular economy strategies? Have the agencies used or planning to use the EU Eco-Management and Audit Scheme (EMAS)?
II. QUESTIONS TO BE ANSWERED BY INDIVIDUAL AGENCIES

BEREC
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?

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?

CEDEFOP
3. 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?

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?

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?

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?

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?

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?

EASO

9. 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?¹

10. 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?²

11. 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 procedures³ 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?

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?

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?

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 EU⁴. However, in 2014, 123 banks were tested⁵. 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?

15. Furthermore, the European Central Bank (ECB) carries out a separate stress test of
another 56 banks under its supervision using the same methodology. 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?

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?

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?

18. On 26 October 2015, the Banking Stakeholder Group had a discussion on
whistleblowing. 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?

ECHA

14. 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?

15. 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?

16. 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

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

17. In the Annual Activity Report 20169, 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?

18. During 2016, ECHA conducted two evaluations10. 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?

EFSA

19. 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?

20. 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?

21. 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?

22. 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"11.

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 emerge12.

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

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9 pages 5 and 9
10 Annual Activity Report, page 23
toxicological safety threshold, given that this threshold is compounded by high environmental contamination?

23. 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?13

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

25. 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?

26. 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 Observatory14, 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?

27. 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 so, can the Agency explain how? Is this conclusion supported by public and published studies?15

28. 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?16

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14 https://corporateeurope.org/efsa/2017/06/recruitment-errors
https://usrtk.org/pesticides/mdl-monsanto-glyphosate-cancer-case-key-documents-analysis/
29. 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?17

EIGE

30. 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.

EMA

31. 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?

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

33. 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?18

34. How does EMA view its dependence on fees from the pharmaceutical industry (89.34%)?19

35. 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?20
   a. Basic salary (€290,000);
   b. Studies & Consultants (€47,700);
   c. Subscriptions to specialised research (€186,200);
   d. Information & publication (€120,000).

36. 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

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to have these personal details, as visitors for ‘general information purposes’ do barely have to provide information?\textsuperscript{21}

37. 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?

38. 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?

39. 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?\textsuperscript{22}

40. 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?\textsuperscript{23}

41. 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?

42. 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?\textsuperscript{24}

43. 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?\textsuperscript{25}

\textsuperscript{21}https://clinicaldata.ema.europa.eu/web/cdp/termsofuse
\textsuperscript{22}http://sargasso.nl/lange-arm-farmaceutische-industrie/
\textsuperscript{23}http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp&mid=WC0b01ac05807d58c&
\textsuperscript{25}Annual Activity Report 2016, p. 19
\textsuperscript{25}https://www.ftm.nl/artikelen/european-medicines-agency-is-te-afhankelijk-van-de-farmaceutische-industrie?share=1
44. 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?26

45. 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 is the Agency’s response to this? How does EMA protect its employees by relocation to one of these Member States?27

46. 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?28

47. 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?29

EMCDDA

48. 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?

ENISA

49. 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?

EUROJUST

50. 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

26 http://www.bmj.com/content/bmj/359/bmj.j4530.full.pdf  
27https://euobserver.com/lgbti/139678  
29Discharge 2015: European Medicines Agency
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?30

EUROPOL

51. 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?

52. As Europol outlines in its Annual Activity Report, 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?31

53. 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?32

FRONTEX

54. 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.

55. 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?

56. 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

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30 Consolidated Annual Activity Report 2016, p.5  

31 Consolidated Annual Activity Report 2016, p.38  

32 Consolidated Annual Activity Report 2016, p.15  
to better co-ordinate their support to the hotspots. What steps have been taken by FRONTEX in this respect?

**GSA**

57. 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?