

Note to the Management Board

EFSA final Programming Document 2020-2022 & draft Programming Document 2021-2023 and Statement of Revenues and Expenditures 2020

1. Objective

The following documents are submitted for possible adoption by the Board:

- Final Programming Document 2020-2022, including the final annual work-programme 2020;
- Statement of Revenues and Expenditures 2020 (Budget 2020)
- Draft Programming Document 2021-2023, including the draft annual work-programme 2021.

2. Background and Scope

In December 2018, the Board adopted the final Programming Document 2019-2021 and the draft Programming Document 2020-2022, in compliance with the requirements of the Programming Document common template of the EU Agencies' Network. These documents continued as in the previous years to build the multiannual programme of EFSA to its strategic objectives defined with the adoption of the EFSA 2020 Strategy.

During the course of 2019, EFSA has started working on the development of its new strategy 2021-2027 with the aim to define its new Strategic objectives from 2021 onwards. EFSA has updated the draft Programming Document 2020-2022 and has created the draft Programming Document 2021-2023 extrapolating for the time being the current strategy to the years 2021-2023. The adoption of the new strategic objectives in June 2020 will significantly impact the final SPD 2021-2023 that will be submitted next year. Both documents now reflect:

- the adoption of the Transparency Regulation and full integration of preparatory and implementation activities and resources
- an extended timeframe of the multi annual programme, until 2023 included.
- the Commission Opinion¹ received in September 2019 (see annex 1 below).

As in the past, please note that the two Programming Documents overlap and coincide to a large extent in view of the intersecting timeframe. For a more convenient review, please note that the parts where the two documents differ are:

- The annual work-programmes (section III in each of the two documents and its Appendices A and B, while Appendices C and D are common)
- The resource annexes (Annex II to IV in each of the two documents)

(¹) Commission Opinion C (2019)7143 of the 9.10.2019 on the draft Programming document 2020-2022 of the European Food Safety Authority

- The annual grants and procurement work programme (Annex IX in each of the two documents)

Regarding the statement of revenues and expenditures the structure reflects the one recently adopted by the Board in June 2019. For clarity purposes, as the years reported span the period 2018-2020, the budget items from the previous structure are still shown in the tables.

3. Next Steps

Following the adoption by the Board (subject to possible revisions that may be made at the Board's meeting), the next steps in the process are envisaged as follows:

- The Final Programming Document 2020-2022 will be published on EFSA's website and submitted to the EU Institutions end January 2020 and become the reference for guiding EFSA's work programme implementation in 2020.
- The Draft Programming Document 2021-2023 will be further processed as follows:
 - by the end of January 2020: the document will be updated as per the actual 2019 execution data, and submitted to the EU Institutions (i.e. Commission, Parliament and Council);
 - during 2020: The document will be revised following the adoption of the new strategic objectives in June 2020 , will be sent for consultation to EFSA's stakeholders, namely Sister Agencies, Advisory Forum and Stakeholders' platform and will be reviewed to address the opinion that will be received from the Commission and to reflect other important developments occurred during the 2020 consultation;
 - by December 2020: submitted for final adoption to the Board.

Annex 1: Key EC comments on draft SPD 2020-2022 and EFSA follow up on final PD 2020-2022 and draft PD 2021-2023

EC opinion para no.	Commission's opinion on the draft Programming document 2020-2022	EFSA's response
5	<i>This is in line with the provisional agreement that the European Parliament and the Council reached on 11 February 2019 on the Commission's proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain, amending Regulation (EC) No 178/2002 and eight sectoral acts ('Transparency Regulation')[1]. The Transparency Regulation was approved by the European Parliament on 17 April 2019 and formally adopted by the Council on 13 June 2019. Its publication in the Official Journal is expected in September 2019. The new Transparency Regulation will enter into force 20 days after publication and into application 18 months after its entry into force (in the first half of 2021). In those 18 months, preparatory work must be carried out both by the Authority and the Commission to ensure a smooth transition to the new legislative framework – with particular emphasis to transparency.</i>	Short para included in the introduction of section II. Multiannual plan and explicit reference on activities per SO in the annual plans. (see p. 17 and specific actions indicated below)
6	<i>The Authority, in particular, will need to set up practical arrangements and infrastructure for a number of new actions:</i>	see specific actions below
6	<i>Provision of general pre-submission advice to potential applicants.</i>	Reference to pre-submission advice has been added in Section II, 2.1, (p. 18) and III, 2.1,(p.50) in the SO1 Regulated products sections ("With the new transparency regulation, EFSA will generalise pre-submission advice to applicant or notify on the applicable rules and the content required for applications or notifications and on study design for renewal applications ") and in Section II, 2.1, the description of the projects under the ART programme ("The project End-to-End Science aims at analysing all EFSA's end-to-end chains of activities delivering core scientific outputs, working towards of Transparency Regulation implementation as well as any other improvement opportunity for risk assessment in food safety. This will range from mandate acceptance, problem formulation and protocol development, initial request, potential pre-submission meetings to data capital, data selection and retrieval processes, pesticide peer re-view and MRLs, to panel, staff and experts interactions and work processes as well as support services including exposure assessment("Support centres") and their organisation underpinning the scientific processes, tool implementation and also preparedness and methods development and implementation including the measurement of the success of guidance.") (p.22)

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6	<i>Notification of studies commissioned both by applicants and by laboratories or testing facilities, as well as the drawing up of the relevant database.</i>	<p>The implementation of notification of studies and the relevant database is being dealt with in the context of the Matrix project, and information on this has been included in section II, 2.2 (p.25): "In addition to MATRIX, a new IMP project (Notification of Studies) has started the design of the processes and the data format for the implementation of a Register of Studies and the obligation set in the new Transparency Regulation to notify to EFSA studies for both new applications and renewals.</p> <p>The two projects are strictly interlinked and, as mentioned in 2020, EFSA will start the implementation of the solutions for the notification of studies obligations and the implementation of the 178 measures related to Regulated Product Assessment (MATRIX)." (p.25)</p>
6	<i>Public consultations on planned and submitted studies.</i>	Mentioned in section II-2.1, III-2.1 (draft 2021 programme) (p.20)
6	<p><i>Implementation of the transparency rules (e.g. system of proactive public disclosure of studies and information that support requests for scientific output, including for authorisation procedures).</i></p> <p><i>Implementation of the confidentiality rules comprising the submission and treatment of confidentiality requests, including confirmatory applications.</i></p>	<p>The implementation of transparency as well as confidentiality rules is being dealt with in the context of the Matrix project, and information on this has been included in section 2.2: "Following the adoption of the Transparency Regulation, the Matrix project has been re-chartered and now focuses on delivering the new Transparency Regulation measures by March 2021. Those measures will focus on ensuring confidentiality assessment - across all food sector areas - and the publication of dossier information in a machine-readable format. The confidentiality decisions are exceptions to the public disclosure requirement introduced by the new Regulation. Matrix will also aim to provide applicants and stakeholders with an electronic-based e-submission and evaluation solution for all regulated product applications.</p> <p>The electronic format will enable the management of regulated product applications (validation and risk assessment), the confidentiality assessment process as well as the dissemination and publication processes." (p.27)</p>
6	<i>The Authority will need to develop new and/or align existing guidance in sectoral legislation in conformity to the new transparency rules (e.g. in smoke flavourings, food contact materials, plant protection products, genetically modified food and feed).</i>	General reference to updated/new guidance documents in relation to sectoral legislation has been added in section II, 2.1. (p.21)
6	<i>The Authority will also need to draw up draft standard data formats for further adoption by the Commission (by Implementing Acts).</i>	Definition of dossier structure and data formats is being handled in the context of the IMP programme (Matrix and Notification of Studies projects), as explained in Section II, 2.2: "In addition, EFSA is working on defining a dossier structure, dossiers' document formats, and dossiers' data format for all food sector areas adopting as much as possible existing standards. Some of those formats and standards will be introduced already in March 2021, others will be introduced at a later stage giving time to industry to be prepared for the electronic submission. In this context, EFSA is exploring the use of the OECD's standards and, in the area of Pesticides is-piloting with ECHA the adaptation of the International Uniform Chemical Information Database (Iuclid) building blocks for possible re-use by EFSA." (p.27)

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6	<i>And provide contributions for the development of the general plan on risk communication.</i>	The project Engagement and Risk Communication (EN.RI.CO), developing engagement and partnering mechanisms will specifically address aspects related to communication, engagement and cooperation with MSs/internationally and with sister agencies throughout its Risk Assessment processes with EFSA's Stakeholders in line with the new science approach and the implementation of a general plan for risk communication. Information on the project has been added in section II-2.1 in Stakeholder engagement and communication paragraph and in the description of the projects under the ART programme. (p.25)
6	<i>The Authority's support and experience will also be needed for the preparation and follow-up of fact-finding missions to be carried out by the Commission on the quality and reliability of data.</i>	Reference to the support by EFSA to EC for fact-finding missions has been added in section II, 2.1 Regulated products (p.20)
6	<i>In addition, the Authority will need to prepare for the involvement of Member States in the Authority's governance and the selection process for experts of the Scientific Committee and Panels.</i>	<p>MS in EFSA's governance:</p> <p>One of the envisaged measures in addressing the Transparency Regulation is the implementation of the new MB composition starting from July 2022. Preparatory activities are planned in this year to address this upcoming change of increase in Member States and stakeholders NGOs representation, which will aim to strengthen in the long-term the Member State involvement in EFSA's work and outputs. In particular, EFSA will review the Board's Rules of Procedure, Code of Conduct and independence rules benchmarking them with the approaches adopted by the Management Boards of the other ENVI Agencies and enquiring the collaboration of the MB Secretariats in those Agencies. As well, EFSA will start performing an overall review of all its governing documents in view of their possible revision to reflect the changes in the Board composition and in the functioning of the Authority following the implementation of the Transparency Regulation. Upon request from the European Commission, EFSA will provide DG SANTE with support in shaping the procedure for the selection of the Board's representatives of civil society and food chain interests. An on-boarding plan for the new Board members will be prepared by end 2021. Changes in the new operating process and Organisation Structure of EFSA aim to address the need for a long-term improved sustainability and increased capacity of EFSA's ways of work. The initial preparatory activities to achieve this, will be done alongside adapting the current management system. (Draft PD 2021-2023 p. 64).</p> <p>Selection process of experts:</p> <p>Mentioned in III-2.1 (draft 2021 plan, p. 54)): "The activities for the implementation of the Transparency Regulation in 2021, include preparation (in 2020) for the implementation of the expert selection rules for the renewal of the panels for the upcoming year, (2021 -2022), addressing the need for an improved long-term capacity for EFSA." (p.34)</p>

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6	<i>The Commission invites the Authority to include in the sections I, II and III of the Programming document updated references to the Commission proposal and complement it with the planning for necessary actions.</i>	Updated references to the Commission proposal and information on the plan for implementing the measures have been added in the relevant sections of the document.
Specific comments on the multiannual (2020-2022) and annual (2020) work programme		
9	<i>The Commission welcomes that the Authority will continue to focus on its core activities, namely the provision of scientific advice in the areas of general risk assessment and evaluation of regulated products. The Commission highlights that this prioritisation also needs to be reflected by the allocation of resources within the Authority and welcomes the Authority's commitment in this respect.</i>	Details on resource allocation are presented in Section II.3 "Financial and human resource outlook for 2020-2023" (PD 2020-2022 p.38). To be noted that an increase is planned for Strategic Objective 1 (in absolute terms), not only because of workload but also in view of the implementation of TR measures
12	<i>With regard to pesticides, the Commission welcomes that the Authority has taken on board the Commission's proposal to start implementing cumulative risk assessment of pesticides in the dietary risk assessments carried out on the basis of monitoring results (which are currently considering each pesticide in isolation), as this will contribute to increased preparedness for risk assessment challenges. It also welcomes that the further development of the methodology is highlighted in the Programming document as a key area for the future. Given that this is a high priority for the Commission, it is important that sufficient human resources are attributed to this task. The fact that several units are now involved in the process should not result in efficiency losses and overlaps.</i>	EFSA has allocated human and financial resources to the project in accordance with the planning at project and programme level, taking into account the level of priority. The overview and monitoring by the RAMPRO programme ensures no overlaps with other projects. (p.34, 60)
13	<i>As regards maximum residue levels of pesticides, the Commission stresses that the agreed minimum number of opinions needs to be respected and that further focus should be on the substances to be assessed.</i>	EFSA is committed to ensure that the MRL bulk evaluation is carried out in line with the plan agreed with EC; to this purpose, further process improvements agreed with Member States will be implemented in 2020, including the option of addressing the question under the peer review renewal for specific substances. It should be noted however that the number of substances that can be addressed by EFSA also depends on the fact that sufficient substances are considered ready for starting the MRL review (strong interdependency with peer review renewal and pending assessment of confirmatory data). In addition to this, and following discussion with DG SANTE services, it should be noted that the indicator monitoring the reduction of MRL Art. 12 bulk evaluation will be revised as of mid-2019, to include questions closed by any output type and not only via reasoned opinion, so to better reflect the status of the bulk evaluation. (p.54)
14	<i>The Authority should consider keeping placeholders for potential additional mandates, either ad-hoc or horizontal, which the Commission may need to send in the next years. For example, the workload related to health claims will largely depend on the results of the ongoing REFIT Evaluation of Regulation (EC) No 1924/2006[2].</i>	EFSA does not allocate resources to placeholders in the initial work programme. Potential additional mandates from the Commission are managed running a portfolio prioritisation exercise any time during the year in the case these are received. Indeed, external mandates are prioritised against internal activities and or self-tasks should they compete for the same set of competencies. (p.43)

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15	<i>The Commission acknowledges the Authority's work on guidance development. However, certain mandates which are characterised as of higher priority are not always referred to in the Programming document (e.g. recent mandate to review the bee guidance document). The Authority is invited to proceed to the necessary adaptations.</i>	The document is adapted in page 33: The work on the revision of the Guidance Document on the risk assessment for bees will continue with the support of the established stakeholder discussion group, an initiative that came out of a joint workshop organised with the European Parliament.
16	<i>The Commission supports the Authority's activities that contribute to the EU research and innovation agenda cycle. The Commission considers it essential to stimulate research and innovation in the area of the Authority's mission in order to support risk assessment activities and policy-making. However, the Commission would caution that creating new working groups/platforms to co-ordinate the research communities may challenge EFSA's role vis-à-vis that of the Commission services and inevitably has resource implications for the Authority.</i>	EFSA will contribute to stimulate research and innovation in order to support risk assessment activities and policy-making. EFSA will organise the second Risk Assessment Research Assembly (RARA) event bringing together EU and national research funders, policy/decision makers and leading food safety researchers annual and multiannual plan 2020 SO3. (p.27, 58).
17	<i>The Commission welcomes the Authority's planned activities on preparedness for future risk assessment challenges and the continuation of working on framework partnership agreements with Member States for data collection or generation. The Commission considers the monitoring of micro-plastic and nano-plastics occurring as contaminants in food, especially in seafood, as a high priority issue.</i>	Mention to micro-plastic and nano-plastics occurring as contaminants in food is considered among the priorities defined together with the Advisory Forum (see dedicated text box in section III, 2.3p.547,)
19	<i>The Commission also supports that the Authority further strengthens cooperation with the Commission services and other EU agencies in order to achieve synergies and efficiencies on both scientific and organisational aspects. It welcomes and continues to encourage the coordination and collaboration on cross-cutting areas, regarding in particular AMR, with the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA) and the European Medicines Agency (EMA), within the limits set by each agency's mission. The Commission also acknowledges the support provided by the Authority to the EU positions in the Codex Committees.</i>	Cooperation activities has been highlighted both under SO3 (summarised) and under the relevant SOs. (p.20, 46)
20	<i>The Commission and the decentralised agencies in the health and food safety area recently launched an initiative for a closer collaboration on IT, which should be fully up to speed in 2020. As they have similar business requirements, they need interoperable IT services and solutions for their stakeholders. The Commission invites the Authority to mention this initiative in the Programming document, taking also into account the implementation needs of the new Transparency Regulation as regards the practical arrangements for the proactive public disclosure of all studies that support requests for scientific output by the Authority.</i>	Description of the "Health Policy Agencies and European Commission Collaboration (HPAC)" initiative and of projects to be rolled-out in 2020 has been added in Section II, 2.5. (p.35)
Comments on budget and human resources		
25	<i>The Commission notes that the EU subsidy to the Authority for 2020 should be EUR 105 459 000 in commitment appropriations and EUR 101 413 013 in payment appropriations, covering the budget as foreseen in the Multiannual Fi-</i>	EFSA has updated budgetary figures in the ANNEXES and provides analysis in section II-3.Resources outlook .(p.38)

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	<i>nancial Framework, as well as the forecasted impact of the Commission proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain (EUR 25 million). The Commission invites the Authority to review and update the budgetary figures in the Programming document accordingly.</i>	
26	<i>The Commission notes that the 2018 figures on 'Evolution of the budget by title' under section II.3.1 of the Programming document (p. 32) need to be updated according to the actual budget implementation.</i>	Section II-3.1 updated. (p.39)
27	<i>For 2020, the Authority requests 19 additional contract agents on top of the 6 additional contract agents authorised by the budgetary authority from 2019. The Commission accepts that these 6 contract agents are maintained in 2020; and asks the Authority to align the Programming document accordingly (total of 131 contract agents for 2020, excluding those provided for in the Commission proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain).</i>	The Programming Document has been aligned considering the current baseline of 131 Contract Agents unchanged (not including the additional capacity related to the 178 Transparency Regulation). (p.46)
28	<i>According to the Commission proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain, the year 2020 should be the first year of the proposal's implementation. The Commission supports EFSA's request for additional staff in 2020, as provided for in the proposal (34 temporary agents and 8 contract agents).</i>	The staff figures reported in the updated Programming Document confirm the additional staff request of +34 Temporary Agents and +8 Contract Agents. (p.46)
29	<i>For the implementation of the Commission proposal, it is noted that EFSA provides for an increase in temporary agent positions by 59 in 2021. Without prejudice to the decisions to be taken as regards the next Multiannual Financial Framework, the Legislative Financial Statement accompanying the proposal provides for 60 additional temporary agents in 2021.</i>	The Programming Document has been aligned with regards to the 2021 Establishment Plan capacity (+60 posts vs. 2019 baseline). (p.46)
30	<i>The Authority requests for 2020 the conversion of six temporary agent AST posts into temporary agent AD posts and further conversions in the following years. The Commission points out that these gradual conversions of temporary agent AST positions into AD positions have a budgetary impact on the longer run and therefore a stronger justification from the Authority is requested.</i>	Several initiatives of project/process improvements have been put in place to achieve efficiency gains, generate "free capacity" as well as financial benefits (see also details reported in Appendix D of the Programming Document). These initiatives also led to the outsourcing of some services freeing up internal FTEs mainly pertaining to the AST category that can be upgraded to ADs. EFSA is aware that the gradual transformation of AST into AD posts has a budgetary impact and will strictly monitor the impact on Title I expenditures. (p.46)

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31	Considering the process of significant recruitment, the Commission invites the Authority to already identify AST/SC positions. Conversion will be gradual but should start from now. If clerical tasks are not performed by temporary agent AST/SC positions, contract agents function group II should perform these tasks. It is however noted that the Programming document provides for a decrease of contract agent function group II positions over the years (p. 140).	Most of the clerical tasks have been outsourced and are being delivered by external providers (i.e. reception, post office, hussier/archive, building safety and security). In the Authority's Competency Library we do not foresee any profiles with a purely secretary clerical tasks. The Admin Assistant Job profile (AST 1-3 and FG I-II) foresees tasks with higher degree of complexity compared to a pure clerical function, such as unit and business coordination, financial management, planning and monitoring, project management, internal communication. Additional distinctive tasks are foreseen for the Admin Assistant staff working in Scientific Units. For the reasons above the Authority doesn't foresee to revert to employing statutory staff for the execution of pure clerical tasks. (p.161)
33	<i>The Commission notes the Authority's performance indicators on human resources aspects (pp. 72-73 of the Programming document); and recommends adding an indicator on the time needed to fill in a vacant post.</i>	The indicator "time to hire" calculated as the time from the publication of the vacancy to the establishment of the reserve list was included in the previous version of the planning document. It was considered that the indicator had a only partial relevance hence it was kept the occupancy rate as indicative of the availability of staff. One option is to re-insert the old indicator (which we monitor in any case) pending the elaboration of a more sophisticated one. (p.94)
34	<i>In Annex IV on the recruitment policy (p. 144), EFSA mentions that it is using an innovative recruitment solution to attract, source and select its staff, without specifying what this innovative solution is. The Commission invites the Authority to provide more details, taking into account the high number of recruitments requested in the three coming years and to help evaluate the capacity of the agency to absorb high numbers of recruitments per year.</i>	The solution implemented by EFSA (Taleo) will allow EFSA to ensure an efficient and effective recruitment of the new staff. In particular the solution provides the following: <ul style="list-style-type: none"> - powerful sourcing functionalities and analytics on the applicants - the possibility to structure data to better support HR and the selection board in the selection process. - a complete paperless process, starting from the application, selection, applicants relationship management and recruitment process for all categories of staff. (p.164)
35	<i>In addition, the Commission would appreciate if more information regarding entry grades of recruitment per type of profiles present in the Authority was included in Annex IV of the Programming document.</i>	Typical entry grades have been added in the text of the PD. (p.165)
36	<i>Regarding the gender balance, the Commission recommends the Authority to fix a target for female representation on middle management positions of at least 40% (timing to be evaluated by the Authority), taking into account that team leaders or heads of sector are not counted by the Commission in the management population.</i>	The current ratio is above the proposed target of 40% for Middle Managers in EFSA, (HoDs + HoUs) i.e. for all middle managers out of 24 members 13 males and 11 females, that is a ratio males/females 54%/46%. Among Heads of Units the ratio is balanced to the ratio 40% females/60% males (8 Heads of Unit out of 20 are females). (p.211) while among HoDs the distribution is even higher 1 male and 3 females that is a ratio of 25%/75%
37	<i>Regarding the geographical balance, the Commission invites EFSA to take advantage of recruitments foreseen in the coming years according to the Commission proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain; and try to rebalance the geographical representation by Member States among the Authority's staff.</i>	Indeed, the new recruitments represent an opportunity to attract and employ staff coming from different Member States to have a more balanced geographical representation, while ensuring the recruitment of the best talents. (p.171)