30/10/2020

Mechanisms to prevent unethical research and funding - Horizon and EDF

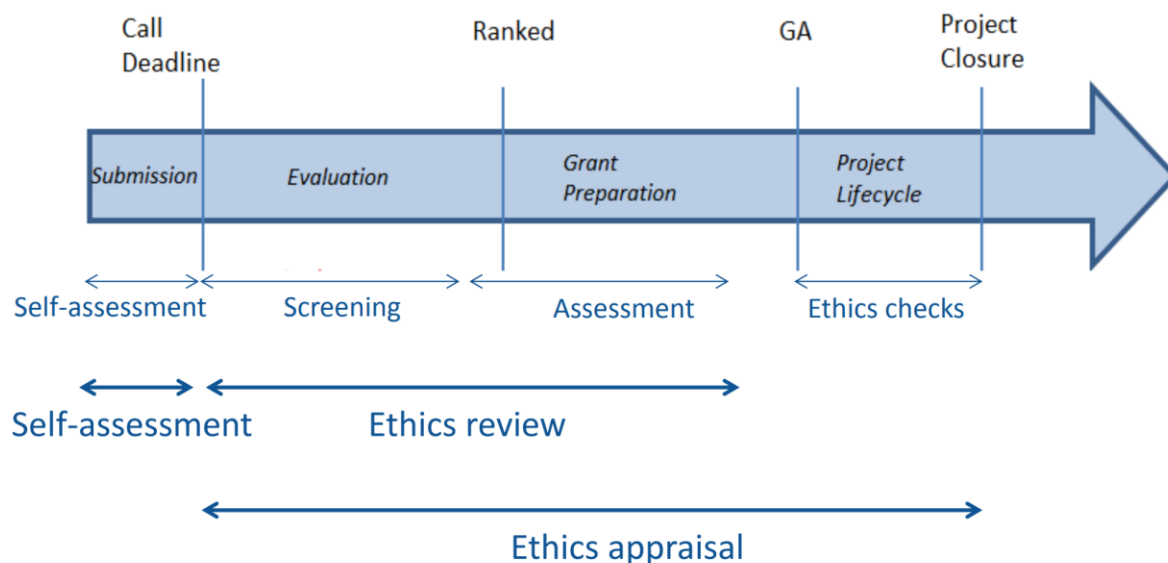## HORIZON 2020

ETHICS PROCEDURE IN HORIZON 2020

Ethics is given the highest priority in EU funded research: all the activities carried out under Horizon 2020 must comply with ethical principles and relevant national, EU and international legislation, for example the Charter of Fundamental Rights of the European Union, the European Code of Conduct for Research Integrity and the European Convention on Human Rights.

Ethics is dealt with extensively in the Horizon 2020 legislation (Horizon 2020 Rules for Participation: Ethics Reviews (Article 13, 14,18, 23), Horizon 2020 - Regulation of Establishment: Ethical principles (Article 19) and the Model Grant Agreement: Ethics (Article 34).

The main fields checked are : 1. Human embryo/foetuses; 2. Human beings; 3. Human cells/tissues; 4. Personal data ; 5. Animals ; 6. Non-EU countries ; 7. Environment, health & safety; 8. Dual-use; 9. Exclusive focus on civil applications; 10. Misuse; 11. Other ethics issues (e.g. new developments in the fields of neurobiology, nanotechnology,genetic enhancement, the creation of androids and cyborgs, etc.)

Horizon 2020 address the ethical requirements through the so called "Ethics Appraisal Procedure".

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Ethics appraisal in H2020

The procedure includes three steps:
1. Ethics Self-Assessment (preparation phase: by the applicant)
2. The Ethics Review (before the finalisation of the grant agreement: by ethics experts)
      i) An Ethics Pre-screening/Screening;
      ii) An Ethics Assessment.
3. The Ethics Checks (for selected projects, after the signature of the grant agreement: by ethics experts)

At the submission step each applicant is responsible for dentifying any potential ethical issues and handling ethical aspects of their proposal, through the Self-assessment tool. All proposals must describe ethical issues raised and how they will be addressed so as to conform to national, European and international regulations.

Once the deadline has passed, all proposals are evaluated by a scientific panel of independent specialists in their fields.

All proposals above threshold and considered for funding will undergo then an Ethics Review carried out by independent ethics experts working in a panel. The Ethics Review Procedure focusses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorizations and ethics approvals, proportionality of the research methods and the applicants' awareness of the ethical aspects and social impact of their planned research.

Ethics experts or an ethics panel of the Commission prepare a report about the application and give one of three proposals: cleared (ethical issues have been clearly described and very well addressed), conditionally cleared (corrections required) and cancelled.
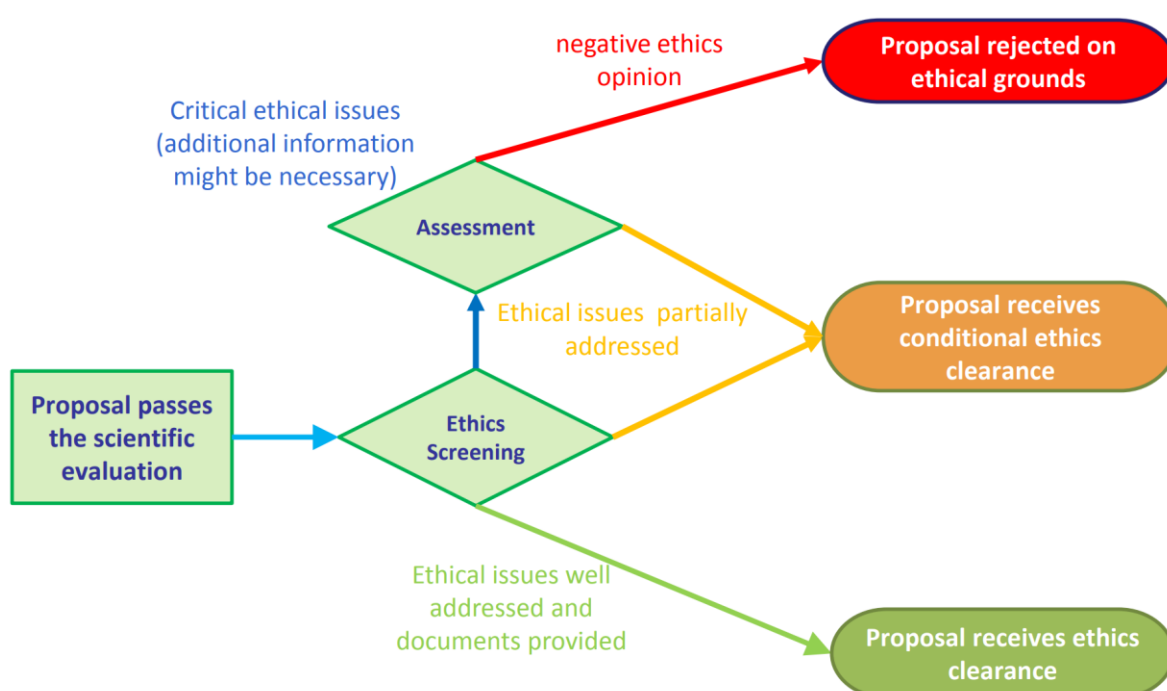
The first phase of the Ethics Review Procedure, the Ethics Screening, is carried out during the scientific evaluation or soon after. When applicants didn't signal ethical issues, the ethics experts first perform an Ethics Pre-Screening taking into account the Self-assessment form of the applicant.

When there is at least one confirmed ethical issues, the proposal is subject to a complete Ethics Screening in which the experts will formulate requirements. The ethics experts may also recommend that the Ethics Screening be followed by an Ethics Assessment prior to the signature of the grant agreement.

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The Ethics Assessment is a more in-depth analysis of the ethical issues of the proposals, taking into account, when available the conclusions of the Ethics screening. It is systematically performed on all proposals involving the use of Human Embryonic Stem Cells.

For each field of concern, the European Commission published Guidance notes to the applicants, as for example "Potential misuse of research", "International cooperation" "Dual use" or "Research on refugees, asylum seekers and migrants"

At the Ethics Screening or the Ethics Assessment step, the experts identify the projects that need an Ethics Check, which is executed during the running of the research project. The procedure can also be initiated by the Commission services. The objective of the procedure is to assist the beneficiaries to deal with the ethics issues raised by their research and if necessary to take preventive or/and corrective measures. The Ethics Check is conducted on the basis of the information provided by the concerned beneficiaries.

In case of substantial breach of ethical principles, research integrity or relevant legislation, the Commission can carry out an Ethics Audit following the provisions and procedures laid down in the grant agreement. The Checks and Audits can result in an amendment of the grant agreement or in severe cases, it can lead to a reduction of the grant or its termination.

In the chart below you can see who is in charge of each step of the procedure:

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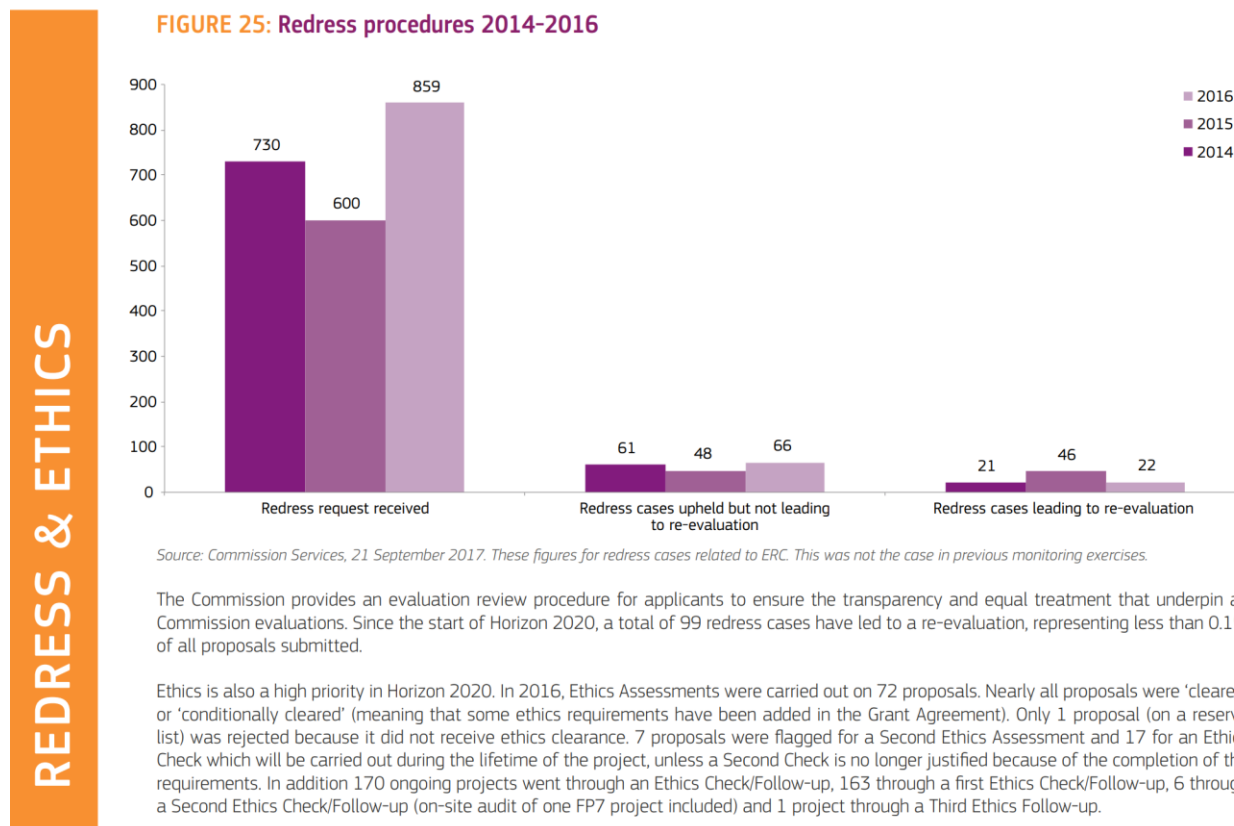
ETHICS APPRAISAL STEPS

Activity	Who?	When?	How?
Ethics Self-assessment	Applicant	Application phase	Consideration of ethical issues of the proposal
Ethics Pre-screening/Screening	Ethics experts and/or qualified staff	Evaluation phase	Review of application material
Ethics Assessment (for proposals involving hESC or raising serious ethical issues: severe intervention on humans)	Ethics experts	Evaluation/ Grant preparation phase	Review of application material
Ethics Check/Audit	Ethics experts	Implementation phase	Review of project deliverables/interview with applicants

The whole procedure is explained here.

External experts are selected through a Horizon 2020 call for independent experts (see pp.85-86: Funding for Independent experts advicing on the implementation of Horizon 2020 Ethics Appraisal Scheme - Horizon 2020 - Work programme 2018-2020 (16. Science with and for Society)).

As an example, on the Research and Innovation Staff Exchange (RISE) 2020 call for proposals (part of the Marie Skłodowska-Curie Actions), ethics evaluation, on the appraisal process each proposal is checked by two experts separately. Then both submit an individual report. If an Assessment has to take place, a larger panel of ethics evaluators (3-5) checks the proposal.

Some statistics from the beginning of Horizon 2020. See p.44 of European Commission publication (2018)

FIGURE 25: Redress procedures 2014-2016

Source: Commission Services, 21 September 2017. These figures for redress cases related to ERC. This was not the case in previous monitoring exercises.

The Commission provides an evaluation review procedure for applicants to ensure the transparency and equal treatment that underpin all Commission evaluations. Since the start of Horizon 2020, a total of 99 redress cases have led to a re-evaluation, representing less than 0.1% of all proposals submitted.

Ethics is also a high priority in Horizon 2020. In 2016, Ethics Assessments were carried out on 72 proposals. Nearly all proposals were 'cleared' or 'conditionally cleared' (meaning that some ethics requirements have been added in the Grant Agreement). Only 1 proposal (on a reserve list) was rejected because it did not receive ethics clearance. 7 proposals were flagged for a Second Ethics Assessment and 17 for an Ethics Check which will be carried out during the lifetime of the project, unless a Second Check is no longer justified because of the completion of the requirements. In addition 170 ongoing projects went through an Ethics Check/Follow-up, 163 through a first Ethics Check/Follow-up, 6 through a Second Ethics Check/Follow-up (on-site audit of one FP7 project included) and 1 project through a Third Ethics Follow-up.

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ETHICS EXPERTS

Anyone can register their interest in being an expert, but most of the experts selected to come from Member States of the European Union and Associated Countries. Experts, as peer reviewers, assist in the evaluation of proposals and the monitoring of actions.

Experts can register in a database on the European Commission website for funding and tenders, in which also the "Calls for expressions of interest for experts" are also published.

Requested about the selection of ethics experts for the Horizon 2020 Programme, the Directorate-General for Research and Innovation - Coordination & Interinstitutional relations (RTD.01), gave the following input:

"In H2020, proposals are evaluated by independent experts (scientific and ethics exerts) who are selected from the database of experts that answered the continuously open call for expression of interest published in the Funding and Tenders Portal (https://ec.europa.eu/research/participants/docs/h2020-funding-guide/experts/expert-registration_en.htm)
The experts for a given call are selected based on their expertise, but also taken into consideration other criteria like gender balance, multidisciplinary, geographical coverage or balance between public and industry sectors, when relevant.

In the case of ethics experts, in addition to the ethics expertise declared when registering in the database, a further selection process is performed on the basis of the analysis of their CV. The resulting list of experts, flagged as ethics experts in the database, are then available to all the services organising ethics reviews (ethics screening and ethics assessment). This list is maintained by the DG RTD ethics department (Research Ethics and Integrity Sector, Unit Chief scientific Adviser-SAM;EGE).

In order to ensure a better coherence in the methodology and improve the knowledge of the experts on the specificities of the ethics process of the EC Framework Programme, each expert, before becoming a member of an ethics review, follows an ethics training organised by the RTD ethics department. As regards EC staff (i Commission and agency services), similar trainings are offered to all newcomers, to project and legal officers. Both types of trainings are either of general nature (based on the Ethics Issues table of the Horizon 2020 application – see "how to complete your ethics self-assessment" document, sited below), and are also organised on specific topics such as data protection and ethics, security , medical research, research integrity and misconduct etc.

The Horizon Ethics Appraisal procedure is described in :
https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm
The topics of focus in the Horizon 2020 Ethics Appraisal procedure can be seen in:
https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

In brief, the ethics appraisal procedure followed for all proposals is carried out in different steps, starting from participants answering a questionnaire included in the proposal template (ethics self-assessment). For the proposals likely to be funded, ethics experts and/or qualified staff first perform an ethics pre-Screening of this self-assessment. For most of the calls pre-screening is only performed on proposals which did not report any potential ethics issue, to confirm that it is indeed the case. The objective of the pre-screening is to list the potential ethical issues but not to assess them.

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The next step of the ethics review procedure, the ethics screening, is carried out by ethics experts during the scientific evaluation or soon after. It concerns all the the proposals with at least one confirmed ethics issues.

For a limited number of proposals (e.g. severe intervention on humans, lack of appropriate ethics framework in the country where the research will be performed, etc.) the ethics screening can be followed by an ethics assessment prior to the signature of the grant agreement. The ethics assessment is an in-depth analysis of the ethics issues of the proposals, taking into account, when available the conclusions of the ethics screening. An ethics assessment is systematically performed on all proposals involving the use of Human Embryonic Stem Cells or Human embryos. Proposals that do not follow ethics principles may be rejected.

The ethics review (ethics screening and ethics assessment) can lead to ethics requirements that are becoming contractual obligation. Whenever necessary and usually following the recommendation of the experts involved in the ethics review, one or more ethics checks can be performed during the project implementation. Those checks are also done by ethics experts selected from the list described above."

More on the topic: [Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects](#) / European Commission, 2012.

EUROPEAN PARLIAMENT ROLE IN HORIZON 2020

Parliament is involved in the legislative of the Horizon Europe giving [criteria](#) for the activities to be funded as well as the [budget](#) allocated.

Requested about these issues, the DG Research provided the following information:
Directorate-General for Research and Innovation - Policy & Programming Centre - Horizon Strategic Planning & Programming (Co-design & Co-creation) (RTD.A.3):
"For Horizon Europe, the drafting of the topic description is done via a process of co-creation and co-design. The (draft) Strategic Plan for 2021-2024, which was co-designed with input from citizens and stakeholders sets out Key Strategic Orientations and impact areas for the period. The topics for the work programme are then identified according to an intervention logic that will deliver on these expected impacts. The topic texts are co-created (drafted) by groups bringing together all DGs and Commission services with a policy interest in that area of research and innovation. The draft topic texts are further refined via interactions with the responsible configurations of the (shadow) Programme Committee.
Upon request, the Commission intends to exchange views with the responsible Committee in the European Parliament on: (i) the list of potential partnerships candidates based on the Articles 185 and 187 of the Treaty on the Functioning of the European Union which will be covered by (inception) impact assessments; (ii) the list of tentative missions identified by the Mission boards; (iii) the results of the Strategic Plan before its formal adoption, and to present and share with that Committee documents related to work programmes."

STUDIES / REPORTS IMPROVEMENTS FOR ETHICS IN HORIZON EUROPE

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In a meeting last January 2019, Commissioner Carlos Moedas indicated about ethics in Horizon Europe: "*Horizon Europe will build on the success of the Ethics Appraisal Scheme under Horizon 2020. This improved substantially the quality of the ethics evaluation, notably by ensuring that all proposals considered for funding are reviewed by ethics experts and by introducing Ethics Checks for sensitive cases.*

For proposals involving the use of human Embryonic Stem Cells or human embryos, the rules will remain identical to those of Horizon 2020. Transparency and clarity will be increased in Horizon Europe, since the rules for participation now include all the main elements that were scattered in several documents under Horizon 2020.

The growing impact of science and technologies (gene editing, big data, AI, robotics) on societies and economies, calls more than ever for the adherence to the highest ethics standards. This will be a global objective of Horizon Europe."

The Horizon Europe proposal describes on its Art. 15 Ethics procedures within the programme and underlines that actions which are not ethically acceptable may be rejected or terminated at any time.

Science with and for Society in Horizon 2020 - Achievements and Recommendations for Horizon Europe / European Commission, June 2020.
See chapter 2 "Research ethics and research integrity", especially point 2.4 "Recommendations"

Needed: tougher ethics policies in EU research projects / Peter Novitzky. In Science Business. July, 2020.
Author describes how responsible research and innovation' policies in Horizon 2020 don't often translate into action. Thus, a broader, deeper effort is needed.

Novitzky, P. *et al.* (2020) 'Improve alignment of research policy and societal values', *Science*, 369(6499), pp. 39–41. doi: 10.1126/science.abb3415.
Historically, scientific and engineering expertise has been key in shaping research and innovation (R&I) policies, with benefits presumed to accrue to society more broadly over time (*1*). But there is persistent and growing concern about whether and how ethical and societal values are integrated into R&I policies and governance. Many policy efforts have emerged in response to such concerns, one prominent example being Europe's Eighth Framework Programme, Horizon 2020 (H2020), whose focus on "Responsible Research and Innovation" (RRI) provides a case study for the translation of such normative perspectives into concrete policy action and implementation. Our analysis of this H2020 RRI approach suggests a lack of consistent integration of elements such as ethics, open access, open innovation, and public engagement. On the basis of our evaluation, we suggest possible pathways for strengthening efforts to deliver R&I policies that deepen mutually beneficial science and society relationships.

Ethics of connected and automated vehicles report and factsheet / European Commission, September 2020.
The European Commission has published a report by an independent group of experts on Ethics of Connected and Automated Vehicles (CAVs). Under the Horizon Europe programme starting in 2021, research and innovation on Cooperative, Connected and Automated Mobility will remain a key priority. EU values and principles need to be at the core of these new technologies to ensure their ethical use and positive impact.

Putting critique to work: Ethics in EU security research / Matthias Leese et al. In: Security Dialogue, Vol.50, n°1 page(s): 59-76, 2019.

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In this article, we examine the possibility of exercising critique through the mandatory ethical coverage that EU security research projects must be subjected to. Applied ethics, so we argue, speaks to several core issues in the critical security studies agenda, such as turning abstract considerations of critique into forms of tangible cooperation, engaging exoteric communities, and placing normative questions about security within concrete contexts of its imagination and production. Accordingly, it can be seen as a concrete way of putting critique to work. At the same time, however, applied ethics does face considerable challenges that result from its location in the middle of numerous cross-pressures, such as political ambitions, economic interests, technological rationales and the demands of security professionals. These challenges risk turning what was intended to be the critical corrective of applied ethics into a legitimizing function of mere 'ethics approval'. Drawing on personal experiences as well as debates on critical security studies and ethics, we discuss some of these challenges and discuss the possibility of and conditions for critique within the arena of EU security research.

European Development Funds

This section was produced by Eric Pichon (EPRS. External Policies)

The European Development Funds are managed by the EU Commission (mainly DG DEVCO) and the EIB, outside of the EU budget. Member States' contribution keys for the EDFs are different from the ones for the EU budget, and are set by the Council for each EDF.

> *'Due to the intergovernmental nature of the EDFs,* **the European Parliament […] is** **not involved in establishing and allocating EDF resources**. *However, the European Parliament is still the discharge authority, except for the Investment Facility, which is managed by the EIB' (European Court of Auditors, 2019).*

For each beneficiary country, a **National Indicative Programme** defines priority sectors (no more than three, according to the Agenda for change). Beneficiary countries and the European Union have a joint responsibility to adopt the National Indicative Programmes (NIPs) and to appraise and monitor projects.

An **EDF Committee** is composed of one representative per Member State. It delivers opinions by a qualified majority of votes, proportionate to the Member States' contribution keys, on the programming, monitoring, and evaluation of the EU aid.

> *'When the EDF Committee has delivered its opinion, the Commission shall adopt measures which shall apply immediately. However, if those measures are not in accordance with the opinion of the EDF Committee, they shall be communicated by the Commission to the Council forthwith. In such a case, the Commission shall defer the application of the measures […]. The Council, acting by the same qualified majority as the EDF Committee, may take a different decision within this period. '* (Council Regulation (EU) 2015/322 *of 2 March 2015 on the implementation of the 11th EDF, Title IV, Decision-making procedures, article 14).*

As for other development instruments, funds are spent using various methods such as budget support, grants or contracts. Depending on the method used, scrutiny over the spending can be more or less deep.

> *'The European Commission keeps both revenue and expenditure accounts. […] The Director-General for Development and Cooperation (DEVCO) of the Commission authorises the appropriations, with both the geographical directors and the heads of EU delegations in the ACP States being authorising officers by delegation. The expenditure can be managed in several ways. In a centralised way, the Commission then implements it directly (40% of the expenditure on average for the 10th EDF); in a decentralised way, it delegates the task to the beneficiary ACP State or regional organisation (25%); in joint management, it is an international partner organisation that implements the expenditure according to its own rules, at the double risk of high management costs and a lower visibility of the European intervention (30%). Finally, in indirect centralised management (3%) the*

implementation of the expenditure is entrusted to a delegated body from an EU Member State.' (Ténier, J., 2019).

For a more detailed description of the procedure, we have forwarded your question (without mentioning your name) to DG DEVCO. Here is their answer:

*'For projects financed by the EDF, as for those financed by the general budget of the Union, all aspects relating to the drafting of guidelines for applicants (which define the **themes and priorities** which are the subject of a call for proposals), as well as the details of the composition and the exact **role of the evaluation committees** responsible for selecting the proposals (to which **the rules do not foresee involving the EP**), are described in the Practical Guide to contractual procedures that you will find here (see chapter 6 on grants). Of course, respect for ethical and environmental standards is always required.'*

Review

The ACP-EU Council of Ministers reviews the results at least once a year. **The ACP-EU Joint Parliamentary Assembly (JPA) - of which 78 MEPs are members - has limited scrutiny over the EDF programming.** However, according to a staff member of the EP delegation to the ACP,

'every time an EP delegation goes on a mission and every time a JPA plenary is held, three or four projects that the EU (co)funds in these countries are carefully selected: they are visited and a political evaluation is made, including an assessment of the ethical criteria. This of course represents a very small proportion of all financed projects. These visits are reported to AFET or DEVE, which can consider taking appropriate action if any shortcoming is found. If a research project was found to be unethical, it would probably be reported but it did not happen so far.'

Each year, the **Court of Auditors** delivers a report on the still running EDFs, examining the legality and regularity of the accounts (for transactions managed by the Commission, not the EIB) rather than the detailed rationale for each programme and project (which can be occasionally addressed in special reports). For the **annual discharge procedure**, the examination by the EP of EDF implementation is mainly based on the ECA report.

Further reading:

European Commission, Practical guide on contract procedures for European Union external action, August 2020

European Commission, Annual Accounts of the European Development Fund 2019, COM(2020) 290 final, 26.6.2020

European Parliament, 2019 discharge: General budget of the EU - 8th, 9th, 10th and 11th EDFs, 2020/2190(DEC) - awaiting Committee decision

European Court of Auditors, Annual Report on the activities funded by the 8th, 9th, 10th and 11th European Development Funds (EDFs) for the financial year 2018, 2019/C 340/02, 8

European Parliament, 2018 discharge: 8th, 9th,10th and 11th European Development Funds (EDFs), 2019/2065(DEC)

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Zygierewicz Anna, [EU-Africa academic cooperation](#), EPRS, December 2019

> *EU-Africa academic cooperation is one of the priority of the strategic partnership between both regions. It allows the mobility of students, researchers and academic staff as well as the cooperation between academic institutions from both regions. The cooperation is supported, not least with the EU funds, through the Erasmus+ and Horizon 2020 programmes as well as through the Inter-Africa Mobility Scheme. With the new financial perspective and the new 'post-Cotonou' agreement, still in negotiations, it is important to ensure the future of the EU-Africa academic cooperation is relevant in scale to the needs and expectations and is focusing on topics important for both regions.*

[International collaboration in Horizon Europe: A new approach to partnering with Africa](#), ECDPM, DSW, 15-06-2020

Ténier Jacques, [Le Fonds Européen de Développement (FED) : L'instrument financier de soixante années de politique de coopération à destination des pays d'Afrique, des Caraïbes et du Pacifique (ACP)](#), *Gestion & Finances Publiques*, 2019/5 (N° 5), p. 108-118.

[Africa-Europe Research and Innovation Cooperation: Global Challenges, Bi-Regional Responses](#). Palgrave Macmillan, 2018

We trust this will be useful, but please do not hesitate to contact us again if you need further information.

Yours sincerely,

Maria Isabel MORAN VIDAL

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