



Annual Activity Report 2021

Health and Digital Executive Agency

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HaDEA IN BRIEF

The European Health and Digital Executive Agency (HaDEA) started its operations on 1 April 2021.

The Agency is located in Brussels and has its own legal personality. The day to day management is in the hands of the Director, while the Agency is supervised by a Steering Committee composed of representatives of its parent Directorates-General (DGs). The Commission has entrusted HADEA with the implementation of the following programmes:

- the EU4Health programme;
- the health research strand of Horizon Europe (Cluster 1);
- the health components of the Single Market Programme (food chain);
- Horizon Europe's cluster 4 "Digital, Industry and Space";
- the digital strand of the Connecting Europe Facility programme;
- the Digital Europe Programme.

HaDEA's mission is "to implement actions that strengthen Europe in the domains of health, food safety, digital technologies and networks, industrial capacities and space. We provide high quality and service-oriented support, with the aim to enable European society to become more healthy, resilient and fair and European industry to become more competitive. We ensure that the projects funded by the HaDEA deliver concrete results that benefit the lives of all EU citizens and provide the European Commission with valuable input for its policies".

The Agency implements its mission in close cooperation with its **six parent DGs**: DG Health and Food Safety (DG SANTE), DG Research and Innovation (DG RTD), DG Communication Networks, Content and Technology (DG CNECT), DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), DG Defence Industry and Space (DG DEFIS) and with the Commission's European Health Emergency Preparedness and Response Authority (HERA). This close cooperation with the parent DGs is essential not only for programme implementation, but also for the feedback the Agency provides to the Commission in view of the latter's policy tasks.

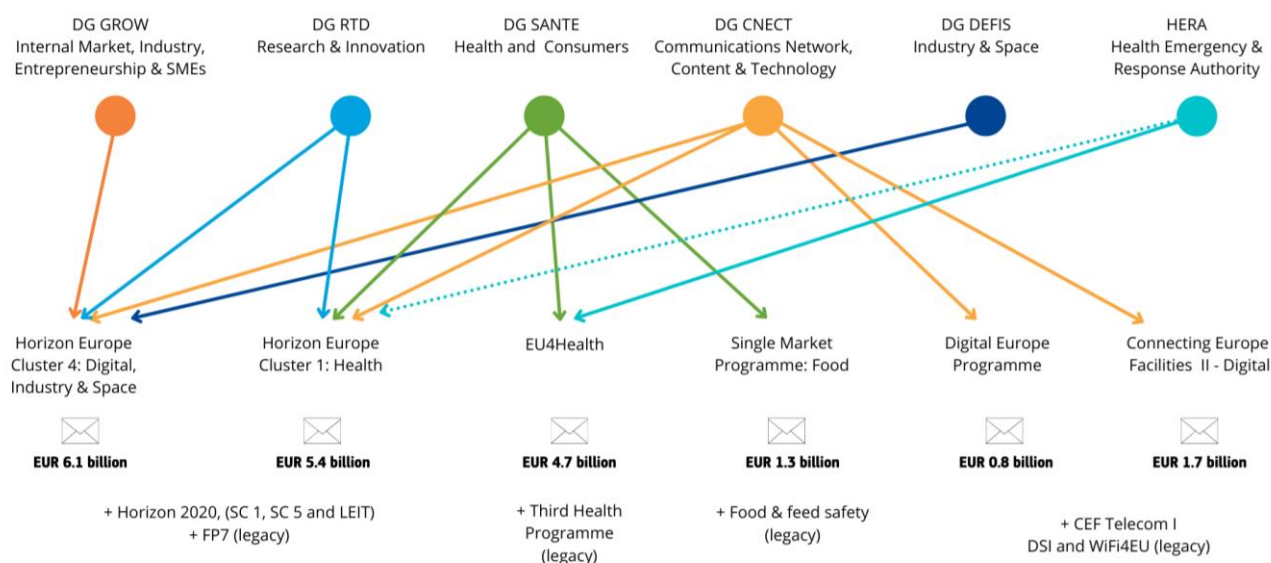


Figure 1: Overview of programmes and budget delegated to HaDEA (2021-2027)

The **challenges and risks** HaDEA is faced with are inherent to being a new entity: the Agency needs to deliver on programme implementation while still developing its structure and procedures and recruiting its staff.

On 1 April 2021, **HaDEA took over the management of several legacy programmes from other Commission services** (European Commission DGs, REA, EASME, INEA, CHAFEA). This annual activity report covers the activities that have taken place the whole reporting year, including, from January to March 2021, when these programmes were managed by other services. In addition, following the winding up of CHAFEA, this report also includes also the financial reports of CHAFEA (see Annex 3).

2014-2020 programmes now managed by HaDEA	'Giving' entity
Third Health Programme	CHAFEA
Horizon 2020: Part III: Societal Challenge 1: Health, demographic change and well-being	European Commission
Horizon 2020: Part II: specific objective 'Leadership in enabling and industrial technologies (LEIT)' - ICT, NMBP, Space	EASME, REA, European Commission
Horizon 2020: Part III: Societal challenge 5: Climate action, Environment, resource efficiency and raw materials	EASME, European Commission
FP7: The theme 'space' of the specific programme cooperation of the Seventh Framework Programme	REA
the Common financial framework in the area of food and feed safety including Better training for safer food	CHAFEA
Connecting Europe Facility: Telecom	INEA, European Commission

Table 1: Overview of the entities previously managing the legacy programmes now managed by HaDEA

Commission Implementing Decision (EU) 2021/173 of 12 February 2021 which established HaDEA foresaw a transitional period for the new Agency during which the Commission shall manage the Agency. For this purpose, the Director-General of the Directorate-General for Health and Food Safety shall act as interim Director and exercise all the duties assigned to the Director. This authority was delegated to Mr. Matthew Hudson on 19 February 2021 who acted as interim Director throughout the year 2021.

On 18 January 2022, the Commission appointed Ms Marina Zanchi as Director of the Agency. She took up functions on 16 February 2022.

EXECUTIVE SUMMARY

This annual activity report is a management report of the Director of the Health and Digital Executive Agency to the College of Commissioners. Annual activity reports are the main instrument of management accountability within the Commission and constitute the basis on which the College takes political responsibility for the decisions it takes as well as for the coordinating, executive and management functions it exercises, as laid down in the Treaties ⁽¹⁾.

A. Implementation of the Agency's Annual Work Programme – Highlights of the year

The Health and Digital Executive Agency (HaDEA) was created on 16 February 2021 and started operations on 1 April 2021. The challenge the Agency was faced with in 2021 was double: setting up from scratch the processes, procedures and resources to make HaDEA an efficient and effective executive agency and at the same time delivering on the legacy programmes it took over from other executive agencies and DGs, and launching the new programmes delegated from the Commission.

Laying out the Agency's foundations for the coming years

Recruitment has been a priority from day one. HaDEA's staff increased by almost 19% over the nine months of its existence, from 273 staff members to 324. The Agency took a participatory approach to the development of its corporate culture. The first step was the definition of HaDEA's mission, vision and values, which will enable the staff, coming from a variety of backgrounds, to rally around common objectives.

To ensure sound financial management the Agency put in place appropriate financial circuits and adopted its anti-fraud strategy. A robust internal control framework was set up to ensure the legality and regularity of the Agency's operations.

In line with the Commission's corporate policy in these areas, HaDEA also equipped itself with its own data protection action plan, and IT governance procedures.

Ensuring a smooth transition in programme implementation

With regard to operational activities, the transfer of the (legacy) project portfolios from other executive agencies and DGs to HaDEA overall went smoothly. A few technical hurdles were encountered which resulted in some delays in the signing of grant agreements for a minority of legacy programmes (Horizon 2020, Third Health Programme).

A significant part of the year was dedicated to the management of legacy programmes. HaDEA also invested in the preparation for the new programmes, training its teams, testing new tools, recruiting experts. Nevertheless, even though most of the work programmes

⁽¹⁾ Article 17(1) of the Treaty on the European Union.

were adopted quite late in the year, HaDEA managed to launch no less than 80 calls for proposals from the 2021-2027 programmes in 2021.

HaDEA's 2021 achievements

Despite the many challenges of establishing a new agency, HaDEA managed to fully execute its operational budget. 99% of payments were made on time, exceeding our target.



Gaining the trust of the Agency's parent DGs was a key objective for HaDEA as a new player in the field. With the objective to create an efficient and effective feedback loop between programme implementation and policymaking, HaDEA developed a feedback-to-policy framework, that was adopted by the Agency's Steering Committee in December 2021. The overarching Memorandum of Understanding that will govern the Agency's interaction with its parent DGs was signed and will be supplemented by five programme-specific MoUs, covering the five delegated programmes, in early 2022.

Supporting the Commission's response to the Covid-19 pandemic

HaDEA directly contributed to the EU response to the Covid-19 pandemic by implementing actions linked to research on Covid-19. An emergency call under Horizon Europe Cluster 1: Health was published in April 2021, before the adoption of the Horizon Europe work programme. Nine grant agreements resulting from this call have already been signed. In addition, the Agency launched a call for tender to map Covid-19 therapeutics in the EU under the EU4Health programme.

Operational challenges for the Agency

The effects of the Covid-19 pandemic resulted in many requests for project extension across the different programmes managed by the Agency, leading to higher unpredictability in budget forecast.

The late adoption of work programmes will pose a challenge for the coming year, when HaDEA will need to manage the calls from 2021 and 2022 as well as the ongoing management of the legacy.

In just nine months, HaDEA developed a robust framework for its operations. The Agency will focus now on moving forward with the implementation of the programmes in its remit, consolidating the new structure and proceeding to adjustments where necessary.

B. Key Performance Indicators (KPIs)

Time to grant Source of data: HaDEA [unit C2.1]	Result: 93% of grants signed within deadlines • Third Health Programme: 88.2% • Horizon Europe, Cluster 1: Health: 100% • Horizon 2020 – Societal Challenge 1: 96% • Horizon 2020 – Societal Challenge 5 / SILC II: 17.6% • CEF 1 – Telecom (DSI): 99.4% Target (2021): 98% of grants signed within deadlines
Time to pay Source of data: HaDEA [unit C2.1]	Result: 99% timely payments • Third Health Programme: 100% • EU4Health: 100% • Horizon Europe, Cluster 1: Health: 100% • Horizon 2020 – Societal Challenge 1: 100% • Horizon 2020 – Societal Challenge 5 / SILC II: 99% • CEF 1 – Telecom (DSI): 100% • CEF 1 – Telecom (WiFi4EU): 77% • Food and feed safety, BTSF: 100% Target: 98% timely payments
% of budget execution (commitments and payments – operational budget) Source of data: HaDEA [unit C2.1]	Result: 100% budget execution Target: 100% budget execution
Overall risk at closure Source of data: HaDEA [unit C2.2]	Result: 1.68% Target: < 2% of relevant expenditure
% of satisfied external clients Source of data: external client satisfaction surveys / evaluation forms events [Director's Office and operational units]	Result: Not available. The late adoption of some of the work programmes resulted in a delay of the launch of the calls. The planned public events, such as the InfoDays, were also held late, in some cases postponed to 2022 or run directly by the European Commission. As a consequence, there was not enough data available in 2021 to draw valid conclusions on a baseline for external client satisfaction. Target: Higher levels of satisfaction by client group/programme

C. Key conclusions on financial management and internal control

In line with the Commission's Internal Control Framework, HaDEA has assessed its internal control systems during the reporting year and has concluded that it is effective, that the components and principles are present and functioning well overall, but that some improvements are needed as minor deficiencies were identified related to the principles 2, 11, 12 and 17 ⁽²⁾. Please refer to section 2.1.3 for further details.

In addition, HaDEA has systematically examined the available control results and indicators, as well as the observations and recommendations issued by the internal auditor and the European Court of Auditors. These elements have been assessed to determine their impact on management's assurance about the achievement of the control objectives. Please refer to section 2.1 for further details.

As regards the legality and regularity of the transactions, HaDEA considers that the cumulative residual error rates are below the established targets for all current programmes, except for the Connecting Europe Facility (CEF) Telecom – Digital Service Infrastructure (DSI) segment. For this segment, the multi-annual residual error rate inherited from CINEA amounted to 3.84% at the end of 2021, which is above the materiality threshold of 2%. Following the administrative transfer of programmes between the executive agencies, this segment does not meet the cumulative criteria to fall below the 'de-minimis rule', as HaDEA had a smaller portfolio in 2021 than its predecessor in 2020. HaDEA has therefore made a reservation for this segment, even though the impact is well below the established exposure limits. The Agency considers this as a "one-off" event, in view of the combined effects of the low financial exposure (EUR 2.38 M EUR), the phasing out of this segment and the improvements already made, resulting in a decreasing error rate. Please refer to Annex 9 for further details.

In conclusion, based on the elements reported above, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director, in his capacity as Authorising Officer by Delegation has signed the Declaration of Assurance albeit qualified by a reservation concerning the segment CEF – DSI (budget line 02.039903).

D. Provision of information to the Commissioner(s)

In the context of the regular meetings during the year between the Director and the parent DGs on management matters, the main elements of this report and assurance declaration,

⁽²⁾ Principle 2: the Agency exercises oversight of the development and performance of internal control; Principle 11: the Agency selects and develops general control activities over technology to support the achievement of objectives; Principle 12: the Agency deploys control activities through procedures that put policies into action; Principle 17: the Agency assesses and communicates internal control deficiencies in a timely manner.

including the reservation envisaged, have been brought to the attention of the Agency's Steering Committee and to the parent DGs' Directors General.

1. Implementation of the Agency's Annual Work Programme – Highlights of the year

This section provides an overview of the activities carried out by the Agency for the implementation of the programmes delegated to the Agency: EU4Health, Horizon Europe (Cluster 1 and Cluster 4), SMP Food, Digital Europe Programme, and Connecting Europe Facility 2 – Digital.

The Agency liaises regularly with its parent DGs on project implementation. HaDEA and its parent DGs signed a **Memorandum of Understanding** (MoU) in December 2021 defining the general provisions and modalities of interaction. This general MoU will be supplemented by programme-specific MoUs covering each of the five programmes delegated to the Agency, to be signed in 2022.

Furthermore, HaDEA adopted a **feedback-to-policy framework**, with the objective to support policy activities in the best and most efficient manner. This framework, developed in agreement with its parent DGs, defines key principles for carrying out feedback to policy activities that apply across all the programmes managed by HaDEA.

HaDEA directly contributed to the **EU response to the Covid-19 pandemic** by implementing actions linked to research on Covid-19. An emergency call under Horizon Europe Cluster 1: Health was published in April 2021, before the adoption of the Horizon Europe work programme. Nine grant agreements resulting from this call have already been signed. In addition, the Agency launched a call for tender to map Covid-19 therapeutics in the EU under the EU4Health programme.

1.1. EU4Health

The first EU4Health annual work programme was adopted on 24 June 2021 ⁽³⁾, with a budget of **EUR 311 684 898** ⁽⁴⁾, almost 4,5 times that of the 2020 annual work programme of the predecessor programme ⁽⁵⁾, reflecting the priority given to health investment by the Commission. The EU4Health actions delegated to HaDEA are key for the delivery of the Commission's objective of building a stronger European Health Union. They support the delivery of *Europe's Beating Cancer Plan* and contribute to the EU response to the Covid-19 pandemic. They also offer support on topics such as crisis preparedness,

⁽³⁾ Commission Implementing Decision on the financing of the Programme for the Union's action in the field of health ('EU4Health Programme') and the adoption of the work programme for 2021.

⁽⁴⁾ HaDEA is responsible for delivering EUR 243.3 million of the work programme 2021: EUR 164.3 million in grants and EUR 79 million for procurement activities.

⁽⁵⁾ The budget of the 2020 annual work programme, funded under the Third Health Programme, amounted to EUR 69 674 000.

including preparatory actions of the Health Emergency Preparedness and Response Authority (HERA); e-health; and the European Reference Networks (ERNs).

HaDEA launched the majority of the actions planned in the 2021 work programme, including all the calls for proposals. In addition, eight calls for tender were published in successive waves upon reception of the tender specifications from DG SANTE.

Call management

HaDEA published two waves of **calls for proposals** on 25 June and on 14 October 2021 respectively. The calls covered 19 topics, ranging from support to the implementation of *Europe's Beating Cancer Plan* (e.g. the improvement of access to human papillomavirus vaccination), through the promotion of healthy lifestyles, to mental health challenges during the Covid-19 pandemic and community-based services for communicable diseases. HaDEA received 11 proposals for the actions listed under the first wave which have been evaluated in December 2021, while the deadline for submission for the second wave of calls is 25 January 2022.

Furthermore, HaDEA launched two waves of **Joint Actions** (JAs) covering 13 topics on 16 September and 15 November 2021 respectively. These offer **Member States and other eligible countries** ⁽⁶⁾ diverse and broad opportunities to implement actions dedicated to e-health, health workforce, telemedicine in care systems for cancer prevention, medicines, and clinical trials (including notably the expedited assessment of clinical trials for Covid-19 therapeutics).

In addition to this, the Agency launched in December 2021 several calls for **direct grants for Member States and other eligible countries** on the following topics: EU Health Digital Service Infrastructure (eHDSI), patient access to health data, and medical terminologies (SNOMED). The Agency also launched 10 **calls for direct grants with international organisations** (WHO, IARC, OECD, EDQM and Orphanet) and one with an identified beneficiary (EuROGEN).

HaDEA liaised with the Slovenian authorities with regard to the organisation of the **Slovenian EU Presidency conference**, which took place in Ljubljana on 15-16 July 2021. The Agency also initiated preparatory work to support the forthcoming French Presidency conference in March 2022.

Finally, the Agency supported the work on the health Awards, managed by DG SANTE. HaDEA took part in the evaluation of the 99 eligible proposals (30 on cancer and 69 on mental health).

⁽⁶⁾ The Decisions to allow the participation of Norway and Iceland in the EU4Health programme were adopted on 24 September 2021 by the EEA Joint Committee. However, their participation has been retroactively set to 1 January 2021, both in terms of eligibility and financial contributions. For more information, please see: <https://www.efta.int/eea/eu-programmes>.

With regards to the **Third EU Health Programme (legacy)**, HaDEA engaged in several funding-related activities, notably to support: the Portuguese Presidency Conference; the coordination activities and registries of the European Reference Networks; non-governmental organisations (operating grants), and the management of direct grant agreements with international organisations.

Public procurement and contract management

HaDEA launched eight tenders in 2021. This work entailed the preparation of the tender specifications, the publication of the calls, the evaluation of the tenders and the assessment of the outcome by the Agency's advisory committee on procurement and contracts (ACPC). These tenders focused mainly on crisis preparedness, including HERA preparatory actions and the eTravel tool⁽⁷⁾. Contracts under these procedures are in the process of being awarded, notably in the area of anti-microbial resistance medical countermeasures and on Covid-19 therapeutics, while the eTravel tool tender has been signed. One call on obstacles to vaccination has been published but not evaluated yet.

All files submitted to the ACPC received favourable opinions, demonstrating the robustness of the evaluation procedures in place.

Not all of the tenders planned in the 2021 annual work programme could be launched. This can be explained by the late adoption of the 2021 work programme, the time needed for the preparation of the tender specifications by the parent DG, and lack of resources (a considerable number of staff for the Agency's EU4Health units still had to be recruited).

HaDEA undertook preparatory work for some 13 other procedures. These calls for tender will be published in February 2022. They include actions on cancer, ERNs, digital health and vaccination programmes' performance.

HaDEA signed and concluded the last series of evaluations of healthcare providers, members of European Reference Networks (ERNs). The Agency also oversaw the delivery of

Defining efficient and effective processes for HaDEA's procurement activity

Given that the Agency's tendering activity will primarily be on EU4Health, HaDEA has set up a dedicated procurement cell within one of the EU4Health units, with the objective to ensure high-quality and timely procurement procedures. This cell will work closely together with the legal sector and the financial teams and provide support to all procurement procedures across the Agency, thereby ensuring uniform procedures. In addition, HaDEA's own advisory committee on procurement and contracts (ACPC) provides independent advice on the compliance of the procedures.

a contract on the assessment, quality monitoring and evaluation of ERNs and their members. This paves the way for the launch of a new framework contract covering the first four years of the EU4Health programme.

⁽⁷⁾ The eTravel tool is a platform for the electronic passenger location forms (ePLF) used in cross-border crossings.

Support to the Commission's policy work

HaDEA contributed to a note on results from past actions to feed into the preparatory steps for the development of the 2022 EU4Health work programme.

On 25-26 May 2021, HaDEA organised a cluster event, bringing together ongoing EU-co-funded projects on vaccination. The Agency also moderated the launch event for the EU health workforce projects cluster on 20 September 2021 ⁽⁸⁾. Finally, on 10-12 November 2021, HaDEA participated in the European Public Health Conference with a virtual stand and a lunch symposium on the EU4Health Programme.

External communication and dissemination

HaDEA showed commitment to outreach and transparency by organising no less than six info sessions on the different EU4Health actions in 2021. HaDEA also published applicants' [questions](#) on its website.

HaDEA participated in three online events organised with Member States: the first focused on the results achieved by Spain under the Third Health Programme; the two others presented the opportunities offered by the EU4Health programme to Italian and Irish health stakeholders.

Four videos were created to present the work accomplished under the Third Health Programme in key areas (cancer, digital health systems and healthcare) between 2014 and 2020, and making the links with the new EU4Health programme.

All aforementioned calls and communication activities were promoted on HaDEA's social media channels (Twitter, LinkedIn), as well as on the Agency's website.

1.2. Horizon Europe

1.2.1. Cluster 1: Health

Through the implementation of Horizon Europe, Pillar 2, Cluster 1: Health, HaDEA contributes to many of the Commission's objectives in the area of health research: finding new ways to keep people healthy, preventing diseases, developing better diagnostics and more effective therapies, using personalised medicine approaches to improve healthcare and wellbeing, and taking up innovative health technologies, such as digital ones.

⁽⁸⁾ HaDEA's information sessions, the cluster event of 25-26 May 2021 and the EU Health Workforce projects cluster event of 20 September 2021 were all hosted by DG SANTE's EU Health policy Platform (HPP).

Call management

In 2021, the Agency launched a total of 22 calls under Cluster 1, for a budget of EUR 987 million.

Special "HERA incubator" emergency call for Covid-19-related research

The first call managed by the Agency was published via an emergency procedure in early April 2021, before the full Horizon Europe work programme was adopted. It focused on vaccines and therapeutic clinical trials to boost Covid-19 prevention and treatment, and on the development of large-scale Covid-19 patient cohorts worldwide, supporting research for a global response to the pandemic.

Due to technical problems with the electronic submission tool, the call deadline had to be postponed twice, but eventually closed on 20 May. The delays were compensated by shortening the evaluation phase: the Agency successfully carried out the full evaluation process in May-June. Nine grant agreements were signed in 2021 (out of 59 proposals, that is, a success rate of 15%), allowing the successful projects to make a speedy start.



Copyright: European Commission

HaDEA proceeded to the rapid implementation of the Covid-19 call, funding nine projects. Among them, COVend, a project launched in August 2021 aims at developing a new effective therapy during mild and moderate Covid-19 stages, to prevent the disease progression to progress to a severe illness.

EU funding: EUR 9,994,979.00

18 partners from 14 countries: AT, BE, CH, DE, ES, FI, FR, IE, IT, LT, NL, PT, RO, SI

Website: <https://covend-project.eu>

Funding to research and innovation

Two additional series of calls were published on 22 June 2021, providing support for health research and innovation, in line with the six destinations of Horizon Europe's Cluster 1. They covered topics ranging from indoor air quality, the prevention of obesity, to mental health, from digital empowerment and health literacy of citizens to health issues of exposure to electromagnetic fields, to mention only a few.

The Agency managed the evaluation process of the first series of nine calls (26 topics) in the last quarter of 2021. The high number of proposals received (593) confirms the very high interest of applicants in Horizon Europe health research funding. The results of the calls were communicated to the parent DGs in January 2022, and applicants will be informed shortly after.

The second series comprising of 11 calls (eight single-stage and three two-stage calls) opened progressively during the last quarter of the year and closed on 1 February 2022.

EU mission on cancer

Finally, HaDEA launched a call related to the implementation of the EU mission on cancer. This specific call addressed cancer screening and early detection, quality of life and patient preference measures for cancer patients and survivors, and risk factors.

Dissemination activities

In 2021, the Agency participated in the information webinar for National Contact Points, sharing information on the 2021-2022 work programme. HaDEA also co-organised the second edition of the [Health Info Day](#) with DG RTD. This fully virtual event took place in October and included a general presentation of the 2022 work programme, sessions dedicated to gender equality and clinical studies, and presentations on all six destinations.

Project management

The Agency implemented the legacy activities of Horizon 2020: Part III: Societal Challenge 1: Health, demographic change and well-being. At the end of 2021, the portfolio included over 500 ongoing projects receiving over EUR 3 500 million of funding in total.

Overall, 190 interim payments and 38 final payments were done in 2021.

The implementation was slightly delayed, mainly due to the Covid-19 extension flexibility measures, which resulted in a very high number of amendment requests to extend the duration of the grant agreements. Health research projects have indeed been particularly affected, as patients and researchers could not access medical research facilities. In 2021, 48% of the amendments signed for health research projects included an extension. These extensions naturally also affect budget implementation.

Support to the Commission's policy work

In parallel to programme implementation, HaDEA provided regular input to its parent DG RTD, in the form of specific information on projects and project portfolios, notably on Covid-19 research.

1.2.2. Cluster 4: Digital, Industry and Space

1. Digital

The actions implemented by HaDEA within the digital strand of the Horizon Europe programme, Cluster 4: Digital, Industry and Space, aim at enabling industry to accelerate and lead the twin green and digital transitions through research and innovation actions. These actions contribute to the Commission's objective "A Europe fit for the digital age".

In addition, the Agency managed the legacy activities of Part II 'Industrial leadership' of Horizon 2020 Specific Programme, and notably the specific objective "Leadership in enabling and industrial technologies (LEIT)".

Project monitoring

189 Horizon 2020 legacy projects were transferred to HaDEA, making up in total an EU contribution of approximately EUR 1 000 million. The main tasks linked to these projects included the follow-up of tasks and deliverables, the setting-up of technical reviews, the recruitment of experts, the monitoring of payments both to project coordinators and experts, as well as the coordination of projects under the same topic to increase synergies.

16 projects were closed in 2021, while the Agency signed four new grant agreements under the Horizon 2020 programme. These projects will kick off in 2022.

At the end of 2021, HaDEA managed a portfolio of 177 projects with an EU contribution of around EUR 964 million, covering mainly the research and innovation areas related to augmented/virtual/extended reality, photonics, Artificial Intelligence, and laser manufacturing.

Call management

HaDEA managed the evaluation of three Horizon Europe calls for proposals ⁽⁹⁾, covering 10 topics, with a budget of EUR 198 million. In total, 187 proposals were submitted, of which 33 were selected.

Communication activities

To raise awareness on the newly published call, the Agency took an active role in the Information Days on Horizon Europe – Cluster 4 for Calls 2021 and Calls 2022, providing several presentations on future call topics.

The success of projects funded by HaDEA granted them visibility: some projects featured in a CORDIS Results Pack dedicated to innovative research for the future of work, while others were highlighted in eight success stories published on CORDIS and in the Horizon Magazine.

Finally, HaDEA contributed to other events such as the Horizon Results Booster and the Horizon Europe Cluster National Contact Point training on 24 November 2021.

2. Industry

The industry strand of Horizon Europe, Cluster 4 aims at increasing industrial competitiveness, sustainability and resilience for the benefit and prosperity of Europe and its citizens. With the successful launch of the first five Horizon Europe calls under this strand, and the management of legacy projects funded under Horizon 2020, HaDEA supports the European Research and Innovation Agenda.

⁽⁹⁾ These calls were managed jointly with the industry strand of Horizon Europe Cluster 4.

Project monitoring

HaDEA took over 689 Horizon 2020 ⁽¹⁰⁾ legacy projects at the start of its mandate, making up a total EU contribution of approximately EUR 4 250 million. Following the last calls under the legacy programme, 17 grant agreements were signed.

At the end of 2021, the Agency was managing 382 legacy projects covering research and innovation areas related to raw materials, advanced materials and sustainable products (amounting to an EU contribution of around EUR 2 800 million).

Call management

HaDEA launched five Horizon Europe calls for proposals ⁽¹¹⁾ for a combined envelope of EUR 696.3 million.

The calls resulted in 451 proposals, confirming the very high interest of applicants for Horizon Europe funding. 101 proposals were selected following the evaluation process which took place in October-November, a success rate of 22%. At the end of the year, HaDEA was working on the preparation of the grant agreements. The first Horizon Europe projects are expected to kick off in May 2022.

The Covid-19 pandemic had an impact on the evaluation process. The mitigation measures in force meant that all consensus and panel review meetings needed to be performed online. The Agency successfully organised and conducted in a timely manner almost 500 remote meetings, while maintaining high quality standards, as verified by the external observers.

Communication activities

The European added value of the projects managed by the Agency led some of them to be featured in a CORDIS Results Pack, highlighting significant scientific and industrial advances in the fields of artificial intelligence in industry. 14 of them were also picked as success stories on CORDIS and the Horizon Magazine. Furthermore, projects were featured in a factsheet on the research and innovation contribution for the Energy/Climate *'Fit for 55 Package'*.

HaDEA organised nine events together with parent DGs and various Horizon 2020-funded projects. Many events were held virtually, due to the Covid-19 pandemic.

HaDEA is particularly proud of three major events co-organised with DG GROW in the framework of the 2021 European Raw Materials Week, namely:

- The second Horizon Technology Success Stories event, held on 15 November 2021.

⁽¹⁰⁾ Horizon 2020: Part III: Societal challenge 5: climate action, environment, resource efficiency and raw materials.

⁽¹¹⁾ Three of these calls were managed jointly with the digital strand of Horizon Europe: Cluster 4.

- The fourth Critical Raw Materials event, on 15 November 2021; and
- Horizon Raw Materials Information Day and Brokerage Event on 16 November 2021.

These events enabled HaDEA to provide information on funding opportunities, to engage with stakeholders and gain visibility.

Furthermore, different projects managed by HaDEA participated in the annual Raw Materials Information System (RMIS) Technical Workshop held on 3 December 2021 (co-organised with the Joint Research Centre). The Agency also supported the Horizon Europe Cluster National Contact Point training on 24 November 2021 and contributed to the EuroNanoForum 2021 conference (5-6 May 2021), organised by the Portuguese Presidency of the Council of the EU.

Furthermore, HaDEA contributed to regular and ad-hoc cluster events, notably the cluster events on “preserving fresh water”, which took place on 12 May and 15 December 2021, organised jointly with 5 SPIRE projects and WaterEurope (for the second event).

Finally, the Agency contributed actively to the Info days on Horizon Europe – Cluster 4, raising awareness on the opportunities offered by the calls 2021-2022.

3. Space

Project Management

In 2021, HaDEA managed the Horizon 2020 Leadership in Enabling and Industrial Technologies (LEIT) Space grants, including related policy feedback, and prepared the first Horizon Europe Space calls.

Horizon 2020 (legacy)

From a total of 269 signed grant agreements receiving EUR 783 million EU funding, 117 projects were closed and 152 projects were still ongoing at the end of 2021. Five grant agreements were signed in 2021 from the last Horizon 2020 LEIT Space call's reserve list.

HaDEA (and before April, REA) carried out 32 final and 38 interim payments for Horizon 2020 LEIT Space projects. The time to pay target was always met with the exception of one slightly delayed payment (2 days) due to the transfer of files from REA to HaDEA and to the time needed for the bank transfer. In addition, 25 pre-financing payments were made.

The Covid-19 pandemic caused various implementation delays. 48 projects requested an extension of their duration in 2021 – an unusually high share out of the 70 amendments that were signed in total in 2021.

Overall, at the end of 2021, the implementation of Horizon 2020 LEIT Space projects was well on track.

7th Framework Programme (FP7) (legacy)

With the final payment of project RemoveDEBRIS-607099 on 5 July 2021, HaDEA ended the last FP7 Space projects.

[Call implementation](#)

The start of Horizon Europe, Cluster 4, Space calls was delayed due to the late adoption of the Horizon Europe Cluster 4 work programme for 2021-2022. Two calls, HORIZON-CL4-2021-SPACE-01 and HORIZON-CL4-2022-SPACE-01, opened on 2 November 2021, the closure date of both is 16 February 2022. HaDEA prepared carefully for the evaluation to take place in 2022, in particular the selection and contracting of experts, and pioneered for the Horizon Europe, Space strand a new expert briefing approach using the EU Academy platform on the basis of a Service Level Agreement with the Joint Research Centre.

Apart from these two calls, HaDEA evaluated in October 2021 a proposal for the support of the network of Space National Contact Points under the topic HORIZON-CL4-2021-HUMAN-01-3.

[Support to the Commission's policy work](#)

The Agency also delivered a crucial set of policy feedback and support activities.

Thus, HaDEA supported DG DEFIS with the organisation of several stakeholder consultation workshops, the outcomes of which will serve to populate future work programmes (EO technologies, SatCom, Access to Space, Critical Space Technologies, quantum gravimetry for EO, Space Traffic Management, as well as a webinar on artificial intelligence in the Copernicus context). HaDEA contributed notably with technical advice, the identification of speakers and session co-moderation.

HaDEA provided tailored input to the Horizon Europe, Space work programme topics. The input was based on the experiences from the implementation of the project portfolio on space research. This included coordination with DG DEFIS and the European Space Agency (ESA) on issues of applicant eligibility in topics of strategic interest for the European Union.

HaDEA contributed significantly to the definition and initiation of a support contract for its stakeholder consultation platform, for communication activities as well as for several studies including EU-funded space project clusterisation.

HaDEA produced input for the cyclic (road)mapping sessions of the Joint Task Force of Commission, the European Defense Agency (EDA) and the European Space Agency (ESA) on European non-dependence in critical technologies, as well as for the European Space technology harmonisation coordinated by the ESA.

HaDEA prepared and delivered a comprehensive 'Horizon 2020 Space country report' for the delegations of the Horizon 2020 Space Programme Committee, and a presentation summarising the relevant Horizon 2020 projects and lessons learned to the Copernicus User Forum and Copernicus Committee.

HaDEA answered numerous ad-hoc requests regarding foreign direct investment and also provided analysis of entities beyond project information, e.g. related to supply chain aspects, technical analysis and inputs related to acquisitions such as the strategic position / importance of potential acquisition targets in a certain area of technology.

Finally, support was provided to the evaluation of the European Innovation Council prize on low-cost space launchers, with suggestions for the selection of experts, the evaluation setup (including expert briefings) and the moderation of consensus meetings.

Communication activities

HaDEA regularly promoted the new Horizon Europe calls on space and related information events on its social media channels (LinkedIn, Twitter).

The Agency supported the Horizon Europe Cluster National Contact Point training on 30 November 2021.

Finally, HaDEA worked on harmonising its communication strategy in space research with that of DG DEFIS, and organising the cooperation with its service contractor.

1.3. Single Market Programme: Food Safety

The Single Market programme (SMP) aims to empower and protect consumers and enable Europe's many small and medium-sized enterprises (SMEs) to take full advantage of a well-functioning Single Market. In doing so, it will ensure continuity in the efficient delivery of the Single Market on the ground, while providing better value for money for EU citizens.

The Agency implements the food safety strand of the Single Market Programme, which supports the safe production of food, the prevention and eradication of animal diseases and plant pests, and the improvement of animal welfare in the EU. The actions under this strand include also support to the fight against antimicrobial resistance as well as to the organisation of reliable official controls by the national competent authorities.

Since 2021 was the first year of operation, the Agency invested in defining clear processes and tools. Competent staff was recruited and trained in only a few months. In parallel, specific procedures and a new model of grant agreement were developed. Time and resources were invested in the **onboarding process of the programme to eGrants**, which should allow the Agency to automatise the grant management to a great extent.

In addition, following the announcement of the forthcoming introduction of lump sums for veterinary programmes and unit costs for phytosanitary programmes, the Agency drafted the corresponding authorising decisions. These new funding mechanisms will be introduced for the actions from the 2021 work programme onwards, with the goal to reduce the administrative burden for Member States and the Commission.

Project management

As a first priority, HaDEA managed the legacy⁽¹²⁾ transferred by DG SANTE, assessing around 230 final reports and proceeding to the payments for ongoing projects. These grants covered mainly veterinary and phytosanitary programmes, grants for European Reference Laboratories and Reference Centres (EURL/EURC) and coordinated control plans for anti-microbial resistance (AMR).

Call management

Despite the late adoption of the SMP regulation (28 April 2021) and of the SMP: food 2021-2022 work programme (6 May 2021), HADEA successfully launched several calls for proposals and calls for tenders.

The four calls for proposals focused on veterinary and phytosanitary programmes (2021-2022), EURL/EURC (2021-2022) and anti-microbial resistance (2021) and were launched between May and September.

The signature of the ensuing **grant agreements**, which was planned for 2021, had to be postponed due to the late adoption of the work programme, and to the need to recruit specialised staff. The grant agreements will be signed in early 2022.

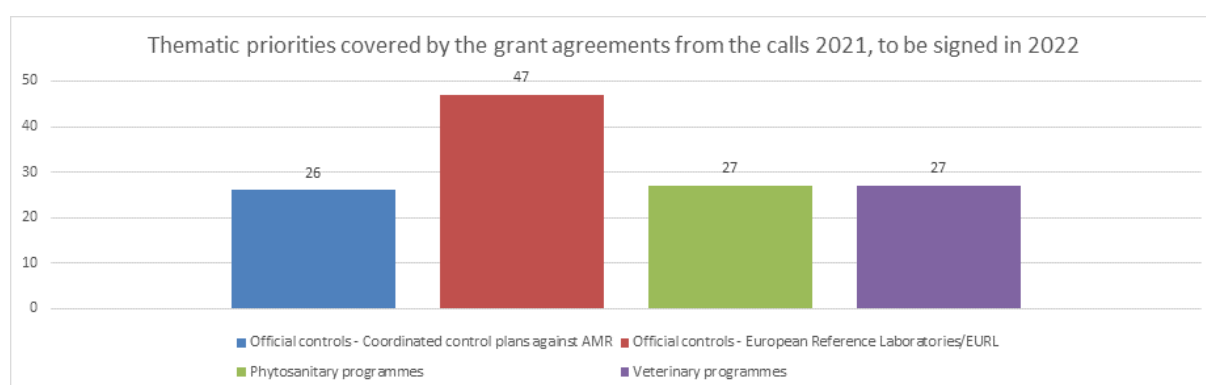


Figure 2: Thematic priorities covered by the grant agreements from the 2021 SMP food calls

Better Training for Safer Food

As regards **procurement**, HADEA launched three calls for tenders for the Better Training for Safer Food (BTSF) initiative, for which contracts were signed in December 2021. In addition, to adapt to the context of the Covid-19 pandemic, existing BTSF contracts have been amended to include the possibility to organise on-line training sessions instead of face-to-face training modules.

Last but not least, the Agency prepared a number of actions relating to the Farm to Fork strategy. Preparatory meetings have been organised with DG SANTE to allow the launch of

¹² Legacy projects are funded under the Common financial framework in the area of food and feed safety including Better training for safer food (Regulation 2014/652).

three calls on food waste prevention stemming from the 2021 annual work programme during the first quarter of 2022.

1.4. Digital Europe Programme

The Digital Europe Programme (DEP) aims to strengthen the EU digital sovereignty, by reinforcing key capacity areas through strategic deployments in artificial intelligence, cybersecurity, high-performance computing, data infrastructure, governance and processing, as well as their best use for critical sectors such as environment, manufacturing, agriculture and health. The programme is also instrumental in supporting the digital transformation of the EU industrial ecosystems.

Building on the experience in managing Connecting Europe Facility – 1 Telecom (Digital Service Infrastructures), HaDEA quickly established excellent working relations with DG CNECT as well as with the DGs from the policy areas concerned with the development of infrastructure.

Evaluation and call preparation

Due to the late adoption of the work programme, the first batch of DEP calls was launched by DG CNECT on 17 November 2021 and then handed over to HaDEA. As the calls are due to close in 2022, no evaluation took place in 2021. The publication of the second batch of calls is planned for 22 February 2022.

The first wave of calls cover two specific objectives (SO): Advanced digital skills (SO4); and Deployment, best use of digital capacities and interoperability (SO5). HaDEA's contribution focused on the practical management of the call, the organisation of the evaluations planned for the first quarter of 2022, including the selection and validation of experts to assist in the evaluation of proposals, as well as the handling of information requests by potential applicants: around 115 inquiries from potential applicants were answered. Moreover, HaDEA participated in five info days organised by – or with the participation of – the DGs working in the policy targeted by an infrastructure development, providing information on the six topics covered in the first calls. HaDEA provided an overview of the application process as well as of the submission tool.

The Agency also finalised the preparatory work for the second batch of calls, in cooperation with the relevant policy Units. These calls will cover topics related to both SO4 and SO5 as well as Data space for cultural heritage (deployment) (SO2).

Legacy activities: Connecting Europe Facility – 1 Telecom (Digital Service Infrastructures)

In addition, HADEA continued the implementation of the legacy activities of the Connecting Europe Facility – 1 (CEF-1) Telecom programme. This programme facilitates cross-border digital interaction between public administrations, businesses and citizens by deploying Digital Service Infrastructures (DSIs). The DSIs implemented by the Agency range from the digitisation of Europe's cultural heritage (Europeana), real-time cooperation between cybersecurity response teams, eHealth networks of rare diseases, interoperable e-Identity

and e-Signature, automated translation tools, encrypted e-Delivery and blockchain solutions for public administrations, safer internet centres, digital skills, European digital media observatory, etc.

In 2021, HaDEA successfully signed the last 164 grant agreements for the programme (calls 2020-1, 2020-2), within the targeted time to grant. The Agency also managed three additional Core Service Platform projects, delegated by DG CNECT (on eArchiving and the EU Student eCard).

HaDEA processed 128 final payments in 2021, the highest number of final payments since the beginning of the programme. Despite the high number of payments, the average time to pay was maintained to last year's average, 60 days.

In the same period, the Agency processed 97 amendments. Similar to the previous year, the requests consisted mainly of modifications in the timing of the actions, a consequence of the Covid-19 pandemic (with an impact on the number of final payments performed in 2021) or of administrative updates.

Communication

The Agency pursued discussions with the relevant DGs (DSIs owners) in the framework of various governance boards meetings, and to update the so-called 'validation approach': before proceeding to balance payments, checks are performed to ensure that the services implemented through the CEF telecom actions are operational.

With regard to communication to the beneficiaries, three webinars were organised. A webinar on grant agreement preparation was held on 19 May 2021 for the successful applicants of the 2020-2 CEF Telecom call, which brought together more than 140 participants. Furthermore, a webinar on personnel costs was organised on 4 March 2021 for all the beneficiaries of ongoing CEF actions, gathering over 230 participants. Finally, a webinar on CEF Telecom grant agreement implementation was organised on 14 October 2021. The satisfaction survey sent to the participants after the webinar showed an 82% satisfaction rate for the webinar.

Communication activities included the preparation of the webpage on DEP and the migration of web content linked to CEF Telecom. Besides, success stories of a specific DSI were presented each month in web articles and social media posts. The monthly theme coincided with EU or international thematic days or events to boost their reach. After the adoption of the 2021 work programme, visibility was given to the calls and info days. HaDEA's social media activity helped increase engagement, interactions and grow the followers base, both for DEP and the Agency.

Synergies and cooperation

With regard to the eHealth component of CEF, a fruitful exchange of information took place with HaDEA colleagues working on health programmes and with DG SANTE. The support and state of play of European Reference Networks under CEF and the Third Health Programme was discussed, as well as future opportunities for CEF beneficiaries under

EU4Health. Finally, a meeting on cybersecurity was held at the end of November with colleagues from DG CNECT to discuss the lessons learnt from CEF, and how these could be used in future projects and activities of DG CNECT and of the European Cybersecurity Competence Centre.

1.5. Connecting Europe Facility: Digital

Preparatory activities – CEF-2 Digital programme (2021-2027)

The scope of the CEF Digital programme reflects the increasing importance of very high-capacity networks for Gigabit and 5G connectivity to make the European economy and society more resilient, sustainable and fit for the digital age ⁽¹³⁾. Together with other EU instruments (RRF, DEP and ESIF notably), the CEF-2 programme will therefore contribute to achieving the 2025 and 2030 connectivity targets set by the European Gigabit Society ⁽¹⁴⁾ and the Digital Compass ⁽¹⁵⁾ strategies respectively.

The CEF Regulation ⁽¹⁶⁾, the legal base of this second generation of the CEF programme, was adopted by the European Parliament and Council on 7 July 2021. While DG CNECT was drafting the CEF Digital work programme 2021-2025, HaDEA focused on preparing the related application templates, drafting the call texts, identifying experts for the upcoming evaluations and other preparatory tasks.

Due to the late adoption of the work programme on 16 December 2021, the publication of the first calls for proposals was postponed to 12 January 2022, with a total budget of EUR 258 million to be managed by the Agency.

A communication campaign was carried out in coordination with DG CNECT. Visibility on HaDEA's website and on social media was given to the adoption of the CEF Digital work programme and to the ensuing calls, as well as to the Info-Day.

HaDEA also cooperated closely with CINEA, the Executive Agency responsible for implementing other parts of the CEF programme (transport and energy), to coordinate common activities and ensure synergies between the three CEF sectors. HaDEA, CINEA and their respective parent DGs (CNECT, MOVE and ENER) met twice in 2021 to supervise these cooperation activities.

⁽¹³⁾ [Political guidelines](#) from President von der Leyen

⁽¹⁴⁾ European Commission communication “Connectivity for a Competitive Digital Single Market Towards a European Gigabit society”, COM(2016)587 of 14.09.2016.

⁽¹⁵⁾ European Commission communication “2030 Digital Compass: the European way for the Digital Decade”, COM(2021)118 of 09.03.2021

⁽¹⁶⁾ Regulation (EU) 2021/1153 establishing the Connecting Europe Facility and repealing Regulations (EU) No 1316/2013 and (EU) No 283/2014; Official Journal of the EU L.249 of 14.07.2021.

WiFi4EU initiative (Connecting Europe Facility – CEF-1 Telecom)

The Agency pursued the implementation of the [WiFi4EU initiative](#), a pioneering voucher scheme funded by the CEF-1 Telecom programme (2014-2020). The WiFi4EU initiative aims to provide free Wi-Fi for all Europeans by supporting 8 802 municipalities (10 % of all municipalities in Europe) with a budget of EUR 132 million. The beneficiaries receive a voucher (EUR 15 000 each) to purchase and install Wi-Fi hotspots in local public places (townhalls, museums, health centres, pedestrian streets, parks, etc.); the municipality commits to keep this public internet connectivity free of charge for all users for at least 3 years (see lists of [beneficiaries](#) and [maps](#)). HaDEA monitors remotely, through the [WiFi4EU portal](#), the deployed WiFi4EU networks.

WiFi4EU initiative: a resounding success

Every day, over 117,000 citizens connect to free public WiFi4EU hotspots across Europe

In order to mitigate the negative effects of the Covid-19 pandemic outbreak, in February 2021 all WiFi4EU beneficiaries were granted a further six-month extension, to help them overcome shortages of equipment and other supply chain disruptions.

HaDEA also put in place measures to boost the implementation rate, as foreseen in the action plan initiated by INEA⁽¹⁷⁾ and pursued by HaDEA from April 2021: (i) additional notifications were sent to the beneficiaries, (ii) webinars targeting both Wi-Fi installation companies and municipalities were organised with the support of the Broadband Competence Offices Support Facility, (iii) phone call campaigns were run, (iv) preventive actions were taken to avoid delays in the bank account validation, and (v) a [video](#) illustrating the steps needed to redeem the voucher was produced.

At the end of 2021, HaDEA was managing a portfolio of 8 393 actions for a total amount of EUR 126 million under the WiFi4EU initiative. Up to the end of 2021, a total of 5 604 payments have been executed (for a total of EUR 84 million) under this initiative.

In 2021, out of the 2 577 payments (almost EUR 38.6 million) processed by INEA and HaDEA, 583 were affected by IT issues and led to late payments (executed in more than 60 days), which impacted negatively the “time to pay” annual target (98% of payments made on time):

- 254 late payments were incurred between January-March 2021 due to issues in reflecting the transition between multi-annual financial frameworks in ABAC, the accounting and payments IT system of the European Commission;
- 329 late payments were incurred between June and October 2021 due to the transfer from INEA to HaDEA. The electronic processing of payments was put on

⁽¹⁷⁾ The executive agency INEA previously managed the WiFi4EU initiative and implemented measures from the action plan from October 2020 to February 2021.

hold due to necessary adaptations in ABAC; notably, no payments could be authorised between 17 March and 4 June due to this IT issue.

HaDEA has analysed a sample of late payments and observed that certain late payments records were unreliable. An IT development is planned in 2022 in order to permanently solve this issue. In the meantime, HaDEA has put measures in place to ensure correct data on the statistics on late payments.

2. Modern and efficient administration and internal control

In 2021, HaDEA implemented 100% of its **operational budget** in commitments (EUR 2 954 million). HaDEA paid on time close to 99% of its operational appropriations aggregating EUR 1.362 billion, demonstrating effective monitoring of payment deadlines.

In addition, the Agency has its own **administrative budget** for which it receives from the EU an annual budget (EUR 26.98 million in 2021). The administrative budget covers the running costs of the Agency, mainly staff expenditure, office related costs, IT and other services. In 2021, HaDEA implemented 95% of its commitment appropriations. The final rate of implementation for payments is 75.5%. This is largely due to the fact that HaDEA was not able to pay the rent and associated costs, for the OIB could not provide provide a final service-level agreement nor debit time on time. 97% of the payments related to the administrative budget were executed on time.

2.1. Financial management and internal control

Assurance is provided on the basis of an objective examination of evidence of the effectiveness of risk management, control and governance processes.

This examination is carried out by management, who monitors the functioning of the internal control systems on a continuous basis, and by internal and external auditors. The results are explicitly documented and reported to the Director. The following reports have been considered:

- the reports from authorising officers by sub-delegation (and also from the Common Implementation Centre ("CIC") to all research related services);
- the contribution by the Head of Department in charge of Risk Management and Internal Control, including the results of internal control monitoring at agency level;
- the results of the annual risk assessment exercise;
- the reports on recorded exceptions, non-compliance events and cases of 'confirmation of instructions' (Art 92.3 FR);
- the outcome of ex-post audit and anti-fraud activities;
- the observations and the recommendations reported by the European Court of Auditors (ECA);
- the results of the corporate indicators reported in the Annex 4.

The contribution of the Internal Audit Service on the state of internal control is not applicable for HaDEA in 2021.

These reports result from a systematic analysis of the available evidence. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a complete coverage of the budget delegated to HaDEA.

This section covers the control results and other relevant elements that support management's assurance. It is structured into 2.1.1 Control results, 2.1.2 Audit observations and recommendations, 2.1.3 Effectiveness of internal control systems, and resulting in 2.1.4 Conclusions on the assurance.

2.1.1. Control results

This section reports and assesses the elements identified by management which support the assurance on the achievement of the internal control objectives (ICO) ⁽¹⁸⁾. The Agency's assurance building and materiality criteria are outlined in Annex 5. The Annex 6 outlines the main risks together with the control processes to mitigate them and the indicators used to measure the performance of the relevant control systems.

The Agency's assurance is built around the principles of effectiveness, efficiency and economy. This section demonstrates how HaDEA applied these principles. The controls focus mainly on the legality and regularity of transactions, as well as on fraud prevention, detection and correction. Ex-ante and ex-post controls are carried out through the following four stages are considered:

1. Programming, evaluation and selection of proposals;
2. Contracting, grant agreement preparation (GAP);
3. Monitoring of the execution;
4. Ex-post controls/audits.

The table 2 below presents an overview of HaDEA's expenditure per activity (grants, procurement and experts) and per programme (legacy programmes and Horizon Europe/SMP Food chain/EU4Health).

Grants cover 99% of HaDEA's expenditure whereas 1% of the Agency's budget was spent on procurement and experts in 2021. Legacy programmes represent almost all (95.3%) of the total expenditure for grants (H2020 77.05%, food chain 7.97%, DSI 5.3%, WIFI4EU 2.87%, Third Health programme 2.04%, FP7 0.05%) while the new programmes represent 4.7% (Horizon Europe 4.67%, Single Market Programme: food chain and EU4Health <1%).

⁽¹⁸⁾ 1) Effectiveness, efficiency and economy of operations; 2) reliability of reporting; 3) safeguarding of assets and information; 4) prevention, detection, correction and follow-up of fraud and irregularities; and 5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (FR Art 36.2). The 2nd and/or 3rd Internal Control Objective(s) (ICO) only when applicable, given the DG's activities.

Risk type / Activities	Grants	Procurement	Other (experts)	Total expenditure	NEI, e.g. revenues, assets, OBS ((in)tangible assets or financial assets and liabilities)
<i>Legacy programmes (2014-2020)</i>					
Horizon 2020	1.037,00	0,00	0,65	1.037,65	
Food chain legacy	107,24	10,06	0,09	117,39	
CEF Telecom	0,00	0,00	0,00	0,00	
DSI	71,27	0,05	0,00	71,32	
Wifi4Europe	38,66	0,00	0,00	38,66	
Health programme	27,39	5,98	0,02	33,39	
FP7	0,70	0,00	0,00	0,70	
<i>Current programmes (2021-2027)</i>		0,00			
Horizon Europe	62,86		0,49	63,34	
Single Market Programme Food Chain	0,00	0,00	0,00	0,00	
EU4Health	0,70	0,30	0,02	1,02	
Vaccines stock (*)					16,45
Total in MEUR	1.345,81	16,39	1,27	1.363,48	20,82
Total in %	98,70%	1,20%	0,09%	100,00%	
Links to AAR annex 3	1.363,48 MEUR; see Table 2 payments made				

(*) This amount is not included yet in HaDEA's provisionnal balance sheet in Annex 3; it will be added in the final accounts of 2022 at the latest.

Table 2: Overview table of HaDEA's expenditure per activity (in EUR million)

Acronyms contained in the table: EA: executive agency; DG: directorate general; EIB: European Investment Bank; EE: entrusted entities; JU: joint undertaking; NEI: non-expenditure items; OBS: Off-Balance Sheet.

This table also includes CHAFEA's payment of EUR 0.11 million for the EU4Health Programme, recorded in 2021. Please see Annex 3 for more details.

In line with the 2018 Financial Regulation, HADEA's assessment for the new reporting requirement is as follows:

- HADEA had **no cases of "confirmation of instructions"** in 2021 (new FR art 92.3);
- There was **no cases of financing not linked to costs** (new FR art 125.3);
- There was **no Financial Framework Partnership exceeding 4 years** signed during the reporting year 2021;
- With regard to **cases of flat-rates >7% for indirect costs** (new FR art 181.6):
HaDEA manages grants under Horizon 2020 and Horizon Europe. The basic acts of these programmes provide for a 25% flat rate for indirect costs, by derogation to the Financial Regulation ⁽¹⁹⁾.
- 93 grant agreements signed in 2021 ⁽²⁰⁾ **derogated from the principle of non-retroactivity** pursuant to Article 193 of the Financial Regulation. In these cases, costs incurred prior to the date of submission of the grant application were not eligible.

1. Effectiveness of controls

a) Legality and regularity of the transactions

HaDEA uses internal control processes to ensure sound management of risks relating to the legality and regularity of the underlying transactions it is responsible for, taking into

⁽¹⁹⁾ Regulation (EU) 2021/695 on Horizon Europe: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.170.01.0001.01.ENG&toc=OJ:L:2021:170:TOC

Regulation (EU) 1291/2013 on Horizon 2020: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013R1291>

⁽²⁰⁾ All 93 instances were similar cases, where the starting date of the project is after the submission of the proposal but before the signature of the grant agreement, and are split as follows:

- 71 cases under Connecting Europe Facility – Telecom. In these cases, the text of the call allows beneficiaries to choose a starting date that is before the grant agreement signature, but not before the date of the submission of the proposal, to ensure the continuity of the various actions financed under different calls;
- 16 cases under Horizon 2020. The earlier starting date is due to IT issues related to the state of the operations in HaDEA;
- 6 cases under Horizon Europe, where the margin of retroactivity is very small – few days in 4 out of 6 cases – duly justified by the beneficiaries.

account the multiannual character of programmes and the nature of the payments concerned.

The Agency assesses the effectiveness of its internal control processes per stage as described in detail in Annex 7. Stages 1 to 3 cover the ex-ante controls. Stage 4 reflects the ex-post controls.

As regards the ex-ante controls the indicators show results that are largely within the target margin. As the vast majority of the payments in 2021 were made for the grants (99%), the indicators below refer mainly to the grants managed by the Agency in 2021.

Stage 1 – Evaluation and selection of proposals

The careful planning of the calls and their wide publication ensure that the application process results in a large number of good-quality proposals, out of which the very best can be chosen.

Programme	Horizon Europe	SMP	EU4health
Indicative call budget	EUR 991 800 000	EUR 3 000 000	EUR 19 000 000
Requested funding in proposals received	EUR 4 503 992 472	EUR 1 200 515	EUR 20 611 990
Recommended funding in proposals accepted	EUR 969 294 406	EUR 1 200 515	EUR 15 354 108

Table 3: HaDEA's accepted funding in call evaluations closed in 2021

The time-to-inform limit was achieved in all cases.

Stage 2 – Contracting

Regarding the time-to-grant, 93% of the grant agreements were signed within deadlines which is slightly below the target of 98%.

Programme	Horizon Europe	Horizon 2020	CEF Telecom	3 rd Health
Time-to-grant	100%	96%	99,4%	88,2%

Please see sub-section 2 on [efficiency of controls](#) for a commentary on the results of time to grant.

Stage 3 – Monitoring the execution

Quantitatively, EUR 19.93 million (or 1.46%) of the submitted amount of EUR 1.363 billion was rejected due to ineligibility of costs/irregularities.

Stage 4 – Ex-Post Controls

The ex-post controls (audits) are carried out on the costs declared to the Agency. Their objective is to verify the legality and regularity of the underlying transactions and consequently, the final eligible EU contribution of the grants.

The main indicator used to assess the legality and regularity of the transactions is the residual error rate detected by ex-post audits.

The final control objective is to have a cumulative residual error rate within a maximum range of 2-5% (or below 2% for Horizon 2020) and which does not exceed 2% by the end of the programme cycle for non-Horizon programmes (in 2021, the programmes concerned for HaDEA were CEF-1 Telecom, Third Health Programme, Seventh Framework Programme and Food and Feed ⁽²¹⁾). The state of play is assessed annually, taking into account the results of the implementation of ex-post audit strategies, the frequency and significance of the errors found, as well as a cost-benefit analysis of the effort needed to detect and correct them. The ex-post audit methodology is explained in Annex 5.

Multi-annual error rates at the end of 2021 are shown in the table below ⁽²²⁾:

Programme	Detected error rates	Residual error rates
Horizon 2020	2.29%	1.73%
Food and Feed	1.13%	1.03%
CEF Telecom	4.11%	3.84%
Public Health	2.15%	1.96%
FP7	5.45%	3.63%

Table 4: Multi-annual error rates per programme at the end of 2021

For the CEF Telecom DSI segment, the multi-annual residual error rate at the end of 2021 is at 3.84%, above the materiality threshold of 2%. Despite the low financial exposure (EUR 2.38 M EUR), its share in budget implemented in 2021 represents 5.23% of the total payments, which is above the threshold of 5.00%. This segment therefore no longer meets the cumulative criteria to fall below the ‘de-minimis rule’ ⁽²³⁾. HaDEA has therefore issued a

⁽²¹⁾ On an annual basis for the Food and feed programme due to the design of the programme and in line with the approach applied by DG SANTE.

⁽²²⁾ An explanation of the methodology for ex-post controls for each programme under HaDEA management is provided in Annex 5 while details of the sources and results of the controls are provided in Annex 7.

⁽²³⁾ In 2019, a de-minimis rule for financial reservations was introduced stipulating that quantified AAR reservations related to residual error rates above the 2% materiality threshold are

reservation for this segment, although the impact is well below the established exposure limits. The Agency considers it as a “one-off” event, in view of the combined effects of the low financial exposure (EUR 2.38 million), the phasing out of this segment and the improvements already made, resulting in a decreasing error rate. See Annex 9 for further details.

Overall, HaDEA’s portfolio consists of segments with a relatively low error rate, i.e. Food and Feed, and segments with a relatively high error rate, such as Horizon 2020 and CEF Telecom DSI grants ⁽²⁴⁾.

This is, respectively thanks to the inherent risk profile of the programme Food and Feed, which uses unit costs option, and due to the related complexities of the funding modalities of the programmes Horizon 2020 and CEF Telecom, (and notably regarding the reimbursement of eligible costs), despite the efforts made in the related segments.

For the Horizon 2020 and CEF Telecom DSI segments, most of the errors relate to incorrect claims for personnel costs that are mainly due to the beneficiaries’ lack of understanding of the rules. SMEs and private entities inexperienced in the financial management of EU funds are indeed more prone to this type of errors.

For Horizon 2020, the decrease in the error rate could be due, among other reasons, to the beneficiaries’ increased knowledge of the eligibility and its inherent learning curve, as well as the results of the communication campaigns, addressed in particular to newcomers and SMEs. In CEF Telecom DSI, the management actions taken to address these weaknesses are a reinforcement of the guidance and controls implemented, and they demonstrated their efficacy, with a lower level of error. However, beneficiaries still make errors, sometimes because they lack an understanding of the rules (in particular SMEs and newcomers).

At corporate level, following the observations made by the European Court of Auditors in its annual report, further simplifications are being designed, paving the way for a significant reduction of the error rate in Horizon Europe. Actions include further simplification, increased use of simplified forms of funding (including lump sums and unit costs), focused communication campaigns targeting more “error-prone” type of beneficiaries with higher than average error rates, such as SMEs and newcomers, and revised ex-ante controls.

Through recoveries and financial corrections, HaDEA has in place an effective mechanism for correcting errors. During the reporting year the executed corrective capacity amounted in total to EUR 20.86 million representing 1.79% of the relevant expenditure. The benefit of

deemed not substantial and are no longer needed for segments representing less than 5% of a DG’s total payments and with a financial impact below EUR 5 million.

⁽²⁴⁾ The Seventh Framework programme (legacy) is not mentioned here as only one project was transferred to HaDEA’s portfolio. The payments for this project, which was closed in 2021, represent only 0,05% of the payments.

ex-ante controls amounts to EUR 19.93 million ⁽²⁵⁾ across all programmes managed by the Agency, whilst recoveries and financial corrections following the results of ex-post controls amounted to EUR 0.93 million.

HaDEA's relevant expenditure, its estimated overall risk at payment, estimated future corrections and risk at closure are set out in Table X: Estimated risk at payment and at closure (Please refer to Annex 9).

The **estimated overall risk at payment** for 2021 expenditure amounts to EUR 25.34 million, representing 2.15 % of the Agency's total relevant expenditure for 2021. This is the Authorising Officer by Delegation's best, conservative, estimate of the amount of relevant expenditure during the year not in conformity with the contractual and regulatory provisions applicable at the time the payment was made.

This expenditure will subsequently be subject to ex-post controls and a proportion of the underlying errors will be detected and corrected in subsequent years. The conservatively estimated future corrections for 2021 expenditure amount to EUR 5.53 million.

The difference between those two amounts is the **estimated overall risk at closure**, which amounts to EUR 19.91 million, representing 1.68% of the Agency's total relevant expenditure for 2021. HaDEA being a newly established entity with a portfolio of programmes inherited from several DGs and Executive Agencies, there is no opportunity for a realistic comparison with previous years.

For an overview at Commission level, HaDEA's estimated overall risk at payment, the estimated future corrections and the risk at closure are consolidated in the Annual Management and Performance Reports.

HaDEA	relevant expenditure	estimated risk (error rate %) at payment		estimated future corrections and deductions		estimated (error rate %) risk at closure	
	m EUR	m EUR	%	m EUR	%	M EUR	%
Grants							
H2020	885,46	20,28	2,29%	4,96	0,56%	15,32	1,73%
Food and feed	127,08	1,44	1,13%	0,13	0,10%	1,31	1,03%
CEF Telecom DSI	62,15	2,55	4,11%	0,35	0,57%	2,20	3,54%
CEF Telecom Wifi4Europe	38,66	0,19	0,50%	-	0,00%	0,19	0,50%
Public Health Legacy	32,11	0,69	2,15%	0,06	0,19%	0,63	1,96%
FP7	1,66	0,09	5,45%	0,03	1,82%	0,06	3,63%
Horizon Europe	0,00	0,00	0,00%	0,00	0,00%	0,00	0,00%
EU4Health	0,70	0,02	2,15%	0,00	0,19%	0,01	1,96%
Procurement	16,33	0,08	0,50%	0,00	0,00%	0,08	0,50%
Experts	1,27	0,01	0,50%	0,00	0,00%	0,01	0,50%
Subtotal	1.165,43	25,34	2,17%	5,53	0,47%	19,81	1,70%
Administrative budget	20,37	0,10	0,50%	0,00	0,00%	0,10	0,50%
TOTAL	1.185,80	25,45	2,15%	5,53	0,47%	19,91	1,68%

Table 5: HaDEA's estimated amount at risk at payment and closure (The full detailed version of the table is provided in Annex 9)

⁽²⁵⁾ Total of ineligible amounts in invoices due to irregularities and recovery orders based on ex-ante controls.

b) Fraud prevention, detection and correction

In 2021, HaDEA developed its anti-fraud strategy and action plan ⁽²⁶⁾, on the basis of the methodology provided by the European Anti-Fraud Office (OLAF). The strategy will be updated regularly, taking into consideration the results of the annual fraud risk assessment exercise and also based on the developments in the programmes managed by the Agency. HaDEA actively participates in the Fraud and Irregularities in Research (FAIR) Committee chaired by the Common Audit Service (CAS) in which the Common Anti-Fraud Strategy in the Research Family (RAFS) and its Action plan are monitored and discussed.

HaDEA held several meetings with OLAF concerning ongoing investigations and participated in the Fraud Prevention and Detection Network (FPD Net) organised by OLAF.

Since its establishment in April 2021, HaDEA did not receive any final report or financial recommendation from OLAF. However, in the context of the transfer of programmes from several Commission services, HaDEA inherited two financial recommendations to be implemented. One recommendation is currently under implementation, and one is under analysis by HaDEA's services.

HaDEA has taken action in the following areas targeting fraud prevention, detection and correction:

- Ethical behaviour of staff;
- Awareness of fraud risks for programme and financial officers ;
- Good cooperation with stakeholders;
- Timely implementation of OLAF recommendations;

The results achieved during the year are described in more detail in Annex 7.

On the basis of the available information, HaDEA has reasonable assurance that the anti-fraud measures in place are effective and that an adequate fraud prevention, detection and correction system is in place.

c) Other control objectives: safeguarding of assets and information, reliability of reporting

HaDEA identified current assets (inventories) of a total value of EUR 16.45 million at 31 December 2021 ⁽²⁷⁾.

⁽²⁶⁾ Approved by the Interim Director on 17/12/2021 and adopted by the Steering Committee on 24/02/2022.

⁽²⁷⁾ This amount is not yet included in HaDEA's provisional balance sheet in Annex 3; it will be added in the final accounts of 2022 at the latest.

The assets pertain to stocks for foot-and-mouth disease antigens (EUR 16 million) and vaccines for lump skin disease and Sheep and goat plague (EUR 0.45 million) in order to carry out emergency vaccination. The Food Chain strand of the Single Market Programme ⁽²⁸⁾ and its predecessor, the Common Financial Framework ⁽²⁹⁾, provide that a Union financial contribution may be awarded for the establishment of stocks of biological products or the acquisition of vaccines doses if the occurrence or the development in a third country or Member State of one of the animals diseases and zoonoses listed in the Common Financial Framework might constitute a threat to the Union. Reserves of foot-and-mouth disease vaccines were already established in 1991 by Council Decision ⁽³⁰⁾.

The main aim of accounting controls is to assure the quality and reliability of the accounts and underlying transactions through methodical checks on the accounting records (data) and timely communication and correction of the errors. HaDEA received the inventory from DG SANTE in the framework of the budget implementation tasks delegated in 2021. DG SANTE reported in its 2020 AAR that the Court of Auditors' annual audits on DG SANTE's accounts did not reveal any observations that would affect the vaccines stocks.

In conclusion, HaDEA considers the current control arrangements for accounting and financial reporting to be sufficient. Proper safeguarding of the inventories was ensured throughout the year as stated in the reports received from the contractors.

2. Efficiency of controls

One of the means to assess efficiency is to use indicators that can be easily quantified and continuously evaluated throughout the implementation of programmes. The Agency uses the following three indicators: time-to-inform, time-to-grant and time-to-pay. Below is a short description of the status of each indicator.

Detailed information per activity can be found in Annexes 2 and 4.

- **Time to inform:** the time to inform applicants was respected in all cases.
- **Time to grant:** 93% of the grant agreements were signed within deadlines. The time to grant limit was respected for the majority of the grants signed. The discrepancy with HaDEA's target of 98%, is mainly explained through the late signature of 12 grants under Horizon 2020 (one to four days over the time to grant), due to the transfer of files between HaDEA and EASME, who previously managed this part of the programme. The grant agreement preparation, which was

⁽²⁸⁾ Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 on the Single Market Programme (SMP) and repealing – inter alia – Regulation (EU) No 652/2014 the Common Financial Framework (CFF); 2021 work programme C(2021)3046 of 6 May 2021.

⁽²⁹⁾ Article 6(5) of Regulation (EU) No 652/2014 with Article 7 or 10.

⁽³⁰⁾ Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines (OJ L 368, 31.12.1991, p. 21)

ongoing at the time of the handover, was put on hold for almost a month. In addition, some grants signed by the predecessor entities under the Third Health Programme exceeded time to grant due to late changes in the consortium composition.

- **Timely payments:** HaDEA paid on time close to 99% of its operational appropriations amounting to EUR 1 362 billion, demonstrating effective monitoring of payment deadlines, and resulting in a negligible amount of late payment interest (EUR 842). This represents an important achievement for a new entity.

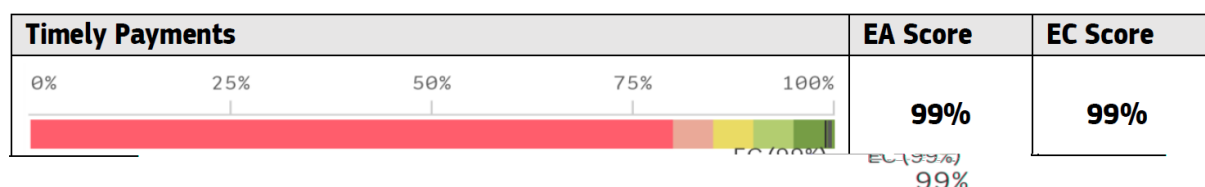


Figure 3: Timely payments indicator – HaDEA's operational budget

Regarding the administrative budget, a few invoices were paid late due to the transfer of files (TOF) from the predecessor agency CHAFEA to HaDEA, and HaDEA's inclusion to the European Commission central accounting system ABAC. However, HaDEA managed to execute 99% of the payments on time thanks to a good monitoring of the payments until the end of the year.

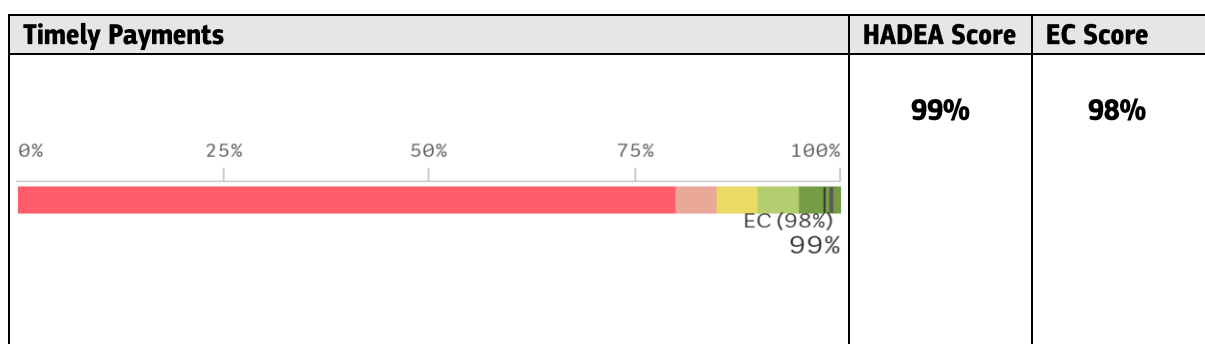


Figure 4: Timely payments indicator – HaDEA's operating budget

- **Time to pay:** HaDEA's net payment time in 2021 is 36 days. HaDEA respected the maximum payment time in the overwhelming majority of the cases (in 98% of the cases for the payment with a 30-day deadline, 78% of the cases for the payments with a 60-day deadline, and 99% for the 90-day deadline). The high number of late payments with a 60-day target are linked to IT delays encountered in the implementation of the WiFi4EU programme. They were caused by the suspension of all operations required to update the local accounting system at the time of the transition of the programme to HaDEA. The major IT issues have been resolved, and there have been no late payments in WiFi4EU since November 2021.

3. Economy of controls

The table below provides an estimate of the total costs of control for direct grant management within HaDEA. The cost of controls is estimated for each of the four stages of grant direct management control system. It was calculated based on the corporate methodology for the estimation, assessment and reporting on the cost-effectiveness of controls. The details of the calculation are available in Annex 7.

The total cost of control within HaDEA for direct grant management can be evaluated to approximately EUR 26.51 million, corresponding **to 1.94% of the total operational grant payments made in 2021** (EUR 1 363.37 million).

HaDEA costs of controls grant management	Costs (in EUR million)			Operational Payments 2021 (in EUR million)	Overall rate (total costs/total amount paid)
	Internal costs	External costs	Total		
Stage 1 – programming and evaluation	3.89	0.98	4.88	1,363.37	0.36%
Stage 2 – contracting	2.81	0.02	2.83	1,363.37	0.21%
Stage 3 – monitoring the execution	17.42	0.47	17.90	1,363.37	1.31%
Stage 4 – ex-post controls and recoveries	0.89	0.02	0.90	1,363.37	0.07%
TOTAL	25.01	1.50	26.51	1,363.37	1.94%

Table 6: HaDEA's costs of controls per control stage

Details of the estimated costs related to shared/pooled control activities carried out by REA and hosted by DG RTD (Common Implementation Centre; Common Audit Service; Common Policy Centre) for the Research and Innovation family are reported in the annual activity reports of REA and RTD.

4. Conclusion on the cost-effectiveness of controls

Based on the most relevant key indicators and control results, HaDEA has assessed the effectiveness, efficiency and economy of its control system and reached a positive conclusion on the cost-effectiveness of the controls for which it is responsible.

The analysis showed that the total benefits of controls significantly counterbalance their overall costs. As demonstrated by the results detailed in the previous sections, the effectiveness and the efficiency of the controls carried out in HaDEA are overall consistently very good and in line with the objectives set for the programmes implemented. They are also proportionate to the risks underlying the operations.

The system of controls in place is therefore considered suitable to fulfil the intended control objectives efficiently and at a reasonable cost. This conclusion is attested by the

satisfactory balance between the largely low error rates, swift time-to-pay and low costs of controls.

The control systems applied in HaDEA aim at keeping the cost of programme implementation at a reasonable level, guaranteeing the quality of the operations and mitigating various risks. Therefore, they are subject to continuous adjustments to the current business environment.

2.1.2. Audit observations and recommendations

This section sets out the observations, opinions and conclusions reported by auditors – including the limited conclusion of the Internal Auditor on the state of internal control. Summaries of the management measures taken in response to the audit recommendations are also included, together with an assessment of the likely material impact of the findings on the achievement of the internal control objectives, and therefore on management's assurance.

Audits from the Internal Audit Service (IAS)

The IAS did not launch any new audits at HaDEA in 2021. As no audit work covering internal controls were performed in HaDEA so far, the IAS stated that there is no element to report nor contribution to provide for the 2021 annual activity report ⁽³¹⁾.

Audits from the European Court of Auditors (ECA)

A) With regards to the operational budget:

In the framework of the statement of assurance (DAS) 2020, the European Court of Auditors (ECA) closed seven transactions related to HaDEA's portfolio in 2021 ⁽³²⁾, with the following findings:

- In three cases there was no financial error, although in two of them, some internal or control system issues were identified (weaknesses in the time-recording system, incorrect method for calculating staff costs, delay in the transfer of funds from the Commission to the beneficiary);
- The financial errors identified in the remaining four cases were wrongly claimed VAT (2.80%), ineligible travel costs (8.96%), an incorrect hourly rate calculation combined with the lack of supporting and accounting evidence (30.91%) and an incorrect hourly rate for SME owners and consultancy costs claimed as personnel costs instead of subcontracting (24.21%). With the exception of the latter case, the ECA concluded that all audit findings were “not detectable” by the Commission

⁽³¹⁾ See ARES(2022)1276997 note from 21/02/2022.

⁽³²⁾ Six transactions related to Horizon 2020 and one related to CEF Telecom programme

services. The Commission agreed with the audit findings except on the issue identified in relation to the consultancy costs.

Following the transfer of the files from the predecessor DGs/Agencies, HaDEA has undertaken corrective actions to address the audit findings accepted by the Commission.

In the 2020 annual report on the implementation of the EU budget, the ECA issued a recommendation addressed to the Research and Innovation family ⁽³³⁾ to extend the scope of the certificates on financial statements to unit cost categories for the Horizon Europe. This recommendation, aimed at increasing the level of detection and corrections of errors in unit cost will be implemented at corporate level. The Commission will also continue its communication campaign on funding rules, including a periodical review of the main causes of error in the financial statements. In its reply, the Commission confirmed that the Commission will continue to provide specific guidance to beneficiaries.

As regards the **DAS 2021**, the ECA has sampled 16 transactions. So far ⁽³⁴⁾, five audits are finalised resulting in no audit findings while one audit has one financial error, due to over-claimed hours declared on the project (1.81%).

B) Administrative budget

With regard to HaDEA, the DAS audit for the 2021 annual accounts is ongoing and scheduled to be completed by the end of March 2022.

The first part of field work, on the legality and regularity of transactions, has been completed. The second part on provisional accounts and budget implementation is scheduled for March 2022.

As for CHAFEA, the ECA audited both (i) the legality and regularity part, and (ii) the provisional accounts. This resulted in minor findings mostly linked to the presentation of the notes to the accounts and not on the substance of the financial statements. The ECA will finalise the audit on the final accounts in May 2022.

C) Performance audit

The ECA launched a performance audit in June 2021 on the effectiveness of the Commission's e-government covering different DGs as well as HaDEA. The audit is ongoing and the final report is expected in the third quarter of 2022.

General conclusions

The Agency does not have any critical new or outstanding audit recommendations, or a combined effect of a number of very important recommendations, which could have a material impact on the achievement of the internal control objectives and the assurance. All

⁽³³⁾ In the Chapter 4 Competitiveness for growth and jobs

⁽³⁴⁾ Cut off date 14/01/2022. One audit is under contradictory procedure.

audit recommendations due in 2021 have been implemented and none of them were overdue by more than six months.

2.1.3. Assessment of the effectiveness of internal control systems

The Commission has adopted an Internal Control Framework based on international good practice, to ensure the achievement of its policy and management objectives. Compliance with the internal control framework is a compulsory requirement.

HaDEA uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles and has due regard to the risks associated with the environment in which it operates.

HaDEA adopted the Internal Control Framework of the Commission by analogy and defined 53 internal control monitoring criteria for 2021. HaDEA performed a **self-assessment on the effectiveness of the internal control system**, in line with the implementation guide of the Commission's Internal Control Framework.

In addition to this, **HaDEA set up an internal control network "ICnet"** with contacts from all units to support the core internal control team and build a strong internal control culture. Awareness-raising activities on internal control matters has been organised.

HaDEA performed two in-depth risk assessments exercises and a monitoring of the risk management action plan. The ex-ante controls (performed in accordance with the programmes' rules), the ex-post control strategy and the anti-fraud strategy are the key elements of the internal control system. Five non-compliance events ⁽³⁵⁾ have also been notified, of which two were related to actions that occurred before the creation of HaDEA. Their action plans have been analysed and followed up.

The graph below shows the status of the 53 internal control monitoring criteria per principle compared to their respective targets:

HaDEA has assessed its internal control system during the reporting year and has concluded that it is effective and the components and principles are present and functioning well overall, but that some improvements are needed as minor deficiencies were identified related to the principles 2, 11, 12 and 17 (please see annex 8 for more information).

Given the nature of the reservation regarding the CEF Telecom segment (as outlined in section 2.1.1 and detailed in Annex 9), the Agency considers that it does not have an impact on the overall assessment on the effectiveness of internal controls.

⁽³⁵⁾ None of these non-compliance events fall under the FR art 92.3

2.1.4. Conclusions on the assurance

This section reviews the assessment of the elements already reported above (in 2.1.1, 2.1.2 and 2.1.3). It draws an overall conclusion to support the declaration of assurance and whether it should be qualified with reservations.

The information reported in Section 2.1 stems from the results of management and auditor monitoring and systematic analysis of the elements listed. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a comprehensive coverage of the budget delegated to the Director of HaDEA.

At the end of 2021 HaDEA had no critical or very important new or outstanding audit recommendations.

Other internal control objectives (reliable reporting, safeguarding of assets and information; and the prevention, detection and correction of fraud and irregularities) for both expenditure and/or revenue operations were respected.

The audit results, the internal control assessment and the control indicators do not reveal any significant weaknesses, with the exception of the ex-post controls results of the CEF Telecom Digital Service Infrastructure (DSI) segment.

For the CEF Telecom Digital Service Infrastructure (DSI) segment, the residual error rate stands at 3.84%, above the materiality threshold of 2% expected for a multi-annual period. Despite the low financial exposure of EUR 2.38 million which is well below the threshold of EUR 5.00 million, its share in the budget implemented in 2021 represents 5.23% of the total payments, which is above the threshold of 5.00%. Thus, this segment does not meet the cumulative criteria to fall within the ‘de-minimis rule’ ⁽³⁶⁾. This situation results from the administrative transfer of programmes between executive agencies, bearing in mind that HaDEA has a smaller portfolio in size than the predecessor Agency, in particular in 2021 during its start up phase.

Based on the reasons outlined above, **the Agency is issuing a reservation**. The Agency considers this as a “one-off” event, as this segment is phasing out, its share within HaDEA’s portfolio will gradually decrease in the coming years. In addition, the necessary improvements have been already implemented, resulting in a lowered residual error rate and a net amount at risk representing 0.17% of the total payments in 2021. Its effect on the overall declaration of assurance is thus considered very limited.

The Seventh Framework Programme (FP7) Space segment is affected by errors, with a residual error rate of 3.64%. However, the combined effects of the low share that it

⁽³⁶⁾ In 2019, a de-minimis rule for financial reservations was introduced stipulating that quantified AAR reservations related to residual error rates above the 2% materiality threshold are deemed not substantial and are no longer needed for segments representing less than 5% of a DG’s total payments and with a financial impact below EUR 5 million.

represents in the budget implemented in 2021 (0.05% of total payments) and of the low financial exposure (EUR 0.06 million) fall within the “de-minimis” threshold that applies to reservations. Consequently, HaDEA is not issuing any reservation for the FP7 expenditure in the declaration of assurance.

In conclusion, based on the elements reported above, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director, in his capacity as Authorising Officer by Delegation has signed the Declaration of Assurance albeit qualified by a reservation concerning the segment Connecting Europe Facility Telecom – DSI (budget line 02.039903).

Reservation title	Financial impact (in M EUR)		Residual error rate 2021	Evolution
	2020	2021		
CEF Telecom Digital Service Infrastructure (DSI)	N/A	2.38	3.84%	New

Table 7: HaDEA’s reservation

2.1.5. Declaration of assurance and reservation

Declaration of Assurance

I, the undersigned,

Director of the Health and Digital Executive Agency

In my capacity as authorising officer for the operating (administrative) budget and authorising officer by delegation for the operational budget

Declare that the information contained in this report gives a true and fair view ⁽³⁷⁾.

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

⁽³⁷⁾ True and fair in this context means a reliable, complete and correct view on the state of affairs in the executive agency.

Confirm that I am not aware of anything not reported here which could harm the interests of the Health and Digital Executive Agency or those of the Commission.

However the reservation on the segment Connecting Europe Facility Telecom – DSI (budget line 02.039903) should be noted. More details are provided in Annex 9.

Brussels, 31 March 2022

e-signed

Marina Zanchi

Director

2.2. Modern and efficient administration – other aspects

2.2.1. Human resource management

Staffing overview

On its first day of operation, HaDEA counted 273 staff members, while its establishment plan included an ambitious target of 381 staff members in place by the end of 2021. The Agency therefore had to recruit more than 100 new colleagues within a timeframe of only nine months. On 31 December 2021, HaDEA employed 324 staff members. 17 additional newcomers were recruited in the last months of 2021 and will be joining HaDEA in the first quarter of 2022, thereby fulfilling the Agency's internal target to recruit 90% of the staff planned in the establishment plan by the end of the year.

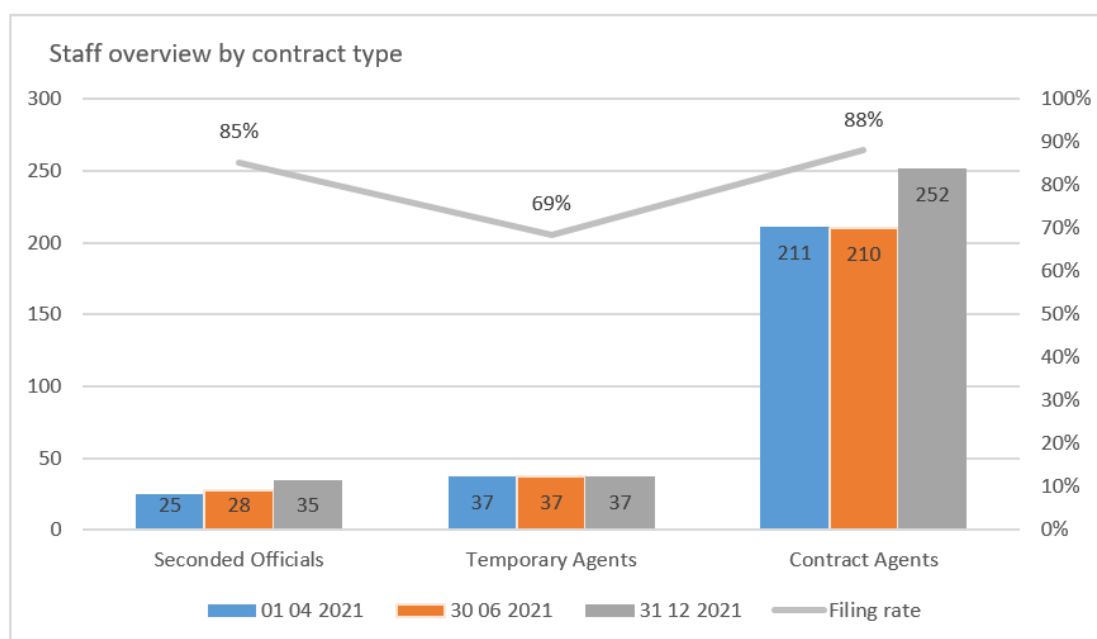


Figure 6: Staff overview by contract type ⁽³⁸⁾

Over its first months of existence, the Agency experienced some challenges with regard to its staffing situation, and notably on the alignment with the number of posts in each grade as originally planned in its establishment plan ⁽³⁹⁾. Moreover, the staff initially allocated for the implementation of Horizon Europe Cluster 4 proved to be insufficient to manage the additional budget delegated to the Agency. The difficulties encountered on the latter issue were brought to the attention of parent DGs, central services and HaDEA's Steering Committee. After discussions in a dedicated working group, all parties agreed to anticipate the planned allocation (frontloading) of eight positions to Department B ⁽⁴⁰⁾, thus providing the capacity to tackle the additional workload.

At the end of 2021, the Agency's overall gender balance was 62% of women and 38% men, while a 50/50 balance was achieved between the number of men and women among middle managers ⁽⁴¹⁾.

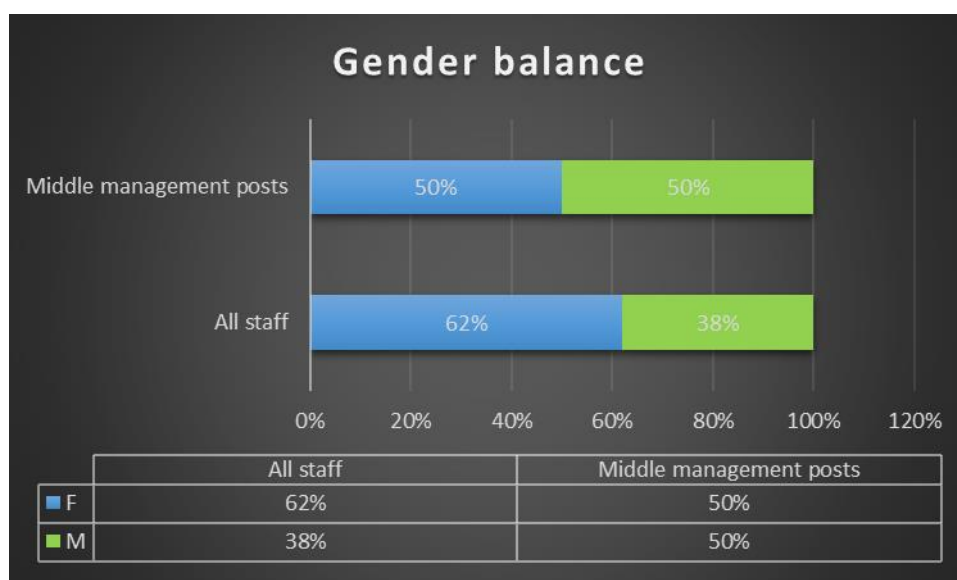


Figure 7: Gender balance ratio

⁽³⁸⁾ Please see Annex 10 for a more detailed breakdown of figures provided in the graph above.

⁽³⁹⁾ The progressive arrival of seconded officials led to a deviation from the figures approved in February 2021. To align the establishment plan with the real situation, HaDEA applied a 10%-flexibility to grades below AD13 in September (within the limits of the maximum posts of temporary agents authorised under the 2021 budget). However, due to subsequent secondments of AD 13 officials at the end of 2021, one deviation at AD13 grade remained.

⁽⁴⁰⁾ The operational teams working on the implementation of Horizon Europe, Cluster 4: Digital, Industry and Space are located within HaDEA's Department B.

⁽⁴¹⁾ Heads of Unit and Heads of Department, appointed by the parent DGs.

Recruitment

By May 2021, HaDEA had put in place the necessary internal policies on selection processes. The Agency's 2021 recruitment plan set priorities based on the urgency to fill the posts and on the type of profiles needed. It also included the most suitable selection procedure for each selection. As a result, HaDEA welcomed 70 new staff members including 13 seconded officials ⁽⁴²⁾. To support HaDEA as a new and growing agency, 25 interim agents reinforced different teams.

HaDEA staff members were recruited from the European Commission's Directorates General, other Executive Agencies (including staff coming from Luxembourg) or from the private sector. To enable staff members from a variety of backgrounds to feel welcome, the Agency rolled out a fully-fledged onboarding programme including tools such as pre-arrival welcome messages, an onboarding guide and a buddy system. ⁽⁴³⁾

Corporate culture

HaDEA's culture is based on staff empowerment, collaboration, communication, trust and respect. The Agency defined its vision, mission statement, and values through a participatory approach, involving all staff. ⁽⁴⁴⁾

HaDEA joined the memorandum of understanding on the roles and responsibilities of trade unions and staff associations, signed with the Directors of the executive agencies, representatives of the trade unions, representatives of the common staff committee and local staff committees of the executive agencies.

The election of the HaDEA staff committee took place in October 2021, immediately after receiving the green light from DG HR to launch the elections. Until the staff committee was in place, a temporary staff committee composed of colleagues from other executive agencies' staff committees was established to ensure a proper representation of staff in HaDEA's activities. After a successful election campaign, **HaDEA's staff committee was established in December 2021.**

The Agency provided ongoing learning support through the organisation of different initiatives such as: the inter-agency women talent programme, the inter-agency job shadowing exercise, the organisation of several courses and the set up of a career guidance service offering personalised coaching and assistance.

⁽⁴²⁾ Seconded officials were selected and recruited by parent DGs, in close collaboration with HaDEA.

⁽⁴³⁾ 55 "Virtual Cafeterias", 4 HaDEA Discovery tours, 14 HR Ateliers and eight "Meet & Greet your Human Resources" sessions for newcomers were organised.

⁽⁴⁴⁾ Please see Annex 10 for more information.

Working conditions

HaDEA adopted the general implementing provisions establishing the Agency's human resources (HR) legal framework. An HR section was developed on the intranet, providing staff with all HR-related information in a user-friendly way. In addition, HaDEA organised several workshops on working conditions, time management, employment rights, reclassification exercise, appraisal exercise, etc..

The Agency also joined the memorandum of understanding on the inter-agency network of confidential counsellors. The selection, training and appointment of the HaDEA confidential counsellors will take place in 2022.

Work environment

HaDEA signed agreements and contracts with relevant central services for the provision of ergonomic furniture and equipment, collaborative meeting spaces and comfortable social spaces.

Following discussions with the Office for Infrastructure and Logistics in Brussels (OIB) and the other executive agencies hosted in the COV2 building, an agreement was found, which will allow to host all HaDEA colleagues in this building from 1 January 2022. To reach that goal, all executive agencies agreed to adopt the approach of a flexible and dynamic workspace, offering 80% of working stations for 100% of the staff. To establish the practical modalities of these new working arrangements, HaDEA conducted a survey among its staff members. A HaDEA internal task force was established to translate the results of the survey into recommendations for implementing these new work modalities in January 2022.

2.2.2. Digital transformation and information management

Digital Transformation

Governance

The Agency established an inventory of IT systems and projects under the Agency's responsibility and appropriate IT governance procedures. These should help ensuring full compliance of HaDEA's IT investments and projects with the Commission's corporate IT principles and rules, including in terms of security and data protection. The IT governance set-up included the **creation of an IT steering group and IT management board** with the clear mandate to identify synergies and validate new IT projects.

Furthermore, HaDEA formally initiated the **onboarding process to the eGrants IT toolset** of both the CEF- II and SMP-food strand programmes. All programmes managed by the Agency are expected to use the corporate IT tools by 2023.

HaDEA cooperated on IT matters with the other executive agencies, re-using IT solutions or IT infrastructure developed by them, and putting IT tools owned by HaDEA at their disposal.

The Agency intends to pursue this close cooperation in the future, which will result in savings.

Data, information and document management

The Agency appointed a Local Data Correspondent (LDC), who serves as a single point of contact for data management and participates in the Commission's LDC network on behalf of HaDEA.

In line with the Commission's data governance and data policies, HaDEA launched the internal reporting on data assets at its disposal at the end of 2021. The aim of this exercise is to create a permanent HaDEA data inventory and to improve the quality of the collection and use of these data.

HaDEA provided input on all the aspects of its data, information and knowledge management strategy to DG SANTE, who represented the Agency in the corporate Information Management Steering Board (IMSB).

HaDEA set up its own intranet (on *My Intracomm* and *Sharepoint* platforms) as the central communication and information hub, allowing each unit/sector to add and update contents on their respective areas of activity. The Agency also enabled the use of *Microsoft 365* and of the *HaDEA Workspace* to work collaboratively on documents and files.

As regards **records management and archival policy**, the Agency defined its filing plan in compliance with the corporate rules and developed document management guidelines. HaDEA also conducted awareness-raising actions and encouraged the pooling of best practices to improve document management efficiency.

Data protection

The protection of personal data is an issue of key importance to the Agency. As a new organisation, HaDEA adopted in 2021 its own **data protection action plan**, built on the objectives identified by the Commission's Data Protection Action Plan.

As first steps in the implementation of its data protection action plan, HaDEA adopted:

- the decision to appoint HaDEA's Data Protection Officer (DPO) and Deputy Data Protection Officer;
- the implementing rules concerning HaDEA's DPO;
- the data breach management procedure;
- the data subject rights requests procedure;
- the internal rules concerning restrictions of certain rights of data subjects.

The DPO also established the register of records of data processing operations and ensured the provision of information to data subjects through the publication of the relevant data protection notices.

In addition, the DPO provided training and information sessions for management and staff. She participated in discussions with the European Data Protection Supervisor and other EU networks and actively contributed to the inter-executive agencies cooperation in the field of data protection.

Access to documents

In 2021, HaDEA handled a total of 25 requests for access to documents. They mainly concerned ongoing projects managed by the Agency.

HaDEA replied to all of the requests within less than 15 working days. No applicant requested a review of the initial decision.

In 2021, HaDEA also developed rules of procedure for the application of the regulation on public access to Commission documents ⁽⁴⁵⁾ and internal practical guidelines for handling access to documents requests.

2.2.3. Sound environmental management

In 2021, HaDEA worked in close collaboration with the Eco-Management and Audit Scheme (EMAS) team of DG HR on the implementation of EMAS within HaDEA.

HaDEA appointed an EMAS correspondent, created a functional mailbox for EMAS-related communication, promoted corporate events and campaigns and took an active part in EMAS discussions.

Taking concrete actions for an environmentally-friendly Agency!

HaDEA implemented several concrete actions in a record time: the creation of paperless workflows aiming at reducing paper consumption; the installation of equipment for videoconferencing and hybrid meetings; the adoption of guidelines for sustainable meetings; awareness-raising on green procurement; the promotion of green commuting through allowances for bike commuting; the development of rules about teleworking, etc..

During the EMAS internal audit which took place in early December, auditors appreciated the rapid progress made by HaDEA!

⁽⁴⁵⁾ Regulation (EC) N° 1049/2001

2.2.4. Initiatives to improve economy and efficiency of financial and non-financial activities

Synergies and efficiencies in the field of horizontal support functions

The six executive agencies meet regularly to reflect on synergies in the field of human resources.

In 2021, a major achievement in this respect was the decision to **harmonise job titles across all executive agencies**. This will foster inter-agency mobility by ensuring that staff carries out the same tasks when moving from one agency to another. The inter-agency collaboration also resulted in the adoption of a common methodology to assess and flag sensitive functions, based on DG BUDG sensitive post policy.

To guarantee that agencies ensure equal opportunities for career progression based on objective and transparent criteria, the six agencies developed a **common approach for the calculation of quotas for reclassification**. This new methodology will enter into force on 1 January 2022.

The collective work on both these dossiers means that HaDEA will not have to develop its own policies, therefore contributing to economies.

In the area of **talent acquisition**, HaDEA took part in joint selection procedures together with CINEA and EISMEA. HaDEA continued using reserve lists from other agencies to fill in specific profiles, thereby reducing the efforts needed for launching new calls for specific profiles.

Furthermore, all executive agencies joined forces to support staff's professional development through the **organisation of different Interinstitutional career opportunity initiatives** such as the inter-agency women talent programme and the inter-agency job shadowing exercise.

Open collaboration between HaDEA and EISMEA on local IT systems and IT infrastructure

HaDEA decided to share resources with EISMEA for the development and maintenance of several internal IT tools. The two agencies, who have agreed to keep their local IT infrastructure, share both the server room and its maintenance, which resulted in a reduction of costs.

Mail distribution

EISMEA and HaDEA collaborated closely to ensure mail distribution during the Covid-19 pandemic: the mail clerks of both agencies worked closely together and backed each other up during absences or when the workload was higher.

Simplification of administrative budget procedures

Fully paperless financial circuits for the administrative budget were implemented in 2021 without any issue. It allowed for efficient teleworking in 2021 and contributed to a proper planning and follow-up of the administrative budget. Ares workflows and relevant

checklists were used for commitments and recovery orders, while the *Speedwell* tool ensured a fully electronic workflow for the management of invoices and payments.

[e-manual of procedures](#)

In 2021 HaDEA conducted a participatory exercise to set up an agency-wide manual of procedures. The resulting manual of procedures groups HaDEA's working processes and procedures together with models, checklists and templates in a single (digital) repository. The processes, procedures and strategies are described in a concise, transparent and user-friendly manner. The manual's aim is to guide staff through the use of these procedures and to create awareness and understanding of the correct application of the rules.

A great majority (approximately 95%) of the procedures had been finalised by the end of the year, with only a few of the most complex ones to be adopted in early 2022.