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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	23 February 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
Subject:	Proposal for a Council Regulation establishing Joint Undertakings under Horizon Europe - Regulatory Scrutiny Board Opinion

Delegations will find attached document SEC(2021) 100 final.

Encl.: SEC(2021) 100 final

EUROPEAN COMMISSION

Brussels, 4.9.2020
SEC(2021) 100 final

REGULATORY SCRUTINY BOARD OPINION

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

{COM(2021) 87}

{SWD(2021) 37 }
{SWD(2021) 38 }

Ref: Ares(2020)4607090 - 04/09/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB(2020)

Opinion

Title: Impact assessment / European Partnership for a Circular Bio-based Europe

Overall 2nd opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The EU has set objectives with regard to climate and the environment, rural development and keeping its industry competitive. One way to pursue these objectives is to promote investment in bio-based industry. To this end, the EU has collaborated with industry to focus on sustainable resource use. Under its Horizon 2020 programme, it allocated EUR 975 million to this partnership, which will end soon.

A successor partnership will take its place. The Horizon Europe programme provides for a European Partnership on a Circular Bio-based Europe.

This report examines alternative forms of such a partnership for the period 2021–2027. It is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes the improvements to the initial impact assessment. The revised report presents a more focussed scope of intervention and a clearer picture of the bio-based industry landscape.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) Despite improvements, the intervention logic is still not specific to the circular bio-based economy and does not focus on the choice of the type of partnership.

(2) Conclusions from evaluating the predecessor partnership are more present in the report, but they do not directly feed into the problem definition, the intervention logic, and the choice of options.

(3) The report does not always present the different and sometimes critical stakeholders' opinions.

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) The central point of the assessment, i.e. the choice of the best form of a research partnership for the circular bio-based economy, is still largely absent from the intervention logic. This makes assessing different types of partnerships difficult, as the link between options, problems and objectives is not properly established.

(2) The problem description should better integrate the results of the evaluation of the current partnership. These include a number of organisational issues that are directly relevant for the choice of the best form of research partnership.

(3) The report should better explain the functioning and expected performance of the governance systems foreseen under each option. For instance, it should explain how these systems would help secure sufficient private sector financial contributions. It should also better describe what the different partners would contribute to the partnership, other than finance. It should also describe how the governance systems would address the potential risk of industry capture.

(4) The report should further clarify the scoring system and in particular the relative importance of the different criteria. It should better justify and explain the assessment of options against the different criteria.

(5) The report should more comprehensively present different stakeholder views. In particular, it should include more critical voices throughout the report.

The Board notes that the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	European Partnership for a Circular bio-based Europe
Reference number	PLAN/2019/5305
Submitted to RSB on	3 August 2020
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation (quantitative or qualitative)***	***Comments***
Direct benefits		
A more competitive primary sector producing biomass		Higher and secure income for primary producers (also in less-favoured regions); secured supply for bio-based industries; economic growth for SMEs.
Cost savings for municipalities and regions regarding waste disposal		Part of the biowaste sold to the bio-based industry as raw material
A more competitive bio-based industry sector		Secured biomass supply for bio-based industries; economic growth for SMEs.
Access to more sustainable products by brand-owners and consumers		Continuously increasing demand satisfied
Indirect benefits		
Reduction of CO_2 emissions due the switch from fossil- to bio-based		A larger proportion of chemicals and materials including plastics produced from biomass and biowaste.
Biodiversity conservation or enhancement		As a result of lower toxicity bio-based products developed and as a result of sustainable management of natural resources, especially biodiversity-friendly biomass generation.

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of direct and indirect costs – Preferred option							
		Citizens/Consumers		Businesses (1)		Administrations (2)	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative costs	Direct costs				€ 1 m per year over 10 years (3)		€ 1 m per year over 10 years (3)
	Indirect costs						
Personnel costs	Direct costs				€ 1.25 m per year over 10 years (for 25 FTE) (4) € 0.4 m per year over 11 years for 4 FTE (5)		€ 1.25 m per year over 10 years (for 25 FTE) (4)
	Indirect costs						€ 0.5 m per year over 11 years for 5 FTE at operational and coordinating Commission units
Coordination costs (or transaction costs)							
Budget expenditure/ investment costs				€ 1,000 to 3,000 m over the whole period (6)		€ 1,000 m over the whole period (7)	

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

[1] Sum of below: 10+12.5+4.4 = EUR 26.9 m.
[2] Sum of below: 10+12.5+5.5 = EUR 28 m.
[3] Other expenses and finance costs of the BBI JU programme office were EUR 2.1 m in 2018 (Accounts 2018, p.8), to be paid 50:50 by the EC and the private partner.
[4] BBI JU programme office staff cost with 20 staff was EUR 2 m in 2018 (Accounts 2018, p. 8). Extrapolation to 25 staff in CBE. To be paid 50:50 by the EC and the private partner.
[5] The private partner's secretariat. Estimation.
[6] 100-300% private contribution (also pending MFF decision and breakdown of the budget). No contribution commitment from private partner yet.
[7] Pending MFF decision and breakdown of the budget.

Ref: Ares(2020)3055973 - 12/06/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / European Partnership for a Circular bio-based Europe

Overall opinion: NEGATIVE

(A) Policy context

The EU has set objectives with regard to climate and the environment, rural development and keeping its industry competitive. One way to pursue these objectives is to promote investment in bio-based industry. To this end, the EU has partnered with industry to focus on sustainable resource use. Under its Horizon 2020 programme, it allocated EUR 975 million to this partnership. This will end soon.

A successor partnership will take its place. The Horizon Europe programme provides for a European Partnership on a Circular Bio-based Europe.

This report examines alternative forms of such a partnership for the period 2021–2027. It is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes the additional written information provided in advance of the meeting. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report defines the problem too widely, in view of what the circular bio-based Europe partnership aims to achieve. It does not sufficiently focus on the choice of form of the candidate partnership.

(2) The report does not make clear which sectors are involved in the bio-based economy that would benefit from a research partnership.

(3) The report does not explain the market failures that the preferred option would address better than the alternative options.

(4) The report does not sufficiently argue the choice of preferred option. In particular, it does not address the risk of industry capture or adequately explain how social and environmental objectives would be safeguarded.

(5) Stakeholder groups' views are not adequately presented.

(C) What to improve

(1) The report should explain better the logic behind the intervention. It should organise the intervention logic around the central theme of the impact assessment, i.e., the choice of partnership form. The report should explain better the links between problems and objectives, and between objectives, targeted impacts and functionalities. The specific objectives should fully cover all stated problems, particularly the lack of circularity and environmental sustainability.

(2) The report should clarify which sectors and types of businesses could participate and benefit from the partnership along the bio-refineries' value chains. It should explain their common research interest and how the candidate forms of partnership would serve this.

(3) The report needs to explain what market failures motivate the partnership, and the mechanisms through which the partnership would address them.

(4) The report should integrate all relevant findings of the evaluation of the predecessor partnership. For instance, it should better integrate the findings on the diversity of private parties and the governance structure in the problem tree and objectives.

(5) The report should explain how private sector (financial) contributions would be ensured to deliver sufficient co-financing of the partnership.

(6) The report should explain in more depth how the preferred option addresses better (compared to other options) the participation of SMEs, the relation between start-ups and established major companies, the improvement of the situation of primary producers and the integration of new and diverse supply-chains. It should be clearer how it would do this while avoiding the risk of industry capture. It should also better explain how the different options would deliver on the social and environmental objectives.

(7) The report should better integrate stakeholder groups' views throughout the discussion, in particular minority positions and Member State views.

(8) The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove any discrepancies between the text and tables, and any inconsistencies in the expected impacts.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	**European Partnership for a Circular bio-based Europe**
Reference number	PLAN/2019/5305

Submitted to RSB on	8 May 2020
Date of RSB meeting	10 June 2020

Ref: Ares(2020)3054258 - 12/06/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / European Partnership for Clean Aviation

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The Green Deal includes measures to reduce the environmental impact of aviation. Part of this agenda involves support for research and innovation in aviation technologies and fuels.

Since 2008, the Clean Sky Joint Undertaking has supported new technologies to reduce aircraft emissions. This report examines ways to design a successor partnership under Horizon Europe.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes the useful additional written information provided in advance of the meeting and commitments to make changes to the report. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report does not clearly describe what would change under the new partnership as compared to the current one and why.

(2) The report is unclear about the division of functions between the Clean Aviation partnership and separate calls for proposals on aviation research, and the links between them.

(3) The report does not show convincingly how the partnership will be able to deliver the ambitious objectives on time.

(C) What to improve

This opinion concerns a draft impact assessment which may differ from the final version.

(1) The report should be clearer about the differences between the new partnership and the current one and the underlying drivers (e.g. evaluation results, policy or market developments).

(2) The report should clarify how the proposed two-pronged approach would work in practice. It should explain the links between the foreseen actions under the traditional calls for collaborative research and the institutionalised partnership. It should explain to what extent these approaches address different problems and have distinct objectives.

(3) The report could explain better the links with other EU policies and instruments in place to support aviation and to tackle its climate and environmental impacts.

(4) The report should specify more precisely the environmental and climate impacts the initiative will address. It should discuss the extent to which the partnership would be able to deliver these ambitious objectives. In this regard, the report should better explain the foreseen sequencing and expected timing of the forthcoming disruptive technologies.

(5) The report should explain how the new partnership would be better able to attract relevant stakeholders and Member States. It should discuss whether smaller companies with potential to provide disruptive solutions are likely to be interested in traditional calls, instead of applying for the partnership.

(6) The report should clarify the logic behind the intervention. It could better explain the links between problems and objectives, and between objectives, targeted impacts and functionalities. The intervention logic should focus on the part of the "two-pronged" approach that the Clean Aviation partnership would address.

(7) The report should integrate the latest realistic expectations on the effects of the Covid-19 crisis on the aviation sector. It should consider these in the analysis of the problems, baseline and impacts.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe. European Partnership for Clean Aviation.
Reference number	PLAN/2019/5304
Submitted to RSB on	08 May 2020
Date of RSB meeting	10 June 2020

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation (quantitative or qualitative)***	***Comments***
Direct benefits		
Impliment Green Deal for aviation	Major contribution to climate neutrality of aviation by 2050, as key policy of the European Union. Significant improvements in pollution related health issues. Reduction of noise around airports	Considering the world-wide impact of the European aeronautics industry, the benefits would have world-wide effects
Increased competitiveness of the European aeronautics industry	Maintain employment. In total, aviation currently supports 12.2 million European jobs.	The technological advancements would significantly increase the quality of the European aircraft helping to maintain the European leadership position in this sector.
The alignment of European, national and company research efforts on basis of a single Strategic Research and Innovation Agenda would significantly increase the impact of aviation research	Increased effectiveness and efficiency of the European research in aviation.	
Better integrated research and innovation landscape	Early involvement of EASA reducing the long research and innovation life cycle in the sector Establish structural links with other sectors (such as batteries and hydrogen) leading to cross sectoral benefits Increased cooperation between European companies across the whole value chain in aviation.	
Indirect benefits		

II. Overview of direct and indirect costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative costs	Direct costs				170		170
	Indirect costs			4	790	4	790
Personnel costs	Direct costs			0	2200	0	2200
	Indirect costs			4	105	4	105
Coordination costs (or transaction costs)					110		110
Budget expenditure/ investment costs				45		45	
				TOTAL (kEUR)		*6,854.96*	

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2020)

Opinion

Title: Impact Assessment / European partnership for clean hydrogen

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Hydrogen is a clean fuel, in the sense that its use does not generate greenhouse gas emissions. However, its production is not necessarily pollution-free, as nowadays it is mainly produced from natural gas. Researchers have been looking for more environmentally friendly ways of producing 'clean hydrogen' that would eliminate CO_2 emissions from the process. Clean hydrogen, as an energy carrier, can contribute to increase the share of renewables in European energy markets. It can store and transport large amounts of electricity. It may also provide clean energy for sectors where CO_2 emissions are difficult to reduce. Clean hydrogen is still expensive and not fully reliable and further research and development is needed to make it competitive for production, distribution and application.

Clean hydrogen will be the subject of a European Partnership under the Horizon Europe programme. In such partnerships, the EU and private and public partners commit to support jointly the development and implementation of research and innovation activities. Already under the previous research programme (Horizon 2020), a Joint Undertaking was devoted to fuel cells and hydrogen. The present impact assessment intends to determine the most suitable form of such partnership for the period 2021-2027.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes useful additional written information provided in advance of the meeting. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative. However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report does not adequately describe the existing partnership, including its strengths and weaknesses.

This opinion concerns a draft impact assessment which may differ from the final version.

(2) The report does not clearly identify which problems and problem drivers the initiative would address.

(3) The report does not adequately explain how greater flexibility in implementation of research projects relates to the desire to focus research. It does not sufficiently describe the competition aspects of the partnership.

(C) What to improve

(1) The report should explain in more detail the current partnership, its objectives and its structure.

(2) The report should use the findings of the evaluation of the existing Joint Undertaking to explain the need for change. It should justify the shift of focus to hydrogen production, distribution and storage in the new partnership.

(3) The report should limit the problems and problem drivers to what research and innovation actions can address. It could clarify how wider problems are addressed by other initiatives.

(4) In this framework, the report should justify why continuation of the current partnership is not the baseline. The report should use its selected baseline (Horizon Europe calls) consistently throughout the report, notably in the impact analysis and in the comparison of the policy options. The report sometimes takes the absence of any research programme as a baseline. The selected baseline should consistently be scored as zero, while the scoring of the other options should be adjusted to reflect their impacts as compared to the baseline.

(5) The report should clarify how the flexibility of a partnership, in particular via changes to its membership, is compatible with the narrower focus on research areas and with potential risks of excluding competitors. It should reflect on the consequences of partners not being willing to accept newcomers to avoid that competitors take advantage of their earlier investments. The report should clarify the changes in the substance of cooperation by moving from research to production and distribution. It should reflect on how to avoid anti-competitive behaviour in product markets.

(6) The report should provide – as far as possible – quantified estimates of the cost of the different partnership types. This would provide evidence for the assessment that cost differences between policy options matter less than differences in benefits. The report should also take into account savings or costs stemming from the continuation or discontinuation of various elements of the already existing partnership in the baseline and policy options.

(7) The report should explain the choice of the specific objectives (in particular the origin of the quantified targets) and clarify the relation between the objectives, the "expected impacts" and the "functionalities". Impacts should be assessed with respect to the specific objectives.

(8) The report should be more transparent about what issues remain open after the impact assessment and will be decided at a later stage, because of the particularities of this exercise where some contextual elements, such as the budget, remain undecided. For example, the report refers to certain selection criteria that will be addressed later.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been transmitted directly to the author DG.

(D) Conclusion **The DG may proceed with the initiative. The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.**	
Full title	Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe: European Partnership for Clean Hydrogen
Reference number	PLAN/2019/5306
Submitted to RSB on	3 March 2020
Date of RSB meeting	25 March 2020

ANNEX: Quantification tables extracted from the draft impact assessment report

(N.B. The following tables present information on the costs and benefits of the initiative in question. These tables have been extracted from the draft impact assessment report submitted to the Regulatory Scrutiny Board on which the Board has given the opinion presented above. It is possible, therefore, that the content of the tables presented below are different from those in the final version of the impact assessment report published by the Commission as the draft report may have been revised in line with the Board's recommendations.)

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation (quantitative or qualitative)***	***Comments***
Direct benefits		
More competitive hydrogen industry	Hydrogen applications are more competitive, efficient and reliable.	
Clean Hydrogen scale up	EU validates its ability to scale-up clean economical hydrogen end-use applications in heavy-duty transport and energy-intensive industries – maintaining global competitiveness.	
Economic growth particularly for SMEs	EU growth in hydrogen economy, especially for SMEs.	When the clean hydrogen value chain develops, it will be possible to monitor the number of SMEs operating in the sector.
Indirect benefits		
Decarbonisation of heavy industry	The EU's maritime, aviation, rail and heavy-duty transport sectors, as well as their gas grid, can progressively decarbonize so the EU can meet its climate targets.	
Reduction in pollution and CO2 emissions	Outdoor pollution can progressively decrease while reducing carbon emissions.	
Incorporation of larger shares of renewable energy in European electricity grids.	The European electricity grid can accommodate larger shares of renewable energy, thanks to flexibility services provided by power to gas installations.	

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of direct and indirect costs – Preferred option								
		Citizens/Consumers		Businesses		Administrations		
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent	
Management/ Administrative costs	Direct costs						Other cost €2.1 million[1].	
	Indirect costs							
Personnel costs	Direct costs						€ 2.9 million corresponding to 27 full time equivalent staff	
	Indirect costs							
Coordination costs (or transaction costs)								
Budget expenditure/ investment costs								

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferre

[1] These are the costs of running the FCH JU from the 2018 Annual report.

Ref: Ares(2020)3053467 - 12/06/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2020)

Opinion

Title: Impact Assessment / European partnership for transforming Europe's rail system

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

National approaches have formed rail transport in Europe for 150 years. Efforts to integrate rolling stock, infrastructure and signaling systems at European level have developed over many years. However, rail systems are still far from integrated. Lack of interoperability costs money and time, making rail transport less competitive. This slows down transition to sustainable transport, as rail transport is environmentally friendly.

Since 2014, the Shift-to-Rail public-private partnership has developed a research agenda for the rail sector. This partnership involves stakeholders and researchers from a number of countries. Based on the new Horizon Europe programme, this impact assessment considers which form of the partnership can best shape future research and development for the rail sector.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board acknowledges the useful additional information provided in advance of the meeting and commitments to make changes to the report. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report does not sufficiently build on the lessons learnt from the existing partnership for the design of the preferred option.

(2) The report does not clearly present what stakeholders and researchers will contribute to the partnership or how Member States will be involved.

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 08/010. E-mail: regulatory-scrutiny-board@ec.europa.eu

(3) The report does not sufficiently explain why progress in the sector has been limited and why the new partnership will be better placed to achieve results.

(C) What to improve

(1) The report should provide more detail on the current partnership, its objectives and its functioning (membership, financing, research focus). It should include more evidence from the evaluation of the partnership and it should better explain how the new partnership will address the weaknesses identified.

(2) The report should analyse stakeholder input on the issues of most relevance to the decision on the future partnership. It should differentiate views of stakeholder groups and explain the views of beneficiaries. It should explain how the new partnership would address stakeholders' concerns.

(3) The report should better explain the barriers the EU rail sector integration has faced and why the new partnership would be better placed to address these. The report should focus more on how the new partnership would obtain the necessary stakeholder commitment and collaboration from Member States to overcome these barriers. This should include the role and prospects of Member State support for the subsequent uptake of common solutions.

(4) The report should better explain the reasons for the changed focus in the research agenda. It should justify the focus on digitalisation, automation and the freight sector. It should explain how the partnership will achieve the necessary changes in membership to serve the changed focus. Overall, the revised governance structure should be more clearly set out and the role of SMEs in the project clarified.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables. The table should indicate more clearly who will bear the costs involved.

Some more technical comments have been transmitted directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe: European Partnership for Rail Systems
Reference number	PLAN/2019/5398
Submitted to RSB on	8 May 2020
Date of RSB meeting	10 June 2020

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Sustainable cost efficient mobility	Increased attractiveness, accessibility and services for rail passenger and freight through new concepts of operations enabled and system integrated approach by breakthrough innovation	The increase of the efficiency and reduction of costs will make travelling by rail more accessible to everyone and hence increase its social inclusiveness.
More competitive rail industry	The transfer of innovative solutions to the market will boost the competitiveness of European suppliers involved in the partnership. The European rail industry will maintain its market leadership at global level by 2050	Development of solutions with broad support across EU–up to 75% market uptake by 2030
Rail system transformation	Integrated approach enabling the delivery of EU policy objectives and the technical integration of rail innovations in the overall mobility digital eco-system for all modes of transport.	The Partnership will be part of a whole-system approach to investment, cutting across the various interfaces, which recognises the long-lived nature of railway assets.
Indirect benefits		
Transport decarbonisation	Modal shift from more carbon intensive modes to rail will make a significant contribution to transport decarbonisation. In addition, the programme will help further reducing rail's carbon footprint.	Contribution to European Green Deal objectives (e.g. shift substantial part of the 75% of inland freight carried today by road to rail and inland waterways).
Increased quality of life	Increasing rail attractiveness would result in integrated journeys with rail at the core of mobility and transport (high speed, regional and urban, freight) through a climate neutral concept of operations and based on a circular economy system.	This includes the positive impact of reduced emissions (e.g expected CO2 reduction between 2.5 and 4 million tonnes in 2031).

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative costs	Direct costs						Yearly running costs other than Personnel: EUR 1.2 million (baseline 2019 AAR – Title 2)
	Indirect costs						
Personnel costs	Direct costs						Yearly running costs for Personnel: EUR 2.3 million (baseline 2019 AAR – Title 1 – 24 FTE [5 TA + 16 CA + 3 SNEs])
	Indirect costs						

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

Ref: Ares(2020)2572738 - 15/05/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / EU-Africa Global Health Partnership

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The EU supports many health research programmes. The EU-Africa Global Health Partnership is one of them.

This impact assessment informs the choice of the form for a health research partnership between the EU and Africa under the Horizon Europe programme. The EU and private and public partners in this partnership jointly support health research and innovation activities. Under Horizon 2020, a Joint Undertaking supported clinical trials and health research cooperation with sub-Saharan Africa.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes the useful additional written information provided in advance of the meeting. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) **The report defines the problem too widely in view of what the EU-Africa health partnership aims to achieve. It does not sufficiently focus on informing the choice of form of the candidate partnership.**

(2) **The added value of the preferred option over an alternative type of partnership is not sufficiently demonstrated.**

(3) **The report does not sufficiently explain which players the new partnership can attract in its upgraded form and what they will contribute to delivering on its objectives.**

This opinion concerns a draft impact assessment which may differ from the final version.

(C) What to improve

(1) The logic of the intervention presented in the report should be clarified to support the analysis. It should focus on the central theme of the impact assessment, i.e. the choice of partnership form. In doing so, the report should better clarify the relationship between the problems, the 'functionalities', 'expected impacts', and the specific objectives. Impacts should be assessed with respect to the specific objectives. In the particular case of establishing a partnership for EU-Africa research health cooperation, the report should narrow down the problem definition. This should build on the experience gathered with the previous research programmes with and in African countries and focus on supporting clinical trials and enhancing research capacities.

(2) The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove the discrepancies between the text and the tables and correct inconsistencies in terms of expected impacts. The report should justify any deviations from the common efficiency analysis.

(3) On this basis, the report should better explain the advantages of an institutionalised Article-187 partnership over other organisational forms. This should include the prospective participation of national, international and private organisations or donors. It should also include the financial requirements and the needed time horizon of the commitment to support clinical trials and grow research capacity in sub-Saharan Africa.

(4) The report should expand on how the preferred form of the partnership would attract private industry and donors. It should explain how it would coordinate with similar global initiatives.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The lead DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	EU-Africa Global Health Partnership
Reference number	PLAN/2019/5240
Submitted to RSB on	16 April 2020
Date of RSB meeting	13 May 2020

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation (quantitative or qualitative)***	***Comments***
	Direct benefits	
Delivering on EU commitments to tackle global challenges	Infectious diseases have a profound economic impact on countries (healthcare costs and lost productivity). The partnership will make an important contribution by advancing in the development of new or improved health technologies to combat these diseases.	The initiative under 187 would be able to incorporate not only Member States and Associated States contributions but also additional contributions from the sub-Saharan countries and other third countries, private charitable foundations and the pharma industry. Some examples from the current initiative would help to understand the benefits of the proposed initiative: During the period, 2014-2019 EDCTP supported 84 large-scale clinical trials and other clinical research activities with €526 million. The PredART trial provided the first evidence of a strategy to reduce the risk of fatal complication when HIV-infected patients begin antiretroviral treatment while being treated with tuberculosis therapy. TB-NEAT consortium generated evidence on new tuberculosis diagnosis.
Boosting scientific excellence and Europe's global competitiveness in research and innovation	The initiative will further increase the EU's global influence within the international research community.	Between 2003 and 2011, over 90% of publications from EDCTP-funded projects were published in high-impact journals. Moreover, papers from Europe-wide or Europe–sub-Saharan Africa collaborations typically have higher citation rates and greater research impact.
Developing the evidence base for national and international health policy-making (bridging the gap between science and policy for health)	The initiative will support multiple studies that will be able to influence national and international health policy and practice.	The predecessor EDCTP, supported the WANECAM study that demonstrated the safety and efficacy of an antimalarial formulation for children, paving the way for its approval by the European Medicines Agency and recommendation by the WHO. EDCTP-UK studies contributed to Paediatric European Network for Treatment of AIDS (PENTA) guidelines. EDCTP established the Pan African Clinical Trials Registry (PACTR), which is the only WHO-endorsed primary registry in Africa, with >1,000 clinical trials registered. EDCTP is a member of the African Medicines Regulatory Harmonisation Partnership Platform, which aims to improve coordination of regulatory systems strengthening and harmonisation activities in Africa. EDCTP also has a long-term working relationship with WHO-AFRO, which hosts the African Vaccine Regulatory Forum (AVAREF). In order to boost country ownership and alignment with specific national health research needs in sub-Saharan Africa, EDCTP has been collaborating with WHO-AFRO on a National Health Research Systems (NHRS) survey project for the assessment of NHRS, informing progress towards the achievement of Universal Health Coverage.
Providing mechanisms to	Globalisation and broad access to international travel coupled with	EDCTP has invested € 23.43 million to support preparedness to respond to infectious disease outbreaks in sub-Saharan

prepare for and respond to public health emergencies in Africa and Europe	the emergence of new communicable diseases highlight the importance of doing local field research to address public health risks.	African countries, including two large multidisciplinary consortia, ALERRT and PANDORA-ID-NET, involving 22 institutions in 18 sub-Saharan African countries and 16 institutions in 6 European countries. Each consortium has actively responded to disease outbreaks in the region (Lassa fever, Ebola, plague, monkeypox, Coronavirus) as well as redirected their research to immediately address the COVID-19 pandemic in sub-Saharan Africa, and jointly enhanced the capacity of African regions to detect, prepare, and to carry out clinical research in emergency situations. Joint calls with the World Health Organisation have developed capacity in responding to Ebola outbreaks, clinical research and implementation research.
Creating and retaining a new generation of African scientists	Africa's potential in science and innovation is handicapped by a shortage of trained scientists. The partnership will contribute to the research capacity building by supporting the researchers' careers in Africa and strengthening national health research systems. .	The majority of EDCTP-funded clinical studies include a capacity-building work package that supports long- and short-term training, including PhDs and Master's degrees, in addition to improving site infrastructure and equipment. 7,488 people have participated in EDCTP project-related trainings and workshops to improve the capacity to conduct clinical trials, on topics such as study protocol, specimen collection, research and administration, Good Clinical Practice and epidemics preparedness. In addition a comprehensive EDCTP fellowship programme is focused on the career development of individual African researchers and already supported 126 individual fellowships (€ 31.28 million). Since its inception in 2003 the EDCTP has supported more than 500 African researchers, including fellows and MSc/PhD candidates, with 90% continuing their research career in Africa.
Supporting integrated capacity building for health research in Africa	As well as a training scientific workforce and leadership, the partnership will contribute to other key aspects of health research capacity by supporting Networks of Excellence in African regions enabling the sharing of research experience, expertise and knowledge, and developing sustainable capabilities; and by supporting for the establishment of functional regulatory systems and capacities for ethical review of clinical research. The partnership will make efforts to address gender, language and regional research and related capacity disparities.	EDCTP has supported the creation of 4 Networks of Excellence across 63 institutions in 42 sub-Saharan African institutions in 28 countries, in Central Africa CANTAM, Western Africa WANETAM, Southern Africa TESA and Eastern Africa EACC, to address disparities between countries in terms of clinical research capacity. EDCTP is supporting 57 projects to strengthen the enabling environment for clinical trials and research in sub-Saharan Africa (EUR 51.28 million), including health systems strengthening, pharmacovigilance activities and the translation of research results into policy and practice. Moreover EDCTP is contributing to the strengthening of national health research systems in sub-Saharan Africa. They have received EDCTP support for the establishment of functional regulatory systems and capacities for ethical review of clinical research. EDCTP is also developing innovative fellowship approaches (such as tandem fellowships), offering grant writing workshops in different languages (English, French and Portuguese) and project and financial management training, amongst other activities. It is also supporting the development of a standardised Financial Management Assessment Tool for assessing the financial capacity of beneficiaries and the international standard for Good Financial Grant Practice for better financial governance.
Developing European and African capacities in clinical research against poverty-	The partnership will encourage interdisciplinary and cross-disease approaches, enabling institutions to build and diversify their expertise to combat infectious diseases and	EDCTP is encouraging collaboration between its Participating States' Initiated Activities and the centrally-managed activities in order to optimise investments in infectious diseases R&D and maximise the impact of the limited financial resources.

related infectious diseases	to build skills in managing global collaborative projects.	EDCTP also collaborates with The Global Health Network to develop online tools to facilitate open source clinical trials and data sharing. This includes a data management tool for better clinical data management; a Clinical Trial Protocol builder for open source development of clinical trial protocols; and a one-stop data sharing portal called EDCTP Knowledge Hub to provide free access to a virtual research community.
Indirect benefits		
Contributing to the achievement of the African Union Agenda	The partnership will contribute to reduce the economic and social impact of infectious diseases on African countries which is central to delivering the Sustainable Development Goals (SDG 3) and Aspiration 1 of African Union Agenda 2063	EDCTP contributes to the Sustainable Development Goals and to African Union Agenda 2063.
Contributing to the provision of safe medical interventions	The partnership will contribute to better national pharmaco-vigilance systems as the safety of new interventions needs to be monitored when they are introduced into routine care and are used by much larger numbers of people.	EDCTP has supported several projects building national and international expertise, from WHO international drug monitoring programme to Uppsala monitoring centre, to strengthen pharmaco-vigilance systems, to build national capacities to detect and respond to possible adverse events and to maintain public confidence. In addition EDCTP is promoting development of cooperation between academic researchers and product developers (PDPs and Pharmaceutical industry), thus matching scientific excellence with efficiency in advancing products along the product development value chain.

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management /Administrative cost (a)	Direct costs					EUR 0.1 million[1] (1FTE)	EUR 0.9-1.0 million[2]/year
	Indirect costs						
Personnel costs	Direct costs					EUR 0.2 million[3] (2FTE)	EUR 4.0-4.5 million[4]/year (35 FTE)
	Indirect costs						

[1] Indicative one-off administrative costs associated for the setting up the Joint Undertaking (logistic structures to adapt from Art 185 to Art 187)

[2] Indicative yearly figure based on draft EDCTP2 Annual Activity Report 2019 (Table 41 Comparison of actual and budget for 2019 Administrative costs). Under EDCTP2 Art 185 this amount covered the expenses incurred by the EDCTP Secretariat in implementing the EDCTP2 programme. The administrative and personnel costs of the initiative will depend on several factors, including the total budget of the initiative.

[3] Indicative one-off personnel costs associated to the setting up the Joint Undertaking (organisation of selection of personnel, etc.)

[4] Indicative yearly figure based on draft EDCTP2 Annual Activity Report 2019 (Table 41 Comparison of actual and budget for 2019 Administrative costs). Under EDCTP2 Art 185 this amount covered the expenses incurred by the EDCTP Secretariat in implementing the EDCTP2 programme. The administrative and personnel costs of the initiative will depend several factors, including the total budget of the initiative.

Ref: Ares(2020)2572708 - 15/05/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2020)

Opinion

Title: Impact Assessment / European partnership for innovative health

Overall opinion: POSITIVE

(A) Context

The EU Charter on Fundamental Rights establishes the right of access to preventive health care and medical treatment under national law and practices. Health sector innovations contribute to delivering on this right. However, many innovations fail or are slow to reach patients and doctors.

The EU currently supports health innovation through the Innovative Medicine Initiative joint undertaking, which is part of Horizon 2020. This report examines ways to design a successor partnership.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Main considerations

The Board acknowledges the useful additional information provided in advance of the meeting and commitments to make changes to the report. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

(1) The report does not sufficiently explain how the problems and challenges addressed by the new partnership differ from those addressed by the present one.

(2) The report does not clearly explain to what extent the different partnership types are likely to attract health industry partners (small or big) and why.

(3) The report does not provide sufficient information about how the partnership would be implemented in practice.

(C) Further considerations and adjustment requirements

(1) The report should clarify the change of scope from the current partnership to the new

one and explain the reasons for the changes. It could provide examples to illustrate how objectives or the nature of the addressed problems have changed. It should explain the importance of promoting collaboration between the targeted players. The problem analysis could further elaborate on the low productivity of the EU biopharma sector and the underlying reasons.

(2) The report should better highlight the differences between the partnership forms, as the main purpose of the impact assessment is to inform this choice. It should clarify why the institutionalised partnership is likely to attract higher participation and larger contributions from big companies, and the advantage of having dedicated staff for managing the programme.

(3) The report should provide a more concrete description of how it will work in practice, such as the identification and the selection of areas for support, the prioritisation of funding or the flexible redistribution of funds in case of sudden changes in priorities (health crises). This could be illustrated by relevant examples from the current partnership.

(4) The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove the discrepancies between the text and the tables and correct any inconsistencies in terms of expected impacts. The report should justify any deviations from the common efficiency analysis. It should outline what risks and uncertainties are attached to the analysis and the final choice.

(5) The logic of the intervention should be reorganised to shed more light on the central theme of the impact assessment, i.e. the choice of partnership form. In doing so, the report should better clarify the relationship between the problems, the 'functionalities', 'expected impacts', and the specifc objectives. Impacts should be assessed with respect to the specific objectives.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been transmitted directly to the author DG.

(D) RSB scrutiny process

The DG may proceed with the initiative.

The DG must take these recommendations into account before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe: European Partnership for Innovative Health
Reference number	PLAN/2019/5302
Submitted to RSB on	15 April 2020
Date of RSB meeting	13 May 2020

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation***	***Comments***
Direct benefits		
Strengthened EU skills and capacity in academic and industrial health research and innovation	New scientific paradigms, new high-impact publications[1].	
EU-wide cross-sectoral health research and innovation ecosystem created	Easier interactions between potential new collaborators: across stakeholder types (e.g industry with academia, SMEs with large industry…) and across sectors (e.g. pharma with medtech). A neutral platform created for interactions between academia, industry, end-users and regulators.	
New scientific paradigms established providing the foundation for innovative health technologies	New health solutions (e.g. drugs, diagnostics, combination products) available to citizens. Potential new business opportunities for industry, incl. SMEs	Potential new solutions might be entering the market in the future, thus changing the competitive position of companies, incl. SMEs.
Indirect benefits		
More productive and globally competitive EU health industries that create jobs and growth	Positive impacts on European economy, including access to new markets for companies.	Potential salary increase for highly-skilled jobs and/or increase of high-salary employment in health sectors.
Better, safe, effective and cost-effective health technologies,	EU citizens will benefit.	Companies may need to adapt to changing landscape and new

[1] The citation impact (which measures how many times a paper is cited in subsequent papers) for all IMI papers is 2.03 (compared to 1.14 for the EU and the baseline of 1 for the world). https://www.imi.europa.eu/sites/default/files/news/Brochure_ResultsImpact.pdf

tools and digital solutions for health		business models.
Increased level of public and private investments into strategic unmet public health needs	EU citizens will benefit.	For companies, need to adapt to new business models and areas.
Improved health outcomes and wellbeing in priority disease areas (SDG3)	EU citizens will benefit.	Health care systems might need to shift focus from treatment to prevention.
Reduced health inequalities and improved access to high quality health care in priority disease areas (SDG 10)	EU citizens will benefit.	For companies, need to adapt to new business models and areas.
Reduced need for travel impacting on climate (SDG 13)	EU citizens will benefit.	Lowered revenues for certain enterprises active in the travel sector.

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/Administrative costs	Direct costs						EUR 4,7 million[2]
	Indirect costs						
Personnel costs	Direct costs						EUR 6.3 million[3] to cover the cost of 56 staff
	Indirect costs						

[2] Figure for IMI2 JU in 2019, based on draft IMI2 JU Annual Activity Report 2019, Title 2 expenditure. Under IMI2 JU, this amount is covered jointly by the EU and by the private JU Member. This value is given as illustration only since the administrative/personnel costs of IHI will depend several factors, including the total budget of the initiative, organisation of the programme office and the number of staff.

[3] Figure for IMI2 JU in 2019, based on draft IMI2 JU Annual Activity Report 2019, Title 1 expenditure. Under IMI2 JU, this amount is covered jointly by the EU and by the private JU Member. This value is given as illustration only since the administrative/personnel costs of IHI will depend several factors, including the total budget of the initiative, organisation of the programme office and the number of staff.

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment /European Partnership for Key Digital Technologies

Overall 2nd opinion: POSITIVE

(A) Policy context

Digital technologies are inputs into many industries such as auto, aerospace and healthcare. They are key to artificial intelligence as well. Many believe that an EU-supported structure is useful to assemble expertise and create critical mass. To ensure that trusted and secure digital technologies are available to EU firms, the EU is currently supporting a Joint Undertaking under Horizon 2020.

The Horizon Europe programme provides for the establishment of a successor European Partnership for Key Digital Technologies.

This report examines alternative forms of such a partnership for the period 2021-2027. It is one of 12 related impact assessments that consider an Institutionalised Partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes improvements to the report.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

(1) The report does not substantiate well the societal impacts of the preferred option.

(C) What to improve

(1) The report could further clarify the envisaged interactions of this partnership with the other projects and recently announced European policies and priorities.

(2) The revised report compares the merits of the different types of partnerships in a more coherent way. However, it should better substantiate the scoring of the preferred option with regard to societal impacts.

This opinion concerns a draft impact assessment which may differ from the final version.

(3) The report should acknowledge the uncertainties in the financing level and the impact this may have on the success of the initiative. It could explore optimal ways of coping with potentially lower financing.

(4) The report could more consistently report the minority views expressed in the public consultation.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG may proceed with the Initiative.

The DG must take these recommendations into account before launching the interservice consultation.

Full title	Proposal for a Council Regulation for a European Partnership for Key Digital Technologies
Reference number	PLAN/2019/5389
Submitted to RSB on	25 June 2020
Date of RSB meeting	Written procedure

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Estimation (quantitative or qualitative)***	***Comments***
Direct benefits		
Build-up of KDT research, innovation and production capabilities in Europe	Combined resources would effectively address the main objectives, where no single Member or Associated State would have the industrial or economic capacity to realise on its own.	The initiative will allow Member States to anticipate requirements early enough in order to facilitate the deployment of key digital technologies at national and European levels.
Joint R&I strategy	Collaboration across the EU will enable R&I stakeholders to further build collaborations, develop new innovations, and ultimately mature, as Europe-wide KDT pilot lines and platforms become accessible.	The complexity of digital products/services entails that no single entity can master all required technologies. Research and industry organisations will benefit from such a collaboration, which will indirectly support the deployment of European leading-edge KDT products and solutions across the market.
Economic growth particularly for SMEs	SMEs would directly benefit from such a specific collaborative environment, as market oriented research topics make use of a more tailored implementing structure, with a large capacity of manufacturing equipment and materials via participation of key large industrial enterprises	EU growth in Key Digital Technologies is evident, especially for SMEs, which are the key role players in emerging and less established technologies, such as novel computing paradigms (neuromorphic), Artificial Intelligence and related software.
Societal	Citizens would benefit from the introduction of KDT in areas of interest, as safe autonomous vehicles and seamless and secure means of communication are realised, as well as novel healthcare techniques and devices.	Addressing societal problems such as climate change or an ageing society, can be made easier with AI enabled computing derived from the combination of efficient, powerful, trusted electronics and advanced sensors.
Environmental	KDTs would contribute to sustainability and in protecting the environment, as technologies developed would improve energy efficiency, make use of renewable energy sources, and look at new low-power (edge) computing paradigms for data processing.	Downstream industries, through KDT, would progressively reduce the energy consumption of their products, develop technologies and applications of high energy efficiency, and substitute existing

		with more environmentally friendly materials.

II. Overview of direct and indirect costs – Preferred option								
		Citizens/Consumers		Businesses		Administrations		
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent[1]	
Management/ Administrative costs	Direct costs						Running cost €2.29 million[2] /year (EC 50%)	
	Indirect costs							
Personnel costs	Direct costs						€ 3.24 million /year - 30 full time equivalent staff (EC 50%)	
	Indirect costs							
Coordination costs (or transaction costs)								
Budget expenditure/ investment costs								

[1] Commitment appropriations

[2] These are the costs of running the ECSEL JU according to the 2018 Annual Activity Report.

Ref: Ares(2020)2572761 - 15/05/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / European Partnership for Key Digital Technologies

Overall opinion: NEGATIVE

(A) Policy context

Digital technologies are inputs into many industries, such as auto, aerospace and healthcare. They are key to artificial intelligence as well. Many believe that an EU-supported structure is useful to assemble expertise and create critical mass. To ensure that trusted and secure digital technologies are available to EU firms, the EU has supported a Joint Undertaking under Horizon 2020. This will end soon.

A successor programme will take its place. The Horizon Europe programme provides for a European Partnership for Key Digital Technologies.

This report examines alternative forms of such a partnership for the period 2021–2027. It is one of 12 related impact assessments that consider an Institutionalised Partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes the additional written information provided in advance of the meeting. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

However, the Board gives a negative opinion, because the report contains the following significant shortcomings:

(1) The report pre-selects certain sectors and technologies for support, instead of setting out the best partnership approach for promoting a competitive innovation environment.

(2) The dividing lines between this partnership and other initiatives that support research and innovation in the ICT sector are not clear.

(3) The report does not sufficiently integrate the mid-term evaluation findings of the existing Joint Undertaking into the problem description and the intervention logic.

This opinion concerns a draft impact assessment which may differ from the final version.

(4) The report does not score the options in a consistent way. It does not justify how it weighs the different impacts when arriving at the preferred option.

(C) What to improve

(1) The report should be clearer on how this initiative fits in with other research and innovation digital initiatives. It should describe their specificities and the dividing lines between them.

(2) The report should clarify the intervention logic. It should focus on the choice of partnership form, which is the subject of this impact assessment, and not on technological choices. It should better clarify the relationship between the problems, the 'functionalities', the 'expected impacts' and the specific objectives. Impacts should be assessed with respect to the specific objectives.

(3) The report should clearly specify how the proposed partnership would differ from the existing Joint Undertaking. It should better explain how and to what extent it would address the weaknesses identified in the interim evaluation of the Joint Undertaking.

(4) The report should not select certain sectors and technologies to receive EU support under this initiative. Instead, it should explain how the areas for support would be selected under the different options. It should spell out which technological attributes define what a key technology is. The report could do more to clarify how the options would avoid creating a cartel or lead to capture by key industry players.

(5) The report should apply more coherent and better argued scores to compare the different types of partnerships. It should remove the discrepancies between the text and the tables and between tables. It should justify any deviations from the common efficiency analysis.

(6) When selecting the preferred option, the report should clarify the relative importance of the different criteria. In particular, it should take into account any differences in performance on societal impacts and cost-efficiency. It should also point out how the preferred option is best suited to respond to technical change in the future and changing political priorities, as intended with this initiative.

(7) The report should clarify how the Partnership will generate co-financing of 1:3 and on which evidence it bases this assumption. It could better assess uncertainties in the financing level and their impacts on the success of the initiative.

(8) The report could also better report stakeholders' views, in particular those of relevant minorities. It should also appropriately treat the views of respondents considered as participating in a 'campaign'.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.

Full title	Proposal for a Council Regulation for a European Partnership

	for Key Digital Technologies
Reference number	PLAN/2019/5389
Submitted to RSB on	16 April 2020
Date of RSB meeting	13 May 2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / European Partnership for Integrated Air Traffic Management

Overall opinion: POSITIVE

(A) Policy context

The European air traffic management (ATM) system ensures that aircraft can take off, land and transit airspace safely. Member States provide infrastructure and services in their own airspace. Division of responsibilities and fragmentation of ATM negatively affects the performance of European aviation. This is in terms of capacity, safety, efficiency and the environment.

The Single European Sky initiative aims to address these shortcomings. The EU currently supports a Single European Sky ATM Research (SESAR) Joint Undertaking. This impact assessment considers the form of the successor European partnership. The aim is to better integrate ATM systems and technologies. The initiative focuses on digitalisation, new forms of mobility such as autonomous air vehicles, and environmental issues.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board acknowledges the useful additional information provided in advance of the meeting and commitments to make changes to the report. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

(1) **The report does not sufficiently explain what the current joint undertaking has achieved and how the proposed new partnership would build on that.**

This opinion concerns a draft impact assessment which may differ from the final version.

(2) The report does not make clear how the partnership would address air safety issues or to what extent it would help reduce ATM fragmentation.

(3) The report does not provide sufficient information about the link with the Digital European Sky and the European Air Traffic Management Master Plan.

(4) The report does not sufficiently explain to what extent the partnership could rally relevant stakeholders.

(C) What to improve

(1) The report should better integrate evaluation findings on the current joint undertaking and explain how the new partnership would address them. The report should be clearer about the differences between the current joint undertaking and the future partnership.

(2) The report should clarify how the partnership will address air safety issues and to what extent this aspect will be considered in the development of innovative ATM solutions. The report should also elaborate on how far the partnership could enhance interoperability and reduce fragmentation.

(3) The report should better describe the wider context in which the new partnership would operate. It should clarify the link with the European Air Traffic Management Master Plan and the Digital European Sky blueprint. It should be more realistic on the baseline developments of European aviation and on what the partnership can achieve.

(4) The report should further elaborate on the partnership's expected role in bringing together relevant stakeholders and Member States around a common research and alignment agenda of European ATM systems.

(5) The report could explain better the links between problems and objectives, and between objectives, targeted impacts and functionalities.

(6) The report should integrate the latest realistic expectations on the effects of the Covid-19 crisis on air traffic. It could consider these in the analysis of the problems, baseline and impacts.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG may proceed with the initiative.

The DG must take these recommendations into account before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	European Partnership for Integrated Air Traffic Management

Reference number	PLAN/2019/5393
Submitted to RSB on	8 May 2020
Date of RSB meeting	10 June 2020

ANNEX – Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
	Direct benefits	
Improve the Ability to handle additional flights enabling growth in air transport	Direct benefits of ATM value chain Cumulative Benefit up to 2050: EUR 510bn	Full **scalability**: creates the capacity needed to handle traffic in the most efficient way where and when capacity is needed. **Safety:** better trained humans using new technologies will increase safety beyond the current (already high) levels.
Enable new economic activity based on drones	Direct benefits of the U-space value chain Cumulative Benefit up to 2050: EUR 350bn	**U-space and urban air mobility:** A digitally native traffic management system will ensure the safe and secure integration of drones in the airspace especially in urban areas, taking into account new and existing air vehicles and autonomous operations. One of the most challenging use cases from U-space will be to enable urban air mobility, which is expected to advance autonomous technologies in a number of areas.
Boost EU industry globally through international agreements and the setting of global standards	Grow market share to 70% of the global market of approximately €4b per annum Cumulative Benefit up to 2050: EUR 84bn	**Leadership of Europe in the world**: Europe is currently the world leader in aerospace and aviation infrastructure technology. Unless this opportunity is taken, it is likely that Europe will lose its leadership position and become more dependent on imports from third countries.
Reducing aviation noise and gas emissions	Reduction of 240 kg to 450 kg of CO_2 on average per flight due to improved flight efficiency Cumulative Benefit in terms of fuel savings up to 2050: EUR 12bn	**Zero environmental waste:** eliminates environmental inefficiencies caused by the aviation infrastructure, ensuring that it offers solutions that will fully exploit the potential offered by the next generation aircraft for cleaner and quieter flight. A digital European sky could save 28 million CO_2 tonnes per year, which is roughly equivalent to CO_2 produced by 3.2 million people or the population in the metropolitan area of a city like

		Madrid.
Indirect benefits		
Improve passenger experience by reducing travel time, delays and costs	Indirect benefits for passengers and EU citizens. Cumulative Benefit up to 2050: EUR 760bn	A digital and optimally managed European sky will ensure that passengers do not lose time at airports or in the air in Europe. In doing so, it could save yearly up to 14.5 million hours that passengers will be able to spend instead with their family or at work.

Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Administrative Costs, including Personnel	Direct costs				EUR 6.1million (annual contribution for admin costs, jointly paid by the current 19 private partners + Eurocontrol)		EUR 3.3million (Union's annual contribution for administrative costs, including 39 FTEs)
	Indirect costs						
Action (b)	Direct costs						
	Indirect costs						

Ref: Ares(2020)2572633 - 15/05/2020

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / European Partnership for Smart Networks and Services

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Digital infrastructures play an important role in the EU's development and strategic autonomy. 'Smart networks and services' (SNS) include connected devices, networks and computing platforms. They affect all economic sectors. They can help to tackle societal and environmental challenges. The sector in Europe faces challenges in infrastructure, ownership of the technology and security.

The EU currently supports innovation through the 5G public-private partnership programme (5G-PPP). This impact assessment examines how to design a successor partnership.

This is one of 12 related impact assessments that consider an institutionalised partnership as an option. The approach to such partnerships has been agreed in the Horizon Europe Regulation.

(B) Summary of findings

The Board notes the useful additional written information provided in advance of the meeting. The Board appreciates the efforts to carry out impact assessments for a number of candidate partnerships in a coordinated manner, while also taking into account the specificities of each initiative.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The problem analysis does not sufficiently focus on the choice of the candidate partnership.

(2) The report does not explain how the partnership would deliver on some of the objectives.

(3) The report does not clearly explain how the various options differ in terms of their impacts. It does not sufficiently examine questions of coherence with other policy measures, programmes and initiatives.

This opinion concerns a draft impact assessment which may differ from the final version.

(4) The report does not sufficiently reflect stakeholder feedback.

(C) What to improve

(1) The report should put greater focus on assessing and justifying the (change of) partnership choice. It should clarify to what extent the problems addressed by this initiative have developed or differ from those that the current 5G-PPP addresses.

(2) The report should clarify the intervention logic and the mechanisms through which the partnership would deliver on its objectives (including the environmental and social objectives). It should elaborate on what can realistically be achieved via the partnership and to what extent it will need to be complemented by other policy initiatives (regulatory, financial, public and private investments and investments by Member States). The report should clearly outline the roles of the key public and private actors. The report should explain to what extent the initiative intends to integrate the deployment of networks.

(3) The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove the discrepancies between the text and the tables and correct any inconsistencies in terms of expected impacts. On this basis, the report should better describe the main differences in impact between a co-programmed partnership and a partnership under Article 187 TFEU, and how significant they are. The report should be clearer on the added value of changing from the current co-programmed partnership to an institutionalized partnership.

(4) The report should explain better how the preferred partnership option would motivate large companies to join, even if this could limit benefiting from size advantages of network industries and opportunities to earn a dominant market position. It should show in more detail how the partnership facilitates a strong prior commitment to public investment.

(5) The report should integrate stakeholders' views throughout the assessment. In particular, it should elaborate on stakeholders' positions on the different options and to what extent the preferred partnership form is expected to attract their participation.

The Board notes the estimated costs of the preferred option(s) in this initiative, as summarised in the attached quantification table.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification table to reflect this.

Full title	Impact Assessment on the Candidate European Partnership for Smart Networks and Services
Reference number	PLAN/2019/5390

Submitted to RSB on	15 April 2020
Date of RSB meeting	13 May 2020

ANNEX: Quantification tables extracted from the draft impact assessment report

The following table contains information on the costs of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of this table may be different from the final version of the impact assessment report, as published by the Commission.

II. Overview of direct and indirect costs – Preferred option[1]							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative costs	Direct costs				€ 800.000 /year		€ 800.000 /year
	Indirect costs						
Personnel costs	Direct costs				€ 1.2 million /year 50% of 19 FTE		€ 1.2 million /year 50% of 19 FTE
	Indirect costs						
Coordination costs (or transaction costs)							
Budget expenditure/ investment costs							

[1] Estimation based on the average expenditures of the H2020 Joint Undertaking ECSELand on the estimation from the SNS industry taskforce ("Smart Networks and Services Partnership Proposal" document).