ECDC **CORPORATE DOCUMENT**

ECDC Policy on scientific integrity and independence

ECDC/POL/04

1. Introduction

The ECDC Founding Regulation states that the Centre *'shall provide independent scientific opinions, expert advice, data and information'*[1], and that maintaining ECDC's scientific integrity – taken to be the sum of *'independence, high scientific quality, transparency and efficiency'* – is essential for maintaining *'the confidence of the Community institutions, the general public and interested parties in the Centre.'*[2]

This policy elaborates upon how scientific integrity – with a special focus on scientific independence – is to be maintained during all ECDC scientific activity, whether conducted internally or in collaboration with other parties. For the purposes of this policy, scientific independence is defined as conducting any scientific activity in a manner that ensures independence from the influence of the commissioning parties, commercial organisations, lobby groups or any other parties with an interest. Further, if the activity results in the production of any scientific output, this should also be published and disseminated free from any of the influences listed above.

This internal policy further recognizes that not only actual independence but also the perception of independence is important, since it can impact upon ECDC's reputation, and thus the perception of ECDCs scientific independence is as indispensable to maintaining the confidence of the Community institutions, the general public and interested parties as scientific independence in fact. Accordingly, this policy also discusses how the perception of independence is to be maintained at all times while carrying out the functions related to ECDC's core mandate.

Finally, maintaining scientific integrity, and especially the perception of independence, is often more challenging for activities that are performed in collaboration with external partners. At the same time, ECDC as a network organization, achieves added value through collaboration. Therefore, this policy also seeks to ensure that by laying out clear guiding principles for collaborating, ECDC can collaborate with all external partners without impacting its scientific integrity – especially as relates to its scientific independence and the perception of it.

2. Scope and applicability

This policy applies to all scientific activity that ECDC staff conduct, participate in, or commission, where scientific activity is defined as any activity related the design, production, analysis, or dissemination – through any format

[1] ECDC Founding Regulation, Art 6(1).
[2] ECDC Founding Regulation, Recital (14).

written or oral – of science or scientific knowledge, in any capacity, which includes taking an advisory, strategic or management role in any of the activities listed above.

3. Governance

This policy sets out the principles and the operational framework for ensuring the integrity and independence of the scientific activities of the Centre. As such, it defines an operational governance framework. The day-to-day oversight of the policy, and the governance framework that it defines, rests with the Scientific Advice Steering Committee, while the approval of the policy, and any updates to it, is overseen by the Director's Consultation Group, and is made in the light of consultation with the ECDC Advisory Forum.

4. Principles, responsibilities and procedures for maintaining scientific integrity and independence

4.1 Maintaining scientific integrity and independence while planning and managing ECDC's scientific work

The principle of independence of the work of ECDC is clearly articulated in its Founding Regulation, viz '*An **independent** agency, named the European Centre for Disease Prevention and Control should serve as a Community source of **independent** scientific advice, assistance and expertise*'[3]. This independence is managed through the Centre's Director, '*who shall be completely **independent** in the performance in his/her duties, without prejudice to the respective competencies of the Commission and the Management Board*'[4], who is required to ensure that '*the Centre carries out its tasks in accordance with the requirements of its users, **in particular with regard to the scientific excellence and independence** of activities and opinions*'[5].

The role and responsibilities of the Director

The Director exercises this responsibility for ensuring scientific excellence and independence, and alignment of activities with the Centre's mandate and priorities, through the following processes and procedures:

- Review and authorisation of all scientific activities defined in the Centre's annual workplans;
- Review and authorisation of the policies and procedures of the Centre, e.g. this policy and policies and procedures listed in the 'Related documents' section of this policy;
- Consultation with the Centre's Advisory Forum on major new scientific activities and scientific advice outputs, in accordance with the Advisory Forum's defined role of supporting the Director in '*ensuring the scientific excellence and independence of activities and opinions of the Centre*'[6].

Scientific activities that are undertaken in immediate response to requests and emerging issues, and so occur between annual planning rounds, are also authorised by the Director, directly or through delegation to the relevant Heads of Unit, and are implemented according to this policy and those policies and procedures listed in the 'Related documents' section of this policy. Any activity that results in the production of major scientific outputs, is also submitted for review by the Advisory Forum.

The Director, directly or through delegation to the relevant Heads of Unit, ensures that, in common with all ECDC activities, any scientific activities undertaken by ECDC, or commissioned out by ECDC to contractors or other partners, should be aligned with ECDC's mandate and priorities, with the motivation for the activity (e.g. approved as part of the single programming document (SPD), response to external request, response to emerging threat, event or development, and where appropriate, also through consultation processes such as ECDC's IRIS framework) and the intended public health benefit clearly defined before the work is initiated.

The Director, directly or through delegation to the relevant Heads of Unit, ensures that for activities that have been commissioned by external parties:

- those activities are aligned with ECDC's mandate and priorities, and that the conduct of the work and the content of the outputs is according to specifications defined by ECDC;

[3] ECDC Founding Regulation, Recital (5).
[4] ECDC Founding Regulation, Art 16(1).
[5] ECDC Founding Regulation Art 16(2f).
[6] ECDC Founding Regulation, Art 18(3).

- the activities that it has been commissioned to undertake do not cause ECDC to deviate necessary resources from previously held obligations or priorities set by ECDC, barring exceptional circumstances such as in the event of an emerging heath threat;
- in the interest of maintaining high standards of scientific excellence, the work commissioned from ECDC allows for the investigation of all scientifically salient points on a given topic or question.

If any of these conditions are not met, ECDC should work with the commissioning parties to modify the request, keeping the view of always striving to maximise public health benefit with ECDC's limited resources in mind.

The responsibilities of management and staff

In the event that a Head of Unit, or other authorising manager, considers that a scientific activity could have ramifications for ECDC's perceived scientific independence (e.g. participation in an external conference or meeting), such activity is subject to approval by the Chief Scientist, and in the case of meetings, an ECDC Internal Procedure on ECDC meetings with commercial organisations active in the field of ECDC's mandate will be set up governing the principles of such meetings.

In line with the principles of transparency and efficiency, every scientific activity undertaken by the Centre must have clearly assigned responsible persons, with clearly defined responsibilities relating to specific parts of the activity within the Centre.

Experts assigned to a scientific output must strive for the highest quality of science, appropriate and feasible within the resources and timescale available. To this end they should evaluate all sources of data, information, evidence, and their own and others' expertise for their currency, representativeness and completeness, and any limitations or uncertainties arising from the assessment must be presented and discussed in any final output, recognizing, that especially in the case of new and emerging health threats, evidence may be limited at the time of producing some scientific outputs.

Methods and standards for maintaining scientific integrity and independence

Scientific activities should be undertaken in a consistent and timely manner. Processes specified in relevant Internal Procedures and Policies, as listed in the 'Related documents' section of this document, should be followed, and where available, harmonized templates should be used.

All scientific outputs will be subject to an internal clearance process, as defined in ECDC/IP/56 (and listed on the SARMS Intranet page) prior to dissemination, to double-check the scientific soundness of the output as well as to ensure consistency between ECDC outputs and the Centre's mandate and priorities, and the political context. Informal peer-review within the Centre is recommended before submission for formal clearance.

All scientific advice (as defined in ECDC/IP/56), and any risk assessments, technical reports or other scientific outputs that the Chief Scientist or Director deems appropriate, shall be submitted for consultation by the Advisory Forum prior to dissemination.

Scientific outputs of ECDC shall be made available in the public domain, unless a clear reason for limiting disclosure exists. The manner of dissemination of scientific outputs shall depend on the type of output and be agreed upon (ECDC/IP/56) before the production of the output in question. In the case of peer reviewed journal output, this shall follow the Internal Procedure on open access (ECDC/IP/105). Authorship will be determined following the Internal procedure on authorship (ECDC/IP/104) for all outputs.

The final reports, or other published outputs (e.g. peer review papers), and any associated evidence reviews (e.g. the systematic review undertaken to inform the development of a public health guidance document) relating to a particular scientific activity must be filed and archived in a manner that will facilitate tracking, statistical monitoring, reporting, and auditing later.

4.2 Maintaining scientific integrity while collaborating

Collaborations initiated or co-initiated (e.g. joint report production with another EU agency or WHO) by ECDC

Before entering into a collaboration, ECDC should first assess whether the proposed collaboration is aligned with ECDC's goals and mandate, and that the proposed collaboration will result in clear, tangible public health benefit.

Collaborations should aim to aid and enhance ECDC's work and not replace it, as the formulation of ECDC scientific advice is ultimately the Centre's responsibility and task and cannot be commissioned out.

Where a project is not to be entirely funded by ECDC, ECDC will seek to negotiate a funding structure that will not impact upon ECDC's independence or the perception thereof prior to the start of a collaboration. If no satisfactory funding strategy can be found ECDC cannot enter into the collaboration.

The decision to collaborate with externals must be taken early in the process of any activity initiated by ECDC.

All external collaborators must be evaluated based on Declarations of Interest as described in the Independence Policy on Non-Staff (MB42/04b Rev.1), unless specifically exempt by European Commission regulations, to ensure that ECDC is able to maintain its commitment to scientific integrity, independence, and objectivity – and the perceptions thereof – while collaborating. ECDC will be especially vigilant to not enter into collaborations where the primary benefit for the other party appears to be lobbying, political activity, monetary gain or perceived endorsement of their activities by ECDC. Should a conflict of interest or the possible perception of one be identified, the Compliance Officer must be consulted, and mitigation measures may be required to be applied or the collaboration cannot be entered into.

ECDC shall strive to maintain impartiality during its collaborations, meaning that where possible ECDC will seek to collaborate with umbrella organizations rather than individual companies or bodies, and where not possible, ECDC will seek to achieve a balance of interests by including additional partners that can present alternative perspectives and/or concerns as a counterweight.

Clear roles and responsibilities must be laid down for all parties participating in a collaboration during the planning stages, and ECDC processes, e.g. the process of scientific clearance, should be communicated to the collaborating party with the understanding that the ECDC cannot deviate from the steps laid out in such process during the collaboration. Furthermore, if any associated third-party agreements are required for the collaboration to take place, these should be developed according to ECDC's internal procedure IP109.

ECDC has a duty to the European Union and its citizens to be a 'source of independent scientific advice, assistance and expertise'. Therefore, ECDC must have final responsibility over any scientific output within ECDC's mandate produced during the collaboration, including clearance according to ECDC's defined processes, and all the eventual publishing/non-publishing in any format of all of such scientific output produced during the collaboration. Exceptions to this rule can be made, where ECDC may cede final clearance of a joint scientific output to an external body (e.g. WHO, or other EU Agency or Centre(s) for Disease Control) – such exceptions should be approved on a case-by-case basis by the Chief Scientist – or in cases where the potential reputational risk is judged to be very high – by the Director or even the Management Board.

ECDC is committed to maintaining the highest level of transparency possible, as such, thorough records of all collaborations, including but not limited to; meeting agendas and notes and earlier drafts of final scientific outputs, will be kept on file, and where judged necessary for maintaining transparency, made publicly available.

In the event that an additional external partner desires to join an existing collaboration or is invited by ECDC or one of the existing collaborating partners to join an existing collaboration, ECDC would evaluate those additional collaborators following the principles outlined in this section (in the paragraph starting 'All external collaborators must be evaluated…') before they join. If the evaluation is not favourable, ECDC will raise an objection to the party joining and reserves the right to withdraw from a collaboration as detailed below.

ECDC reserves the right to withdraw from a collaboration at any time if it feels that the collaboration threatens the Centres scientific integrity – or the perception thereof.

ECDC further reserves the right to withdraw from or cancel a collaboration if the collaboration runs into an irreconcilable difference of opinions on one or more scientific areas within ECDCs mandate. ECDC may in very rare instances, when working with an external organisation, agree to stay in the collaboration, under the condition that its dissenting view be clearly noted in any final scientific output.

Special considerations for collaborations initiated by external partners where ECDC has a purely advisory or limited, operational role

ECDC may also enter into a collaboration initiated by an external partner (e.g. WHO, Advisory Boards to EU Joint Actions and research projects) where ECDC is expected to play a purely advisory or limited, non-decision-making, operational role, in the event that the involvement is likely to deliver benefits in terms of realising synergies with ECDC's activities, or offer development opportunities, or is likely to mitigate risks of duplication of activities.

In the event of such a collaboration ECDC cannot expect to maintain final rights over any scientific outputs produced by a project. Therefore the paragraph above starting 'ECDC has a duty to the European Union and its citizens…' does not apply in this case. Instead, if ECDC feels that the final scientific output produced by a such a collaboration does not confirm to ECDC's principles of scientific integrity, ECDC will choose to withhold endorsement of the final output.

Ideally, ECDC should join a collaboration initiated by an external partner at the planning or early operational stages of the activity, but joining projects midway with external collaborators is possible, provided that all the other principles in this policy still apply.

4.3 Requests for ECDC staff to contribute to scientific activities as independent experts

Requests from external organisations or authorities to ECDC staff to provide scientific advice as an independent expert should be directed through the Director's Office (for recording in the chrono system). The Director will assess whether the provision of the requested advice falls within ECDC's mandate, in which case the Director may propose that the activity is undertaken by the expert as a representative of ECDC, rather than an independent expert. If the provision of the requested advice does not fall within ECDC's mandate, or the requesting body will only accept the input as *ad hominem* independent advice, then the Director will decide, in consultation with the relevant Head of Unit, whether the request meets with the principles set out directly below.

The Staff Regulations (Article 12b) states that every staff member must first obtain permission from the Appointing Authority before:

- undertaking any type of work outside the institution, whether paid or unpaid, or;
- holding any office outside of the European institutions.

At a practical level, such an external activity should not:

- be so time-consuming as to impact negatively on their work at the ECDC, or constitute a job in itself;
- give rise to any possible appearance of a conflict of interest or be in some other way discreditable, so as to risk bringing the ECDC into disrepute.

5 Publication of this policy

As this policy is of general public interest, and in the interest of transparency, it shall be published on the ECDC website following its adoption.