



# **Impact Assessment Institute**

The Institute for Impact Assessment and Scientific Advice on Legislation and Regulation

*"Impartial Analysis for Policy Making"*

## **Procedures for Conduct of Studies**

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## 1. Identification and definition of studies

The Institute's primary role shall be the performance, documentation and publication of analysis on the impact of existing, planned and prospective legislation, regulation and other policy initiatives. In particular, the Institute shall carry out studies analysing the following:

1. Roadmaps and Inception Impact Assessments published at the start of a regulatory development process.
2. Impact Assessments compiled by regulatory bodies (in particular the European Commission) accompanying legislative proposals (i.e. ex-ante Impact Assessments).
3. Impact Assessments compiled by regulatory bodies to accompany policy communications.
4. Draft secondary legislation where accompanied by an Impact Assessment.
5. Regulatory reviews in particular European Commission Evaluations and REFIT actions (i.e. ex-post Impact Assessments).
6. Relevant reports compiled by non-regulatory bodies.

The procedures below are applicable for the above types of studies, with specific provisions identified for different types where necessary. They are to be applied to and if necessary adapted for individual studies at the discretion of the Secretariat with the guidance of the Studies Committee. Studies shall be performed at the discretion of the Institute's Sponsors according to the selection procedure described herein.

Amendments to these procedures or procedures relating to additional types of studies may be adopted. Procedures and amendments thereof are to be adopted by decision of the Board.

## 2. Role of sponsors in selecting studies

As defined in the Bylaws, certain Sponsors shall be entitled to define the compilation of at least one study in each year of its affiliation.

Each sponsor shall be allocated a number of votes proportional to its sponsorship contribution. At the discretion of the Board, non-sponsoring organisations may be allocated the entitlement to define the compilation of a study or allocated votes.

## 3. Information background for potential studies

The Institute shall maintain an up-to-date database of prospective legislative and regulatory roadmaps, proposals and policy communications and their accompanying Impact Assessments, on which the Institute might compile an analysis. The information shall be acquired by the Institute through its Secretariat and sponsors from published material and other information that can be gained from relevant institutions and bodies.

## 4. Study selection

Before the start of each calendar year, a list of potential studies of interest on known policy or regulatory actions shall be compiled by the Secretariat based on its own investigations and on information and recommendations from its sponsors and stakeholders.

The list of potential studies shall be prioritised by discussion of the Studies Committee by consensus where possible, with due regard to the advice of the Secretariat and the available studies budget. Where consensus cannot be reached, the Secretariat is to introduce an appropriate voting procedure to execute prioritisation of the full list or part thereof.

The voting procedure will allocate votes to Sponsor organisations proportional to their sponsorship contribution for the year.

The priority list of studies shall be administered by the Secretariat. The Secretariat shall compile an estimate for the number of the studies that can be commissioned according to the studies budget, maintaining a prudent budget reserve to allow for unforeseen circumstances. The list and the budget comparison are disseminated to the Studies Committee.

## 5. Specially commissioned studies

Due to the need to maintain impartiality, the Institute does not perform studies on the sole request of any single organisation. There is no client/provider relationship in the standard sense.

Exceptions to this rule are possible in cases where a specific study is explicitly supported by two or more parties known to cover a sufficiently broad range of stakeholder opinion. This support may be in the form of joint funding of the study, explicit support for the study or through agreement on specific parameters, for example the selection of expert consultants contributing to the study. A simple example of a sufficiently broad range of support would be a trade association for an industrial sector and the civil society organisation active in the relevant policy domain.

The decision to undertake such studies shall be taken by the Board of Directors, with due regard to the opinion of the Oversight Board, Studies Committee and the Secretariat. Such decision shall ensure full adherence to the four principles of the Institute.

Where the impartiality of such a study would be in doubt due to a lack of sufficient balance in the range of policy positioning of the involved parties, the Board shall reject the commission.

## 6. Amendments to decision making on studies

To allow for changes during the year, the priority list and the budget comparison are reviewed every three months through a “quarterly studies review”. Depending on the results of this review, the list shall be amended, for example:

- To cover the performance of studies on previously unforeseen policy or legislative initiatives, to be identified and prioritised by decision of the Studies Committee;
- To take into account any amended estimates of the cost of studies;
- To take into account changing budget circumstances, for example additional Sponsorship contributions;
- To cover any other unforeseen circumstances.

Decisions on the performance of previously unforeseen studies during the year shall be made by the Secretariat with guidance from the Studies Committee based on the principles of representativeness and budget prudence, reflecting the greater certainty in budget figures as the year progresses.

## 7. Commissioning studies

Studies shall be performed using the Institute's own resources if these are sufficient in capacity and expertise, or commissioned to external organisations at the discretion of the Secretariat, by open tender where this is considered necessary by the Studies Committee and/or Secretariat.

Where an external party or expert is selected at the discretion of the Secretariat or where the Institute's own resources are deployed, the rationale for the decision shall be clearly documented and communicated to all sponsors and stakeholders.

Where applied, tenders shall be opened at the earliest viable date at which the intention to perform the study can be confirmed. This may, for example, be the date on which the publication date of proposed legislation is officially announced, determined at the discretion of the Secretariat. The tender shall include the following information:

- The thematic scope of the Impact Assessment or report to be studied;
- Expected content (see article 8);
- Expected timing of the report (see article 11).
- Maximum budget;
- All available background information as annexes or internet links.

The tendering organisations or individuals shall be assessed according to the following criteria:

- Expertise in the relevant domain;
- Experience in compiling studies on legislative and regulatory matters;
- Reputation for impartiality and factual analysis;
- Absence of conflict of interest;
- Proposed cost of the study;
- Estimated time required to complete the study according to the Institute's guidelines.

Tendering parties shall be requested to compile a tendering report detailing the above criteria. The Secretariat shall make available a template allowing inclusion of the stated criteria, which shall be used by all tendering parties.

The commissioning of studies, evaluation of the tenders, decision making on the successful tendering organisations (the “author”) and securing of the resulting contract shall be performed by the Secretariat.

The details of the evaluation of the tenders and the decision making shall be included in the final study report by the Secretariat.

## 8. Performance of studies

Studies shall be performed and documented by the Secretariat, or by the authoring organisation in full cooperation with the Secretariat. Studies shall analyse the content of the subject Impact Assessment or report factually and scientifically only, assessing the evidence presented, or lack thereof, and performing alternative analysis where appropriate.

The interim and final reports from the author shall include, but not be limited to, the following information and related explanations on the subject Impact Assessment or report:

- Assessment of the rhetorical language used.
- Assessment of the assumptions made.
- Assessment of the data used.
- Assessment of the analysis performed.
- Identification of critical elements not included.
- Assessment of the results presented.
- Assessment of the conclusions reached.
- Assessment of the extent to which the analysis has been reflected in the related legislative proposal or other relevant policy initiative.
- A statement on the accuracy of the conclusions of the Impact Assessment as they relate to policy implications, stating either a level of uncertainty or proposing alternative results, with full reasoning.

The author shall request and employ all and any resources and data sources required to complete the study with the highest level of quality.

For studies authored by external consultants, the Secretariat shall maintain a constant exchange with the consultant during the compilation of the study. The consultant shall provide all available and current information about the status of the study at any time and shall respond to and reflect the requests of the Secretariat. The Secretariat is to acknowledge the constraints on the consultant due to limitations of time and resources within the context of the contract.

Interim and final reports shall be formatted using a standard template, which may be amended at the discretion of the secretariat on consultation with the author.

## 9. Peer review

Peer review is a key element of the Impact Assessment Institute's study procedures being the formal opportunity to ensure that the IAI work is informed with the most accurate and up-to-date technical and policy information. All the Institute's studies are subject to peer review.

A formal peer review process is implemented to ensure the opportunity for all relevant data to be provided by stakeholders, with the nature and timing dependent on the type of study.

Peer review is requested separately from two groups:

- Stakeholders: these include the Institute's Sponsors and Associates as well as other organisations determined by the Secretariat to be parties with interest and expertise in the policy dossier in question;
- The public at large, approached through the Institute's home page and through active communication to all individuals and organisations identifying themselves as interested parties.

In this process, stakeholders and the public are requested to provide comments of the following nature:

- Alternative assumptions supported by clear factual or scientific evidence;
- New or newly discovered sources of relevant data and evidence;
- Alternative analysis clearly describing the scientific or analytical methodology;
- Alternative conclusions reached according to the new inputs mentioned above;
- Any additional comments relating to the factual and scientific accuracy of the target Impact Assessment or the study.

The feedback so provided is to have the following characteristics:

- Factual, technical and scientific information relevant to the dossier and specifically responding to the draft IAI study, without policy orientation;
- Timely - within the set deadline where possible;
- Written input in general, with face-to-face meetings to take place only where essential, in which case they are to be clearly and transparently reported.

Interim studies are distributed directly to stakeholders for review by email according to the timing outlined in section 11 below relevant to the type of study.

Draft final and final versions of studies shall be published for review on the Institute's website and actively informed to identified stakeholders by email notification according to the timing outlined in section 11 below relevant to the type of study.

The duration of the review shall be adapted from the standard timings according to the specific circumstances of the study, in particular the expected timings of the ongoing legislative process and the topic's complexity.

All comments shall be taken into account by the author in compiling any updated version of the study. The author shall consider comments where these are clearly backed up by fully referenced evidence and, where appropriate and material, take them into account in the report.

The updated report shall include an annex tabulating the peer review comments made and providing a response to each one, detailing whether changes have been made accordingly, whether the comments have not been taken into account and in either case, the reasoning.

## 10. Reporting of studies

Progress of studies shall be made public at three points in their development: at the commencement of the study, at the interim results stage (where applicable) and the final report.

All interested parties identifying themselves to the Secretariat as stakeholders in the relevant domains of the Institute’s work shall be entitled to receive active notification at each stage.

The fact of the commencement of the study shall be announced on the home page of the Institute’s website and informed by email to identified stakeholders in the relevant domain.

Where relevant, the interim results of the study shall be published on the Institute’s website and informed by email to identified stakeholders in the relevant domain.

The final report shall be published on the Institute’s website and informed by email to identified stakeholders in the relevant domain.

One week in advance of the publication of the final study, the final draft version shall be provided to the main stakeholder organisations as a courtesy, normally but not limited to the European Commission, the main interested trade association(s) and the main interested civil society organisation(s).

The Institute may use social media to publicise the status of studies, at the discretion of the Secretariat taking into account the guidance of the Board and Committees.

## 11. Timing of studies

Due to the need to provide timely analysis of the evidence presented to inform the regulatory process, timely completion of the Institute’s studies is necessary.

For the six types of study (as listed in Section 0), the following table describes the appropriate timing for publication of the final study. A more complete description is shown in Annex 1.:

Subject type	EC consultation deadline	Interim study	Final draft study	Final study
1. Roadmaps and inception IAs	4 weeks	3 weeks	4 weeks	10 weeks
2. EU legislative IAs	8 weeks	7 weeks	8 weeks	15 weeks
3. IAs accompanying policy communications	case-by-case			



4. Draft secondary legislation and IAs	4 weeks	n/a	4 weeks	10 weeks
5a. Roadmaps for Evaluations	4 weeks	3 weeks	4 weeks	10 weeks
5b. Evaluations (e.g. REFIT actions)	Does not apply	8 weeks	12 weeks	16 weeks
6. Other assessments	case-by-case			

*Table 1: Indicative timing of studies*

In the case of roadmaps and inception Impact Assessments as well as evaluations and REFIT actions, the purpose of the interim study is to inform the main stakeholders of the content in order to feed their own advocacy activities.

In the case of legislative Impact Assessments, the interim study acts as a courtesy notice of the final draft for the main stakeholders in advance of the publication of the final draft.

In all cases the interim study signals the start of the stakeholder peer review process, with the deadline for responses in each case dependent on the type of initiative (see also Section 9. Peer review). The peer review process therefore exceeds the formal consultation period in most cases. This is necessary in order to allow sufficient time for compilation of the IAI study and for a full review by stakeholders. New information acquired through peer review can still be fed into the ongoing policy process in each case even after the end of the formal consultation.

Organisations wishing their input to be taken into account before the publication of the final draft study are invited to provide their responses at an earlier stage.

A full overview of the standard timings for each type of study is shown in Annex I. These timings may be amended by the Secretariat with the guidance of the Studies Committee according to the individual circumstances and needs.

Each year a review and analysis of the timing of legislative processes and the publication of studies shall be performed. If considered necessary by the Board, on consultation with the Secretariat and Studies Committee, a revision of the timing and actions shall be undertaken.

## **12. Communication of stakeholders with the author**

As a general rule, communication with the author during the period of the study shall be undertaken by the Secretariat only, whether the study is compiled by an external consultant or the Secretariat itself.

Exceptions are permitted in cases where, in the estimation of the Secretariat, direct contact with the author by an organisation or individual offering expert input is deemed to be necessary to ensure the quality of the study. Any meeting or other contact in this respect shall take place under the supervision of the Secretariat.

When in doubt, the principle of maintaining actual and perceived impartiality shall remain paramount.

The nature, duration, persons involved and other relevant details of any approach or contact to the author by any organisation or person on the matter of the study shall be clearly recorded in an annex to the final report.

### **13. Oversight Board supervision of studies**

The function and structure of the Oversight Board (OB) are detailed in the Institute's Rules for Procedure. In order for the OB to carry out its duties to oversee adherence to the four principles in the practical cases of the studies, the following procedures shall be followed:

- Once per month, the Secretariat shall provide to all OB members an update on the status of all studies under development, detailing all actions taken by the secretariat or reported by the authors in respect of the studies. The report shall in particular highlight studies nearing completion of their interim, final draft or final versions and include in particular details of the identity of the study author(s) and any communications with expert or interested stakeholders that have taken place in respect of the study.
- The Secretariat shall make available to all OB members the draft for peer review and final draft for publication as soon as these are completed, in advance of their external dissemination. On request of any member of the OB the Secretariat shall provide information on the content of studies in any stage of preparation.
- A study in preparation may be assigned to a single member of the OB, who in that case shall have the responsibility to lead the monitoring of that study. Such assignments shall be made by agreement between the OB members with the support of the Secretariat. The lead OB member for the study shall have the responsibility to compile and communicate the opinions of the other members and of his/herself to the Secretariat.
- The OB shall assess and comment upon procedural and structural issues in respect of the studies, such as the objectivity of the authors and the balance of additional expertise accessed. OB members are not expected to read and comment upon the content of the studies, but may do so in order to help assess the procedural conduct and in the case of issues arising. If at any time any OB member identifies any actions taken in respect of studies which, procedurally in their view, do not fully reflect the four principles of the Institute, this shall be reported to the Secretariat by the lead OB member for that study.
- If such instances are identified, they shall be resolved by the Secretariat to the satisfaction of the OB, at which time the publication may proceed. If necessary to enable completion of the Board's scrutiny, the deadline for dissemination of the relevant version of the study shall be delayed.
- In the case of unresolvable issues identified by the OB in respect of the compilation of a study, the Secretariat may publish the study at its discretion. Any concerns identified by the OB, or one or more of its members, as to the

adherence to the four principles or the impartiality are to be transparently published to accompany the study.

Once per year to coincide with the Annual General meeting, the OB, with the assistance of the Secretariat, shall compile in its annual report an overview of the adherence of the studies undertaken to the four principles. This shall include a statistical analysis, identification of any instances of non-adherence and the nature of action taken to resolve these instances.

#### **14. Ex-post review of studies**

Any party, including the Institute's sponsors, identified stakeholders or other organisations or individuals having interest in the results of completed studies may provide information ex-post of material relevance to the result of the studies.

If new information with a potential material impact on the results of a published study is received by the Institute, the study shall be reviewed by the Secretariat as soon as practicable. If, in the estimation of the Secretariat, the potential impact of the new information is of sufficient scope to put into question materially the results of the study, a review study shall be proposed and placed on the list of pending studies for assessment at the quarterly studies review.

The sponsors are therefore given the option to recommend reopening of studies when new information is available.

*Annex I: Timings of studies*

Type of study	EC consultation period	Impact Assessment Institute deadlines				
		Start of study*	Interim study to main stakeholders / start of stakeholder peer review	Publication of final draft study / start of public peer review	End of peer review	Publication of final study
1. Road maps and inception IAs	4 weeks	Publication date of roadmap	3 weeks	4 weeks	9 weeks	10 weeks
2. IAs accompanying legislative proposals	8 weeks	Publication date of proposal	7 weeks	8 weeks	13 weeks	15 weeks
3. IAs accompanying policy communications	n/a	Publication date of communication	case-by-case			
4. Draft secondary legislation and accompanying IAs	4 weeks	Publication date of draft	n/a	4 weeks	10 weeks	12 weeks
5a. Road maps for evaluations	4	Publication date of roadmap	3 weeks	4 weeks	8 weeks	10 weeks
5b. Evaluations (e.g. REFIT actions)	Does not apply	Publication date of review	8 weeks	12 weeks	14 weeks	16 weeks
6. Relevant reports compiled	n/a	Publication date of report	case-by-case			

by non-regulatory bodies			
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\* Study may be started earlier where sufficient data is made available