

eIOPA Final Report on Public Consultation No. 14/005 on the Implementing Technical Standard (ITS) on internal model approval processes

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1. Executive Summary

Reasons for publication

According to Article 15 of Regulation (EU) No 1094/2010 (EIOPA Regulation) EIOPA may develop implementing technical standards by means of implementing acts under Article 291 TFEU, in the areas specifically set out in the legislative acts referred to in Article 1(2) of the Regulation.

Before submitting the draft implementing technical standards to the European Commission, EIOPA shall conduct open public consultations and analyse the potential costs and benefits. In addition, EIOPA shall request the opinion of the Insurance and Reinsurance Stakeholder Group (IRSG) referred to in Article 37 of the Regulation.

According to Article 114(2)(a) of Directive 2009/138/EC¹ (Solvency II Directive) as amended by the Omnibus II Directive, EIOPA shall develop draft implementing technical standards (ITS) on the procedures for the approval of an internal model and on the approval of major changes to an internal model and changes to the policy for changing an internal model referred to in Article 115.

As a result of the above, on 2 April 2014 EIOPA launched a public consultation on the draft ITS on the internal model approval processes.

The consultation paper is also published by EIOPA on its website².

Content

This Final Report includes the feedback statement to the consultation paper (EIOPA-CP-14/005) and the full package of the Public Consultation, including:

Annex I: Impact Assessment and cost and benefit analysis.

Annex II: Resolution of comments.

Annex III: Draft Implementing Technical Standard.

¹ OJ L 335, 17.12.2009, p. 1–155

² https://eiopa.europa.eu/consultations/consultation-papers/2014-closed-consultations/april-2014/public-consultation-on-the-set-1-of-the-solvency-ii-implementing-technical-standards-its/index.htm

Next steps

In accordance with Article 15 of EIOPA Regulation, the draft ITS in Annex III will be submitted to the European Commission for endorsement by October 31, 2014, as requested by Article 86(3) of the Solvency II Directive.

According to Article 15 of the EIOPA Regulation, the European Commission shall forward it to the European Parliament and the Council.

Within 3 months of receipt of the draft ITS, the European Commission shall decide whether to endorse it in part or with amendments, where the Union's interests so require. The European Commission may extend that period by 1 month.

If the European Commission intends not to endorse a draft ITS or intends to endorse it in part or with amendments, it shall send it back to EIOPA explaining why it does not intend to endorse it, or, explaining the reasons for its amendments, as the case may be.

Within a period of 6 weeks, EIOPA may amend the ITS on the basis of the European Commission's proposed amendments and resubmit it in the form of a formal opinion to the European Commission. In this case EIOPA must send a copy of its formal opinion to the European Parliament and to the Council.

If on the expiry of the 6 weeks period, EIOPA has not submitted an amended draft ITS, or if it has submitted a draft ITS that is not amended in a way consistent with the European Commission's proposed amendments, the European Commission may adopt the implementing technical standard with the amendments it considers relevant or it may reject it.

Where the European Commission intends not to endorse a draft ITS or intends to endorse it in part or with amendments, it shall follow the process as set out in Article 15 of EIOPA Regulation.

2. Feedback Statement

Introduction

EIOPA would like to thank the Insurance and Reinsurance Stakeholder Group (IRSG) and all the participants to the Public Consultation for their comments on the draft ITS. The responses received have provided important guidance to EIOPA in preparing a final version of the ITS for submission to the European Commission. All of the comments made were given careful consideration by EIOPA. A summary of the main comments received and EIOPA's response to them can be found below and the full list of all the comments provided and EIOPA's responses to them can be found in Annex II.

General comments

Overall, stakeholders supported the provisions set out in the consultation paper.

However, a number of responses received raised important questions. In particular stakeholders asked whether there will be a separate ITS on approval of group internal models. EIOPA clarified that there will be no separate ITS on the procedure for the approval of group internal models, as the empowerment given by the Omnibus II Directive for EIOPA for drafting an ITS refers only to the approval process for solo internal models. The process for internal models used for the calculation of the group SCR will be addressed as part of the Implementing Measures by the European Commission.

Some stakeholders pointed out in their comments that the ITS as drafted leaves some level of discretion for national supervisors, which may create uncertainty for undertakings. EIOPA has sought to find the right balance between too much prescription and flexibility, allowing for an effective approval process both for undertakings and National Supervisory Authorities. In particular the issue of the consequences of the absence of decision has been addressed.

Some concerns were received regarding the request to provide in the application to use an internal model the estimation of the SCR calculated with the standard formula at the most granular level according to the undertaking's risk categorisation. EIOPA has clarified in the resolution of comments that the aim of this requirement is for undertakings to prepare for the eventuality that their internal model as applied for is not approved, therefore helping them in dealing with this contingency; and for supervisory authorities to use this information as one of the tools to assess the application. In addition, EIOPA explained that the requirement refers to an estimation of the SCR with the standard formula at the most granular level, but not a comparison at the most granular level as the structure of the internal model might be different than the structure of the standard formula. The ITS has been redrafted on this point.

The provisions of the ITS should apply in a consistent manner to the procedures for group internal models, as stated in the Recitals to the ITS.

Comments were also made about the concept of extensions to the internal model and whether these extensions are to be considered as model changes or trigger a new approval process. EIOPA has clarified the concept of extension (extensions are new risks or new business units that were not in the scope of the initial internal model) and that such extensions are not to be considered as model changes but are subject to supervisory approval as the initial approval of the internal model.

General nature of the participants to the Public Consultation

EIOPA received comments from the Insurance and Reinsurance Stakeholder Group (IRSG) and eight responses from other stakeholders to the public consultation. All comments received have been published on EIOPA's website.

Respondents can be classified into four main categories: European trade, insurance, or actuarial associations; national insurance or actuarial associations, (re)insurance groups or undertakings, and other parties such as consultants and lawyers.

IRSG opinion

The IRSG opinion on the draft Implementing Technical Standard (ITS) for approval processes, as well as the particular comments on the draft ITS at hand, can be consulted under the following link:

https://eiopa.europa.eu/about-eiopa/organisation/stakeholder-groups/sgs-opinion-feedback/index.html

Comments on the Impact Assessment

No comments were received on the Impact Assessment regarding the expected costs and benefits of introducing the ITS.

Annex I: Impact Assessment and cost benefit analysis

Procedural Issues

According to Article 15 of the EIOPA regulation, EIOPA conducts analysis of costs and benefits in the policy development process. The analysis of costs and benefits is undertaken according to an Impact Assessment methodology.

Consultation with stakeholders

The feedback from the consultation with stakeholders conducted in 2014 is summarised in the respective section of the final report.

Issues assessed

The analysis below presents the EIOPA's considerations on the expected costs and benefits with respect to the **key areas** of this ITS:

- **1.** Approval process of internal models, including
- a) the application submitted by the undertaking;
- b) the assessment by supervisory authorities;
- c) the decision on the application;
- 2. Transitional plan to extend the scope of the model; and
- **3.** Approval process of major changes to the internal model and of changes to the policy for changing the internal model.

Baseline

When analysing the impact from proposed policies, the Impact Assessment methodology foresees that a baseline scenario is applied as the basis for comparing policy options. This helps to identify the incremental impact of each policy option considered. The aim of the baseline scenario is to explain how the current situation would evolve without additional regulatory intervention.

The baseline is based on the current situation of the market, taking into account the progress towards the implementation of the Solvency II framework achieved at this stage by insurance and reinsurance undertakings and supervisory authorities.

In particular the baseline for this implementing technical standard includes:

- The content of Directive 2009/138/EC, as amended by Directive 2014/51/EC;
- The relevant Implementing Measures.

Policy Objective

The objective of developing this ITS is to ensure a harmonised approval processes for internal models.

Analysis of policy issues

Analysis of key area 1a): the application submitted by the undertaking.

The provisions on application establish a set of evidence that has to be provided by the undertaking in order to demonstrate compliance with the relevant requirements to use an internal model which already set out in the Solvency II Directive and the corresponding Implementing Measures. Some specific requests to the undertaking are also included, like the need to provide contact information of the relevant people involved in the activities related to the internal models and an inventory of the documents and sets of evidence included in the application. These requests can generate some limited costs to the undertaking, but have the benefit of increasing the efficiency of the process, as they will make easier the communication between the undertaking and the supervisory authority during the whole approval process and will facilitate the assessment of the application by the supervisory authority.

Analysis of key area 1b): the assessment by supervisory authorities:

Regarding the assessment of the application, on the criteria to assess the completeness of the application by the supervisory authority, there is no discretion incorporated in the ITS as the policies are mainly consistent with the provisions set out in Implementing Measures for internal models for groups, with the only difference of the number of days needed to assess the completeness (30 days for solo internal models, 45 days for group internal models). This difference does not generate material costs, as in principle, group internal models are more complex than solo ones, so the assessment of completeness would be easier for solo models. Regarding the possibility of supervisory authorities to request further information or adjustments to the internal model, this is normal in any approval process and is beneficial both for supervisory authorities and undertakings, as it facilitates the assessment and makes sure that a final decision on the application can be made. The request of further information or adjustments can be seen as a potential cost for the undertaking, but in this case the undertaking has the possibility to request a suspension of the six months for the approval.

Analysis of key area 1c): the decision on the application

With respect to the decision, the proposed policies specify the provisions already set out in Article 112(4), (5) and (6) of the Solvency II Directive. The specific ITS policies give certainty both to the supervisory authorities and undertakings regarding the decision on the application and the reasons to be given by the supervisory authority. The possibility of having terms and conditions subject to the decision is in line with Article 231 of the Directive which foresees this possibility in case of group internal models.

EIOPA considers that the proposed policies for the first key area ensure a consistent application of the Solvency II Directive, in particular Article 112, and contribute to a more efficient approval process of internal models and to a more efficient allocation of resources, for both supervisory authorities and undertakings. The proposed ITS is also

consistent with Implementing Measures, which set out the specificities for the approval process of internal models for groups.

In this respect, it can be concluded that the policies do not generate material incremented costs compared to the baseline.

Analysis of key area 2): Transitional plan to extend the scope of the model

and

key area 3): Approval process of major changes to the internal model and of changes to the policy for changing the internal model

With regard to key areas 3 and 4, the analysis of potential costs and benefits shows that the proposed policies do not generate material incremental costs due to the fact that there is no discretion incorporated in the respective areas. For instance the proposed requirements on the transitional plan to extend the scope of the model in fact only makes explicit and operational the requirements set out in Article 113(2) of the Solvency II Directive. EIOPA is of the opinion that the ITS provisions improve the effectiveness of the request for a transitional plan by national supervisory authorities setting out the process which shall be followed; they also clarify the consequences in case the undertaking fails to act according to the plan. On the approval process of major changes and changes to the policy for changing the internal model, the proposed policies develop Article 115 of the Solvency II Directive. EIOPA is of the view that more specific provisions on these areas improve the consistency and the efficiency of the process, both for undertakings and supervisory authorities.

Monitoring Indicators

The following indicators may be relevant in assessing whether the ITS has been effective and efficient in respect of the objective specified above:

To ensure a
harmonised approval
processes for internal
models.

Possible indicators of progress towards meeting the objective may be:

- Averaged length of time taken by supervisory authorities to determine that an application is complete and number of applications considered not complete with respect to the number of applications submitted.
- Number of applications approved, approved with terms and conditions or rejected with respect to the number of applications submitted.
- Number of applications where additional information was requested by the supervisory authority and time for decision was suspended at the request of the undertaking;

Annex II: Resolution of comments

Summary of Comments on Consultation Paper

CP-14-005-ITS on internal model approval processes

EIOPA would like to thank Insurance and Reinsurance Stakeholder Group, CFO Forum and CRO Forum, Deloitte Touche Tohmatsu, Financial Supervisory Authority of Romania, Insurance Europe, International Underwriting Association of London, Lloyds, The Actuarial Association of Europe, and University of Barcelona Riskcenter-IREA.

The numbering of the paragraphs refers to Consultation Paper No. EIOPA-CP-14/005.

No.	Name Reference	4. Comment	Resolution
1.	IRSG General Comments	The CP has a process focus, which is justified by the already highly detailed nature of Level 1 and Level 2.	Noted. EIOPA appreciates these comments.
		 The CP contributes to the objective of harmonization and consistency through laying down the ground rules for an approval process applicable in al MS. For a first approval of an internal model, six months sooms to be a reasonable period of time. However, for 	Partially agreed. According to Article 115 of the Solvency II Directive, major changes to the internal model are subject to the same process as laid down in Article 112. Therefore NSAs have also 6 months to take a decision on the application for a major change. Nonetheless this is the maximum time for taking a decision. Depending of the nature of the change, the approval process may take less time than 6 months. Also it is expected that NSAs and undertakings have an on-going dialogue in relation to the model and start discussing major changes even before a formal application for the approval of the major change is submitted (see also Recital 5 of the ITS which is also applicable in the case of changes to the model). This can make the
		 For a first approval of an internal model, six months seems to be a reasonable period of time. However, for subsequent approvals related to eg model changes, faster 	discussing major formal application major change is of the ITS which

processes would be feasible (unless the model has changed dramatically).	Disagreed. EIOPA wants to clarify that no response by NSAs after the 6 months means neither rejection nor approval.
 No response from the supervisory authority within the deadline should not be considered lack of approval. There is no justification to leave an undertaking in a situation of uncertainty when the application is complete and receipt of submission has been received. 	As the 6 months to take a decision is legally binding (Article 112.4 of the Solvency II Directive), it should be obvious that if the NSAs do not take action, they expose themselves to legal procedures.
	Noted. This kind of provision cannot be included in the ITS as the empowerment given by the Omnibus II Directive is only related to solo internal models in relation to Article 112, so there is no possibility of including provisions related to Article 231. Having said that, a Recital has been included in the ITS, and in the Implementing Measures (Recital 131) to make clear that the approval process
When the timeline for approval has elapsed, the undertaking should be able to consider that the item has been approved and be allowed to use it.	for group models should be consistent with the one established in the ITS for solo models. EIOPA has also included, in the internal models Guidelines (Application Chapter), some specific Guidelines applicable to the approval process for groups. One of these Guidelines states that "in the case of an application for the use of a group internal model under Article 231 of Solvency II Directive, the applicant should include for each related undertaking that applies to use the group internal model for the calculation of its Solvency Capital Requirement the information set out in Article 2 of the EIOPA draft Implementing Technical
The approval process should be clearly defined and	Standard on Internal Models Approval Processes which is specific to this related undertaking, unless this information is already covered in the documents submitted by the

certainly not be perceived as a never ending process.	participating insurance or reinsurance undertaking".
	Noted. As it happens for the previous comment, this provision cannot be included in the ITS as the empowerment given by the Omnibus II Directive does not cover group internal models processes. Guidelines on this are provided in the relevant Chapters of the Internal Models Guidelines.
• From a legal perspective it is not assured whether the undertakings that are using the group internal model for the calculation of their individual SCR (Art. 231) should include in the application package the documents required for individual internal model as described in this ITS.	EIOPA is taking this concern into consideration. Although a temporary approval will not be legally consistent with the SII framework, EIOPA recognizes this is an important issue and is in favour of a flexible approach. When it comes to the calculation of the SCR and for the purposes of reporting, it is clear that the undertaking shall use the last version of the model approved by NSAs (i.e. with no major change); but when it comes to the use test for instance, more flexibility
 More information is needed about the policy for changing the model and the changes to this policy, in particular in the case when the internal model is a group internal model (Art. 231). 	needs to be considered both by undertakings and NSAs. On this issue, a new Guideline has been introduced in the Use test Chapter of the Internal Models Guidelines (See Guideline 12). Also engaging early with the NSAs in relation to changes to the model as pointed out above can help in making the major change approval process more efficient.
A temporary approval on major changes may be	

			 Some elements do create some uncertainty, as supervisory authorities are granted a certain level of discretion in their decision-making process (e.g. as signaled by the terms 'recommendations', 'adjustments', 'terms and conditions' etc.). We acknowledge it may be impossible to define hard and fast rules which would apply for all conceivable applications, however, clearer guidance would be advisable and beneficial to both undertakings as well as supervisory authorities. Question: The CP seems to deal with approval of internal models for solo purposes – will there be a separate ITS on approval of group internal models? If not the specific issues relating to an application for using a group internal model should be included. The guidance should require the relevant supervisors to agree on the key components of the IM application and related interpretation of requirements (e. g. whether valuation methodologies are part of the IMAP or not). If no agreement can be reached, the issue should be directly addressed to EIOPA to ensure EU wide consistent interpretation. 	Noted. EIOPA considers that the current wording of the ITS has the right balance between too much prescription and flexibility and allows for an effective approval process both for undertakings and NSAs. More details on these issues are included in the resolution of some specific comments below. Noted. No, there will be no separate ITS on group internal models approval process, as the empowerment given by Omnibus II refers only to the solo process. The process for group internal models will be addressed as part of the Implementing Measures by the European Commission. Finally some specific provisions have been included in the Internal Model Guidelines in relation to group internal models to complement the Regulation on this topic. EIOPA mediation is regulated in Article 231 of the Solvency II Directive and EIOPA Regulation.
2.	CFO Forum and CRO Forum	General Comments	Thank you for opportunity to comment on CP-14-05. The CFO Forum and CRO Forum welcome the publication of this consultation paper. We have set out our comments on the individual articles of the paper below. However, we would like to emphasise that there should be a clear decision /feedback provided by the supervisor within the given period of six months, in order to give undertakings sufficient certainty in planning for the application for approval of the internal model. We note also that the ITS as drafted leaves	wording of the ITS has the right balance between too much prescription and flexibility and allows for an effective approval process both for undertakings and NSAs.

			some level of discretion for national supervisors, which may create uncertainty for undertakings. We would welcome clearer guidance, and note that dedicated guidance for group internal model applications has not been provided. We would also note in general that the references to the draft Delegated Acts in the ITS will need to be updated as the Delegated Acts are finalised and adopted.	in 1. Agreed that the references to Implementing Measures will need to be updated if needed.
3.	Financial Supervisor y Authority of Romania (ASF)	General Comments	It is better to devide the text in two sections: I. the procedure to be followed for the approval of applications II. the procedure to be followed for the approval of the applications concerning major changes and changes to the policy for changing the internal model	Partially agreed. EIOPA considers that the current structure reflects already this.
4.	Insurance Europe	General Comments	Insurance Europe welcomes the opportunity to comment on this consultation Paper on the Implementing Technical Standards with regard to the Supervisory Approval Procedure to use Internal Models. The issues related to this paper and which are of great concern for us are the following:	- ·
			Group internal model - Policy for changing the model (Art.231) More information is needed about the policy for changing the model and the changes to this policy, in particular in the case when the internal model is a group internal model. It is not certain if the procedure and the requirements followed at group level under Art. 231, should be the same as those describe in this ITS at local level. The only reference to the Groups is the one described in recital 8. However there is some specificity to take into account when the internal model is a group internal model under the Art. 231.	On this particular issue, the Guideline 9 of the Internal Models Guidelines deals with that.
			In particular it is not clear if a major change at individual level should or should not be considered a major change at	The Application Chapter of the Guidelines on

group level and, if so, who will approve it. It is also not clear Internal Models provides some guidance on if there is one policy for changing the model at individual this topic. level for each undertaking using the internal model or one policy for changing the model at group level that covers all the changes (individual vs group). Group internal model – individual requirements (Art. 231) In the case of a group internal model under Art. 231, there is only an approval process at group level. Nevertheless the See answer to relevant comment in 1 above. supervisory authorities concerned may be able, with the group supervisor coordination, to directly request information at local level from the undertaking it supervises to assess the compliance of the group internal model with the tests and standards and other relevant requirements in respect of the Solvency Capital Requirement of this related undertaking. Policy for Changing the Model: When the insurance undertaking is applying for approval of a major change and of changes to the policy for changing the internal model, a temporary approval may be needed to avoid situations where no approved model exists. Supervisory authorities may decide, on a case-by-case See answer to relevant comment in 1 above. basis, to grant a conditional approval of a major change in the full or partial internal model on a temporary basis. The temporary approval can be withdrawn at any time if the insurance or reinsurance undertaking fails to comply or ceases to comply with required conditions. The internal model has to be used in the system of governance on a continuous basis. Thus, a temporary approval may be needed to avoid situations where no approved model exists. Otherwise the undertaking will use an inadequate model, the old approved that no longer fit to the risk profile, to calculate its SCR.

			The lack of approval or a clear process defining the way forward if no response from supervisor is reached within the deadline. Further clarity should be provided in this respect. If the timeline for approval has elapsed, the undertaking should be able to consider its internal model as approved and be allowed to use it. There is no justification for leaving an undertaking in a situation of uncertainty when the application is complete and submission has been acknowledged. The approval process should have a clearly-defined ending and there should be no possibility of its becoming a never-ending process, as this will discourage undertakings from taking this route. Additionally, other interdependencies (e.g. use of SPV) need to be taken into account in the internal model and further clarification should be specified with regards to these interdependencies (e.g. what happen with the application for the use of an internal model if the use of an SPV has not been granted by the supervisor? How is this mitigated by supervisors?)	This case is similar to the previous one. It should be obvious that if the NSAs do not assess completeness in the timeframe to do so, they expose themselves to legal procedures.
			We also note that the paper remains silent on what happens when the supervisor breaches the 30 days' timeline for notifying that the application is complete and the 6 months allotted to render its decision on approval of the application. Further clarification is required.	
5.	INTERNATI ONAL UNDERWRI TING ASSOCIATI ON OF LONDON	General Comments	We welcome the clarity brought by the draft implementing technical standards. However, more consideration needs to be given to the application of the requirements to groups and firms within groups. What should be the treatment for a major change in one entity within a group? It needs to be clear in what circumstances it should be dealt with by the local entity supervisor or through the supervision of the group internal model.	See answer to relevant comment in 1 above.

6.	Lloyds	General Comments	Lloyd's welcomes the opportunity to respond to this consultation paper on implementing technical standards (ITS) on internal models approval processes.	Noted.
			Lloyd's is a society of members which operates as an insurance and reinsurance market in London. In line with existing EU insurance directives and the Solvency II Directive, Lloyd's is and will be authorised to carry on insurance and reinsurance business as a single entity. It proposes to use an internal model to calculate its Solvency Capital Requirement, subject to supervisory approval.	
7.	University of Barcelona Riskcenter- IREA	General Comments	References to Article 114(2)(a) and (b) of Directive 2009/138/EC is ambiguous. Does it refer to L335/56 and 57 (December 17, 2009, Official Journal of the European Union)? In that case, what do (a) and (b) refer to?	The references are to Articles of the Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 (Solvency II Directive), OJ L 335, 17.12.2009, amended by the Omnibus II Directive. The Omnibus II Directive sets the scope of the technical standards to be drafted by EIOPA to support the implementation of the new regime. One of technical standards is foreseen for Articles 114 of the Solvency II Directive, in relation to the approval process for internal models, and the approval process for major changes to internal models and changes to the policy for changing the model.
8.	The Actuarial Association of Europe	Recital (2)	It is not entirely clear whether the mentioned changes refer to changes before, during and/or after approval of the model. For example, in recital (5) it is stated that communications between undertaking and supervisor should start prior to the formal application. The ITS could describe	In the Recital (2) mentioned, the reference to changes refer to the changes made to the internal model by the undertaking after approval of the model referred to in Article

	(AAE)		the process when changes to the model are needed during the approval process (for example that the application has to be updated on relevant parts, and that the supervisory authority decided on a case by case basis how much time needs to be added to the six months period), and that the full model change policy, including prior supervisory approval of major changes, needs to be implemented at the same time as submitting the formal application.	115 of the Solvency II Directive.
9.	Insurance Europe	Recital (4)	The Art. 112 does not refer to supervisory approval with regards to the inclusion of "new elements". Therefore this appears to be a new policy requirement rather than a technical standard. We would welcome clarification on what "new elements" means.	New elements refer to the extension of the internal model to include new risks or business units. This will naturally trigger a new approval process, as the scope of the model will be different compared to the initial approval, and therefore the appropriateness of the internal model for the risks or business units should be assessed by NSAs.
10.	Lloyds	Recital (4)	This Recital goes beyond the Directive. Directive Article 115 says that « major changes to the internal modelshall always be subject to prior supervisory approval ». The Directive does not require supervisory approval of « the inclusion of new elements in the internal model ».	See answer to comment 9.
			ITS « shall be technical, shall not imply strategic decisions or policy choices and their content shall be to determine the conditions of application » of the legislative act under which they are made (Article 15 Regulation No. 1094/2010). We therefore question whether a recital to an ITS should make an assertion about supervisory policy that does not conform with the policy set out in the underlying legislative act. It go beyond ensuring « uniform conditions of application » of the relevant Directive Articles, to constitute	Disagreed. EIOPA considers that this Recital is useful and linked with the subject matter of the draft ITS.

			the imposition of a new regulatory requirement on insurance undertakings. We therefore suggest that this recital is removed.	
11.	IRSG	Recital (6)	o "During the approval process supervisory authorities should be able to give recommendations on the need of adjustments to the internal model or for a transitional plan []" – The term 'recommendation' is not defined within the scope of the ITS, resulting in uncertainty as to the nature, scope, and required response to recommendations. o In general the possibility for supervisors to require adjustments is seen positive as the previous binary decision on model approval is softened. On the flipside this also means that the approval process might require more documentation and model adjustments therefore also taking more time (a corresponding suspension of the approval period is possible, c.f. Art. 4(9)).	Agreed. "Recommendations" will be replaced by "requests". Agreed. EIOPA considers this contributes to a more flexible process for NSAs and undertakings.
12.	CFO Forum and CRO Forum	Recital (6)	We would suggest that the nature, scope and expected response to the recommendations that may be made by supervisory authorities should be clarified.	EIOPA considers that the current wording of the ITS strikes the right balance between too much prescription and flexibility and allows for an effective approval process both for undertakings and NSAs.
13.	Insurance Europe	Recital (6)	"During approval process supervisors should be able to give recommendations" The term "recommendation" is not defined within the scope of the ITS, resulting in uncertainty as to the nature, scope and required response to recommendations	Agreed. "Recommendations" will be replaced by "requests".

14.	Lloyds	Article 1	Paragraph (b) is not in line with Directive Article 114(2). The two provisions read as follows :	Partially agreed. Changes made in the relevant Article to be more in line with the Solvency II Directive empowerments.
			Directive Article 114(2):	
			« EIOPA shall develop draft implementing technical standards on the procedures to be followed concerning:	
			(b) the approval of major changes to an internal model »	
			ITS Paragraph (b) :	
			The ITS specifies «the procedure to be followed as regards the applications submitted by insurance and reinsurance undertakings for approval of a major change to the internal model ».	
			The ITS should not therefore be restricted to covering only procedures relating to applications for approval of major changes. To meet the Directive's requirements, they should cover all the procedures relating to approval of major changes, including procedures that supervisory authorities should follow when they are considering giving approval.	
			Paragraph (b) should therefore be redrafted to read :	
			«the procedure to be followed as regards the approval of major changes to the internal model »	

			Changes are therefore required to ITS Article 8. As drafted, this Article is addressed entirely to undertakings and imposes requirements on their applications. It should also contain provisions regarding the procedures supervisory authorities should follow when approving major changes.	
15.	Insurance Europe	Article 2 (2)	Duplicates art 112.3 in Solvency II Directive	Partially agreed. The Article includes in addition the specific case of partial internal models and Article 113 of the Solvency II Directive. Therefore EIOPA considers that the drafting of the Article is fine.
16.	The Actuarial Association of Europe (AAE)	Article 2 (2)	It would be helpful to confirm that the evidence should cover material compliance ie compliance in all areas material to the fitness of the model	Partially agreed. The Article is based on Article 112.3 of the Solvency II Directive. The proportionality principle, established in Article 29.3 of the Solvency II Directive always applies, and needs to be taken into account.
17.	IRSG	Article 2 (3)	"[] an estimation of the Solvency Capital Requirement at the most granular level according to the insurance or reinsurance undertaking risk categorization, calculated with the internal model and with the standard formula for the last point in time []" – It may be questioned whether the provision of such SCR data at the most granular level would actually be beneficial to the decision-making process.	Noted. EIOPA considers this provision useful for both for supervisors and undertakings. Supervisors will use this estimation as one of the tools to assess the application. Undertakings needs to prepare for the eventuality that their internal model, as applied for, is not approved, so having the estimation of the SF results will help them in dealing with this contingency.
18.	CFO Forum and CRO Forum	Article 2 (3)	A comparison at the most granular level between the Standard Formula SCR and the Internal Model SCR is required. We would question whether a comparison at the most granular level is necessary.	The requirement is to provide an estimation of the SCR at the most granular level, but not a comparison at the most granular level. The structure of the internal model might be different than the structure of the standard

				formula, in such a case the most granular level of the SCR calculated using the internal model will be different from the structure of the SCR using the standard formula.
19.	Deloitte Touche Tohmatsu	Article 2 (3)	(b) Comment: Punctuation appears to be missing. Proposed update(s): We propose 'undertaking Where' is replaced by 'undertaking. Where'.	Agreed. Change will be made.
			(k) Comment: The Level 1 and draft Level 2 Solvency II texts refer to data as 'accurate, complete and appropriate'. Proposed update(s): We propose that 'adequate' is replaced with 'accurate' to maintain consistency with the Level 1 and draft Level 2 regulatory texts.	Agreed. Change will be made.
			(n) Comment: The requirement to prepare an inventory of the documentation of the internal model is prescriptive and adds limited value to the review of the application given that it lists the documents that a firm has in relation to its internal model.	Disagreed. EIOPA considers this requirement useful as it facilitates the assessment of compliance with the documentation requirements of Article 125 of the Solvency II Directive and contributes to a more efficient process.
			Proposed update(s): We propose that this requirement is removed and firms are left to decide whether to develop an inventory or to present the documentation in a different way within their application. (p)	Disagreed. See answer to comment 17 and 18.

			Comment: Given the level of depth and detail of review of the internal model application, and that the purpose of an internal model is to better match the risk profile of the business, a granular comparison with the standard formula should not be required. This requirement appears to go against the spirit of the Level 1 regulatory text in relation to the application for approval to use an internal model.	
			Proposed update(s): We propose that this requirement is removed. If this requirement remains, we propose that the paragraph is reworded to 'an estimation of the Solvency Capital Requirement according to the insurance or reinsurance undertaking's risk categorisation and an estimation of the the Solvency Capital Requirement using the standard formula at the same date of calculation'.	
20.	Financial Supervisor y Authority of Romania (ASF)	Article 2 (3)	(a) v art. 308a (2) does not list any items, it refers to the powers of the supervisors; maybe 308a (1)?	EIOPA will update the Articles if needed according to the final legal text.
				Disagreed. "The" would be more prescriptive.
			 (k) a the directory of data used in the internal model, [] (q) an identification of those parts of the business of the insurance or reinsurance undertaking which have been classified as a major business unit [] - what is understood by business unit? 	Major business unit is defined as a defined segment of the insurance and reinsurance undertaking that operates independently from other parts of the undertaking and has dedicated governance resources and procedures within the undertaking and which contains risks that are material in relation to the entire business of the undertaking. It will be defined by the Implementing Measures.
21.	Insurance Europe	Article 2 (3)	ii.The definition of the internal model is unclear	Disagreed. The point of this provision is
	Latope		ii.The definition of the internal model is unclear	related to the period for which the internal

	Redraft suggestion: `A description of which aspects of the internal model has been in use in risk management and decision making processes prior to the application' According to Art.4 (2) of this ITS, it is the supervisory authority who assess whether the application is complete upon reception of the application, i.e, not the insurance or	model has been used before the application. Disagreed. Undertakings have the primary responsibility to ensure the completeness of the application. This provision aims to state that. Then supervisors will then assess whether this is the case.
	reinsurance undertaking" a confirmation that the application is complete" should be deleted. v. This paragraph should be deleted. The supervisory authority should have internally the information about other approval process.	Disagreed. This information also includes future applications foreseen by the undertaking within the next 6 months, so in this case NSAs will not have this information. Further this provision is useful for the planning of the NSAs related to a particular undertaking and will indirectly benefit the undertaking itself, as it will make more efficient the different approval processes.
		Disagreed. The second sentence complements the first one, as the requirement to cover all the material and quantifiable risks of the undertaking is for the risks within the scope of the internal model. In the case of PIMs justification must be provided in relation to the provisions of Article 113. Partially agreed. This provision refers naturally
	(b) The first sentence covers all internal models, full internal models as well as partial internal models, whereas the	to plans already known by the undertaking in the moment of applying.

second sentence provides additional requirements in the case of partial internal models. Requiring the internal model in the first sentence to cover all the material risks would not make it applicable to partial internal models.	
Suggestion: delete all in the first sentence.	
	Noted. The materially of the impact will depend on each undertaking and its risk profile.
(d) The undertaking should ()" also outline its plan for the future material improvements of the internal model" Is missing the expression: ()"identified weakness or limitations or, where applicable, to develop or extend the internal model".	Disagreed. This provision is related to Article 112.5 of the Solvency II Directive which says that NSAs shall give approval only if they are satisfied that the systems of the undertaking for identifying, measuring, monitoring, managing and reporting risks area adequate ().
It should be acknowledged that undertakings, beyond any processes they have to manage their internal models, may not know their plans to improve their internal models in advance, as this can depend, to some extent, on decisions made by top management that impact the business and, in turn, the risk profile and the intenal model. Enough flexibility with regards to this plan shall be given to undertakings	See answer to comment 17 and 18.
(f) The definition of `significant impact' should be up to undertakings. Supervisors need only to ensure minimum consistency among undertakings.	
(g) Demonstrating adequacy of the internal control system should be restricted to the internal model:	
"With respect to the internal model and its uses the undertaking should"	

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			(p) Allocation of estimated SCR at the most granular level is not clear and needs further clarification; it could imply reporting on e.g. each instrument or each contract which in our opinion would be at a too granular level, or, if the internal model risk categorisation differs from the standard formula, does this requirement make sense? It may be questioned whether the provision of such SCR	
			data at the most granular level would actually be beneficial to the decision making process.	
			() "in case of an application before any Solvency Capital Requirement is calculated, an estimation of the Solvency Capital Requirement at the most granular level". It is important to clarify that this point in time the entire Pillar I requirements are in force.	
22.	Lloyds	Article 2 (3)	(p) It is unclear what « an estimation of the Solvency Capital Requirement at the most granular level according to the insurance or reinsurance undertaking risk categorisation » means.	See answer to comment 17 and 18. In doubt firms in a pre-application process could seek clarification with their NSA as to how this applies to their particular circumstances.
			Calculating the SCR with an internal model at the level of granularity which the model uses is a tautology. Reporting a split at that level is likely to entail providing information on a vast number of risk categories, which would be of no benefit to supervisors. It is not clear what this means for calculation of the SCR using the standard formula.	
			We suggest that this requirement is re-drafted. The words « at the most granular level according to the insurance or reinsurance undertaking risk categorisation » should be removed, both here and later on in the paragraph. They do	

			not provide useful clarification of the application of the rules.	
23.	The Actuarial Association of Europe (AAE)	Article 2 (3)	Should the comparison to the standard formula be done with the standard formula parameters in any case, as opposed to comparing to the SF with USPs if the undertaking is using such, which the text now implies? Both alternatives are reasonable.	The comparison should be done with the SF parameters (without USPs) for an application before 1/1/2016. The expression "in case of an application before any Solvency Capital Requirement is calculated ()" tries to clarify that.
24.	University of Barcelona Riskcenter- IREA	Article 2 (3)	 [Article 2(3)(a)(iv)]: When is a reinsurance or insurance undertaking obliged to start a new application for an internal model? 	Article 2(3)(a)(iv) refers to the situation where a different application to use an internal model has been approved or has been submitted for the calculation of the group SCR.
			If a group acquired a new insurance or reinsurance company, does this necessarily imply that a new application for a new internal model such be started?	If the group want to use the mode to cover the new acquired company, it has to submit a new application as there is a change in the scope of the internal model. The references are to Articles of the Directive 2009/138/EC (Solvency II Directive), OJ L 335, 17.12.2009, amended by the Omnibus II Directive. The Omnibus II Directive sets the scope of the technical standards to be drafted by EIOPA to support the implementation of the new regime.
			☐ [Article 2(3)(a)(v)] Reference to Article 308(a)(2) of Directive 2009/138/EC is ambiguous. Does it refer to L335/115 (December 17, 2009, Official Journal of the European Union)? In that case, what does (a) refer to?	See answer to comment 20. It is up to the

		undertaking to define what it constitutes for it a major business unit.
		Undertakings need to provide a justification of the classification in relation with the definition.
	☐ [Article 2(3)(I,q)]:	That might depend on how the firm organises itself
	o What is the exact definition of a major business unit? Is it the one stated in CEIOPS-DOC-61/10 of January 2010? o Can one major business unit be defined as such if it represents a substantial percent volume of premia? Simultaneously, can another major business unit be considered as such due to its strategic value for the company?	It is up to each undertaking to define major business units according to the definition outlined above and the scope of its particular model. Then the justifications of that are submitted to the NSAs who should assess them.
	o Is it possible to have different major business units definitions for different insurance companies of the same group?	There is no such directory. It is up to each undertaking to decide which external data to use, bearing in mind the requirements established in the Solvency II Directive and the Implementing Measures. See EIOPA Opinion on External Models and Data of May
	 In case of a partial internal model for underwriting non-life risk, is it refereeing to line of business, or an aggregation of them? 	2012 (in EIOPA website) where this issue is dealt with. See answer to comment 17 and 18.
	☐ [Article 2(3)(f)]: When a business unit has not enough historical statistical information to be modelled independently in an internal model, should it be modeled	In doubt firms in a pre-application process could seek clarification with their NSA as to

			together with another business unit with more data even if the latter is managed by another party within the company? Or should it necessarily be modeled together with other business units under the same management unit?	how this applies to their particular circumstances.
			[Article 2(3)(o)]: How is the use of external data regulated? Is there a directory of firms and institutions that are entitled to provide data to insurance or reinsurance undertakings for their use in internal models? Can external data be public? Can external data be purchased? If data providers sell data bases to insurance or reinsurance undertakings for the internal model, should those data be accessible to regulators?	
			☐ [Article 2(3)(p)] The article mentions "most granular level" according to the insurance or reinsurance undertaking risk categorization. Does this refer to line of business, or risk categorization sub-modules as premium and reserve, CAT and so on?	
. 25.	Deloitte Touche Tohmatsu	Article 2 (5)	Comment: This requirement appears to be very similar to Article 2(3)(n). Proposed update(s): As set out in response to Article 2(3)(n), we propose that this requirement is removed and firms are left to decide whether to develop an inventory or to present the documentation in a different way within their application.	Disagreed. Article 2(3)(n) is related to the "inhouse" documentation of the internal model set out in Article 125 of the Solvency II Directive, while Article 2 (5) refers to the documents and sets of evidence included in the application, which are only a subset of the whole "in-house" documentation.
26.	CFO Forum and CRO	Article 3	(1)(b) does not appear to be clearly worded. We assume the intention is that the policy should not be approved if it	

	Forum		enables the inclusion of new risks or business units without approval by the supervisory authorities, which is a reasonable objective. However, as worded, a policy which set out a process to be followed to seek approval for inclusion of new elements in the model would not be capable of approval by the supervisory authorities.	covered now by the Guidelines on the
. 27.	Deloitte Touche Tohmatsu	Article 3	(a)(v) Comment: It appears that this paragraph has been numbered when it applies to all of the preceding paragraphs. Proposed update(s): We propose that the numbering is removed in order that the statement 'that would impact the Solvency Capital Requirement of the undertaking' applied equally to points (i) to (iv).	Disagreed. (v) is independent from (i) to (iv)
28.	Insurance Europe	Article 3	 (b) It is unclear if the inclusion of "new elements" in the model should trigger a new approval process. There is no mention in the Directive of "new elements". A requirement that they trigger resubmission is a policy issue and should appear in the Delegated Acts, not the ITS. Use of the phrase "such as" here is vague and risks imposing a requirement for resubmission for quite minor changes. It is not clear here whether a new business unit would or would not trigger resubmission of the entire internal model. Clarification should be provided but we strongly disagree that a new portfolio or a new business unit will trigger the resubmission of the entire internal model – this should be limited to the the new risk and/or business units and all related interdependencies with existing business prior to the 	See answer to comments 9 and 26. The paragraph aims at additional risks and business units. The inclusion of a new portfolio within an existing business unit will be treated as a change to the internal model

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				See answer to comment 4.
			(c) Further explanation should be given in the case that the internal model is a group internal model (Art. 231).	
			The following case should be clarified further, (including but not limited to):	
			- How is a major change at solo level classified at group level?;	
			- Is the policy for changing the model only one policy at group level?;	
			- At what level the combination of minor changes should be seen (group level vs. solo level)?	
			- What are the authorized people who sign-off the major changes (group level vs. local level)?	
29.	Lloyds	Article 3	(b) As noted in our comments on Recital (4), the reference to « new elements » introduces a new requirement which does not appear in the Directive or the draft Delegated Acts. This is contrary to Article 15 of Regulation No. 1094/2010.	See answer to comments 9 and 26.
			If the policy for changing the internal model must not cover the inclusion of « new elements », it appears that undertakings using internal models will have to submit an application for approval of a new internal model every time they take on additional risks or business units, irrespective of the materiality of the change to their risk profiles, although this is not entirely clear. Such a requirement goes significantly further than the Directive and could make it difficult or impossible for some undertakings (and groups) ever to have an approved model.	
			An ITS is not an appropriate instrument to introduce an entirely new regulatory concept such as « new elements »	

			with significant implications for undertakings. In any case, the term « new elements » requires clear definition, as otherwise it will be a source of uncertainty for supervisors and undertakings alike. We therefore suggest that this condition be removed.	
30.	The Actuarial Association of Europe (AAE)	Article 3	1 (b) The term « additional risks » could be interpreted as additional policies (or lives or properties insured). It may be helpful to restate this as «additional risk types »	Partially agreed. Some changes will be made to clarify that.
31.	University of Barcelona Riskcenter- IREA	Article 3	☐ [Article 3(1)(c)]: o Who will determine the classification of what is a minor or a major change, in case of disagreement between supervisory authorities and the insurance or reinsurance undertaking?	It is the responsibility of the undertaking to define what constitutes a major or a minor change and include this in the policy. NSAs will assess the appropriateness of the policy as part of the application and take a decision on this part of the model (approve or reject).
			 Can the classification of a minor or a major change in the internal model depend on the impact of SCR? 	Yes, it can, but qualitative criteria should be also used.
			 If the Partial Internal Model (PIM) runs simulations to establish the final result. Will a change in the number of simulation iterations be considered as a major change? 	Criteria could be set in the policy for changing the model to address specific cases. As develop further in the draft EIOPA guidelines, qualitative as well as quantitative indicators could be used to classify changes
			 If the Partial Internal Model (PIM) runs simulations to establish the final result. Will a change in the chosen copula be considered as a major change? 	

32.	Insurance Europe	Article 4 (2)	In order to be aligned with other approval processes, supervisors should confirm completeness of the application to use an internal model within 30 days.	Agreed. The current drafting does not contradict that.
33.	Lloyds	Article 4 (2)	The words « and communicate this in writing » should be inserted at the end of the first sentence. This will align the process for internal models with other processes for supervisory approval.	Disagreed. The outcome of the completeness assessment is established in paragraphs (3) and (4).
. 34.	INTERNATI ONAL UNDERWRI TING ASSOCIATI ON OF LONDON	Article 4 (3)	We believe that the supervisory authority should implement an active internal policy of ensuring that approvals are provided promptly and that there is a regular dialogue with firms about progress and any issues that may arise.	Noted.
35.	Insurance Europe	Article 4 (5)	The unrestricted power of supervisory authorities to request ()"any further informationto assess the application to use the internal model" seems to give too much unjustified freedom in requesting documentation and creates a risk to ensure convergence and effectiveness of application of the regulation.	Disagreed. EIOPA considers that the current wording allows for an effective approval process both for undertakings and NSAs. In the case any further information is requested, undertakings have the possibility of asking a suspension of the six months approval period.
			Please add the following: "as long as it pertains to article 2 (2)". In addition to this concern, it is unclear whether this additional information requirement can be request at a local level when applying for the group internal model under Art. 231. If so, the risk of creating a lack of convergence inside the group is high.	Not possible to include provisions for groups according to the empowerment given in Omnibus II, but as consistency between group internal models and solo processes, it is expected that additional information can also be asked in respect of local undertakings using the group internal model.

36.	Insurance Europe	Article 4 (6)	Not all documents will be available in electronic form. For example, documentation on elements of the internal model based on the implementing software supplied by an external services provider may not be available to the insurance or reinsurance in an electronic form. Provision should be made for documentation provided from vendor models when there is no clear mention of documentation in any clause in the services level aggreement between the undertaking and the external services provider.	Agreed that not all documents will be available in electronic form. On the specific issue of vendors, the use of external models, according to Article 126 of the Solvency II Directive, shall not be a justification for exemption to comply with the internal models requirements. In any case proportionality applies, and as pointed out in Guideline 55 of the Internal Models Guidelines, undertakings may leverage on documentation provided by the undertaking.
37.	IRSG	Article 4 (7)	"[] adjustments to the internal model []" – Preferably there would be some additional language on what basis adjustments can or may be requested, in order to ensure harmonization and consistency.	See relevant answer to comment 1 and 2.
38.	CFO Forum and CRO Forum	Article 4 (7)	'Adjustments' to the internal model can be requested by supervisors. We would suggest that further language describing the scope of adjustments is required to ensure harmonization and consistency.	See relevant answer to comment 1 and 2.
39.	Insurance Europe	Article 4 (7)	Some additional text is needed to know on what basis adjustments can or may be requested in order to ensure harmonisation and consistency. Clarification and justification for asking these "adjustments" is needed. It is not clear if those adjustments can be request at solo level when applying for a group internal model under Art. 231. If so, how does this request will work at a local level as a supervisory authority concerned? Authorization for asking this "adjustments" is needed at college level?	See relevant answer to comment 1 and 2. This issue is similar as the one pointed out in comment 35. College agreement for this request is encouraged.

40.	INTERNATI ONAL UNDERWRI TING ASSOCIATI ON OF LONDON	Article 4 (7)	It is not clear whether local adjustments would need to be approved at the level of group supervision of the group internal model.	See relevant answer to comment 39.
41.	Lloyds	Article 4 (7)	We suggest the following amendment «and, in the case of a partial internal model, for a transitional plan as set out in Article 113». This will ensure proper alignment with Article 113 of the Directive.	Agreed. Changes will be made.
42.	The Actuarial Association of Europe (AAE)	Article 4 (7)	It is stated that requests may be made by the supervisor to make amendmends to the model during the application process. The relationship of these required amendments to the model change policy should be clarified.	Noted. Adjustments are made during the approval process of the internal model per se, while the requirements related to the policy for changing the model refer to changes to the internal model after approval.
. 43.	IRSG	Article 4 (8)	"[] adjustments to the internal model []" – Preferably there would be some additional language on what basis adjustments can or may be requested, in order to ensure harmonization and consistency.	See relevant answer to comment 1 and 2.
44.	The Actuarial Association of Europe (AAE)	Article 4 (8)	Change "may" to "shall": If the supervisory authorities determine that it could be possible to approve the internal model subject to adjustments to the internal model being made, they shall notify this to the insurance or reinsurance undertaking.	The responsibility to submit an application compliant with the requirements rests with the undertaking. This provision provides some additional opportunity to produce a compliant application, but the responsibility is for the undertaking.

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45.	Insurance Europe	Article 4 (9)	It is unclear if the new expiry date starts from the beginning or starts from the suspension date.	Noted. The new expiry date will take into account both.
			Nothing is said about when the undertaking needs to submit a transitional plan, as set out in Art.113. May the undertaking request a suspension of these six months?	The timeline for the transitional plan that may be requested to the undertaking is linked to the decisions by NSAs on the application (see Article 4(6)(b). So it is a different issue than an adjustment and therefore cannot trigger a suspension of the 6 months period.
46.	IRSG	Article 6 (1)	☐ It seems questionable if the criteria mentioned here for a rejection of the internal model by the national supervisory authorities are sufficient when taking local jurisdiction into account. E.g. the BaFin must be able to provide evidence at an administration cost that the acceptance of an application was not possible (given the relevant provisions).	We consider that the criteria provide a harmonised basis for a rejection.
47.	Insurance Europe	Article 6 (1)	The sentence is the negative form of Art. 112 (5). Clarification is required to understand the need for it.	Noted. The aim is to make clear what the reasons for rejection are.
48.	CFO Forum and CRO Forum	Article 6 (3)	We expect that the six month approval period should be generally adhered to. After six months, we believe that applicants should have certainty on their ability to use their internal model.	
49.	Insurance Europe	Article 6 (3)	We strongly disagree with this paragraph. Directive Article 112(4) is clear that "supervisory authorities shall decide on the application within six months from the receipt of the complete application". Failure by supervisory authorities to make a decision on internal model approval within six months is therefore in direct contravention of the Directive, yet there are no provisions in these standards for enforcing that obligation. The "six months' approval period" to which	issue.

			the standards refer is therefore of limited significance, since supervisory authorities can exceed it with impunity. There are risks that supervisory authorities will take considerably longer to consider an application, leaving an undertaking in a situation of uncertainty when the application is complete and receipt has been received. We suggest that this article is removed.	
50.	INTERNATI ONAL UNDERWRI TING ASSOCIATI ON OF LONDON	Article 6 (3)	We believe that the supervisory authority should implement an active internal policy of ensuring that approvals are provided within a reasonable timescale and certainly within the prescribed timescale. There should also be a regular dialogue with each firm about progress and any issues that may arise.	See answer to comment 34.
51.	Lloyds	Article 6 (3)	This provision negates Directive Article 112(4), which says « The supervisory authorities shall decide on the application within six months from the receipt of the complete application ».	See answer to relevant comments in 1 on this issue.
			Supervisory authorities that do not decide on an application within six months will directly contravene the Directive. The ITS should recognise this and include enforcable obligations on supervisory authorities to comply with this requirement. Otherwise, the ITS will have been drafted so as to render a Directive provision ineffective.	
52.	Insurance Europe	Article 6 (4)	(b) This statement does not give clear direction as to what kind of terms and conditions are deemed acceptable. This statement can opens up a wide range of terms and	Partially agreed. EIOPA wants to clarify that terms and conditions are not expected to mitigate any failure of the compliance with the internal model requirements in relation to

			conditions. Further clarity is required.	material and quantifiable risks within its scope. EIOPA will work to build an appropriate framework for these terms and conditions and ensure convergence of supervisory practices in this respect.
			(d) It is unclear if, when the supervisory authority has required a transitional plan in accordance with Art. 113, the decision of approval is dependent on this transitional plan. Art 7 (2) says that "Supervisory authorities shall evaluate the plan" not approve it.	The consequences of failing to implement the plan are set out in Article 7(3).
53.	Deloitte Touche Tohmatsu	Article 6 (6)	Comment: It is currently not clear whether there is any possibility for the insurance undertaking to appeal against the decision of rejection.	This possibility is set out in the Solvency II Directive and it is applicable in general to supervisory decisions affecting an undertaking.
54.	INTERNATI ONAL UNDERWRI TING ASSOCIATI ON OF LONDON	Article 7 (1)	In our view, in order to reflect changing reality, there should be provision for ensuring that there is continuous approval of the different versions of the internal model being used by the undertaking during the period of the transition and after.	The transitional plan is only applicable in the case of partial internal models with a limited scope. The issue raised in the comment seems to refer to a different matter.
55.	IRSG	Article 7 (2)	"The transitional plan shall be approved by the administrative, management or supervisory body []" – Given the technical nature of transitional plans required by supervisors to extend the scope of partial internal models it should be sufficient to have the transitional plan approved by appropriate Risk Committees rather than administrative, management or supervisory body.	Disagreed. Since the transitional plan is linked with the decision on the application that has to be signed by the administrative, management or supervisory body, this body shall also take responsibility for the transitional plan.

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56.	CFO Forum and CRO Forum	Article 7 (2)	Given the technical nature of the transitional plan, approval by the Risk Committee may be more appropriate than the administrative, management or supervisory body.	See answer to comment 55.
57.	Deloitte Touche Tohmatsu	Article 7 (2)	Comment: The term 'extension' referring to the scope of the internal model prescribes a widening of the scope, however the scope may not always be expanding. Proposed update(s): We propose that 'extension of' is replaced with 'change to'. We also propose the addition of 'key milestones' to the requirements of the transitional plan (e.g. delivery of enhancements in the methodologies or documentation).	Disagreed. Article 113 of the Solvency II Directive refers to transitional plan to extend the scope of the model. The ITS shall be consistent with this.
. 58.	Deloitte Touche Tohmatsu	Article 7 (3)	Comment: The term 'extend' referring to the scope of the internal model prescribes a widening of the scope, however the scope may not always be expanding. Proposed update(s): We propose that 'extend' is replaced with 'change'.	See answer to comment 57.
. 59.	University of Barcelona Riskcenter- IREA	Article 7 (3)	☐ If the reasons explained by the supervisory authorities are not shared by the insurance or reinsurance undertaking, which steps must be followed in order to reach a consensus?	The undertaking is able to use legal procedures if it disagrees with the measure taken by NSAs.
60.	Lloyds	Article 8 (1)	Please see our comments on Article 1.	See answer to comment 14.
			This Article should cover the procedures that supervisory authorities should follow when approving major changes.	

			It would be helpful and appropriate for the Article to suggest the time period within which supervisory authorities should normally reach a decision on major changes. Furthermore, the ITS should provide guidance on which model an undertaking should use whilst the supervisory authority is considering the request for approval. Should it use the « old », approved version, even though it may no longer fit its risk profile? Or should it use the « new », amended version, even though it has not yet been approved?	Noted. The decision on model changes shall be taken within 6 months as Article 115 refers to the Article 112 in this respect. See answer to relevant comment in 1 on this topic.
61.	The Actuarial Association of Europe (AAE)	Article 8 (1)	What would be done if, without a major change ,the undertaking would no longer comply with the mentioned requirements due do changes in the business or external environment? Especially in case the changes are not (yet) approved, the situation may occur that the existing, previously approved model is no longer adequate, and the amended model not yet approved. In the past we have discussed fast track temporary approvals – is this a possibility?	See answer to relevant comment in 1 on this topic. Agreed. Changes will be made.
			It is difficult to understand what the evidence would be in «evidence that, after applying the major change ». As the change has not yet taken place when applying for its approval, there can not yet be any evidence. However, a description of how the model would comply, would be relevant.	
62.	IRSG	Article 8 (3)	Article 8.3 includes the following sentence: "Minor changes to the internal model shall be communicated in a summarised report that describes both the quantitative and qualitative impacts of changes and the cumulative quantitative and qualitative effects of the changes on the	Agreed. Most of the draft Article 8(3) has been removed from the ITS to align the content with the empowerment of the ITS; the content is being covered now by the Guidelines on the approval of internal models.

			approved internal model."	
			To be able to report the cumulative quantitative effects of minor changes exactly would require the management of more than one version of the internal model – it would require that the latest version of the model approved by the regulator, without minor changes made thereafter, would be kept "alive". That unnecessarily increases complexity and costs. This can be avoided by allowing such cumulative effects to be reported approximately. That allows the cumulative effect to be computed as the sum of effects from changes of successive versions of the internal model, rather than as the cumulative effect from the latest version of the internal model that was approved by the supervisory authority.	
			Proposal: Insert "approximate" in the said sentence as follows: "and the approximate cumulative quantitative and qualitative effects"	
63.	Insurance Europe	Article 8 (3)	Text refers to minor changes where "appropriate": this type of wording is too broad and vague	Noted. The intention is to give some flexibility to allow for more frequent reporting when deemed useful by NSAs and/or undertakings.
			We disagree that all minor changes have to be communicated to the supervisor as this can generate additional unnecessary work (production of a report, etc). However, undertakings shall agree internally on the minor changes and have a process to manage them. As a combination of minor changes may constitute a major change in accordance with ITS Art 3(1)(c) on the model change policy, there is no need to report on minor changes to the supervisor.	Disagreed. NSAs need to be aware of all minor changes to be able to adequately monitor the on-going appropriateness of the internal model. Minor changes refer to changes to the latest
			It should be clarified what the minor changes should refer to if the undertaking is in the approval process for a major change.	version of the model approved by NSAs.

64.	INTERNATI ONAL UNDERWRI TING ASSOCIATI ON OF LONDON	Article 8 (3)	A distinction needs to be made between minor modifications and changes significant enough to alter the internal model to a degree that might be of concern to the regulator. Otherwise, the proposal could create a great deal of work for the company and the supervisors.	Noted. NSAs need to be aware of all minor changes to be able to adequately monitor the on-going appropriateness of the internal model.
65.	Lloyds	Article 8 (3)	We suggest that this provision is discretionary rather than mandatory and that supervisory authorities have discretion over its application. The process of providing constant reports on minor changes may well entail a great deal of work for both the supervisor and the undertaking and a supervisor may find that, in practice, it is unnecessary and does not contribute usefully to its supervision of the undertaking. Supervisors may therefore want the ability to vary or disapply this provision. We therefore suggest that the word « shall » in the first and second sentences is replaced by « may ».	_
66.	The Actuarial Association of Europe (AAE)	Article 9 (1)	It is difficult to understand what the evidence would be in «evidence that, after applying the changes, the requirements set out in Article 3 are complied with«. As the change has not yet taken place when applying for its approval, there can not yet be any evidence. However, a description of how the model would comply, would be relevant.	Agreed. Changes made.

67.	Insurance Arti Europe	` ,	,,	Noted. EIOPA considers that comprehensive is linked with the rest of the sentence referring to the relevant Articles of the Solvency II Directive.
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Annex III: Draft Implementing Technical Standard



EUROPEAN COMMISSION

Brussels, XXX [...] (2011) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of []

COMMISSION IMPLEMENTING REGULATION (EU) No .../... laying down implementing technical standards with regard to the procedure to be followed concerning the approval of an internal model according to Directive 2009/138/EC of the European Parliament and of the Council

of []

THE EUROPEAN COMMISSION.

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/138/EC of the European Parliament and of the Council of 19 December 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II Directive)³ and in particular Article 114(2)(a) and (b) thereof,

Whereas:

- (1) Under Solvency II an insurance or reinsurance undertaking applying for the use of an internal model to calculate the Solvency Capital Requirement has to comply with the Directive 2009/138/EC requirements for internal models as further specified in the [Implementing Measures].
- (2) Insurance and reinsurance undertakings may change their internal model. This change should be done in accordance with the approved policy for changing the model.
- (3) Major changes to the internal model, a combination of minor changes that is considered a major change, and changes to the policy for changing the model are subject to prior supervisory approval. The provisions set out in this Regulation for the approval process for internal models should apply on a consistent mamner to the approval of major changes to the internal model and changes to the policy for changing the model.
- (4) The inclusion of new elements in the internal model, such as the inclusion of additional risks not included in the scope of the internal model or business units, are subject to supervisory approval as laid down in Article 112 of Directive 2009/138/EC.
- (5) The procedure to be followed for the approval of an internal model and major changes to the internal model should envisage on-going communication between the supervisory authorities and the insurance or reinsurance undertaking. It is considered best practice to begin the communication before the formal application is submitted to the supervisory authorities. The communication should continue after the internal model or major change is approved through the supervisory review process.
- (6) During the approval process supervisory authorities should be able to request adjustments to the internal model or for a transitional plan as set out in Article 113 of Directive 2009/138/EC.
- (7) The provisions in this Regulation are closely linked, since they deal with the supervisory approval of an internal model as stated in Article 112 of Directive 2009/138/EC, as well as the supervisory approval of major changes to the model and of changes to the policy for changing the model as stated in Article 115 of Directive 2009/138/EC. To ensure coherence between those provisions, which should enter into force at the same time, and to facilitate a comprehensive view and compact access to them by persons subject to those obligations, it is desirable to include both implementing technical standards required by Directive 2009/138/EC in a single Regulation.
- (8) The provisions set out in this Regulation on the procedures to be followed concerning the approval, the approval of changes to the internal model and the approval of the policy for changing the model for internal models used at individual level should apply in a consistent manner to the procedures for

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³ OJ L 335, 17.12.2009, p. 1–155

- internal models for the calculation of the consolidated group Solvency Capital Requirement and for group internal models.
- (9) This Regulation is based on the draft implementing technical standards submitted by the European Insurance and Occupational Pensions Authority to the European Commission.
- (10) The European Insurance and Occupational Pensions Authority has conducted open public consultations on the draft implementing technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the opinion of the Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1094/2010.

HAS ADOPTED THIS REGULATION:

Article 1 Subject matter

- (1) This Regulation specifies:
 - (a) the procedure to be followed referred to in Article 112 of Directive 2009/138/EC as regards the approval of applications submitted by insurance and reinsurance undertakings to use full and partial internal models for the calculation of the Solvency Capital Requirement;
 - (b) the procedure to be followed as regards the approval of applications submitted by insurance and reinsurance undertakings for a major change to the internal model and of changes to the policy for changing the internal model according to Article 115 of Directive 2009/138/EC.

Article 2

Application to calculate the Solvency Capital Requirement using an internal model

- (1) The application by an insurance or reinsurance undertaking to calculate the Solvency Capital Requirement using an internal model shall be provided to the supervisory authorities in writing in one of the official languages of the Member State in which the insurance or reinsurance undertaking has its head office or in a language that has been agreed with the supervisory authorities.
- Where applying to use an internal model to calculate the Solvency Capital Requirement, insurance and reinsurance undertakings shall submit, as a minimum, documentary evidence that the internal model fulfils the requirements set out in Articles 101 and 120 to 125 of Directive 2009/138/EC and in the case of a partial internal model also Article 113 of Directive 2009/138/EC.
- (3) The information referred to in paragraph 2 shall include, at least, the following:
 - (a) a cover letter including:
 - i. a request for approval to use an internal model to calculate the Solvency Capital Requirement starting from a specified date and a general explanation of the internal model including a brief description of the structure and the scope of the model;
 - ii. a confirmation of the period prior to the application for which the internal model has been used in the risk management system and decision making processes in accordance with the requirements set out in Article 120 of Directive 2009/138/EC;
 - iii. a confirmation that the application is complete and includes an accurate description of the internal model and that no relevant facts have been omitted;
 - iv. a confirmation on whether the insurance or reinsurance undertaking is part of a group using an internal model for the calculation of the consolidated group Solvency Capital Requirement or whether an application to use any internal model for calculating the consolidated group Solvency Capital Requirement was submitted without having received the notification of the decision;

- v. information of other applications submitted by the insurance or reinsurance undertaking or currently foreseen within the next six months for approval of any of the items listed in Article 308(a)(1) of Directive 2009/138/EC, together with the corresponding application dates;
- vi. contact information of the relevant personnel within the insurance and reinsurance undertaking involved in the activities related to the internal model, as well as to the relevant personnel within this undertaking to whom the requests for supplementary information can be submitted.
- (b) an explanation of how the internal model covers all the material and quantifiable risks of the insurance or reinsurance undertaking. Where the application for the approval relates to a partial internal model, the explanation shall be limited to the material and quantifiable risks within the scope of the partial internal model and the insurance or reinsurance undertaking shall also provide an explanation of how the additional conditions referred to in Article 113 of Directive 2009/138/EC have been satisfied;
- (c) an explanation of the adequacy and effectiveness of the integration of the internal model into the risk management system and the role it plays in the system of governance, including how the internal model allows the insurance or reinsurance undertaking to identify, measure, monitor, manage and report risks on a continuous basis; for this purpose, the application shall include the relevant extracts of the risk management policy referred to in Article 41(3) of Directive 2009/138/EC;
- (d) an assessment and a justification by the insurance or reinsurance undertaking of the material strengths, weaknesses, and limitations of the internal model, including a selfassessment of the compliance with the requirements referred to in paragraph 2; the insurance or reinsurance undertaking shall also outline its plan for the future improvement of the internal model in order to address identified weaknesses or limitations or to develop or extend the internal model;
- (e) where the insurance or reinsurance undertaking is part of a group using an internal model for the calculation of the Solvency Capital Requirement or where an application to use any internal model for calculating the consolidated group Solvency Capital Requirement was submitted without having received the notification of the decision, a justification on why the group internal model is not fit for the risk profile of the undertaking and the differences between the internal model to be used at individual level and the group internal model;
- (f) the technical specifications of the internal model, including a detailed description of the structure of the internal model, together with a list and justification of the assumptions underlying the internal model where an adjustment to these assumptions would have a significant impact on the Solvency Capital Requirement;
- (g) an explanation of the adequacy of the internal control system of the insurance or reinsurance undertaking taking into account the structure and coverage of the model;
- (h) an explanation of the adequacy of the resources, skills and objectivity of the personnel responsible for the development and validation of the internal model;
- (i) the policy for changing the internal model referred to in Article 115 of Directive 2009/138/EC;
- (j) a description of the process which ensures the consistency between the methods used to calculate the probability distribution forecast with the methods used to calculate technical provisions according to Article 121(2) of Directive 2009/138/EC;
- (k) a directory of data used in the internal model, specifying their source, characteristics and usage and a description of the process which ensures that data are accurate, complete and appropriate;
- (l) the results of the last profit and loss attribution and the specification of the profit and loss attribution in accordance with Article 123 of Directive 2009/138/EC including the profit

- and loss, the major business units of the undertaking and the attribution of the overall profit or loss to the risk categories and major business units;
- (m) a description of the independent validation process of the internal model and a report of the results of the last validation in accordance with Article 124 of Directive 2009/138/EC, including what recommendations were made and how they were acted upon;
- (n) the inventory of the documents that form part of the documentation of the internal model set out in Article 125 of the Directive;
- (o) where an insurance or reinsurance undertaking uses a model or data obtained from a third party as referred to in Article 126 of Directive 2009/138/EC, a demonstration that the use of such external model or data does not impair the ability of the insurance or reinsurance undertaking to meet the requirements set out in Articles 101 and 120 to 125 of Directive 2009/138/EC and in the case of a partial internal model Article 113 of Directive 2009/138/EC, the suitability for the use of that model or data within the internal model and an explanation of the preference of external models or data to internal models or data;
- (p) an estimation of the Solvency Capital Requirement calculated with the internal model at the most granular level according to the insurance or reinsurance undertaking risk categorisation, and an estimation of the Solvency Capital Requirement calculated with the standard formula at the most granular level of the standard formula for the last point in time prior to the date of the submission of the application where the Solvency Capital Requirement was calculated with the standard formula. In case of an application before any Solvency Capital Requirement is calculated, the estimation of the Solvency Capital Requirement according to the standard formula shall be calculated with the standard formula parameters and not parameters specific to the insurance or reinsurance undertaking;
- (q) an identification of those parts of the business of the insurance or reinsurance undertaking which have been classified as a major business unit and a justification for this classification;
- (r) in the case of partial internal models, an explanation of how the integration technique proposed fulfils the requirements set out in Article 113(1) of Directive 2009/138/EC, and, in case of a technique different from the default one referred to in Article 239(1) of the draft Implementing Measures, a justification of the integration technique proposed;
- (4) The insurance and reinsurance undertaking shall submit documentary evidence of the approval of the application by the administrative, management or supervisory bodies as set out in Article 116 of Directive 2009/138/EC.
- (5) The insurance or reinsurance undertaking shall provide an inventory of all the documents and sets of evidence included in the application. Where there are connections between different documents the insurance or reinsurance undertaking shall highlight these connections and include cross-references.

Article 3

Assessment of the application

- (1) The supervisory authority shall confirm receipt of the application of the insurance or reinsurance undertaking.
- (2) The supervisory authorities shall determine whether the application is complete within 30 days from the date of the receipt of the application. An application to use an internal model to calculate the Solvency Capital Requirement shall be considered as complete if it includes all the documentary evidence set out in Article 2(2).
- (3) Where the supervisory authorities determine that the application is not complete, they shall immediately inform the insurance or reinsurance undertaking which has submitted the application that the six month approval period has not begun and specify the reasons why the application is not complete.

- (4) Where the supervisory authorities determine that the application is complete, they shall inform the insurance or reinsurance undertaking which has submitted the application that the application is complete and the date from which the six months period starts. That date shall be the date on which the complete application was received.
- (5) Where the supervisory authorities have considered an application to be complete, this shall not prevent the supervisory authority from requesting additional information necessary for its assessment. The request shall specify the additional information and shall include the rationale for the request.
- (6) The insurance or reinsurance undertaking shall ensure that all documents referred to in Article 125 of Directive 2009/138/EC are made available, including in electronic form whenever possible, to the supervisory authorities throughout the assessment of the application.
- (7) The assessment of the application shall involve on-going communication with the insurance or reinsurance undertaking and may include requests for adjustments to the internal model and, in the case of a partial internal model, for a transitional plan as set out in Article 113 of Directive 2009/138/EC.
- (8) If the supervisory authorities determine that it could be possible to approve the internal model subject to adjustments being made to the internal model, they may notify this to the insurance or reinsurance undertaking.
- (9) Where supervisory authorities request further information or adjustments to the internal model, the insurance or reinsurance undertaking may request a suspension of the six months approval period referred to in Article 112(4) of Directive 2009/138/EC. That suspension shall end once the insurance or reinsurance undertaking has made the necessary adjustments and the supervisory authorities have received an amended application providing documentary evidence of the adjustments. The supervisory authorities shall then inform the insurance or reinsurance undertaking of the new expiry date of the approval period.

Article 4

Right to withdraw the application by the undertaking

(1) The insurance or reinsurance undertaking which has submitted the application to use the internal model to calculate the Solvency Capital Requirement may withdraw that application in writing by notifying to the supervisory authority at any time before the decision on the application is reached.

Article 5

Decision on the application

- (1) The supervisory authorities shall reject the application for the use of an internal model if they are not satisfied that the systems of the insurance or reinsurance undertaking for identifying, measuring, monitoring, managing and reporting risk are adequate, and in particular if they are not satisfied that the internal model fulfils the requirements set out in Articles 101, 112 and 120 to 125 of Directive 2009/138/EC and Article 113 in the case of a partial internal model.
- (2) In addition, the supervisory authorities shall reject the application for the use of an internal model if they are not satisfied that the policy for changing the model fulfils the requirements set out in Article 115 of Directive 2009/138/EC.
- (3) Insurance and reinsurance undertakings shall only consider their application for an internal model approved upon receipt of the decision from the supervisory authorities.
- (4) The application for the use of an internal model shall not be considered as approved where the supervisory authorities fail to make a decision within the period referred to in Article 112 of Directive 2009/138/EC. Where the supervisory authorities have assessed the application and decided on it, they shall, without delay, notify its decision to the insurance or reinsurance undertaking. The decision shall include:

- (a) when the supervisory authorities approve the application, the starting date from which the model shall be used to calculate the Solvency Capital Requirement;
- (b) any terms and conditions together with the reasons for those terms and conditions;
- (c) when the supervisory authorities reject the application, the reason on which the rejection is based;
- (d) where the supervisory authorities have required a transitional plan in accordance with Article 113 of Directive 2009/138/EC, a decision about the approval of the transitional plan referred to in Article 6.
- (5) Supervisory authorities shall not disclose that an insurance or reinsurance undertaking has applied to use an internal model to calculate the Solvency Capital Requirement, and that an application was rejected or withdrawn.

Article 6

Transitional plan to extend the scope of the model

- (1) In the case referred to in Article 113(2) of Directive 2009/138/EC, the supervisory authorities shall explain the reasons for requiring a transitional plan and set the minimum scope which the internal model must cover after the implementation of the transitional plan.
- (2) The transitional plan shall be approved by the administrative, management or supervisory body of the insurance or reinsurance undertaking and shall clearly identify the period for implementing the plan, the extension of the scope and the measures and resources necessary to extend the scope of the internal model. Supervisory authorities shall evaluate the plan presented by the undertaking. Supervisory authorities may, where necessary require an amended plan approved by the administrative, management or supervisory body to be submitted for approval.
- (3) When the undertaking fails to implement the transitional plan to extend the scope of the model, the supervisory authorities may, without prejudice to any other available supervisory measures, take the following measures:
 - (a) extend the time period to implement the plan;
 - (b) extend the time period to implement the plan, subject to amendments to the plan;
 - (c) require the insurance or reinsurance undertaking to calculate the Solvency Capital Requirement according to the standard formula set out in Articles 103 to 111 of Directive 2009/138/EC; or
 - (d) allow the use of a partial internal model with a more limited scope than the minimum scope referred to in paragraph 1.

Article 7

Changes to the internal model

- (1) The insurance or reinsurance undertaking shall include in the application for approval of a major change to the internal model documentary evidence that after applying the major changes to the internal model the requirements set out in Articles 101, 112 and 120 to 126 of Directive 2009/138/EC and Article 113 in the case of a partial internal model, would be complied with.
- (2) The insurance or reinsurance undertaking shall include in the application the documents set out in Article 2 where their content would be affected by the major change to the internal model, together with an indication of the changes made to them, and a detailed description of the qualitative and quantitative impacts of the major change to the approved internal model and its results.

Article 8

Changes to the policy for changing the internal model

(1) The insurance or reinsurance undertaking shall include in the application for approval of a change to the policy for changing the internal model the reason for changing the policy for changing the internal model and evidence that, after applying the changes, the requirements to approve this policy would be complied with.

(2) Supervisory authorities shall approve the application to change the policy for changing the internal model only if they are satisfied that the scope of the policy is comprehensive and that the procedures described in the policy for changing the internal model ensure that the internal model meets on a continuous basis the requirements set out in Articles 101, 112 and 120 to 125 of Directive 2009/138/EC and in the case of a partial internal model Article 113 of Directive 2009/138/EC.

Article 9

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, []	
	[For the Commission The President]
	[On behalf of the President]
	[Position]

This Regulation shall be binding in its entirety and directly applicable in all Member States.