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Public consultation on the draft guidelines on Business-wide risk assessment under Article 10 (4)

Fields marked with * are mandatory.

Draft guidelines on Business-wide risk assessment under Article 10 (4) – AMLR

Objective of the consultation

AMLA would like to receive feedback on provisions of the draft guidelines under article 10(4) of Regulation (EU) 2024/1624 ('AMLR') and in particular on the specific questions set out below.

Comments are most helpful if they:

- respond to the question stated;
- indicate the specific point to which a comment relates;
- contain a clear rationale;
- provide evidence to support the views expressed/ rationale proposed; and
- describe any alternative regulatory choices AMLA should consider.

Such comments should be sent by **15 July 2026, 23:59 (CET).**

Personal data protection:

The protection of individuals with regard to the processing of personal data by the AMLA is based on Regulation (EU) 2018/1725. Further information on the processing of the personal data is available in the Data Protection Notice.

All legal details can be found in our Specific Privacy Statement (SPS).

How to provide feedback

All the fields marked with an asterisk (*) are mandatory.

We are using a survey format to help us analyse feedback effectively and efficiently. For this reason, document uploads are not enabled for this exercise, and we kindly invite you to share your comments directly within the survey.

Please note that by submitting your contribution, you acknowledge that it will be published on AMLA's website. Contributions will always be published. The name of organisations submitting their contribution will also always be published. The name of the natural person providing a contribution will be published unless they object to said publication. Please refrain from inserting further personal information beyond what we ask from you. In particular, please refrain from providing confidential information or special categories of personal data (that is "personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation"). Your email address will never be published.

Before publication, AMLA staff will perform a limited screening of all contributions provided for the sole purpose of filtering any inappropriate submissions. After this, the replies are made available to the public directly on AMLA's public consultations page.

Please note that your contribution may be subject to a request for access to documents under Regulation 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

Language disclaimer

AMLA welcomes submissions in all official EU languages. You can change the displayed language of this public consultation using the language selector in the top right corner of the EU Survey platform. Please note that all language versions other than English have been produced using machine translation and may contain inaccuracies. When in doubt, please refer to the English version.

Should you encounter issues with submitting your responses, please contact us by email at public.consultations@amla.europa.eu no later than 48 hours before the deadline of the consultation period.

Respondent profile

* This contribution is made by:

An organisation

* Name of the organisation

200 character(s) maximum

AMF Italia - Associazione Intermediari Mercati Finanziari

* First name of individual (individual respondent or representative of organisation)

100 character(s) maximum

Miriam

* Surname of individual (individual respondent or representative of organisation)

100 character(s) maximum

Felici

* Email (note that your email address will not be published)

100 character(s) maximum

amfitalia@amfitalia.org

* Publication of your name and surname

- (●) I agree to the publication of my name and surname (note that your email address will never be published).
- ( ) Contribution to be published without my name and surname (note that your email address will never be published).

* Which of the following best describes your activity or organisation? Obliged entities are those listed in Article 3 of Regulation (EU) 2024/1624.

Maximum 1 selection(s)

- [ ] Obliged entity in the non-financial sector
- [ ] Obliged entity in the financial sector
- [ ] Self-regulatory body in the sense of Regulation (EU) 2024/1624 Article 2(1) point (47)
- [ ] Industry association representing non-financial sector obliged entities
- [x] Industry association representing financial sector obliged entities
- [ ] Civil society organisation/non-governmental organisation
- [ ] Other

* Financial sector

- [ ] Credit institutions
- [ ] Bureaux de change
- [ ] Collective investment undertakings
- [ ] Credit providers other than credit institutions
- [ ] E-money institutions
- [x] Investment firms
- [ ] Payment institutions
- [ ] Life insurance undertakings

- [ ] Life insurance intermediaries
- [ ] Crypto-asset service providers
- [ ] Other financial institutions

* Please select the country from which you or your organisation carry out your main activities:

IT - Italy

Public consultation questions

Question 1: Do you agree that the proposals set out in these draft GLs can be applied across all obliged entities and allow for an effective application of a risk-based and proportionate approach towards compliance with AML/CFT requirements?

If not, please:
(i) specify the provision concerned with clear reference to the paragraph; and
(ii) provide concrete drafting proposals and explain why the specific measures you propose would be more appropriate.

	Provision/ Guidelines paragraph	Comment
Comment 1	*Only values between 1 and 32 are allowed* 8	*3000 character(s) maximum* We consider that the definition of “non-complex obliged entity” set out in paragraph 2.1, point 8(a) ("Non-complex OEs are those that cumulatively meet criteria in terms of size and activity for reduced frequency of the supervisory risk assessment under RTS on Article 40 (2) of the AMLD") should be aligned with Article 40(2) AMLD and with the definition provided in the Draft RTS on the assessment of the inherent and residual risk profile of obliged entities under Article 40(2). In particular, Article 40(2) AMLD and the related Draft RTS appear to define a non-complex obliged entity on the basis of meeting at least one of the criteria laid down in the legislation. This approach appears to differ from the wording used in the Guidelines, which seems to require the cumulative fulfilment of certain criteria. During the Open Hearing, it was clarified that this difference reflects the different scope of application of the two instruments, given that the RTS under Article 40 (2) AMLD applies exclusively to the financial sector, whereas the Guidelines apply to all obliged entities. Nevertheless, we consider that this distinction should be further clarified in the Guidelines in order to ensure terminological consistency and a consistent application of the proportionality principle.

Comment 2	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 3	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 4	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
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Comment 8	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 9	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 10	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*

Question 2: Do you agree with the proposed minimum requirements for the content of the BWRA set out in these draft GLs?

If you do not agree, please specify:
(i) the provision(s) concerned, with clear reference to the paragraph; and
(ii) the rationale for your position.

Please provide concrete drafting proposals to resolving the issue and explain why the measure you propose would be more appropriate.

	Provision/ Guidelines paragraph	Comment
Comment 1	*Only values between 1 and 32 are allowed* 26	*3000 character(s) maximum* Paragraph 2.5 of the Guidelines, concerning the quality of AML/CFT /non-implementation and evasion of TFS controls, requires, as a minimum requirement, that each inherent risk be clearly linked to specific controls designed to mitigate that risk. The assessment of the quality of controls should be evidence-based and should take into account both the design and the effective implementation of those controls. In this regard, we would welcome further clarification on the expected level of granularity of the mapping between inherent risks and mitigating controls, as well as on the methodology to be applied where sufficient historical data are not available to assess the effectiveness of a recently introduced control. In such circumstances, it would be helpful to clarify whether, and to what extent, obliged entities may rely on qualitative assessments and appropriately documented expert judgement, particularly in the context of an approach proportionate to the nature, size and complexity of the obliged entity.
Comment 2	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 3	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 4	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 5	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
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Comment 9	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 10	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*

Question 3: Do you agree with the proposals for additional sources of information to be taken into account when carrying out the BWRA set out in these draft GLs?

If you do not agree, please specify:
(i) the sources you disagree with; and
(ii) the rationale for your position;
(ii) the sources that should be included.

5000 character(s) maximum

- With regard to the provisions on additional sources of information set out in paragraph 2.2, we consider it useful for AMLA to expressly clarify that the use of such sources is not mandatory. The repeated use of the term "should" could give rise to uncertainty as to the extent to which obliged entities are expected to rely on these additional sources. In our view, the obligation to use sources of information should remain limited to those expressly listed in Article 10(1) of the AMLR, while the use of the additional sources referred to in the Guidelines should be left to the discretion of the obliged entity, taking into account their relevance to its business model and risk profile. This principle could be more clearly reflected in paragraph 18.

- Paragraph 2.2, point 19, clarifies that the list of information sources is not exhaustive and that obliged entities should consider whether additional sources may be relevant. In this regard, we believe it would be helpful for the Guidelines to provide further guidance on the criteria to be used when assessing the relevance and reliability of any additional sources of information. In particular, where appropriate, AMLA could refer to the criteria already set out in Article 8 of the Draft RTS under Article 28(1) AMLR on CDD, in order to promote a consistent approach to the assessment of the information sources used.

Question 4: Do you foresee any operational challenges in implementing these GLs?

If so, please specify:
(i) the provision(s) concerned with clear reference to the paragraph; and
(ii) the rationale for your position.

	Provision/ Guidelines paragraph	Comment

Comment 1	*Only values between 1 and 32 are allowed* 3	*3000 character(s) maximum* Paragraph 3.3 of the “Background and rationale” chapter refers to the need for a close interconnection between the business-wide risk assessment (BWRA) and the individual risk assessment. In this respect, we would find it useful for AMLA to clarify in greater detail, including through practical examples, how the two assessments should feed into and influence each other. In particular, it would be appropriate to specify whether such interaction mainly concerns methodological consistency and the information flow between the two assessments, or whether the outcome of the BWRA should also directly affect the methodologies adopted for the individual risk assessment.
Comment 2	*Only values between 1 and 32 are allowed* 5	*3000 character(s) maximum* With respect to paragraph 2.1, point 5, the Guidelines should provide further details on how the BWRA is to be drawn up by the compliance officer and on the content of the approval by the management body. While these roles are expressly provided for in Article 10(2) AMLR, it would be useful for obliged entities to have further guidance on (i) how the compliance officer may perform such a complex role (for instance, by making explicit the possibility for the compliance officer to draw on the expertise of the first line of defence and of all other functions concerned), and (ii) the form of approval required from the management body (namely, whether it should consist of a formal approval entailing a substantive review of the assessment, or a mere acknowledgement of the presentation of the results of the assessment; and, further, whether the approval should cover only the results of the risk assessment or also the methodology adopted for the assessment itself).
Comment 3	*Only values between 1 and 32 are allowed* 10	*3000 character(s) maximum* With regard to paragraph 2.1, point 10, we would find it useful for the Guidelines to clarify when and under which circumstances the BWRA should be carried out separately for different business areas.

Comment 4	*Only values between 1 and 32 are allowed* 11	*3000 character(s) maximum* With reference to paragraph 2.1, point 11, we consider it appropriate for the Guidelines to provide further clarification on the requirement concerning the adoption of a “common methodology” by all entities of the group. In large financial groups, obliged entities with significantly different business models, activities, products, services and risk profiles may indeed coexist (for example, banks, insurance undertakings, financial holding companies, central securities depositories (CSDs) and other types of entities). In such contexts, the application of a fully uniform methodology for conducting the business-wide risk assessment could prove difficult to implement in practice and may not adequately reflect the operational specificities of the individual entities. We therefore believe it would be useful to clarify that the concept of “common methodology” should not be understood as the adoption of a single, identical methodology for all group entities, but rather as the use of a common set of principles, criteria and rules ensuring the consistency, comparability and aggregability of the business-wide risk assessments of the various group entities, while at the same time allowing the necessary flexibility to adapt methodologies, risk factors and indicators to the specificities of each individual entity. Such a clarification would also be consistent with the approach set out in the RTS adopted pursuant to Article 40(2) AMLR, which identify a common set of factors and information to be taken into account, while nonetheless leaving entities the possibility to adapt their methodologies to the characteristics of the specific activity carried out.

Comment 5	*Only values between 1 and 32 are allowed* 15	*3000 character(s) maximum* The reading of paragraph 2.2, point 15, raises certain potential implementation challenges with regard to the requirements concerning the weighting of risk factors and the documentation of the assessments carried out by obliged entities. First, the paragraph requires obliged entities to document the rationale underlying the weighting decisions attributed to the various risk factors, ensuring that it is clear how the relevance of each factor has been determined in the context of their business model. In this respect, we consider it appropriate for AMLA to provide further guidance on the level of detail required for such documentation. In the risk assessment methodologies adopted by larger entities, the number of risk factors and indicators considered can indeed be extremely high, potentially in the order of hundreds of elements. It would therefore be useful to clarify whether the documentation requirement should be understood as an obligation to provide a detailed and specific rationale for each individual indicator or risk factor, or whether it may be satisfied through an overall methodological explanation setting out the criteria used to determine the weightings, possibly accompanied by examples or by a description of the main categories of factors considered most relevant. An excessively granular approach could indeed entail significant documentation burdens without necessarily improving the quality of the risk assessment, whereas an approach based on the description of the underlying methodological criteria would ensure adequate transparency and traceability, in line with the principle of proportionality.

Comment 6	*Only values between 1 and 32 are allowed* 15	*3000 character(s) maximum* Second, the paragraph requires obliged entities to make informed, evidence-based judgements on the relevance of each risk factor in the context of their business model. On this aspect as well, we consider it appropriate for AMLA to provide further clarification, in particular as to how this requirement should be applied and demonstrated in practice. Specifically, it would be useful to understand which elements may be considered sufficient to support, in an objective and verifiable manner, the conclusion that a given risk factor carries greater or lesser weight than other factors within the entity's business model. The assessment of the relevance of risk factors cannot always be traced back exclusively to quantitative evidence or to observable historical events. In many cases, the determination of the weighting reflects a combination of quantitative and qualitative elements, such as the nature of the activity carried out, the operating model, the type and geographical distribution of the customer base, the exposure to specific products or distribution channels, as well as judgements deriving from the entity's experience and from the results of internal controls. Moreover, situations may arise in which the entity does not have directly usable historical evidence to support the weighting attributed to individual risk factors. This may occur, for example, in the case of smaller entities, or upon the adoption or revision of the business-wide risk assessment methodology, where different risk factors, classification criteria or weighting methodologies were used in previous exercises. In such circumstances, it may not be possible to demonstrate empirically, on the basis of the entity's historical experience, that a given risk factor has a greater impact than another. It would therefore be useful to clarify whether AMLA expects entities to provide specific and detailed evidence supporting the relevance attributed to each individual risk factor, or whether it is sufficient to document the methodological and decision-making process through which such judgements have been made, possibly also drawing on authoritative external sources, scenario analyses, industry best practices or duly reasoned expert judgement. A clarification in this regard would ensure a consistent and proportionate application of the requirement, avoiding an interpretation of the concept of "evidence-based" judgement as an obligation to demonstrate empirically, for each individual factor, a direct correlation with the observed level of risk.
Comment 7	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 8	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*

Comment 9	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*
Comment 10	*Only values between 1 and 32 are allowed*	*3000 character(s) maximum*

Question 5: Within the boundaries of the mandate as defined in Article 10(4) AMLR, do you identify any need to introduce additional provisions?

If so, provide concrete drafting proposals.

5000 character(s) maximum

No

Thank you very much for your feedback.

Contact

Contact Form