Subject: **EMA Response to the consultation on the draft Guidelines on business-wide risk assessment under Article 10(4) of Regulation (EU) 2024/1624**

Date: 15. 07. 2026

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.

The EMA broadly supports the risk-based approach reflected in the draft Guidelines and agrees that a common framework applicable across all obliged entities is necessary to ensure consistency. However, specific provisions would benefit from clarification to ensure proportionate implementation. Throughout, the EMA recommends including additional examples of good practice to further illustrate the expectations under the guidelines.

Paragraph 5(c) – Governance arrangements and approval of the BWRA

The current text lacks sufficient clarity regarding the respective roles of the management body in its management function and its supervisory function, as well as the communication obligations associated with each role. This ambiguity may result in inconsistent implementation across obliged entities.

EMA would also welcome clarification regarding the approval of the BWRA. Paragraph 5(c) provides that the BWRA should be approved by the management body in its management function and communicated to the management body in its supervisory function. However certain national competent authorities currently require approval of the BWRA by the Board or equivalent supervisory body at least annually or following a material change. Clarification on how these expectations should be reconciled would help ensure consistent implementation across Member States and reduce the risk of conflicting governance requirements for firms operating on a cross-border basis.

Proposed amendment:

Ensure that the BWRA is drawn up under the oversight of the Compliance Officer, approved by the management body in its management function in accordance with Article 10(2) of the AMLR and, where such body exists, communicated to the management body in its supervisory function.

Paragraphs 6 and 8 – Application of the proportionality principle

While the Guidelines emphasise proportionality, additional clarification would be helpful regarding their application to obliged entities that do not undertake customer-facing activities. Financial groups frequently include financial holding companies established solely for ownership or asset protection purposes. These entities do not provide services to customers or undertake operational activities. Although a parent financial holding company remains responsible for carrying out the group-wide risk assessment under Article 16 AMLR, requiring non-operational holding companies to conduct separate entity-level BWRAs would create a largely administrative exercise that is not aligned with the principle of proportionality reflected in Paragraph 6.

Proposed amendment:

"Obliged entities that do not undertake customer-facing or operational activities are not required to perform a BWRA at entity level. However, obliged entities acting as group parent undertakings remain responsible for carrying out the group-wide risk assessment."

Paragraph 8(a) – Simplified qualitative BWRAs

Paragraph 8(a) permits non-complex obliged entities to perform simplified qualitative BWRAs by reference to the criteria set out in the RTS under Article 40(2) AMLD6. However, the Guidelines appear to require those criteria to be satisfied cumulatively, whereas Article 5(3) of the RTS applies the criteria alternatively (using the term "any"). This creates an unintended inconsistency between the Guidelines and the RTS. EMA therefore proposes amending Paragraph 8(a) to align with the wording of Article 5(3) of the RTS, thereby ensuring consistency across the AML framework.

However, the exemption in Paragraph 8(a), which allows certain non-complex obliged entities to perform simplified qualitative BWRAs, still excludes non-client-facing obliged entities with highly limited activities, such as financial holding companies. EMA therefore reiterates its proposal in Paragraphs 6 and 8 – Application of the proportionality principle, to explicitly exempt non-client-facing obliged entities without operational activities from the requirement to conduct individual BWRAs.

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.

Pre-operational assessments

Further clarification would be beneficial regarding the approach for assessing products and services during pre-launch or during the authorisation process.

Newly authorised institutions may face practical challenges when performing detailed effectiveness and residual risk assessments in the absence of historical operational data, transaction monitoring outcomes, internal incidents or audit findings. The Guidelines would therefore benefit from additional clarification and practical examples regarding proportionality expectations during the authorisation process and early-stage operations. In particular, it should be recognised that such firms may need to rely initially on qualitative assessments and that the requirements should be applied proportionately until sufficient operational history and data are available.

Paragraph 11 – Branch and subsidiary BWRAs

Further clarification would be helpful regarding the expectation in Paragraph 11 that parent undertakings ensure all group branches and subsidiaries conduct individual BWRAs. In particular, the Guidelines would benefit from additional clarity regarding:

- **the definition of obliged entities**, as not all branches and subsidiaries carry out regulated activities or qualify as obliged entities for AML/CFT purposes;
- **the application of the proportionality principle**, recognising that many branches operate solely as internal operational or back-office functions and do not undertake customer-facing activities, meaning that requiring a standalone BWRA may provide limited additional value where the relevant risks are already captured within the parent undertaking's assessment; and
- **jurisdictional and regulatory considerations**, recognising that branches operating in different Member States may be subject to distinct local risk environments, national BWRA methodologies and supervisory expectations. While a coordinated group methodology is desirable, it would be helpful to clarify how this is intended to interact with existing national BWRA methodologies and how firms are expected to comply where these coexist, while retaining sufficient flexibility to address host-state regulatory requirements, support a consistent approach across Member States and avoid unnecessary duplication.

Accordingly, a blanket requirement for all branches and subsidiaries to undertake individual BWRAs may not always be proportionate. The Guidelines would benefit from clarifying that parent undertakings may determine, on a risk-based basis, whether a separate branch BWRA is necessary or whether the branch's risks can be appropriately captured within the parent undertaking's BWRA.

Proposed amendment:

"Group parent undertakings should assess whether group entities that are branches should conduct their own business-wide risk assessments or contribute directly to the BWRA of their parent undertaking. This assessment should follow a risk-based approach, taking into account: (i) whether the branch is an obliged entity carrying out regulated activities; and (ii) the size, nature and complexity of the branch, including whether it undertakes customer-facing activities or performs solely supporting or back-office functions."

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.

Additional information sources and use of NRAs/SNRA

The proposed additional sources of information are generally supported. However, their practical value will depend on the extent to which they remain current and accurate.

Regular updates by relevant authorities would help ensure that firms can continue to rely on these sources when assessing emerging risks and typologies, as well as broader strategic risk indicators.

Paragraphs 18 and 19 – Additional information sources

While Paragraph 18 indicates that the type and volume of information sources should depend on the nature, size and complexity of the obliged entity, Paragraph 19 states that the listed sources "are to be taken into account". This could be interpreted as requiring obliged entities to consider every source listed, which appears inconsistent with the intended risk-based and proportionate approach. Without further clarification, there is a risk that the non-exhaustive list of sources could be interpreted as a supervisory checklist rather than as guidance, encouraging firms to prioritise the quantity of sources considered over their relevance to the firm's business model and risk profile. This could be particularly burdensome for firms operating across multiple jurisdictions, where not all sources will be equally relevant.

Proposed amendment:

"In this regard, obliged entities may consider, as appropriate, the following non-exhaustive list of additional sources of information when preparing their BWRA."

Additional practical examples illustrating how obliged entities may prioritise and incorporate these sources into their BWRAs according to their business model and risk profile would further support consistent implementation.

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.

Paragraph 23 – RTS under Article 40(2) data points

Paragraph 23 requires obliged entities to "at least refer to the data points listed in the RTS on Article 40(2) of the AMLD" when identifying and classifying inherent risks.

As not all RTS data points are relevant to every category of obliged entity, the current wording could be interpreted as requiring firms to consider information that is not applicable to their business model, sector or risk profile. While the RTS data points were developed primarily to support supervisory risk assessments under Article 40(2) AMLD6, the BWRA should remain an entity-specific assessment that enables obliged entities to apply the principle of proportionality. Requiring firms to refer to all RTS data points irrespective of their relevance may create unnecessary implementation burdens and does not fully reflect the intended risk-based approach. EMA therefore proposes clarifying that obliged entities should consider only those RTS data points that are applicable to their particular business model, sector and risk profile.

Paragraph 27 – Control effectiveness assessments

Implementation of the control rating requirements may increase the operational effort associated with the BWRA process, particularly where firms are expected to document control assessments across a large number of risk indicators. Firms would benefit from additional clarification regarding supervisory expectations to support a proportionate approach.

Clarification regarding targeted financial sanctions integration

The integration of targeted financial sanctions (TFS) within the BWRA framework may create practical challenges regarding overlap with separate sanctions compliance obligations and guidance frameworks.

Further clarification would be beneficial regarding:

- whether TFS assessments should operate as standalone assessments or integrated BWRA components;
- the interaction between AMLA guidance, EU sanctions guidance, EBA restrictive measures guidance and other sanctions frameworks;
- proportionality expectations for firms with limited sanctions exposure; and
- how duplication of assessments and governance arrangements can be avoided.

Group-wide BWRA assessments

Further clarification would be beneficial regarding group-wide BWRA expectations, particularly for cross-border groups.

Further clarification would also be beneficial regarding governance expectations where group-wide assessments involve separate compliance, governance or outsourcing frameworks.

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.

Article 10(1) AMLR – New products, services and business practices

The Guidelines would benefit from further clarity and practical examples on how the requirements under Article 10(1) AMLR, requiring obliged entities to identify, assess, manage and mitigate ML/TF risks before launching new products, services or business practices, should be incorporated into, or linked with, the BWRA. This would promote a consistent and proportionate approach across obliged entities.

Paragraphs 14-16 – Risk-weighting methodology

EMA notes that firms may face practical challenges in justifying differentiated risk weightings where sufficient historical data is not available. The Guidance should acknowledge this, recognising that firms may need to adopt alternative approaches where appropriate. This could include qualitative weighting methodologies or simplified categorisation of risk factors, provided these are appropriately documented, proportionate, and reflect the firm's business model and risk profile.

Practical implementation examples

The Guidelines would benefit from practical implementation examples and case studies illustrating the proportionate application of the requirements across different business models, entity types and levels of complexity. In particular, examples demonstrating the application of the Guidelines within financial groups comprising different types of obliged entities, including non-operational holding companies, branches and subsidiaries, would support a more consistent and proportionate implementation.

Additional clarification would also be beneficial regarding outsourcing arrangements, white-labelling models, agents and distributors, and the allocation of BWRA responsibilities across outsourced or delegated arrangements.

Further clarification and practical examples regarding emerging technologies, including digital onboarding, artificial intelligence, automated decision-making tools, digital assets and evolving payment technologies, would also support consistent implementation.

Status of supporting materials

Additional clarification would be beneficial regarding the legal and supervisory status of accompanying AMLA support materials and the extent to which competent authorities may rely upon such materials during supervisory assessments.

Interaction with the wider AML framework

The practical implementation of these Guidelines will be closely linked to the wider AML legislative framework, including the accompanying regulatory technical standards and other AMLA guidance. Given their dependence on these supporting measures, their timely publication ahead of the AMLR application date of 10 July 2027 will be important to support consistent and proportionate implementation.

The EMA therefore encourages AMLA to publish the remaining implementing measures as early as possible and to provide timely clarification where necessary. This would facilitate firms' preparation for the transition to the new AML framework.