ESAS JOINT OPINION ON THE RISKS OF MONEY LAUNDERING AND TERRORIST FINANCING AFFECTING THE UNION'S FINANCIAL SECTOR







JOINT COMMITTEE OF THE EUROPEAN SUPERVISORY AUTHORITIES

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# Joint Opinion

on the risks of money laundering and terrorist financing affecting the Union's financial sector







## **1. Executive Summary**

Article 6(5) of Directive (EU) 2015/849 requires the European Supervisory Authorities (ESAs) to issue a joint 'opinion on the risks of money laundering (ML) and terrorist financing (TF) affecting the Union's financial sector'. It serves to inform the Commission's supranational risk assessment, the European Supervisory Authorities' work on fostering supervisory convergence and a level playing field in the area of anti-money laundering and countering- the financing of terrorism (AML/CFT) and Member States' competent authorities in their application of the risk-based approach to AML/CFT supervision.

This Joint Opinion finds that problems exist in key areas such as firms' understanding of the ML/TF risk to which they are exposed and the effective implementation, by firms, of customer due diligence policies and procedures. It also points to difficulties associated with the lack of timely access to intelligence that might help identify and prevent terrorist financing, and considerable differences in the way competent authorities discharge their functions.

These factors, if not addressed, risk diminishing the robustness of Europe's AML/CFT defences.

This Joint Opinion considers the ML/TF risks affecting the Union's financial sector at a particular point in time. In the absence of a common European approach to the collection of data on supervisory visits and supervisory findings in relation to AML/CFT, it reflects competent authorities' perceptions of their sector's performance and draws on quantitative data only to the extent that this was available.

In line with Article 6(5) of Directive (EU) 2015/849, the ESAs will issue another Joint Opinion in two years' time.







## 2. Legal Basis and Methodology

- 1. Article 6(5) of Directive (EU) 2015/849 requires the European Supervisory Authorities (ESAs) to issue a joint opinion on the risks of money laundering (ML) and terrorist financing (TF) affecting the Union's financial sector.
- 2. This Joint Opinion serves to inform:
  - the assessment of the risks of money laundering and terrorist financing affecting the financial internal market and relating to cross-border activities the Commission has to conduct in line with Article 6(1) of Directive (EU) 2015/849;
  - the ESAs' work on fostering supervisory convergence and a level playing field in the area of anti-money laundering and countering the financing of terrorism (AML/CFT); and
  - competent authorities in their application of the risk-based approach to AML/CFT supervision.
- 3. The ESAs' perspective on ML/TF risk is a limited one: the ESAs' focus is on fostering an effective and consistent level of financial sector AML/CFT regulation and oversight across all Member States, and working towards the coherent application of the Union's AML/CFT framework by national competent authorities. National competent authorities, in turn, focus on the credit and financial institutions ('firms') they supervise and the preventative arrangements these firms put in place; the focus of national competent authorities is not on the underlying ML/TF threats posed by those who use these firms.
- 4. For this reason, this Joint Opinion concentrates on ML/TF risks associated with the financial sector's AML/CFT systems and control vulnerabilities and the impact of divergent supervisory expectations and approaches. It considers how these vulnerabilities transcend national boundaries to affect the overall ML/TF risk to which the Union's financial sector is exposed at the time of writing and over the course of the next two to five years.
- 5. This Joint Opinion does not systematically distinguish between the systems and controls firms have put in place to identify, assess and manage ML risk and those they have put in place to identify, assess and manage TF risk and findings related to one will be relevant for the other, unless specified. This is because many of the systems and controls firms have put in place to counter terrorist finance, such as monitoring and other customer due diligence measures, overlap with their AML systems and controls.







- 6. There are, however, important differences between ML and TF: whereas persons looking to launder money seek to disguise the criminal origins of their funds, a person funding terrorism may use legitimate, and often small, funds to pursue illicit aims. This means that at the time of writing, and in the absence of clear TF risk indicators, firms and competent authorities are unlikely to be able to detect or prevent terrorist finance before an atrocity is committed unless they are given specific information from law enforcement. However, attempts are now being made at the international, supranational and national levels to better understand TF risk and identify the factors that may be conducive to a more preventative approach going forward.<sup>1</sup>
- 7. In drafting this Joint Opinion, the ESAs took into account the views expressed by AML/CFT competent authorities as well as responses to a self-assessment questionnaire, which was sent to members of the ESAs' Boards of Supervisors in August 2015. This questionnaire sought to gather information on perceived levels of compliance by sector, identify any recurrent or systemic weaknesses and help competent authorities assess the extent to which these weaknesses affect the money laundering and terrorist financing risk to which the EU's financial sector is exposed. It did not seek to establish a common methodology for assessing levels of compliance across the financial services industry. Due to differences in the way competent authorities recorded supervisory action, quantitative data was used for illustrative purposes only. 46 AML/CFT competent authorities from 31 EU and EEA jurisdictions responded to this questionnaire.

<sup>&</sup>lt;sup>1</sup>See, for example, FATF (October 2015): Emerging Terrorist Financing Risks:

http://www.fatf-gafi.org/publications/methodsandtrends/documents/emerging-terrorist-financing-risks.html and the EU Commission's forthcoming Supranational Risk Assessment under Article 6(1) of Directive (EU) 2015/849







# 3. Money laundering and terrorist financing risks affecting the Union's financial market

## A. Introduction and background

- Money laundering and terrorist financing (ML/TF) undermine the integrity of Europe's financial sector. Firms have a central role to play in the fight against ML/TF, and so are required to put in place and maintain effective policies, controls and procedures to identify, assess and manage ML/TF risk.
- 9. The AML/CFT obligations of firms and competent authorities are set out in Directive 2005/60/EC as transposed by Member States. This Directive has been repealed by Directive (EU) 2015/849 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing. Member States must transpose Directive (EU) 2015/849 by 26 June 2017.<sup>2</sup> Firms carrying out person to person transfers also have to comply with Regulation (EU) 2015/847.
- 10. Directive (EU) 2015/849 aims to bring European Union legislation in line with the International Standards on Combating Money Laundering and the Financing of Terrorism and Proliferation that the Financial Action Task Force (FATF), an international AML/CFT standard-setter, adopted in 2012.
- 11. Like the FATF's standards, Directive (EU) 2015/849 puts the risk-based approach at the centre of the European Union's AML/CFT regime. It recognises that risks can vary and that Member States, national competent authorities and obliged entities must take steps to identify and assess that risk to decide how best to manage it.
- 12. The ESAs are clear that an effective risk-based approach depends on:
  - timely access to relevant information on ML/TF threats;
  - a common understanding of ML/TF risk factors and the steps required to identify and assess them;

<sup>&</sup>lt;sup>2</sup> Amendments to this Directive are currently being negotiated but are unlikely to affect the transposition deadline.







- the availability of sufficient and suitably-qualified staff to make informed judgements on the level of the risk and its management; and
- sufficient human and financial resources to ensure that policies and procedures designed to address these risks are adequate and implemented effectively.
- 13. Specifically in the context of the Union's internal market, an effective risk-based approach also depends on a consistent interpretation of relevant Union law by national authorities, as well as a coherent approach to supervising and assessing the adequacy of firms' AML/CFT efforts. Without these, the adoption of a risk-based approach could result in Europe's AML/CFT defences being less robust.

#### B. Risks

- 14. The ESAs consider that, at the time of writing, the Union's financial sector is exposed to ML/TF risks arising from:
  - a. ineffective AML/CFT systems and controls, which leave firms vulnerable to abuse by financial criminals;
  - b. firms taking advantage of significant differences in Member States' approaches to AML/CFT regulation and oversight to obtain authorisation in Member States whose AML/CFT regime is perceived to be less demanding, with a view to passporting services to other Member States;
  - c. lack of access to intelligence on terrorist suspects undermining efforts to curb terrorist financing; and
  - d. high risk transactions being driven underground, as firms withdraw from offering services to less profitable customers that are associated with higher ML/TF risk.

#### Risks associated with firms' AML/CTF systems and controls

15. The ESAs consider that the Union's financial sector is exposed to ML/TF risks arising from ineffective AML/CFT systems and controls, which leave firms vulnerable to abuse by financial criminals. Several competent authorities responsible for the AML/CFT supervision of firms have pointed to problems with firms' overall levels of compliance , and no sector was perceived as having 'good' or 'very good' compliance levels by all competent authorities.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> Competent authorities were asked to rate perceived levels of compliance by sector, with five ratings ranging from 'very good' (levels of compliance are good overall and there are no significant grounds for concern. Where regulatory action is required, this is one-off rather than a regular occurrence) to 'very poor' (levels of compliance are very poor, with systemic compliance failures across the majority (> 50%) of firms).







- 16. When asked about the most common compliance issues they had identified, almost all competent authorities raised concerns about the quality of firms' ML/TF risk assessments. Shortcomings were identified in relation to both business-wide ML/TF risk assessments and firms' assessment of the ML/TF risk associated with individual business relationships. Competent authorities pointed to firms' failure to understand how their products and services were vulnerable to abuse for ML/TF purposes, properly to assess the ML/TF risk associated with different delivery channels or to identify higher customer risk indicators that should have given rise to enhanced due diligence measures. Some were also concerned that some firms took a short-term view of ML/TF risk and focused on specific alerts only, rather than carry out a comprehensive risk assessment that would have provided the foundations for more preventative AML/CFT policies and procedures.
- 17. Similarly, while competent authorities generally considered firms' AML/CFT written policies to be adequate, competent authorities in two third of EU and EEA Member States found the implementation of these policies to be deficient. Competent authorities stated that Customer Due Diligence (CDD) measures were often not commensurate to the ML/TF risk associated with a business relationship or fell short of the standards expected, especially in relation to the identification of customers, their beneficial owners (where applicable), and the verification of their identity. They were also concerned that some firms approached CDD measures as a box-ticking exercise, rather than to inform their risk assessment of individual business relationships.
- 18. Finally, while wider internal AML/CFT controls, such as group-wide AML/CFT policies and processes, were largely deemed acceptable in most sectors, several competent authorities found that payment institutions' oversight of agents and agent networks was inadequate, especially where agents were established in another Member State. This was of particular concern in light of the widely documented ML/TF risk associated with some payment service providers' activities and distribution channels. Some competent authorities suggested that similar considerations applied in relation to electronic money issuers and persons distributing electronic money on behalf of these issuers.
- 19. Supervisory findings pointed to a number of causes for these shortcomings. These included:
  - senior management of some firms affording low priority to AML/CFT issues. An apparent unwillingness to challenge unusual behaviour of long-standing or particularly profitable customers, and remuneration structures that rewarded turnover and profit rather than compliance, were among the examples provided for all sectors. Markets supervisors also pointed to firms in their sector deliberately lowering their AML/CFT defenses in light of increased competition from foreign internet platforms with inadequate AML/CFT controls, while AML/CFT supervisors of banks raised concerns about some banks' willingness, in light of increasing competition and an unfavourable macroeconomic





environment, to take on higher risk, more profitable business that they were illequipped to manage ;

- insufficient AML/CFT awareness and expertise, often as a result of inadequate training. Relevant staff did not understand what was expected of them, did not follow AML/CFT procedures and failed to identify higher ML/TF risk factors. This lead to the application of lower CDD standards than necessary in light of the level of ML/TF risk and was highlighted as an issue in particular in the banking, asset management and securities sectors; and
- inadequate business-wide ML/TF risk assessments, often as a result of insufficient AML/CFT expertise, and in particular firms' failure to understand how their products and services were vulnerable to being abused for ML/TF purposes. In this context, several competent authorities pointed to the ML/TF risk associated with technological advances and financial innovation, which some firms appeared ill-equipped to assess and manage. This was highlighted as a particular issue in the e-money and asset management sectors.
- 20. Lack of senior management buy-in, in particular when paired with a corporate culture that pursues profits at the expense of robust compliance, can stand in the way of effective AML/CFT systems and controls. They are often accompanied by poor levels of compliance with AML/CFT policies and procedures that remain unchallenged, failure by senior management to take responsibility for ML/TF risks, for example in relation to the onboarding of particularly high risk customers, and insufficient resources for both, key AML/CFT functions and AML/CFT training. They therefore threaten to undermine a firm's efforts effectively to prevent or detect ML and TF.
- 21. The quality of firms' ML/TF business-wide and customer risk assessments in particular has a significant impact on the ML/TF risk to which the Union's financial sector is exposed, both under the current regime and looking ahead to June 2017 when the AMLD will have been transposed. This is because under a risk-based approach, the risk assessment determines which systems and controls firms put in place to manage that risk effectively, including, for example, the level and type of customer identification measures, the intensity of transaction monitoring. Where these measures are inadequate, be this due to a lack of AML/CFT capability or because of a corporate culture which does not foster effective ML/TF risk management, firms will struggle to identify unusual activity and, therefore, fail to report suspicious transactions.

#### Risks associated with uneven transposition and regulatory arbitrage

22. The ESAs consider that the Union's financial sector is exposed to ML/TF risks arising from firms taking advantage of differences in Member States' approaches to AML/CFT







regulation and oversight to obtain authorisation in Member States whose AML/CFT regime is perceived to be less demanding.

- 23. The ESAs note that the steps competent authorities take to assess firms' compliance with their AML/CFT requirements differs, as does their satisfaction with their sectors' compliance with applicable AML/CFT rules. For example, competent authorities responsible for the AML/CFT oversight of banks and/or life insurance companies perceived overall compliance levels in their sector to range from 'very good' to 'poor'.
- 24. These differences are due at least in part to:
  - the minimum harmonisation nature of relevant Directives, which set common standards but leave Member States some flexibility in the transposition of the Directive's requirements; and
  - significant differences in competent authorities' approaches to AML/CFT supervision, including in relation to the resourcing of specialist AML/CFT functions and the way AML/CFT oversight is conducted. While some differences are expected and in line with a risk-based approach, the ESAs note that more intrusive and intensive, dedicated on-site AML/CFT reviews tend to yield more pessimistic assessments of firms' compliance.
- 25. Internal market rules, in particular passporting rights and the free provision of services mean that these differences can have potentially significant implications for the robustness of the Union's AML/CFT defences as well as the integrity and stability of the Union's financial market. This is because firms may be able to obtain authorisation, and provide their services, from Member States with AML/CFT regimes they perceive as less demanding. Divergent rules and supervisory expectations may also negatively affect the implementation of group-wide AML/CFT policies and hamper the effectiveness of national and European ML/FT defences.

#### Terrorist financing risk

- 26. The ESAs consider that the Union's financial sector is exposed to TF risks as firms' CFT efforts are hampered by lack of access to intelligence from law enforcement that would help identify terrorist funds before attacks have been carried out.
- 27. Over the course of the last two years, terrorist attacks have been committed in several EU Member States. There is evidence to suggest that in at least some cases, terrorists abused legitimate payment channels to facilitate their actions.
- 28. The risk to the EU's financial system from TF exists because terrorist funds can appear legitimate and inoffensive, and in the absence of clear TF risk indicators or specific intelligence from law enforcement, it will be difficult or impossible to identify such funds







early enough. The identification of clear TF risk indicators becomes even more challenging where customers have legitimate reasons for being unable to produce traditional types of identity documentation. This can be the case, for example, where customers are asylum seekers.<sup>4</sup>

29. The value in CFT controls therefore lies mainly in the *post facto* identification of terrorist networks. However, where these controls are not adequate, or effectively implemented, as appears to have been the case in some firms or sectors that are perceived to be particularly vulnerable to abuse for TF purposes, this will not be possible.

#### Cost of compliance

- 30. The ESAs consider that the Union's financial sector is exposed to ML/TF risks as a result of high risk transactions being driven underground as firms withdraw from offering services to higher risk customers that do not generate sufficient profit.
- 31. The cost of compliance, including (but not limited to) the cost of compliance with AML/CFT rules, continues to prove challenging for smaller firms in particular. This includes difficulties in recruiting sufficiently qualified compliance staff that are equipped to oversee the transition to a more risk-based AML/CFT regime.
- 32. There are also suggestions that the perceived cost of compliance may have contributed, among other causes, to some firms' decision to withdraw from offering services to higherrisk customers that were not sufficiently profitable and a subsequent risk that higher risk customers who lost access to the financial system as a result of 'derisking' might use informal payments channels instead, away from effective AML/CFT controls and oversight.

### C. Conclusion

- 33. The ESAs believe that the ML/TF risks highlighted in this Joint Opinion mean that more has to be done to ensure that the Union's AML/CFT defences are effective. This is particularly important as Member States move towards a more risk-based AML/CFT regime that presupposes a level of ML/TF risk awareness and management expertise that this Opinion suggests does not yet exist in all firms and all sectors.
- 34. Several initiatives are already underway, which, in the short to medium term, will serve to address many of the risks identified. These include:

<sup>&</sup>lt;sup>4</sup> See also EBA Opinion on the application of CDD measures to customers who are asylum seekers from higher risk third countries or territories (April 2016):

http://www.eba.europa.eu/documents/10180/1359456/EBA-Op-2016-

<sup>07+%28</sup>Opinion+on+Customer+Due+Diligence+on+Asylum+Seekers%29.pdf







- Proposed amendments to Directive (EU) 2015/849, which will serve to clarify the responsibilities of home and host competent authorities in relation to the AML/CFT supervision of firms operating on a cross-border basis;
- ESA initiatives to improve the cooperation of competent authorities responsible for the AML/CFT supervision of firms operating on a cross-border basis including in relation to the AML/CFT supervision of payment service providers and their agents, and electronic money issuers and persons distributing electronic money on such issuers' behalf; and
- the Joint Risk Factors Guidelines and the Joint Guidelines on Risk-Based Supervision, 5 which aim to create a common understanding of the risk-based approach to AML/ CFT, and how it should be applied.
- 35. However, the ESAs believe that:
  - to ensure timely access to relevant information on ML/TF threats, FIUs and other law enforcement agencies should identify ways to work more closely with firms to facilitate the identification of such risks and provide feedback on emerging ML/TF threats and typologies;
  - competent authorities should consider taking enhanced steps actively to raise awareness of supervisory expectations, for example by providing targeted guidance on key AML/CFT issues they have identified in their sector. This is particularly important where the move to a more risk-based approach to AML/CFT creates legal and regulatory uncertainty as a result of both, a significant shift in many competent authorities' approaches to AML/CFT supervision and legal changes associated with the transposition, by Member States, of Directive (EU) 2015/849 (and proposed amendments to that Directive);
  - competent authorities should collect AML/CFT supervisory data in a more consistent way to facilitate comparisons and track progress; and
  - the Commission, the Union legislators and the ESAs should give further thought to identifying ways in which the ESAs, and competent authorities, can ensure that the Union's AML/CFT law and the ESAs' AML/CFT guidelines are implemented effectively and consistently in all Member States.

<sup>&</sup>lt;sup>b</sup> <u>http://www.eba.europa.eu/regulation-and-policy/anti-money-laundering-and-e-money/guidelines-on-risk-based-</u> <u>supervision</u> and <u>http://www.eba.europa.eu/regulation-and-policy/anti-money-laundering-and-e-money/guidelines-on-</u> <u>risk-factors-and-simplified-and-enhanced-customer-due-diligence</u>







36. The ESAs remain committed to the risk-based approach as the most effective means to tackling ML/TF risks and are confident that it will contribute to facilitating the adoption of a more consistent and effective European AML/CFT regime.







## 4.Annex

This annex summarises the main responses to the questionnaire sent to competent authorities in August 2015. Responses to this questionnaire helped inform this Joint Opinion.

#### Banking

Most competent authorities did not distinguish between different types of banks. Nearly 2/3 of respondents considered that levels of compliance in the banking sector were 'good' or 'very good'. However, this assessment was often accompanied by high levels of corrective action; and four competent authorities assessed levels of compliance as 'poor'.

Problems with banks' implementation of CDD policies and procedures was the most commonly identified compliance issue, with 'monitoring' being ranked worse than identification and verification. A significant number of respondents also pointed to problems with the adequacy of the sectors' business-wide risk assessments. These issues were perceived to be due to inadequate or ineffective training, resulting in insufficient levels of expertise and understanding of AML/CFT issues; lack of resources and an organisational culture which was not conducive to good ML/TF risk management.

Many respondents also identified contributing factors, including failure by senior management to prioritise AML/CFT issues and incentive structures that reward profit rather than compliance and good financial crime risk management.

#### Credit Unions

Not all competent authorities were able to provide answers on Credit Unions. The reasons for this were varied; for example, some competent authorities classified credit unions as banks, and others had insufficient information on credit unions because they were deemed to present a low ML/TF risk. It is worth noting that the size and nature of credit unions can vary significantly between Member States.

Less than half of those who responded considered levels of compliance to be good or very good.

Respondents identified failure by credit union staff to understand their legal and regulatory AML/CFT obligations as the most important compliance issue; insufficient resources (including staff expertise), inadequate senior management support, including poor organisational culture and inadequate systems were identified as the most likely causes.

The voluntary nature of credit unions may go some way towards explaining why corporate culture, good governance and ML/TF risk awareness appears to be less than in other financial







institutions. There is also a risk that due to the shared interest by members, staffs' willingness to challenge unusual behaviour might be reduced.

#### Asset management, securities and securities management

There was a risk of discrepancies in the way competent authorities responded to the questionnaire, as some felt that the sectors 'asset management' and 'securities and securities management' were not clearly defined. As a result, a minority of respondents provided aggregate data for both sectors only.

Nevertheless, respondents considered levels of compliance in the asset management sector to be satisfactory overall. By far the largest number of respondents identified problems with firms' implementation of CDD policies and procedures as the biggest compliance issues, but a significant number also pointed to deficiencies in firms' assessment of risk associated with their business and individual business relationships. These were said to be caused by insufficient resources and lack of expertise, including failure to understand the legal and regulatory obligations. By contrast, no respondent pointed to problems with firms' policies as the root cause of compliance problems.

Respondents considered levels of compliance in the securities sector to be good overall. Where respondents identified problems, these consisted mainly in the inadequate implementation of CDD policies, the risk assessment of individual customers and the identification of suspicious activities. Respondents pointed to inadequate resources, including lack of awareness and expertise and a poor organisational culture as the main causes for compliance breaches.

A number of respondents suggested that weaknesses in these sectors' levels of compliance could be explained by the absence of proactive risk management (which leads to the application of inadequate CDD measures) and often long-standing customer relationships contributing to complacency and less willingness to challenge unusual behaviour or transactions. These were further exacerbated by lack of expertise and failure to understand ML/TF risk, which were not addressed through adequate training opportunities. Finally, one respondent highlighted that remuneration structures in both sectors constituted a challenge, with contractual partners and marketing staff being paid on the basis of turnover, rather than AML/CFT compliance.

#### Life insurance

Not all competent authorities were able to provide information on levels of compliance in the life insurance sector; at times, this was because life insurance was perceived to be associated with low ML/TF risk and competent authorities had therefore not prioritised the AML/CFT supervision of firms in this sector. It is worth noting that the nature of the life insurance sector differs across Member States.

ESAS JOINT OPINION ON THE RISKS OF MONEY LAUNDERING AND TERRORIST FINANCING AFFECTING THE UNION'S FINANCIAL SECTOR



JOINT COMMITTEE OF THE EUROPEAN SUPERVISORY AUTHORITIES

Where respondents were able to provide information, they assessed levels of compliance as good overall, though this included some respondents who raised concerns about the adequacy of their sectors' AML/CFT compliance efforts and assessed levels of compliance as poor.

Where respondents had identified problems with some firms' AML/CFT controls, these were said to be caused primarily by the firm's failure to understand their legal or regulatory obligations. This included some firms' failure adequately to understand and assess ML/TF risk, which was perceived to arise in particular in relation to early cancellation and partial redemption of life insurance policies. Together with senior management affording low priority to AML/CFT issues and a culture driven by profit considerations rather than compliance meant that some respondents found that some firms failed effectively to implement their AML/CFT policies and procedures and to configure their AML/CFT systems appropriately. The adequacy of CDD processes along the chain of parties involved in selling the insurance products was perceived as a particularly weak point.

#### Payment service providers and electronic money issuers

Not all competent authorities were able to distinguish between different types of payment service provider or between payment service providers and electronic money issuers. A minority therefore provided aggregated data for both sectors.

Most competent authorities perceived compliance levels among e-money issuers to be good or satisfactory overall. Compliance issues in the e-money sector were similar to those respondents identified in other financial services sectors: implementation of CDD policies and procedures was the most commonly quoted compliance issue and several respondents pointed to weaknesses in e-money issuers' risk assessments of both individual customers and their wider business.

By contrast, Compliance levels were perceived to be satisfactory overall for payment service providers, although competent authorities in nine Member States assessed compliance levels as 'poor' or 'very poor'. Respondents pointed to specific compliance issues in relation to payment service providers, which differed from those identified for other sectors: respondents considered that payment service providers struggled with their business-wide risk assessment, had problems related to wider internal AML/CFT controls and deficiencies in relation to the identification and reporting of STRs. This was consistent with views expressed by a significant number of respondents that payment institutions' oversight of agents and agent networks was inadequate in spite of suggestions that the ML/TF risk associated with the use of agents was high.