

## **Framework of engagement with non-State actors**

### **Report by the Director-General**

The Director-General has the honour to transmit to the Open-ended Intergovernmental Meeting the report of the External Auditor on the implications for WHO of the implementation of the framework of engagement with Non-State actors (see Annex).

ANNEX

**External audit report on the  
implications for the World Health  
Organization of the implementation of  
the framework of engagement with  
Non-State actors (FENSA)**

March 2016



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## **EXECUTIVE SUMMARY**

### **Rationale for the review**

1. The World Health Organization (WHO) engages with non-State actors (NSAs) in the advancement and protection of public health in order to foster the use of NSAs' resources in favour of public health and to encourage NSAs to improve their own activities to protect and promote public health.
2. As part of the WHO reform agenda, the governing bodies have requested the Director-General to develop a framework of engagement with non-State actors (FENSA), which shall provide separate policies on the engagement with different groups of NSAs, to include nongovernmental organizations (NGOs), private sector entities, philanthropic foundations and academic institutions.
3. The draft FENSA was presented to Member States in a series of consultations and meetings but no final consensus was reached in view of their differing views on the adequacy of the implications for WHO of the implementation of FENSA.
4. After a series of consultations, the Executive Board adopted the decision, among others, to request the Secretariat to prepare an objective and balanced analysis of the implications for WHO of implementing the framework, with inputs from headquarters and the regional and country offices. The purpose of the paper was to provide an overview of the possible implications of the implementation of FENSA, describing its impact and effects from a policy, financial and human resource perspective at all levels of WHO.
5. In order to ensure a balanced and objective report to Member States, the assistance of the External Auditor was sought on the aspects of validating and commenting on the replies to a questionnaire, as well as commenting on and enhancing the detailed matrix of analysis of the implications for WHO of the implementation of FENSA, and thereafter writing a final report on the matter.
6. Hence, this report contains the results of the independent assessment conducted by the External Auditor.

### **Methodology**

7. The review of the WHO FENSA policy and its implications for the Organization within the context of its planned implementation utilizes a framework that considers the alignment of the policy context with specific policy requirements, as well as the financial and governance arrangements.
8. To this end, a pre-prepared questionnaire was floated to 6 regional offices, 17 country offices and 7 clusters at WHO headquarters. The set of questions was intended to obtain information from respondents on essential matters involving WHO's previous and existing exposure to and experience with NSAs. A draft matrix of analysis of the implications of the implementation of FENSA was also required for respondents to comment on.
9. The responses to the questionnaire and the detailed matrix of analysis of information from all WHO regional offices, clusters at headquarters and a selection of country offices primarily served as inputs to the report, with the addition of the perspectives of the External Auditor, based on their

evaluation of the draft framework and the existing related WHO policies and regulations and documentations on engagement with NSAs.

### Review highlights

10. Results of the qualitative review and analysis of the rationale, principles, opportunities and risks to WHO of implementing FENSA in accordance with its mandate highlighted the following:

- (a) Respondents had the common perception that FENSA adoption could result in opportunities and positive results, but there are possible risks that need to be effectively managed and, where appropriate, avoided.
- (b) Some of the critical areas of FENSA where opportunities and risks were identified by respondents included (a) overall engagement framework, (b) due diligence and risk assessment procedures, (c) transparency and accountability, (d) register of non-State actors, (e) conflict of interest, and (f) oversight of engagement.
- (c) If the trend resulting from the replies of the respondents was sustained upon FENSA implementation, WHO shall be dealing mostly with NGOs, followed by academic institutions, the private sector and philanthropic foundations.
- (d) The “participation” type of engagement by NSAs registered the highest volume of engagements with 38%, followed by technical collaboration (34%), advocacy (13%), evidence (10%) and resources (5%).
- (e) Similarly, the “participation” type of engagement registered the highest volume in 2015 in emergency situations by type of NSA, representing 39% of the total engagements, followed by advocacy (26%), evidence (17%), technical collaboration (13%) and resources (5%).
- (f) Some FENSA policy components need further improvement, and specific policies and guidance on implementation must be crafted to make the framework clearer across the Organization. Some of the policy areas where improvement may be considered include (a) applicability to emergencies, (b) due diligence and risk assessment procedures and (c) receiving and providing resources.
- (g) As presented in the non-paper of the Secretariat, the adoption and implementation of FENSA will involve considerable costs, from a policy, financial and human resource perspective, at all levels of the Organization.
- (h) As a major part of the additional workload could be undertaken in the technical units and at country level, the financial and human resource implications cannot be estimated with a sufficient degree of accuracy to provide a solid figure, but will need to be monitored as FENSA is progressively implemented.
- (i) The proposed change in the oversight function of the Executive Board will impact both the reporting accountabilities and the structure of WHO governing bodies but can be considered as an improved practice to enhance transparency.
- (j) Engagement with NSAs has been and always will be an essential part of WHO’s day-to-day existence, such that the absence of a framework that is applied consistently and uniformly

across all levels of the Organization and is understood by all provides an element of risk and puts the entire Organization in a precarious position.

(k) There are concerns that need to be considered before and during the adoption of FENSA, such as:

- (i) the possibility that additional changes to the draft framework may lessen the value of the evaluation made by the External Auditor, or perspectives may not be applicable;
- (ii) timely provision of streamlined guidelines and processes including the necessary information technology (IT) infrastructure to implement FENSA;
- (iii) provision of appropriate and sufficient controls in the policy guidelines in order to manage the risk of policy override;
- (iv) an implementation strategy across the Organization; and
- (v) adoption of a phased approach of implementation.

## Summary statements

11. On the basis of feedback received from all the survey respondents, the independent analysis of the draft framework, and all the available review guidance and literature, the following conclusions are drawn:

- (a) FENSA as an overarching framework can already stand on its own and can be considered for adoption, as it already embodies the strategic context of WHO on its engagements with NSAs. Specific policy guidelines, however, need to be separately provided to clarify the mechanism of the framework.
- (b) There is no alternative to a strong and solid policy framework upon which all specific guidance and processes of the Organization will be anchored, to ensure transparency, accountability, uniformity and consistency in application and treatment of all engagements with NSAs in all levels of the Organization. While the framework provides the backbone, the specificities of the delivery guidelines and related processes can also spell the success and failure of the policy change.
- (c) Setting up due diligence and risk assessment procedures is largely a matter of good judgement as to which is the greater priority – a system that is quick and easy, but does not assure safeguards for the interests of WHO; or a system that is rigid and firm, protecting the reputation and integrity of the Organization, though requiring time and resources to perfect and institutionalize the system through tried and tested operational procedures.
- (d) The overriding benefits of transparent processes and operations far outweigh the anticipated risks. All of those will be addressed as the operational procedures are revisited and enhanced. Clear accountability lines in all engagements, and recognition of the effective roles and responsibilities of internal stakeholders, are essential requirements.

(e) While there are implementation issues that can be addressed by the operational procedures, clarity of guidelines for establishing a register of non-State actors, and the availability of an efficient mechanism to maintain the register, will be of prime consideration.

(f) Conflict of interest will always be an issue and a risk, with or without FENSA. It is essential, therefore, that the framers of the operational procedures ensure that all possible issues and risks that could occur are anticipated, and the measures to address them are incorporated in the operational procedures, in order to minimize the impact of these risks. Reference to the WHO Accountability Framework will guarantee clearer definition of roles and responsibilities, particularly on the part of WHO.

(g) A monitoring and evaluation mechanism must be in place to provide support to all engagements with the end view of ascertaining that the intended benefits or results are achieved.

(h) Taking into account the issues and considerations already identified (particularly the feedback of stakeholders), the volume and types of engagements, the current transaction costs and increments, and the challenges identified, Member States may consider a phased implementation of the framework and its operational procedures, rather than opt for a full and complete implementation of both the framework and the operating procedures at one time. This could afford the Secretariat more flexibility in adjusting and aligning the proposed procedures to the other issues and considerations already identified. They may also want to prioritize implementation of the operational procedures for the less critical and less voluminous engagements so that lessons learned are identified early in the process and policy adjustments made.

## **PART A: INTRODUCTION AND REVIEW METHODOLOGY**

### **I. Introduction**

12. The World Health Organization (WHO) acts as the directing and coordinating authority on international health work (Article 2, WHO Constitution). In line with its mandate, WHO establishes and maintains effective collaboration with diverse organizations and promotes cooperation amongst scientific and professional groups that contribute to the advancement of health. The Constitution further mandates the World Health Assembly or the Executive Board, and the Director-General, to enter into specific engagements with other organizations.

13. The demands of the present times and their attendant complexities brought WHO to its present process of reform, which is Member State-driven and inclusive, and has the following three aims, as defined at the Sixty-fourth World Health Assembly and at the 129th session of the Executive Board:

- (a) programmatic reform to improve people's health;
- (b) governance reform to increase coherence in global health; and
- (c) managerial reform in pursuit of organizational excellence.

14. It is under the second objective of governance reform that WHO seeks to clarify and strengthen its position in an effort to achieve greater coherence among the many players involved in global health. This can be better achieved by improving governance practices internally and engaging more effectively with external stakeholders.

15. WHO's engagement with non-State actors (NSAs) supports implementation of the Organization's policies and recommendations as decided by the governing bodies, as well as the application of WHO's technical norms and standards. Such engagement with NSAs at global, regional and country levels also calls for due diligence and transparency measures under the draft framework of engagement with non-State actors (FENSA).

16. After a series of consultations and deliberations on the draft FENSA, the Executive Board adopted decision EB138(3), by which a consensus text of the draft framework and a draft resolution would be submitted to the Sixty-ninth World Health Assembly through the Programme, Budget and Administration Committee. It was correspondingly decided to request the Secretariat to present an objective and balanced report on the implications for WHO of the implementation of the framework, well in advance of the final session.

17. In order to ensure a balanced and objective report to Member States, the assistance of the External Auditor was sought on the aspects of validating and commenting on a questionnaire sent to all regions and clusters and selected country offices, as well as commenting on and enhancing a detailed matrix of analysis of the implications for WHO of the implementation of FENSA, and thereafter providing a final report on the matter.

### **II. Review methodology**

18. The following activities were carried out in accordance with the terms of reference for the engagement:

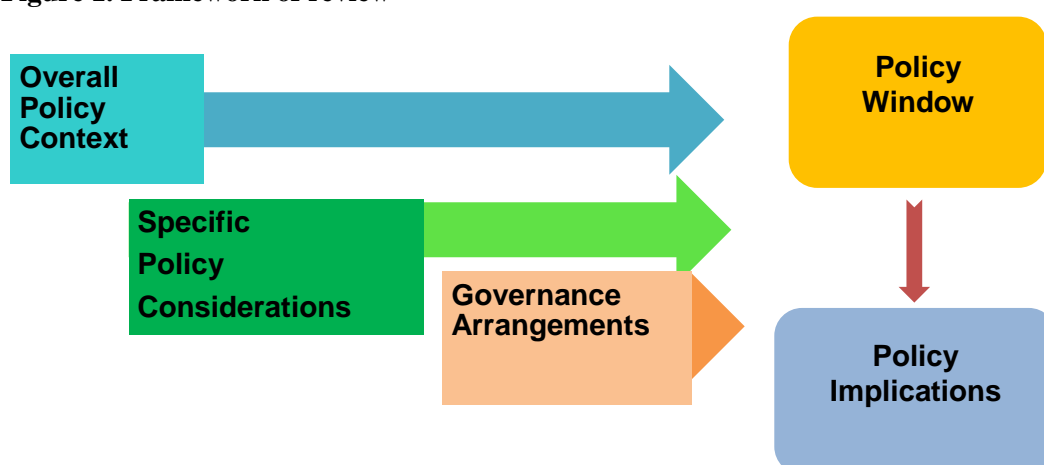


- (a) The Secretariat provided the External Auditor with all the necessary background material, including the current policy framework for engagement with NSAs (incorporating the principles governing relations between WHO and nongovernmental organizations (NGOs) and the guidelines on interaction with commercial enterprises to achieve health outcomes), the proposed version of FENSA and published background material, and the proposed draft matrix of analysis of opportunities and risks arising from the implementation of FENSA.
- (b) A survey questionnaire was developed, to be sent by the Secretariat to regional offices, clusters and selected country offices to collect preliminary data on the types of issues facing the implementation of FENSA.
- (c) The External Auditor validated the matrix of analysis and draft questionnaire, following which the Secretariat sent the questionnaire to all regions and clusters, and assisted the External Auditor in the compilation of the responses to be included in the final report.
- (d) Simultaneously, the Secretariat invited FENSA focal points in all regions and clusters to comment on the revised matrix of analysis for further validation by the External Auditor.
- (e) The External Auditor then summarized into a draft final report the main issues and points arising from the validation of the answers to the questionnaires and the matrix of analysis, incorporating in the report conclusions on the completeness of the matrix of analysis, issues and concerns raised in the responses to the questionnaires and clarificatory interviews. The External Auditor then submitted the draft report to the Secretariat for further validation and comment.

19. The covering terms of reference required that the Secretariat be provided with an opportunity to validate and comment on the External Auditor's report. The External Auditor was expected to engage closely with the Secretariat while retaining the independence to express freely its judgement.

20. The review of the WHO FENSA policy and its implications for the Organization within the context of its planned implementation utilizes a framework that considers the alignment of the policy context with specific policy requirements as well as the financial and governance arrangements, as presented in Figure 1.

**Figure 1. Framework of review**



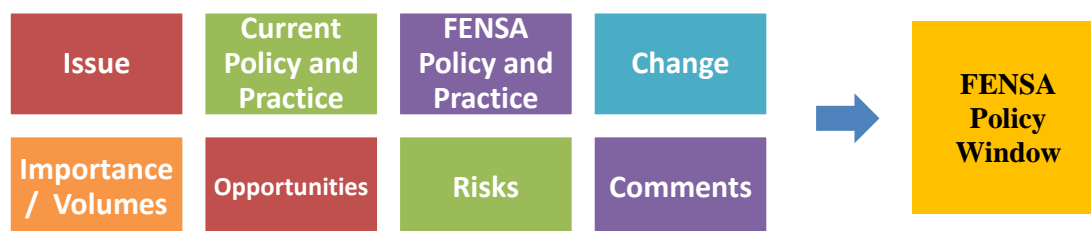
- (a) **Overall policy context.** The overall policy context will provide the overarching trajectory of the review, including the policy design and its anchors.
- (b) **Specific policy considerations.** The specific components contained in the proposed policy will be examined based on agreed criteria.
- (c) **Financial and governance arrangements.** The planned implementation of the policy will be reviewed within the context of governance mechanisms in place for risk management and lines of accountability.
- (d) **Policy window.** The defined policy arrangements, including specific requirements and governance mechanisms within the overall policy context, will be elaborated upon consideration of the results of discussions with relevant stakeholders.
- (e) **Policy implications.** These are the assumptions and scenarios envisioned when the policy is implemented. They will greatly depend on the design of the proposed policy, within the context of the defined policy window.

21. The starting point for the specific policy review requirement was the validation by the External Auditor of a pre-prepared questionnaire, which was intended for completion by selected respondents within the Organization. The set of questions aimed to obtain information from respondents on essential matters involving WHO's previous and existing exposure to and experience with NSAs, principally on the following:

- (a) volume of WHO engagements with NSAs in 2015, as a basis for projecting the volume of engagements that may take place under the proposed framework, and in the process breaking these down into smaller engagement types, identified specifically as participation, resources, evidence, advocacy and technical collaboration;
- (b) main opportunities and risks that may arise from adoption and implementation of the proposed framework;
- (c) specific resources that are currently utilized by various levels of the WHO organizational hierarchy in existing engagements with NSAs; and
- (d) expected incremental resources that are perceived to be necessary to implement FENSA.

22. The respondents to the questionnaires were representatives of all seven clusters at headquarters, together with all six WHO regional offices, who in turn were given the discretion to choose at least three additional respondents from among their respective country offices.

23. The series of previous discussions formed the basis for the development of a draft matrix of analysis of the implications of implementation of FENSA, which was distributed simultaneously with the questionnaires to the same respondents for comments and observations on the possible implications of full FENSA implementation, providing further evidence for eventual analysis and validation by the External Auditor. The matrix contains the basic policy considerations for the proposed FENSA, as shown in Figure 2.

**Figure 2. Basic policy considerations for proposed FENSA**

24. Of the previously targeted respondent offices, only the clusters Health Security and Environment (HSE) and Health Systems and Innovations (HIS) responded to the request for comments on the draft matrix of analysis, while survey returns from the questionnaires were received from the following:

#### **Headquarter clusters**

General Management (GMG)

Family, Women's and Children's Health (FWC)

Health Systems and Innovations (HIS)

Health Security and Environment (HSE)/ERM

HIV/AIDS, TB and Neglected Tropical Diseases (HTM) and  
UNITAID

Noncommunicable Diseases and Mental Health (NMH)

Director-General's Office (DGO) (DGO and separately Polio)

**Regional and country offices**

(All regions provided with the questionnaire answered from a regional office perspective and separately by the mentioned country offices)

**Regional Office for Africa (AFRO)**

- Democratic Republic of Congo
- Zimbabwe

**Regional Office for the Americas (AMRO)**

- Mexico
- Colombia

**Regional Office for the Eastern Mediterranean (EMRO)**

- Afghanistan
- Egypt
- Lebanon
- Oman
- Sudan

**Regional Office for Europe (EURO)**

- Albania
- Kyrgyzstan
- Turkey

**Regional Office for South-East Asia (SEARO)**

- Bangladesh
- Sri Lanka
- Nepal

**Regional Office for the Western Pacific (WPRO)**

- Philippines
- Malaysia

**PART B: FENSA POLICY WINDOW****I. Overall policy context of FENSA****Rationale**

25. The global health landscape has become more complex in many respects; among other things, there has been an increase in the number of players, including NSAs. WHO engages with NSAs in view of their significant global role in the advancement and promotion of public health, and to encourage them to use their own activities to protect and promote public health.

26. In order to strengthen its engagement with NSAs for the benefit of global public health, WHO needs to simultaneously strengthen its management of the associated potential risks. This requires a robust framework that enables engagement and serves as an instrument to identify the risks, balancing them against the expected benefits, while protecting and preserving WHO's integrity, reputation and public health mandate.

27. It is anticipated that the adoption and implementation of FENSA will modify the way WHO manages its engagement with NSAs, with certain expected policy effects, such as:

- (a) FENSA will cover all engagements with all NSAs, while the current policies cover engagements with private sector entities and NGOs in official relations only.
- (b) Transparency will be increased through the register of non-State actors (including information on objectives, governance and funding of NSAs and description of engagements).
- (c) FENSA requires consistent implementation at all three levels of the Organization, in all regions and with all hosted partnerships through an electronic workflow, due diligence by the central unit, a guide for staff and a clear decision-making process.
- (d) FENSA will increase accountability towards Member States through strengthened oversight by the Executive Board.
- (e) The Director-General will report annually on engagements with NSAs.

### **Pathway to FENSA**

28. In the context of the Sustainable Development Goals, the international community has been requesting the United Nations and its agencies to strengthen its engagement with NSAs. Specifically, as part of the WHO governance reform, the governing bodies requested the Director-General to develop a framework of engagement with NSAs and four separate policies on engagement with different groups of NSAs.

29. After a series of consultation and issue papers in 2013 and 2014 to agree on the approach to be adopted for this policy revision, the Secretariat presented a first draft FENSA to a Member States consultation in April 2014. A revised version was considered by a drafting group of the 2014 Health Assembly, which requested consultations with all regional committees. Based on this input, the Secretariat submitted a revised draft FENSA to the Executive Board in January 2015, where Member States decided to establish an intergovernmental working group on FENSA. However, the working group and the 2015 Health Assembly did not find an agreement on FENSA, and accordingly another open-ended intergovernmental meeting was established. At the same Health Assembly, the Secretariat committed to present an analysis of FENSA's practical and resource implications at the time of the submission to the Executive Board and Health Assembly.

30. The open-ended intergovernmental group met twice formally, from 8–10 July 2015 and 7–9 December 2015, as well as for informal consultations for nine days in September and October 2015. On the request of some Member States, the Secretariat provided a non-paper on the implications of FENSA to the informal consultations in October. Member States had different views on the adequacy of discussing the implications before concluding the negotiations on FENSA. These differences in

views were reflected during the debates of the January 2016 meeting of the Programme Budget and Administration Committee of the Executive Board, where ultimately a compromise was found.<sup>1</sup>

31. Under the compromise, the Executive Board, having considered the report of the open-ended intergovernmental meeting on the draft framework of engagement with NSAs, and the report of the Programme, Budget and Administration Committee of the Executive Board, decided on the following:

- (a) to endorse the request of the Open-ended Intergovernmental Meeting to extend its mandate, so that it may resume its work for a final session from 25 to 27 April 2016, in order to submit a consensus text of the draft framework and a draft resolution to the Sixty-ninth World Health Assembly through the Programme, Budget and Administration Committee;
- (b) to request the Secretariat to present an objective and balanced report on the implications for WHO of the implementation of the framework, well in advance of the final session.

32. In addition to this formal Executive Board decision the following guidance was given to the Secretariat:

- (a) the Director-General committed to provide the report four weeks in advance of the intergovernmental meeting in six languages. With the time needed for translation, the report needed to be finalized by 11 March 2016.
- (b) Member States expected the report to be based on inputs from regions, country offices and clusters. The sensitivity of the issue made it clear that the objectivity requested could not be achieved by the Secretariat alone, while a mandate to an entity external to the Secretariat would not be realistic in view of the timelines.

33. Furthermore, the chair of the open-ended intergovernmental meeting, in a summary of the discussion, said that there would be a mission briefing on the report at least one week prior to the intergovernmental meeting, and that the intergovernmental meeting would start with consideration of FENSA itself before considering the draft resolution and the report on its implications.

34. In view of the importance of finalizing the draft framework, the Secretariat was requested to prepare an objective, balanced analysis of the implications of implementing the framework, with inputs from headquarters and the regional and country offices. The purpose of the paper was to provide an overview of the possible implications of the implementation of FENSA, describing its impact and effects from a policy, financial and human resource perspective at all levels of WHO.

## **II. Specific policy components**

35. The policy review highlights the major implication issues in the implementation of the draft FENSA, particularly the provisions already agreed upon by Member States during the 134th session of the Executive Board. It includes key information that links the opportunities and risks to changes in WHO policies, and implementation issues in terms of processes and procedures. Resource implications, both financial and human, were also reviewed in conjunction with the information presented by the three levels of the Organization.

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<sup>1</sup> EB138/3: Report of the Programme, Budget and Administration Committee of the Executive Board; and decision EB138(3): Framework of engagement with non-State actors.

36. This report contains a qualitative review and analysis of the rationale, principles, opportunities and risks to WHO of implementing FENSA in accordance with the mandate under its Constitution, in view of the increasing number of engagements with NSAs in the arena of global health. A quantitative matrix of the NSAs engaged with in 2015, by type and engagements, was used to support the analysis made.

37. To this end, the replies to the questionnaire and the detailed matrix of analysis of all WHO regional offices, clusters at headquarters and a selection of country offices primarily served as inputs to this report, with the addition of the perspectives of the External Auditor, based on the evaluation of the draft framework and the existing related WHO policies, regulations and documentations on engagement with NSAs.

38. It is emphasized, however, that practically all respondents, when asked to comment on the methodology used, expressed difficulty in estimating, establishing and capturing numbers and figures, due to lack of documentation and records, lack of templates for data collection, lack of clarity and the vast number of engagements. A number of respondents also expressed concern over the unrealistic timeline, unavailability of technical personnel and the multiple forms of engagement, which at times traverse different types of engagement and cover several areas of interaction, causing much confusion and complication.

39. While the numbers supplied by all respondents were not absolutely exact, as these were based on recollection in the absence of structured monitoring of the continuing engagements with NGOs and private sector entities, the data were considered by the External Auditor as a fair reflection of reality.

40. A summary of the estimated number of the different types of NSAs engaged with in 2015, as reported by the different categories of respondents, is presented in Table 1.

**Table 1. Numbers of NSAs engaged in 2015**

NSA	Regional office	Country office	HQ clusters	Total	%
NGOs	2 188	1 603	5 116	8 907	40%
Private sector entities	132	253	4 425	4 810	21%
Philanthropic foundations	151	493	873	1 517	7%
Academic institutions	797	715	5 640	7 152	32%
Total				22 386	

41. Based on the replies of all respondents, NGOs registered the highest percentage of NSAs engaged in 2015, equivalent to 40% of the total NSAs. This was followed by the academic institutions with a share of 32%, private sector entities with 21%, and the philanthropic institutions as the lowest with 7%. It should be noted that the methodology did not prevent double-counting in instances where different departments, regional offices or country offices engaged with the same NSA several times. This distinction will only be possible once the register of non-State actors is fully rolled out. Furthermore, all kinds of engagements, ranging from a single participation in a meeting to a large resource contribution, were counted as one engagement.

42. The information received also showed that “participation” was the main of engagement for all categories of NSAs, at 38% overall, followed by technical collaboration (34%), advocacy (13%), evidence (10%) and resources (5%) (Table 2).

**Table 2. Volume of engagements by type of NSAs, 2015**

Type of engagement	NGOs	Private sector entities	Philanthropic foundations	Academic institutions	Total	%
Participation	3 157	627	283	1 995	6 062	38%
Resources	284	178	130	203	795	5%
Evidence	387	115	169	1 014	1 685	10%
Advocacy	1 224	233	132	477	2 066	13%
Technical collaboration	2 961	626	117	1 772	5 476	34%
Total	8 013	1 779	831	5 461	16 084	
Percentage	50%	11%	5%	34%		

43. The numbers of NSAs engaged by type of engagements and by volume of engagements made in 2015 are vital pieces of information for consideration in the proposed FENSA and its guidelines in order to manage the risks associated with its implementation. Decisions on where WHO needs to focus its resources, and the extent and type of controls to be adopted in order to mitigate the risks associated with its implementation, need to take account of the volume of the different types of NSAs and the nature of the engagements involved.

44. If the data are indicative of trends that will be sustained upon FENSA implementation in the future, WHO should be dealing mostly with NGOs throughout its implementation, followed by academic institutions and the private sector, with philanthropic foundations the least likely category of NSA for WHO to be engaging with. WHO needs to take those trends into account when prioritizing future activities, and aligning its risk assessment and management accordingly.

45. WHO needs to consider the implications of dealing with “participation” as the main type of engagement with NSAs, as that activity could engage an undue proportion of its efforts, resources and decision-making processes, relative to technical collaboration, advocacy, evidence and resources, in order of volume of engagement.

46. For engagements in cases of emergency, the data in Table 3 were collated from respondents.



**Table 3. Estimated number of engagements in emergency situations in 2015**

	NGOs	Private sector entities	Philanthropic foundations	Academic institutions	Total	%
Participation	250	150	200	40	640	39%
Resources	30	20	20	20	90	5%
Evidence	150	10	90	30	280	17%
Advocacy	200	30	150	40	420	26%
Technical cooperation	120	20	45	25	210	13%
Total	750	230	505	155	1 640	
Percentage	46%	14%	31%	9%		

47. As to the estimated number of engagements in emergency situations by type of NSAs, Table 3 reflects a similar trend, with “participation” as the main type of engagement with 39% of the total engagements in 2015, followed by advocacy with 26%, evidence with 17%, technical collaboration with 13%, and resources with 5%.

48. With regard to engagements in emergency situations, NGOs again represented the highest volume of engagements with 46%, though philanthropic foundations, which registered the smallest volume for all engagements, now registered the second highest level of engagement, followed by the private sector and academic institutions.

49. The above trends in estimated number of engagements in emergency situations were summarized from the response of a European country office, the only one among 30 respondents that provided disaggregated figures. The replies from other respondents were too varied and diverse to undertake similar analysis. It is apparent though that on those occasions when WHO has to deal with NSAs in emergency situations, NGOs and philanthropic foundations, in particular, play a major role in many of those engagements.

50. Two offices provided feedback on the policy matrix survey; Table 4 summarizes their responses to the policy components defined in the matrix.

**Table 4. Feedback on policy components defined in the matrix of analysis**

Policy component	Feedback
Policies and their application; and, overall engagement principles	<p>In its current state, FENSA is overwhelming in many respects: the complexity of the text and the lack of clarity of (or inconsistency between) many of the terms has the potential to create a chilling effect on the willingness of NSAs to engage with WHO.</p> <p>The risk of over-regulation is high. FENSA looks at individual engagements on a case by case basis. The high number of administrative processes in the electronic workflow might lead to risk that a lot of time is spent to deal with non-problematic, diluting attention to more ambiguous situations.</p>

Policy component	Feedback
Engagements: Definition and distinction of actors, participation in governing bodies and in other meetings	<p>Many Universities are private or funded from private sources. Does this make them private sector?</p> <p>An additional accreditation system would imply more changes and possibly an increase of numbers. How can due diligence be undertaken if one does not know in advance who will attend a meeting or contribute to a public consultation?</p> <p>High volumes of engagements will necessarily create delays. The preparation of WHO meetings involving NSAs and the participation of WHO staff in NSA meetings would become very complex.</p>
Resources: Receiving and providing	<p>Under the PIP framework, manufacturers are expected to pay a yearly contribution equal to 50% of the running costs of GISRS. However, Member States and other stakeholders are also encouraged to contribute. Likewise, manufacturers commit to provide in-kind resources to WHO at the time of pandemic. These mechanisms should be guaranteed to fall outside FENSA.</p> <p>Cost recovery/fees schemes such as financing of pre-qualification should not be impacted by FENSA.</p>
Evidence	Although individual experts do not fall under FENSA, there is a risk that we will be restricted in the diversity of experts that can be consulted.
Management of individual conflicts of interest	Management of individual conflicts of interest is not regulated in FENSA.
Due diligence and risk assessment procedures	<p>What exactly does this entail? How often must due diligence be conducted? For what types of interactions?</p> <p>Very cumbersome process, which will need regular “refresh”.</p>
Risk management	How do we comply with this if the advice comes after the engagement has occurred?
Register of non-State actors	<p>Who will gather the information and enter it into the system? What if a company cannot provide certain information due to company policy/proprietary information issues? Are there any potential anti-trust implications/ramifications/concerns that could arise as a result of the types of information that will be asked of companies? Is there a chance that the register could in fact reduce competition among companies? There has to be clarity about what will be made public.</p>
Oversight of engagement	<p>This seems inordinately burdensome especially if there is a public register.</p> <p>Micromanagement is the result of mistrust and will generate more mistrust.</p>
Applicability to emergencies	<p>Clarity will be absolutely critical; temporary suspension of compliance should be provided if compliance impedes response efficiency.</p> <p>Any kind of administrative bottleneck is unacceptable for emergencies.</p>

51. Even if there are limited data on policy perceptions as referenced above, it is still clear that the FENSA policy has to further improve in terms of clarity of the framework itself and the acknowledgement that specific policies and guidance must be crafted. Another valid concern that

needs to be addressed is the apprehension that the proposed processes may prove cumbersome and therefore delay the engagement. Another pressing concern is the fact that a number of NSAs may not be ready to provide certain proprietary information that would find its way onto the register of non-State actors, and thus may opt out of any engagement with WHO.

### **III. Governance arrangements**

#### **Cost of the policy choice**

52. As had already been elucidated in the non-paper by the WHO Secretariat<sup>1</sup> for consideration during the informal meeting of Member States, 19–23 October 2015, the adoption and implementation of FENSA is not without considerable costs, from a policy, financial and human resource perspective, at all levels of the Organization.

53. For one, it had been ascertained that the proposed adoption of FENSA intends to establish an overall oversight function of the Executive Board through its Programme Budget and Administration Committee by examining an annual report of the Director-General on WHO's engagement with NSAs. With this comes the possible abolition of the Executive Board Standing Committee on NGOs, with its functions transferred to the Programme Budget and Administration Committee. This could mean an additional agenda item to the Committee's usual agenda (the annual report on engagement, the proposals to admit NSAs into official relations and the review of official relations every three years). As already emphasized, the Programme Budget and Administration Committee might need to add systematically a third day to its January session, resulting in additional use of resources.

54. In addition, the non-paper by the WHO Secretariat projected direct financial and human resource costs related to implementation of FENSA. Specifically, the direct financial costs of implementing FENSA at the central level have been calculated and budgeted as follows:

- (a) Building up and maintaining a system for the register of non-State actors: Global engagement management (in 2015): US\$ 734 000 start-up costs, thereafter US\$ 76 000 per year.
- (b) Training costs for launching the register of non-State actors and FENSA: Estimate US\$ 100 000 (for 2016).
- (c) Communication of change internally and externally: Estimate US\$ 50 000 (for 2016).
- (d) Possibly an extra day of the Programme Budget and Administration Committee: US\$ 30 000 per year (as of 2017).

The Secretariat will have to re-evaluate these figures in light of the final text of FENSA.

55. However, it has been stressed clearly, and merits further careful consideration, that there is an expectation that a major part of the additional workload could happen in the technical units and at country level. As expressed in the non-paper, given that who engages with thousands of NSAs in tens of thousands of engagements per year, this workload is significant, and need to be performed by professional offices across the Organization as part of their daily work. Its financial and human

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<sup>1</sup> Document accessible on the webpage <http://www.who.int/about/collaborations/non-state-actors/en/>

resource implications cannot be estimated with a sufficient degree of accuracy to provide a solid figure, but will need to be monitored as FENSA gets progressively implemented.

56. As further emphasized in the non-paper, each region and cluster has already appointed a focal point on FENSA, usually performing that function in addition to other functions. With the full implementation of the framework, the workload of these focal points will increase to take an estimated half to full-time professional officer's post per region and cluster.

57. Also, it was emphasized that the number of professional positions in the central unit performing due diligence and risk assessment has already been increased from three to five. With the 2016–2017 budget, an additional professional officer will be recruited. During the roll-out of FENSA, an evaluation of the unit workforce capacity will have to be conducted so as to identify the needs and adjust accordingly. FENSA will also lead to additional workloads for other specific departments, such as the Office of the Legal Counsel; governing bodies; Compliance, Risks and Ethics; and the Department of Finance.

58. As it stands now, even the regional and country offices have already incurred considerable costs in the implementation of the present engagements with NSAs. The answers to the question on the specific resources (staff and activity costs) currently working on engagements with NSAs within their respective areas of responsibility may have greatly varying answers, but these answers are indicative of considerable costs that are already being incurred by the various WHO offices. A detailed cost estimation of regional offices and selected country offices is presented in Appendix 1.

59. On the question on specific incremental resources (staff and activity costs) that would be necessary to work on engagement with FENSA, there was commonality in the responses in the sense that there is certainly a need to hire additional staff to undertake related activities the moment FENSA is adopted. This includes resource needs for focal points and the attendant processes, separate from the resource needs of technical units. As seen from the responses, estimations quoted were quite substantial and significant. Appendix 2 provides the details of these.

### **Opportunities and risks**

60. The opportunities and risks foreseen with the implementation of FENSA have been discussed at length in earlier gatherings of policy framers and key officers and players of WHO. This brought about the framing of the matrix of analysis of the implications of FENSA implementation. In support of what has already been established and deliberated on during previous discussions on the framework, two questions raised in the questionnaires were meant to elicit respondents' perceptions on opportunities and risks that could go along with the adoption of FENSA.

61. Premised on the present WHO policies and practices on engagement with NSAs comparable with the proposed policies and practices envisioned under FENSA, distinct changes were identified. The answers of respondents seemed to affirm what had already been duly established and presented in the matrix.

62. Respondents were in unison with the common perception that adoption of FENSA could result in opportunities and positive results. There was also agreement on the possible occurrence of risks, which needed to be effectively managed and, where possible, avoided.

63. Based on the opportunities and risks signified by the respondents (Appendix 3), several critical areas of policy choice are presented:

**1.1.1.1 (a) Overall engagement framework**

64. There is no alternative to a strong and solid policy framework upon which all specific guidance and processes of the Organization will be anchored, to ensure transparency, accountability, uniformity and consistency in application and treatment of all engagements with NSAs in all levels of the Organization. While the framework provides the backbone, the specificities of the delivery guidelines and related processes can also spell the success and failure of the policy change.

65. As mechanisms should be put in place to assure consistency of application of the policy, rigid measures should be adopted so that all engagements by all offices and at all levels of the Organization abide by the framework. As provided for in the draft framework, non-compliance by an NSA can have consequences after due process, including a reminder, a warning, a cease and desist letter, or other measures.

66. However, the implementation of the framework comes at a price or cost. Effective reporting and monitoring are thus necessary activities in ensuring and exacting accountability, an essential operational element in any organization.

67. Further, as reporting understandably entails use of resources and could require costs on the part of both the NSA and the Organization, a reporting and monitoring mechanism that is logical, streamlined and effective will benefit both the NSA and the Organization.

68. The detailed delivery guidelines and operational processes must clearly define and spell out which actor goes into which major classification of NSA. As provided for under Section 38 of the draft FENSA, a WHO register of non-State actors would be established as an Internet-based, publicly available electronic tool to be used by the Secretariat to document and coordinate engagement with NSAs. The register would contain the main standard information provided by NSAs and high-level descriptions of the engagement that WHO has with these actors. All these details will go into the operational processes and therefore need not be in the overarching framework itself. This identified risk is expected to occur during the implementation itself, and thus need not affect the adoption of the overarching framework.

69. The clarity that is needed in the above instances must be apparent in the detailed operational guidelines and procedures. It is therefore important that the detailed operational procedures are clear enough to address possible issues that could emerge. Operational guidelines and procedures should include provisions with certain flexibilities and leeway in instances where ambiguities could impede efficiency, as in emergency situations.

70. The adoption of the overarching framework and the resulting operational guidelines and processes should streamline activities and simplify accreditation of actors. It is only when transitioning from the existing system to the proposed framework and operational processes that changes in the volume of transactions will be noted. The system should operate much more smoothly and efficiently once it is in place and all staff and NSAs become accustomed to how it functions.

**1.1.1.2 (b) Due diligence and risk assessment procedures**

71. Setting up due diligence and risk assessment procedures is largely a matter of good judgement as to which is the greater priority – a system that is quick and easy, but does not assure safeguards for the interests of WHO; or a system that is rigid and firm, protecting the reputation and integrity of the

Organization, though requiring time and resources to perfect and institutionalize the system through tried and tested operational procedures.

72. While the specific clearance process may be longer with the proposed FENSA, such a system would ensure that the interest, integrity and good name of WHO are preserved.

#### **1.1.1.3 (c) Transparency and accountability**

73. The overriding benefits of transparent processes and operations far outweigh the anticipated risks. All of those will be addressed as the operational procedures are revisited and enhanced. Clear accountability lines in all engagements, and recognition of the effective roles and responsibilities of internal stakeholders, are essential requirements. Reference to the WHO Accountability Framework has to be made at all times.

#### **1.1.1.4 (d) Register of non-State actors**

74. While there are implementation issues that can be addressed by the operational procedures, clarity of guidelines for establishing a register of non-State actors, and the availability of an efficient mechanism to maintain the register, will be of prime consideration.

#### **1.1.1.5 (e) Conflict of interest**

75. Conflict of interest will always be an issue and a risk, with or without FENSA. It is essential, therefore, that the framers of the operational procedures ensure that all possible issues and risks that could occur are anticipated, and the measures to address them are incorporated in the operational procedures, in order to minimize the impact of these risks. Reference to the WHO Accountability Framework will guarantee clearer definition of roles and responsibilities, particularly on the part of WHO.

#### **1.1.1.6 (f) Oversight of engagement**

76. A monitoring and evaluation mechanism must be in place to provide support to all engagements with the end view of ascertaining that the intended benefits or results are achieved.

### **PART C: OVERALL IMPLICATIONS OF THE POLICY CHOICE**

77. It had been established that in its generic sense, implementing FENSA will have clearly foreseeable and intended consequences. On a positive note, it can put WHO's engagement with NSAs on a more solid base and strengthen the management of risks of engagement. On the other hand, it will also change and influence the working environment across the Organization, which could have major unintended consequences. If FENSA as a policy and system becomes too cumbersome for NSAs and the Secretariat, it could lead to a reduction in WHO's engagement with NSAs and thereby impede WHO's ability to fulfil its mandate.

78. As there is currently no structured and systematic monitoring and documentation process for engagements with NSAs, the adoption of FENSA will provide a single, unified system and transparent policy for all types of engagements with NSAs across the Organization. Accountability of responsible units and individuals at the different levels of the Organization could be enhanced with the implementation of FENSA.

79. The existing principles governing relations between WHO and NGOs (resolution WHA40.25) and the guidelines on interaction with commercial enterprises to achieve health outcomes (document EB107/20) will be replaced by FENSA. Once FENSA is adopted, it will be the overarching framework for engagement with NSAs, and the four specific policies will apply to all engagements with such NSAs at all levels of the Organization.

80. As a new provision in the draft FENSA, a change in the oversight function of the Executive Board through the Programme Budget and Administration Committee is being proposed. The new provision will impact both the reporting accountabilities and the structure of WHO governing bodies but can be considered as an improved practice to enhance transparency.

81. By and large, previous discussions on the framing of FENSA have adequately considered all angles, factors, possibilities and opportunities related to its adoption. All that needs to be done is for the WHO governing body to move forward in the direction that it needs to take. As clearly established, implementing FENSA in its generic form will have foreseeable and intended consequences, and will put WHO's engagement with NSAs on a more solid base and strengthen the management of risks of engagement. On the other hand, FENSA will change and influence the working environment across the Organization, with possible unintended consequences. On balance, however, FENSA can and will help increase coherence in engagements with NSAs, which could greatly help WHO sustain its role in global health.

82. It is emphasized that WHO has been engaging with NSAs for years, without the benefit of a formal overall framework that is accepted and widely applied across all levels of the Organization, thus constantly running the risk of compromising its position and mandate of providing global leadership in public health. Engagements with NSAs have been and always will be an essential part of WHO's day-to-day existence, such that the absence of a framework that is applied consistently and uniformly across all levels of the Organization and is understood by all provides an element of risk and puts the entire Organization in a precarious position.

83. It is vital that extra care and caution are duly exercised in the crafting of the specific policies aligned with the overarching framework. The reservations, comments and uncertainties noted during the numerous discussions on the matter, as well as in the responses to the questionnaires, must be considered.

84. Among the more important points and pressing concerns that should be carefully considered before and during the adoption of FENSA are the following:

- (a) The results of the evaluation conducted by the External Auditor may lessen its value, or perspectives may not be applicable when additional changes to the draft framework will be made as a result of future agreed-upon proposals by Member States.
- (b) There is a need for timely provision of streamlined guidelines and processes, including the necessary information technology (IT) infrastructure to implement FENSA.
- (c) The FENSA guidelines need to provide appropriate and sufficient controls in order to manage the risk of policy override. On the basis of lessons learned from past engagements with NSAs, WHO may reconsider the adoption of alternative control processes for voluminous, recurring and less risky engagements.

(d) Clarity of policies and guidelines and their consistent application may be threatened by factors such as communication line breakdowns. WHO therefore needs to have an implementation strategy across the Organization, particularly in the regional and country offices, where engagements with NSAs are more evident.

(e) With the expansion of the engagement with NSAs under FENSA, and considering the readiness of the requirements to consistently and properly adopt its guidelines across the different levels of the Organization, Member States can consider a phased implementation of the framework and its operational procedures, rather than opt for full and complete implementation of both the framework and the operating procedures at one time. This could afford the Secretariat more flexibility in adjusting and aligning the proposed procedures to the other issues and considerations already identified, particularly through feedback from stakeholders. Such issues include the volume of engagements in relation to the types of engagements; the current transaction costs and increments; and the challenges identified. To this end, the Member States may want to identify the operational procedures, by type of engagement or type of NSA, to be given priority in implementation, as warranted by circumstances and situations, so that lessons learned are identified in a timely manner and policy adjustments are made.

85. Discussions on FENSA and its possible adoption have been going on for years, and the transaction costs entailed have been borne by the Organization in terms of financial, human and other resources. Despite the policy investments that WHO has put into the development of FENSA and the efforts made to incorporate it into the overall organizational agenda, FENSA has barely taken off, at least in the form of a formal framework from which specific policies can emanate. The FENSA policy development corridor has been long, arduous and costly. Hence, it is essential that a definite decision on its implementation be made at this time.

## **PART D: SUMMARY STATEMENTS**

86. FENSA as an overarching framework can already stand on its own and can be considered for adoption but specific policies are needed to clarify the mechanism of the framework. The overarching framework, as written, already embodies the strategic context of WHO on its engagements with NSAs.

87. For practical purposes, the Member States can consider a phased implementation of the framework and its operational procedures, rather than opt for a full and complete implementation of both the framework and the operating procedures at one time.

88. The adoption of FENSA has been impeded by concerns, often related to specific aspects of the framework, that can otherwise be addressed by specific guidelines, and as such need not be viewed as compelling reasons for further delaying its adoption. The costs of the policy choice and the opportunities presented by adoption of the policy need to bear fruit now.



## Appendix 1A

**CURRENT COST ESTIMATION OF SELECTED REGIONAL OFFICES AND COUNTRY OFFICES**

REGIONAL/COUNTRY OFFICES								
SEARO	BANGLADESH	SRI LANKA	NEPAL	AMRO	MEXICO	MALAYSIA	PHILIPPINES	WPRO
Direct HR Cost – US\$ 149 750	Direct HR Cost US\$ 537 450	Direct HR Cost US\$ 26 630		PAHO/AMRO currently has two senior level staff members devoting significant time to due diligence/risk assessments, with occasional support from other professional staff.	No Answer	Staff time spent on programme budget implementation and engagement of NSA contractors, etc = 2.5-3 FTE. Activity costs being used to engage contractors are those from the biennial country budget, approximately US\$ 350 000+ per biennium.	Approximately 20% of staff time and 60% of activity costs due to government preference for WHO direct implementation.	There is currently one P3 Technical Officer and a G5 in the Regional Director's Office working on external relations and partnerships specifically. This is in addition to the time spent by technical staff in engaging with NSA which could not be estimated due to lack of time.
Indirect HR Cost – US\$ 155 750	Indirect HR Cost - US\$ 10 000	Indirect HR Cost US\$ 1 000				Engagement by P staff and NPO with NSAs for participation (meetings/conferences) and advocacy varies considerably throughout the year, but is roughly 5–10% of time on average.		
Activity Cost – US\$ 52 500	Activity Cost - US\$ 200 000	Activity Cost US\$ 28 000						
Total – US\$ 208 250	Total US\$ 747 450	Total US\$ 55 630						

## Appendix 1B

## CURRENT COST ESTIMATION OF SELECTED WHO CLUSTERS

CLUSTERS				
HSE	NMH	ERM	UNITAID	HTM
Still working on this for non-PIP matters. For PIP alone, however, 4 professional staff currently work on engagements with NSA but significant activity costs are also expended.	Staff: All staff in the NMH Cluster are engaged in engagements with non-State actors, varying from 10% to 80% of a full-time staff member. The estimated total cost is the equivalent of 30 professional staff members working full-time on engagement with non-State actors, totalling around US\$ 1 million.	One Technical Officer (P3) for Global Health Cluster engagement.	UNITAID grant management staff, including programme and grant finance responsible officers, supported by external consultants on specific areas of expertise , as needed.	Depending upon the unit within the department and the level (volume) of engagement with non-state actors resources gets deployed. HTM has 4 departments and a partnership and all of them incur specific activity cost and staff cost. Since units does not have a specific staff assigned to the engagement with NSAs, it is very difficult (very time consuming exercise, if not impossible) to assess to proposition of resources working/used in these engagements with the proportion of NSAs participating in the engagements. Within each unit a technical officer, Coordinator and other disease programme officer normally work on all engagement of that unit.
	Activity costs: US\$ 2 million	– 2 Technical officers for Standby partner engagement.		
		– 2 Technical offices for resource disbursement/receipt.		
		Awaiting information from countries and regions on country health clusters.		
		One off resources/costs.		
		– The process of negotiating, registering and gathering the information required for the due diligence process for what could be up to 1000 NSAs will require at least 1 person per country cluster (24), plus a dedicated team in HQ to brief/train countries and facilitate the process. It may take several months or years depending on the capacity put in place.		
		Recurring or Ongoing resources/costs.		
		Similar to above with additional resources (especially at country level) for acute emergencies.		

## Appendix 2A

## INCREMENTAL COST ESTIMATION OF SELECTED REGIONAL OFFICES AND COUNTRY OFFICES

SEARO	BANGLADESH	SRI LANKA	NEPAL	AMRO/PAHO	MEXICO	MALAYSIA	PHILIPPINES	WPRO
Direct HR Cost – US\$ 241 800	Direct HR Cost – US\$ 612 950	Direct HR Cost – US\$ 63 100	Direct HR Cost – US\$ 58 100	One off resources/costs: Regional capacity building and training of staff, including costs for new training materials, preparation of training materials, and travel expenses.	NA	One off resources/costs.	One off resources/costs.	This is still very difficult to describe given the role of Regional and Country Offices has not been specifically articulated. However, some estimations below: One off resources/cost.
Indirect HR Cost – US\$ 8 000	Indirect HR Cost – US\$ 25 000	Indirect HR – Cost US\$ 5 000	Indirect HR – Cost US\$ 1 000	Recurring or Ongoing resources/costs: At a minimum two (2) additional professional staff to help with due diligence/risk assessment/risk management, and one (1) general service staff. These additional staff will be needed to help conduct due diligence processes and the different reports for each of the four levels, as well as to provide on-going training and guidance to staff.		A. Training (and this needs to be proper training appropriately tailored for country level activities, not the usual stuff we get); periodic updating/retraining as more experience is gained in using the FENSA.	– Practical staff training on FENSA (i.e. what it is about, why it is important, how it impacts their day- to-day work and future actions they need to undertake to comply), incl. due diligence exercises as “common sense” may help to limit the number of due diligence requests being sent to HQ – no tobacco/arms etc.	

SEARO	BANGLADESH	SRI LANKA	NEPAL	AMRO/PAHO	MEXICO	MALAYSIA	PHILIPPINES	WPRO
Activity Cost – US\$ 170 000	One off incl Start up US\$ 210 000	One off & start up US\$ 24 000	One off & start up US\$ 5 500			B. A system set up that enables (i) input by individual staff, but reviewed by appropriate technical managers and a “focal point” to ensure consistency before final submission to the “specialised” due diligence/risk management unit; (ii) regular sharing of examples and experience; (iii) central handling of due diligence so we do not have many country offices duplicating efforts to assess the same NGOs or agencies.	– Training on the NSA register itself (if staff in RO and COs are really required to input data?), as well as to empower them to utilise it to deduce information and for better coordination.	– Practical staff training on FENSA (i.e. what it is about, why it is important, how it impacts their day-to-day work and future actions they need to undertake to comply), incl. due diligence exercises as “common sense” may help to limit the number of due diligence requests being sent to HQ – no tobacco/arms etc.
Recurring cost– US\$ 140 000	Reoccurring cost US\$ 105 000	Reoccurring costs US\$ 42 000	Reoccurring cost US\$ 5 500			Recurring or Ongoing resources/costs.	– Development of aforementioned training materials and implementation.	
<b>Total – US\$ 559 800</b>	<b>Total US\$ 847 950</b>	<b>Total US\$ 92 100</b>	<b>Total US\$ 64 600</b>			1. Depends on processes developed – if the centralised unit does not rely on the engaging unit's assessment/summary of materials that can be found on the internet, or submitted by the organisation concerned about the background of the NSA or the event, then there may be significant additional resources needed at country level to translate webpages and other documents (eg from Khmer, Bahasa, Vietnamese, Chinese, etc.)	Trainings will have to be repeated regularly especially for new staff.	– Development of aforementioned training materials and implementation.
						2. Whatever mechanism is put in place, in any country office there will have to be a mechanism that what is submitted for approval/recommendation	Recurring or Ongoing resources/costs.	Trainings will have to be repeated regularly especially for new staff.

SEARO	BANGLADESH	SRI LANKA	NEPAL	AMRO/PAHO	MEXICO	MALAYSIA	PHILIPPINES	WPRO
						is reviewed by a focal point to ensure it is the FENSA application is being submitted correctly and with some degree of consistency. This will need to be a P staff member, as the technical content needs to be understood. In a large country office this could add up to a significant amount of time of the PMO or similar, as there are often many different engagements in meetings simultaneously, so it may be necessary to engage additional staff to undertake this role. We already do due diligence on speaking engagements, etc and are careful to consider our engagement across any of the categories. But having to increase the documentation and submit this will take additional time. If it includes procurement of technical support, there is no doubt that additional resource will be needed to handle this – for a small office, estimate another 0.2–0.25 FTE may be needed.		
						3. Given different time zones and the essential need to be responsive globally, I assume the centralised “specialised” due diligence/risk management unit will operate 18–24 hours a day, and not just during Geneva working days and times.	– Potentially employing additional staff to work as FENSA focal point and to guide around due diligence/train others etc.	Recurring or Ongoing resources/costs.

SEARO	BANGLADESH	SRI LANKA	NEPAL	AMRO/PAHO	MEXICO	MALAYSIA	PHILIPPINES	WPRO
							– Financial allotment for the respective Director who is part of the FENSA 'Engagement Coordination Group' to attend meetings/hearings (cannot come from RO budget).	– Training and updating of training materials as FENSA evolves.
								– Potentially employing additional staff to work as FENSA focal point and to guide around due diligence/train others etc.
								– Financial allotment for the respective Director who is part of the FENSA "Engagement Coordination Group" to attend meetings/hearings (cannot come from RO budget).

## Appendix 2B

### INCREMENTAL COST ESTIMATION OF SELECTED WHO CLUSTERS

CLUSTERS				
HSE	NMH	ERM	UNITAID	HTM
We are still working on this for the broader cluster. For PIP only, given the significant weight of the partnership with industry in the benefits sharing element of the Framework, the following would be anticipated.	One off resources/costs.	The non-monetary costs has been outlined above: FENSA might lead to a reduction of number of active partners as well as a loss of impact and importance of the health cluster as well as WHO as the cluster lead agency.	The incremental additional resources required for us to monitor and provide the information required by WHO would be considerable and contrary to our Board's desire to maintain a lean Secretariat.	One off resources/costs: Training cost and deployment cost as needed. It is not fully clear yet what needs to be done at the technical unit level in the implementation of FENSA. Incremental costs could be low if it is just an additional characteristic added to the meeting list of participants etc., but if it needs tracking more details, then a dedicated staff may be required at the Department level.
<u>One off resources/costs</u> : 2 FTE professional and 1 FTE general service staff would be required to develop the initial data entries.	Training across the NMH Cluster: US\$ 200 000			Recurring or Ongoing resources/costs: We estimate 1 Professional and 1 General staff per department.
<u>Recurring or On-going resources/costs</u> : At least 1 FTE professional and 1 FTE general service staff would be required to manage FENSA compliance for PIP on an on-going basis.	Recurring or Ongoing resources/costs.			
	Additional staff and additional activity costs would need to be doubled (compared to resources described in question 14).			

## Appendix 3

**OPPORTUNITIES AND RISKS, WITH EXTERNAL AUDITOR'S COMMENTS**

<b>Areas/issues</b>	<b>Main opportunities in the work of each region/cluster/country office through the adoption and implementation of FENSA</b>	<b>Main risks in the work of each region/cluster/country office through the adoption and implementation of FENSA</b>	<b>External Auditor's comments</b>
Overall engagement framework	<p>Create an all-encompassing policy that will be applied to all engagements with non-State actors (NSAs); put in place an overarching framework that will be used not only by NSAs but also by WHO staff and other stakeholders; apply uniformity and consistency of application across the Organization and at all levels, particularly on which entity/NSA is subject to which specific policy.</p> <p>Facilitate engagement with large number of potential private sector entities.</p> <p>Facilitate generation of funds/mobilization of resources from private sector.</p>	<p>The complexity of the issue and the lack of clarity of (or inconsistency between) many of the terms and provisions due to matters that may be left out or omitted in the deliberations for the drafting thereof has the potential to create a chilling effect on the willingness of NSAs to engage with WHO – and the incentive of WHO to reach out to NSAs as partners to address important public health matters.</p>	<p>There is no price for a strong and solid framework upon which all policies and processes of the Organization are anchored, to ensure transparency, accountability, uniformity and consistency in application and treatment of all engagements with NSAs. The framework is only the backbone, the nitty-gritty shall be in the implementing guidelines and processes.</p>
		<p>If one region does not participate, it could create double standards, resulting in a potential loophole that may leave FENSA as a useless and unworkable policy framework.</p>	<p>Mechanisms should be in place to assure consistency of application. Rigid measures should be adopted that all engagements by all offices and levels of the Organization abide by the framework. As provided for in the draft framework, non-compliance by an NSA can have consequences after due process, including a reminder, a warning, a cease and desist letter, or other measures. The bottom line is non-renewal of official relations. Note: How about non-compliance by staff of members of the Organization?</p>



Areas/issues	Main opportunities in the work of each region/cluster/country office through the adoption and implementation of FENSA	Main risks in the work of each region/cluster/country office through the adoption and implementation of FENSA	External Auditor's comments
		An additional accreditation system would imply more changes and possibly an increase of numbers.	<p>It goes without saying that the implementation of this framework comes with a price/cost. Reporting is a necessary tool in ensuring and exacting accountability, which is an essential requirement in any organization.</p> <p>Reporting understandably entails use of resources and could require costs on the part of both the NSA and the Organization. A reporting system that is logical, streamlined and effective will redound to the benefit of both the NSA and the Organization.</p>
		Some NSAs might disagree with their attribution by WHO to one of the groups.	<p>The detailed guidelines and operational processes must clearly define and spell out which actor goes into which major classification of NSA. As provided for in Section 38 of the draft FENSA, a WHO register of non-State actors would be established as an Internet-based, publicly available electronic tool to be used by the Secretariat to document and coordinate engagement with NSAs. The register would contain the main standard information provided by NSAs and high-level descriptions of the engagement that WHO has with these actors. All these details will go into the operational processes and therefore need not be in the overarching framework itself. This identified risk is bound to occur during implementation, but need not affect the adoption of the overarching framework.</p>

Areas/issues	Main opportunities in the work of each region/cluster/country office through the adoption and implementation of FENSA	Main risks in the work of each region/cluster/country office through the adoption and implementation of FENSA	External Auditor's comments
			On the contrary, the adoption of the overarching framework and the resulting operational guidelines and processes shall streamline activities and simplify accreditation of actors. It is only when transitioning from the existing system to the proposed framework and operational processes that changes in the volume of transactions will be noted. Once in place, and all staff and NSAs get the feel of the “running” of the system, things will be a lot simpler and more efficient.
		Clarity will be absolutely critical; temporary suspension of compliance should be provided if compliance impedes response efficiency.	True. The clarity that is needed here is on the detailed operational guidelines and procedures. It is therefore vital that the detailed operational procedures are clear enough to address possible issues that could emerge. Operational guidelines and procedures should include provisions with certain flexibilities and leeway in instances where ambiguities could impede efficiency, such as but not limited to emergency situations.
Due diligence and risk assessment procedures	More systematic due diligence; clear standard operating procedures and electronic workflow, harmonization of applicable clearance processes.	High volumes, bottleneck with delays. There may be difficulty in identifying whether WHO is dealing with an institution or an individual. An additional accreditation system would imply more changes and possibly an increase of numbers.  Due diligence cannot be undertaken if one	It is simply a choice as to which is the greater priority – a system that is quick and easy, but does not assure safeguards for the interests of WHO; or a system that is rigid and firm, protecting the image and integrity of the Organization, though it may take some time and resources to perfect and institutionalize through tried and tested operational procedures.

Areas/issues	Main opportunities in the work of each region/cluster/country office through the adoption and implementation of FENSA	Main risks in the work of each region/cluster/country office through the adoption and implementation of FENSA	External Auditor's comments
		<p>does not know in advance who will attend a meeting or contribute to a public consultation.</p> <p>Uncertainty as to what exactly this will entail – how often must due diligence be conducted and for what types of interactions?</p>	While the specific accreditation process may be longer with the proposed FENSA, on the positive side, the system is such that the interest, integrity and good name of WHO are preserved.
Transparency	<p>Transparency improves accountability and processes. WHO will be less open to criticism that the Organization has concealed an engagement.</p> <p>Member States will be more aware of which NSA in governing bodies has which background.</p>	<p>Transparency can expose inconsistencies publicly, lead to attacks on individual decisions and might expose NSAs in some situations.</p> <p>Some entities will disagree if the Executive Board excludes them from official relations. May have negative consequences, such as potential exposure to claims or lawsuits for reputational harm.</p>	The overriding benefits of transparent processes and operations far outweigh the risks that are being anticipated. All of these will be addressed as the operational procedures are revisited and enhanced.
Register of non-State actors	The register could become a central database of all main global health actors and thereby strengthen WHO's coordinating role in global health. Internally the register should provide better intelligence on actors and thereby create synergies and efficiency gains in engagements.	<p>NSAs might challenge the fact that their information is published and some might choose not to engage, fearing this transparency.</p> <p>Who will gather the information and enter it into the system?</p> <p>What if a company cannot provide certain information due to company policy or proprietary information issues? Are there any potential anti-trust implications, ramifications or concerns that could arise as a result of the types of information that will be asked of companies? Is there a chance that the register could in fact <i>reduce</i> competitiveness among companies?</p>	These are implementation issues that can be addressed by the operational procedures.

Areas/issues	Main opportunities in the work of each region/cluster/country office through the adoption and implementation of FENSA	Main risks in the work of each region/cluster/country office through the adoption and implementation of FENSA	External Auditor's comments
		This seems inordinately burdensome, especially if there is a public register.	
Conflict of interest	Protect WHO integrity and reputation. Help WHO manage conflict of interest and other risks of engagement using systematic steps.	Undue influence by few big private sector donors/donor-driven priorities. Some may use FENSA as a scapegoat for lack of compliance with Pandemic influenza preparedness.  WHO may be engaging more with some NSAs compared with others. WHO may be driven by NSA agenda.	Conflict of interest will always be an issue and a risk, with or without FENSA. It remains a necessity, therefore, on the part of the framers of the operational procedures to ensure that all possible issues and risks that could occur are anticipated and the measures to address them are incorporated in the operational procedures, in order to minimize the impact of these risks.
Oversight of engagement	Stronger oversight can strengthen trust in the Secretariat.	Micromanagement by the Secretariat. Decreased capacity of the secretariat to conduct technical work mandated by Member States. Increased administrative and operational costs.	The operational guidelines are there to provide the basis for the conduct of the oversight function. It is therefore crucial that such guidelines address all possible risks associated with it.