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FORMAL SAFETY ASSESSMENT

Report of the Correspondence Group

Submitted by Japan

SUMMARY

Executive summary:	This document provides the report of the Correspondence Group on Formal Safety Assessment established by the Committee at its eighty-seventh session
Strategic direction:	12.1
High-level action:	12.1.1
Planned output:	12.1.1.1 and 12.1.1.2
Action to be taken:	Paragraph 62
Related documents:	MSC 83/INF.2, MSC 87/26, MSC 87/WP.7, MSC 87/18, MSC-MEPC.3/Circ.3, MSC-MEPC.2/Circ.6 and MSC/Circ.1022-MEPC/Circ.391

Background

1 The Committee, at its eighty-seventh session, established the Correspondence Group on Formal Safety Assessment with the following terms of reference:

> "Based on documents MSC 87/18 (paragraphs 40 to 49) and MSC 87/WP.7 (paragraph 21), to:
>
> .1 prepare draft revised FSA Guidelines (MSC/Circ.1023 – MEPC/Circ.392, as amended);
>
> .2 prepare draft revised guidelines on the use of HEAP and FSA relating to the review of FSA studies (MSC-MEPC.2/Circ.6); and
>
> .3 submit a report to MSC 89."

2 The coordinator distributed a discussion document in a style of the draft report of the group to the members. The members from Argentina, China, Finland, Germany, Greece, Japan, Republic of Korea, Russian Federation, the United States, International Association of Classification Societies (IACS), Cruise Lines International Association (CLIA) and Royal

Institution of Naval Architects (RINA) contributed to the group by submitting their comments to the discussion document. This document describes the outcome of the Correspondence Group on FSA.

Matters raised at MSC 87

3 In document MSC 87/18 (paragraph 49), the FSA Experts Group recommended that the FSA Guidelines and the Guidelines on use of HEAP and FSA should be considered for improvement in the following matters:

.1 description/discussion of experts participation in FSAs (i.e. expansion of specification for 10.1.5 of the FSA Guidelines);

.2 description of the structure, selection and composition of the project team, HAZID team and any other team, if established for taking any decision making (i.e. expansion of specification of 10.1.5 of the FSA Guidelines);

.3 information and analysis on root causes and details of casualties, with a view to obtaining RCOs focused on prevention rather than mitigation;

.4 development of risk models;

.5 unification of terminologies;

.6 reporting the method and justification for the final selection of RCOs;

.7 indices for cost-benefit analysis for risks other than safety of life;

.8 clarification on the use of NCAF and GCAF;

.9 methodologies to analyse possible side effect of RCOs;

.10 methodologies for sensitivity and uncertainty analysis;

.11 consideration of the human element (to have more detailed and specific guidance);

.12 methodologies to reach the consensus or agreement as well as reporting the degree of agreement, or concordance;

.13 how to present reports; and

.14 how to review FSA studies.

Description/discussion of expert's participation in FSAs (TOR 3.1 and 3.2[*])
Methodologies to reach the consensus or agreement as well as reporting the degree of agreement, or concordance (TOR 3.12)

4 In terms of method and degree of agreement in expert groups, there was general understanding in the group that it is recommended in paragraph 3.3 of the FSA Guidelines to report the level of agreement among the experts in the results of FSA, and the paragraph also refers to Appendix 9 "Degree of agreement between experts concordance matrix".

[*] TOR number refers to subparagraph number in paragraph 3.

There was also an opinion supported by some members that concordance in Appendix 9 is only one method for measuring degree of agreement and this should not become the mandatory method. There was another view that disagreement among experts in an FSA should be reported but it may not be necessary to report any decision making process in FSA.

5 Taking paragraphs 16 to 18 of document MSC 87/18 and paragraph 4 above into account, paragraph 10.1.5 of the FSA Guidelines can be revised as follows:

> ".5 describe the composition and expertise of ~~the~~ each group that performed the FSA process [for hazard identification] [of step 1] by providing a short curriculum vitae of each expert and describing the method of selection of the experts."

There was an opinion that guidance may be necessary for "method of selection of the experts" (this opinion applies also to paragraph 6 below).

6 In addition, the following new paragraph 10.1.6 should be added to the FSA Guidelines:

> ".6 describe the method of decision making in the group(s) that performed the FSA process (see paragraph 3.3)."

In this context, it was duly noted that paragraph 3.3 of the FSA Guidelines refers to Appendix 9 as an example and the method of concordance in the appendix is not a mandatory tool.

7 In this connection, Appendix 8 "Standard Reporting Format" should be amended as follows:

> "5.1 Composition and ~~level of~~ expertise of those having ~~carried out the application (name and expertise in an annex)~~ performed the FSA process by providing an explanation of the background of each expert (e.g., a short curriculum vitae) and the method of selection of the experts and name and contact point (e-mail address, telephone number and mailing address) of the coordinator of the FSA.
>
> 5.2 Description of how the assessment has been conducted in terms of ~~number of meetings,~~ organization of working groups and, method of decision-making in the group(s) that performed the FSA process."

Information and analysis of root causes and details of casualties (TOR 3.3)

8 Paragraph 22 of document MSC 87/18 stresses the importance of information and analysis of root causes of casualties, and near miss data. In this regard, paragraph 5.2.1 may be expanded to emphasize the importance by adding a new paragraph 5.2.1.3 and paragraphs 5.2.1.2 and 5.3 should be amended and harmonized with paragraph 6.3 of Appendix 8 as follows:

> "5.2.1.2 A coarse analysis of possible causes and initiating events and outcome of each accident ~~category~~ scenario should be carried out. The analysis may be conducted by using established … whenever possible and in line with the scope of the FSA.
>
> [5.2.1.3 An analysis of initiating events in each accident scenario should be carried out in order to provide data and information for step 2 and 3, in particular for consideration of preventive risk control measures.]"; and

"5.3.1 a list of hazards and their associated scenarios (including initiating events) ~~prioritized by risk level~~; and

5.3.2 ~~a description of causes and effects~~ an assessment of accident scenarios (prioritized by risk level)."

9 Some member expressed the view that coarse analysis and development of accident scenario are tasks in step 2 of FSA where significant effort should be concentrated on in-depth analysis on accident scenario and initiating events in relation to significant hazards identified in step 1. Others, noting existing paragraph 5.2 in the FSA Guidelines requires to conduct coarse analysis and to develop accident scenario, expressed that coarse analysis and development of accident scenario are indispensable for hazard ranking and these are tasks in step 1. Therefore, proposed paragraph 5.2.1.3 was enclosed in square brackets (same in paragraph 10 below) for further consideration. The group felt that this should be clarified further by discussion.

10 In relation to the proposal in paragraph 8 above, Appendix 8 should be amended as follows:

"6.3 outcomes of each step of the FSA methodology, including:

STEP 1 – HAZARD IDENTIFICATION
(refer to paragraph 5.3 of the FSA Guidelines)

- Prioritized list of hazard and description of their associated scenarios
- Identified significant accident scenarios[including initiating events]".

11 Paragraphs 23 to 25 of document MSC 87/18 highlight important suggestions to improve the GISIS casualty database and the method of handling the database within IMO, and it was felt that these findings should be sent to the FSI Sub-Committee and its working group on casualty analysis.

Development of risk models (TOR 3.4)

12 Paragraph 27 of document MSC 87/18 talks about development of risk models for FSA, bearing in mind that future risks may not be totally/completely derived from past casualty data of existing ships. It is also necessary to bear in mind that hazards associated with new concepts, designs and systems of ships/vessels would not be identified from historical casualty data.

13 It is generally understood that different FSAs require different risk models depending on their definitions of problems and/or generic models as mentioned in paragraph 4 of the FSA Guidelines. The FSA Guidelines may give guidance to develop risk models rather than give generic risk models.

14 The development of risk models would be a huge task and cannot be accomplished in only one session of the correspondence group. Moreover, it would be necessary to consider whether it is possible or quite necessary to develop risk models (see paragraph 12 above), and how to develop risk models in an exhaustive and holistic manner, applicable to all types of ships and operations. Therefore, it was felt that such necessity and possibility, together with the methodology of the development of risk models, should be further considered.

15 There was a proposal to revise paragraph 6.2.1 of the FSA Guidelines to guide people to use suitable technologies and analytical methodologies as mentioned in Appendix 3, as follows:

> "6.2.1 ~~The construction and quantification of fault trees and event trees are standard risk assessment techniques that can be used to build a risk model (see Appendix 3). An example of a conceptual risk model is the Risk Contribution Tree (RCT) as shown in Figure 6. Whilst the example makes use of fault and event tree techniques, other established methods (e.g. Bayesian network) could be used, if appropriate.~~ There are several methods/tools that can be used to perform a risk analysis. The scope of the FSA, types of hazards identified in step 1, or the level of failure data available will all influence which method/tool works best. Examples of the different types of risk analysis methods/tools are outlined in Appendix 3."

16 There was an opinion that it may be necessary to reorganize Appendix 3 of the FSA Guidelines taking into account the sequence of analyses (hazard identification and risk analysis).

Unification of terminologies (TOR 3.5)

17 Paragraph 41 of document MSC 87/18 talks of the unification of terminology, in particular the use of "frequency" and "probability". The FSA Guidelines define "frequency" in paragraph 2. For clarity, the group developed a draft definition of the term "probability" to be added to paragraph 2 as follows:

> "**Probability**: the degree of confidence in the occurrence of an event, measured on a scale from zero to one. An event with a probability of zero means it is believed to be impossible; an event with the probability of 1 means that it is believed it will certainly occur."

18 There was another proposal to include "the relative possibility that an event will occur, as expressed by the ratio of the number of occurrence to the total number of possible occurrences". However, some members expressed the view that the definition should be fairly broad for use in FSA while noting that the FSA Guidelines have a clear definition of "frequency" for the purpose of analyses in FSA. The group felt that more theoretical consideration would be required of the definition of "probability".

19 The term "frequency" should be used when explaining the number of occurrences per unit time (e.g., per year) and "probability" should be used when explaining the chance of an event in a certain situation. The terms "frequency" and "probability" should be properly used in terms of quantifying risk according to the definition of "risk" in paragraph 2 of the FSA Guidelines.

20 The term "probability" seems to be used in the FSA Guidelines in a wider meaning; sometime as "possibility", e.g., in paragraph 7.2.1, and this does not seem to cause any harm or confusion. The term "probability" in paragraph 7.2.1 cannot be replaced with "frequency".

21 Appendix 2 "Guidance on the human reliability analysis (HRA)" of the FSA Guidelines defines "Human error probability (HEP)" in paragraph 2, and HEP is used widely in Appendix 2. It was felt that the use of this term does not create any confusion with the use of "frequency".

22 In conclusion, there is no confusion with regard to the use of the terms "frequency" and "probability" within the FSA Guidelines. However, it is strongly recommended that, in any report of an FSA study, the terms defined in the FSA Guidelines should be used.

Reporting the method and justification for the final selection of RCOs (TOR 3.6)

23 Paragraphs 34 to 36 of document MSC 87/18 discuss the method and justification of selection of RCOs for step 4 of the process. There were mainly three items highlighted in the discussion of the FSA Experts Group, namely:

.1 interdependence between/among RCOs should be analysed [before adopting a combination of RCOs];

.2 the risk reduction factor of each RCO should be transparently demonstrated; and

.3 reason and justification of the selection of RCOs for step 4 of the process should be clearly indicated, in particular in relation to the HAZID and risk ranking [and the scope of the FSA].

24 Paragraph 7.1.1 of the FSA Guidelines should be amended to clarify the relationship between RCM and RCO by following:

"7.1.1 The purpose of step 3 is to ~~propose effective and practical RCOs and comprises the following four principal stages~~ first identify Risk Control Measures (RCMs) and then to group them into a limited number of Risk Control Options (RCOs) for use as practical regulatory options. Step 3 comprises the following four stages:

.1 focusing on risk areas needing control;

.2 identifying potential risk control measures (RCMs);

.3 evaluating the effectiveness of the RCMs in reducing risk by re-evaluating step 2; and

.4 grouping RCMs into practical regulatory options (RCOs)."

25 In addition, the first sentence of paragraph 7.2.3.1 should be amended as follows:

"7.2.3.1 The purpose of this stage is to group the RCMs into a limited number of well thought out ~~practical regulatory options~~ Risk Control Options (RCOs)."

26 Paragraph 7.2.3 of the FSA Guidelines does not mention the risk reduction factor of an RCO, while paragraph 7.3.1 talks about effectiveness of reducing risk. Therefore, a new paragraph 7.2.3.3 should be added as follows:

"7.2.3.3 After developing each RCO, its effectiveness in reducing risk should be assessed and analysed. This should include evaluating side effects of each RCO."

27 Existing paragraph 7.2.3.3 of the FSA Guidelines (to be renumbered as 7.2.3.4) describes the method of interdependence analysis for RCOs, and this should be followed in any FSA when more than one RCO are considered to be implemented at the same time, and the risk reduction factor of such combination should be also evaluated. Therefore, the following new 7.2.3.5 should be added:

"7.2.3.5 Where more than one RCO are proposed to be implemented at the same time, the effectiveness in reducing risk of such combination should be assessed."

28 RCOs should be prioritized in terms of their effectiveness in reducing risk and the method of analysis of effectiveness of risk reduction should be clearly indicated. Therefore, subparagraph 7.3.1 should be amended and a new subparagraph 7.3.4 should be added in paragraph 7.3 of the FSA Guidelines as follows:

".1 a prioritized list of RCOs with a description of the effectiveness in reducing risk;

.2 (no change)

.3 (no change)

.4 results of analysis of side effects of RCOs."

29 It is noted that Appendix 8 already specifies in paragraph 6.3, step 3 that "assessment of the control options as a function of their effectiveness against risk reduction", and this should be clearly reported as the transparent reason and justification of selection of RCOs for step 4 of the process.

30 It should be further noted that risk reduction capability is one component to measure the suitability of an RCO, but its effectiveness in terms of cost per unit of risk reduction is another important component to consider. In other words, some RCOs may not be so good in risk reduction but may be very cost effective to implement. Being that risk reduction capability is only available in step 3, care should be taken not to discard RCOs in step 3 that may potentially be cost beneficial when evaluated later in step 4.

Indices for cost-benefit analysis for risks other than safety of life (TOR 3.7)

31 As reported in paragraph 17.4 of document MSC 88/26, MEPC is still working on CATS (cost averting ton of spill) as a index for cost-benefit analysis for combating oil spill aiming at finalizing this subject at MEPC 62 (July 2011), and therefore MSC should wait for the outcome of MEPC.

32 For a fully holistic approach, it would be necessary to consider other factors relating to marine and atmosphere environmental protection, such as bio-fouling, noxious, acid and greenhouse gas emission, dumping of garbage and cargo residues, and underwater noise emission. However, it is necessary to develop indices for such elements before introducing them into the FSA Guidelines. In this context, it is recommended to keep paragraph 46 of document MSC 87/18, for future consideration on this issue.

Clarification on the use of NCAF and GCAF (TOR 3.8)

33 The last sentence of paragraph 46 of document MSC 87/18 briefly discusses this issue. It was pointed out, in the discussion of FSA Experts Group, that while one RCO may need a small cost and give a small benefit, another RCO may give a larger benefit with higher cost. Then, the GCAF of them would be nearly equal. This may happen also for NCAF. Therefore, CAF, as a ratio of cost and benefit as described in Appendix 7 of the FSA Guidelines, would not be a criterion sufficient for decision making in step 5 of FSA, and, for instance, effectiveness of risk reduction of RCO should also be important for consideration in step 5.

34 There would not be a quick solution for the concern mentioned in the paragraph above and no proposal for improving the FSA Guidelines is suggested at this moment. This concern should be further considered.

35 It was pointed out, with regard to the cost effectiveness criteria in Table 2 of Appendix 7, that these values should be correctly understood as being installed are for an illustrative purpose only, as mentioned in paragraph 3.2 of the Appendix 7. The same paragraph also states that the value is not a static value and should be reviewed taking into account the average risk free rate of return and/or other methodologies. Therefore, it is recommended to review periodically the values in Table 2 of Appendix 7.

36 It would be necessary to clarify the negative NCAF in paragraph 3.3 of Appendix 7 of the FSA Guidelines by modifying subparagraph .2 as follows:

> ".2 Negative NCAF
> Recent FSA studies have come up with some risk control options (RCO) where the associated NCAF was negative. Assuming that the RCO has a positive risk reduction potential ΔR (i.e. reduces the risk), a~~A~~ negative NCAF means that the benefits in monetary units are higher than the costs associated with the RCO. It should be noted that a high negative NCAF with positive ΔR may result from either of the following two facts:".

Methodologies to analyse possible side effect of RCOs (TOR 3.9)

37 Paragraph 47 of document MSC 87/18 discusses that side effects of RCOs should be taken into account in the analysis of step 4 (for example, a RCO against a risk might create or increase another risk). While the methodology in step 4 of FSA seems to concentrate on a comparison of cost and benefit on each RCO, the methodology for analysing or reviewing adverse side effects of RCOs including possible environmental side effects, should be considered and mentioned in the FSA Guidelines. A proposal is to add the consideration of adverse side effects in paragraph 7.2.3.3 of the FSA Guidelines (see paragraphs 27 and 28 above). Such methodology has not yet been established, but should be developed as an urgent matter.

Methodologies for sensitivity and uncertainty analysis (TOR 3.10)

38 As mentioned in paragraphs 30, 31 and 32 of document MSC 87/18, expert judgment and assumptions are inevitable, because HAZID cannot be conducted based only on historical casualty data, in particular for the consideration of new situations which may be created by new ships and/or new systems. It is recommended that a full explanation and justification of assumptions should be provided.

39 Paragraph 37 of document MSC 87/18 discusses the importance of sensitivity and uncertainty analysis and it is recommended to include the process of these analyses in the FSA Guidelines, because annex 3 "Guidance for practical application on FSA to the IMO rule-making process" (MSC-MEPC.2/Circ.6) states, in its review of an FSA study (paragraph 28), that "check whether uncertainty and sensitivity issues have been properly addressed in the FSA study", but the FSA Guidelines do not specifically mention such analyses (only in paragraph 6.4.8.1 of annex 1 for HRA sensitivity analysis is mentioned).

40 Sensitivity and uncertainty analysis (quantitative analysis) may be required in step 2 (risk calculation, risk models and tree analysis), step 3 (analysis of effectiveness of RCMs and RCOs) and step 4 (CBA), and available methodologies of sensitivity and uncertainty analysis should be reviewed.

Consideration of the human element (TOR 3.11)

41 Paragraph 38.2 of document MSC 87/18 discusses matters relating to the human element as an opinion of the FSA EG, that careful consideration should be given to the influence and consequence of each RCO upon human element, and that it is necessary to review the FSA Guidelines and the Guidance on the use of HEAP and FSA in light of the consideration on the human element.

42 Incorporation of the human element is described in paragraph 3.4 and Appendix 1 of the FSA Guidelines, and Figure 4 specifies tasks required to incorporate Human reliability Analysis (HRA) in each step of FSA. It can be understood by Appendix 1 of the FSA Guidelines that HRA can be conducted independently from FSA. On the other hand, the FSA Experts Group found, through review of SAFEDOR FSA reports, that it is necessary to consider the human element within the process of FSA. Therefore, it is recommended to consider either:

.1 incorporation of Appendix 1 into the main body of the FSA Guidelines (specifically paragraphs 5 to 9 of Appendix 1 should be incorporated into each step of FSA in the main body of the FSA Guidelines); or

.2 that human element consideration should be mentioned in each step (1 to 5) as well as in the process of problem definition (paragraph 4 of the FSA Guidelines) of FSA and with relevant reference to paragraphs of Appendix 1.

43 The FSA Guidelines can be revised/improved in terms of human element consideration based on the discussion of the above matters. It should be borne in mind that the FSA Guidelines should be concise and easily understandable when the tasks as described in 42.1 or 42.2 above are conducted.

44 In this connection, annex 1 of MSC/Circ.1022-MEPC/Circ.391 "Guidance of the use of Human Element Analysing Process (HEAP) and Formal Safety Assessment (FSA) in the IMO rule-making process should be reconsidered and revised, if necessary, in a way that the human element is considered within the process of FSA.

How to present reports (TOR 3.13)

45 Paragraph 48 of document MSC 87/18 presents an opinion that a summary of FSA should be clear enough and understandable for decision making by the relevant bodies of IMO, while its main report should be complete and detailed enough for review.

46 The results of each FSA conducted by the former SAFEDOR project were reported by a summary report, supported by an information document that presented a full report of the FSA. It was found, during the review process of the FSA Experts Group, that some data and information of FSA conducted were available through internet websites that were referred to in the FSA report, and such data and information were useful for the review of the FSA studies.

47 It was noted, during the review process of FSA Experts Group, that commercially available casualty databases might not be available for review due to the contractual terms between the data provider and user. It was also noted that when using commercial casualty databases, it is recommended that the FSA team makes the used data available to reviewers in some form, in order to be able to validate the FSA results.

48 It was felt that for a high level FSA which may totally assess the safety of a type of ship, the limitation of the length of the report prescribed in Appendix 8 of the FSA Guidelines is too strict to present all the necessary information, and the limitation of the length of the FSA report should be reviewed.

49 Therefore, it would be advisable that results of FSA may be reported by:

.1 a summary report of limited length;

.2 a full report that includes detailed presentation and explanation; and

.3 an internet site which is accessible by nominated reviewers.

50 There was a view, supported by some members, that in order for FSA to assist in the IMO rule-making process, the summary report of FSA should be clear, comprehensive and well understandable for non-experts of FSA and the full report should be exhaustive for review by FSA experts.

How to review FSA studies (TOR 3.14)

51 The method of review of FSA studies is described in the revised annex 3 "Guidance for practical application of FSA to the IMO rule-making process" (MSC-MEPC.2/Circ.6) of the "Guidance on the use of HEAP and FSA in the IMO rule-making process" (MSC/Circ.1022-MEPC/Circ.391).

52 The FSA Experts Group was established to review the results of five FSA studies conducted by the former SAFEDOR project, and the group worked according to annex 3.

53 During the review process of the FSA Experts Group, it was found that the list of review points in paragraph 28 of annex 3 does not properly cover all the aspects of review points. It was felt that the review points should include adequacy of:

.1 scope of the FSA;

.2 definition of the problem;

.3 identified hazards and their ranking;

.4 risk models and calculated risks;

.5 identified RCMs and RCOs;

.6 selection of RCOs for Cost Benefit Analysis (CBA),

and the review points should also include the relevance of:

.1 method of reaching agreement in groups;

.2 method of HAZID;

.3 method of calculation of risks;

.4 method and indices for CBA; and

.5 sensitivity and uncertainty analysis,

as far as they affect the results of the FSA.

54 As for the FSA Experts Group, it was felt that it should be clearly mentioned that:

.1 Member States as well as organizations in consultative status with IMO should have the right to nominate experts for the review group;

.2 the review work can be conducted by holding meetings of the group as well as by correspondence; and

.3 the review work should be conducted concisely in order to give timely conclusion to the Committee/Sub-Committee.

55 Therefore, annex 3 of the Guidance on the use of HEAP and FSA in the IMO rule-making should be reviewed in light of the matters mentioned in paragraphs 53 and 54 above. There is a suggestion that once the Guidance is revised, this should be mentioned in the Guidelines on the method of work of the committees.

Any other business

56 It was sometimes recognized that international rules applicable to ships depend on the type and size as well as the construction date of ships and this fact should be well understood in casualty data analysis and FSA. In relation to this recognition, the following proposal was made:

.1 at the end of paragraph 4.2 of Appendix 8 "Standard Reporting Format" of the FSA Guidelines, add:

"4.2 Casualty statistics ... <u>including data analysis (i.e. time dependence, ship size influence, variability assessment, hypothesis testing, etc.)</u>";

.2 at the end of first sentence of the current paragraph 3.2.2 of the FSA Guidelines, add "<u>as required in paragraph 4.2 of annex 8</u>".

57 The group, while recognizing that this would not be within its terms of reference, felt that this proposal could be presented to the attention of the Committee.

Conclusion

58 The group reviewed and considered points of discussion and considerations raised in documents MSC 87/18 and MSC 87/WP.7. The group, therefore, prepared some suggestions for revising paragraphs of the FSA Guidelines as set out in paragraphs 5 to 8, 10, 15, 17, 24 to 28 and 36 of this document.

59 The group also prepared discussion points and suggestions for further work on the revision of the FSA Guidelines and the Guidance on the use of HEAP and FSA in the IMO rule-making process, as set out in paragraphs 9, 13, 14, 18, 29, 33, 35, 40, 42 to 44, 47 to 50, 53 to 57 of this document.

60 The group noted that the issue of the cost/benefit indicator for environmental issue is currently under consideration in the MEPC (paragraphs 31 and 32).

61 The group could not prepare full draft texts of the revised FSA Guidelines and Guidance on the use of HEAP and FSA in the IMO rule-making process, but believes that this document meets the given terms of reference and contributes to the consideration of the Committee on Formal Safety Assessment.

Action requested of the Committee

62 The Committee is invited to consider this report, in particular the conclusion in paragraphs 58 to 61 and take action as appropriate for review and improvement of:

.1 the Guidelines for Formal Safety Assessment (FSA) for use in the IMO rule-making process; and

.2 the Guidance on the use of Human Element Analysing Process (HEAP) and Formal Safety Assessment (FSA) in the IMO rule-making process.