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Impact assessment compilation part 2; Comparison between IMO FSA and the EC IA

European Maritime Safety Agency

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Task and objective: Compare the EC Impact Assessment Guidelines to the IMO Formal Safety Assessment Guidelines.

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1 PREFACE

This report is a deliverable according to the Framework Service Contract Number EMSA/OP/10/2013. This is the third study commissioned by EMSA related to the damage stability of passenger ships. The previous studies focused on ro-ro passenger ships.

This study aims at further investigating the damage stability in an FSA framework in order to cover the knowledge gaps that have been identified after the finalization of the previous EMSA studies and the GOALDS project.

The project is separated in to 6 studies:

- Identification and evaluation of risk acceptance and cost-benefit criteria and application to risk based collision damage stability
- Evaluation of risk from watertight doors and risk based mitigating measures
- Evaluation of raking damages due to groundings and possible amendments to the damage stability framework
- Assessment of cost effectiveness or previous parts, FSA compilation and recommendations for decision making
- Impact assessment compilation
- Updating of the results obtained from the GOALDS project according to the latest development in IMO.

The project is managed by DNV-GL and is established as a joint project which includes the following organisations:

Shipyards/designer:

Euroyards representing Meyer Werft, Meyer Turku, STX-France and Fincantieri

Knud E. Hansen AS

Operators:

Royal Caribbean Cruises

Carnival Cruises

Color Line

Stena Line

Universities:

National Technical University of Athens

University of Strathclyde

University of Trieste

Consultants:

Safety at Sea

Software manufacturer:

Napa OY

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4 ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
BIMCO	Baltic and International Maritime Council
CATCH	Cost of Averting a Ton of CO_2 equivalent Heating effect
CLWP	Commission's Legislative and Work Programme
DALY	Disability Adjusted Life Year
DG	Directorate General
EC	European Commission
ECDIS	Electronic Chart Display and Information System
EU	European Union
ENC	Electronic Navigational Charts
FSA	Formal Safety Assessment
GCAF	Gross Cost of Averting a fatality
HEAP	Human Element Analysis Process
HTA	Health Technology Assessment
IA	Impact Assessment
IAB	Impact assessment Board
IACS	International association of Classification Societies
IAIA	International Association for Impact Assessment
IASG	Impact Assessment Steering Group
ICFTU	International Confederation of Free Trade Unions
ICS	International Chamber of Shipping

III Code	IMO INSTRUMENTS IMPLEMENTATION CODE (III CODE)
INTERCARGO	International Association of Dry Cargo Ship-owners
INTERTANKO	International Association of Independent Tanker Owners
IPCC	Intergovernmental Panel on Climate Change
ISC	Inter-Service Consultation
IUMI	International Union of Marine Insurance
JRC	Joint Research Centre
MCDM	Multi-Criteria Decision Making
NCAF	Net Cost of Averting a Fatality
GISIS	Global Integrated Shipping Information System
IMO	International Maritime Organisation
MEPC	Maritime Environmental Protection Committee (of IMO)
MSC	Maritime Safety Committee (of IMO)
OCIMF	Oil Companies International Marine Forum
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget (in US)
PLL	Potential Loss of Life
PPP	Purchasing Power Parity
P&I	Protection and indemnity insurance
RCO	Risk Control Option
RIA	Regulatory Impact assessment
SIGTTO	The Society of International Gas Tanker and Terminal Operators
SG	Secretary General
SPP	Strategic Planning & Programming
VOLY	Value Of a statistical Life Year
VOSL	Value Of s Statistical Life
VPF	Value of Preventing a Fatality
VSL	Value of a Statistical Life
QALY	Quality Adjusted Life Year
QRA	Quantitative Risk assessment

Note:

VPF, VSL, VOSL are different terms for the same

VOLY, and the value of preventing a DALY or gaining a QALY are also similar, but not necessarily identical (Authors use slightly varying definitions)

5 EXECUTIVE SUMMARY

The EC Impact Assessment (IA) and the IMO FSA Guidelines and processes are compared in order to identify similarities and differences.

The EC IA evaluation is based on the IA Guidelines of 2009 (EC, 2009), extended with Tool #12: 'Risk Assessment and Management' and tool #27 'Impact on Health' in the EC IA Guidelines of 2014.

The evaluation of the IMO FSA Guidelines is based on the 2015 version (IMO, 2015a), and 20 years of experience with the development of the guidelines and its use at IMO.

It is concluded that whilst EC Impact Assessment and the IMO FSA Guidelines have different origins and have developed from different traditions, there are many similarities between the two Guidelines and methodologies and processes.

The main similarities are:

- IA and FSA are used to assess the effect of regulatory changes compared to the current situation
- IA and FSA will contain statements of the future that can be verified later
- IA and FSA are meant to support decision making
- IA and FSA are meant to provide transparency and openness
- IA and FSA are evidence or fact based
- IA and FSA both result in extensive use of data and analysis
- IA and FSA rely on previous IAs and FSAs
- IA and FSA gradually build standardized models
- IA and FSA are referred to as 'scientific' or inspired by 'scientific methods'
- IA and FSA both exist in qualitative and quantitative versions, with a preference for the quantitative
- IA and FSA applications result in a need for review processes
- IA and FSA are multidisciplinar
- IA and FSA may be very extensive analysis (many man-years)
- IA and FSA tend to identify lack of knowledge, and therefore need for research
- IA and FSA methodologies and traditions are both traced back to the sixties
- IA will in many cases have to include risk assessment (Most IA Guidelines contain one chapter or more about risk assessment).

There are also differences:

Table 1: Differences between EC IA and IMO FSA	
EC IA	**IMO FSA**
Origin amongst economists	Origin amongst engineers
Origin in public management	Origin in hazardous industries
Cost – benefit analysis	Cost effectiveness Analysis
Internalizing external costs	Reducing Risk
Broad Scope	Narrow scope
Unclear definitions of decision criteria	Clear definition of decision criteria
Often with limited scope for quantification	Always quantitative
Carried out by EC units	Carried out external to IMO
Review by EC Impact Assessment Board	Reviewed by IMO EG/FSA (Open participation)
VPF by human Capital Approach	VPF by revealed preferences (LQI)

In addition, there are a large number of differences between the EC IA Guidelines and the IMO FSA Guidelines, which stems from the large differences between the two organizations where the guidelines are used. EC is the executive arm of EU with many resources available; IMO is an UN body, with a secretariat and with limited resources.

In some aspects, it is not sufficient to compare the EC IA Guidelines with the IMO FSA Guidelines, since there is no such one to one relation. For example many of the issues covered in the EC IA Guidelines, are better compared to the IMO 'Method of Work' Guidelines (IMO, 2015b).

Both EC IA and IMO FSA could learn from each other:

For many decision making processes at IMO, there would be benefits from extending the FSA Guidelines to complete IA Guidelines.

The IMO FSA Guidelines contain clear decision parameters and criteria. This is missing in the EC IA Guidelines, resulting in inconsistencies between different IAs and non-optimum use of resources.

6 ABSTRACT

The report compares the EC IA and the IMO FSA regulatory decision-making processes by comparing the associated Guidelines. The Guidelines have distinctly different origins. The EC IA Guidelines are based on public management traditions, whilst the IMO FSA Guidelines are developed from the risk assessment traditions in the hazardous industries. The professions involved in the development are also different; the EC IA Guidelines seems to have been developed by economists, whilst the IMO FSA Guidelines are based on engineering risk traditions. Despite these very different traditions and backgrounds, the two Guidelines have a lot in common. The reason is that in principle the two Guidelines have the same purpose: to improve regulations by applying rational, fact based analysis. The large differences come from the fact that the EC IA Guidelines have very wide scope, from regulations in the consumer markets to the finance sector, from health and safety to competition law. The IMO FSA Guidelines are applicable mainly to safety in shipping. When the Guidelines are both applied on issues relating to safety, the similarity are even more pronounced: The decision parameters are largely the same.

7 INTRODUCTION

7.1 Regulatory Impact Assessment

According to IAIA, impact assessment, simply defined, is the process of identifying the future consequences of a current or proposed action.

The purposes of RIAs are to improve the regulatory process by:

- Primarily, informing policy makers about potential economic, social, and environmental ramifications
- Improving transparency so that contributions to sustainability and better regulation are disclosed and special interest lobbying (single cause organizations) is discouraged
- Increasing public participation in order to reflect a range of considerations, thereby improving the legitimacy of policies
- Clarifying how public policy helps achieve its goals and priorities through policy indicators
- Contributing to continuous learning in policy development by identifying issues that inform ex-post review of policies

RIA intends to use scientific approaches to regulatory processes, and to be evidence or fact based.

Whilst there is no general agreement on where and when RIA originated, many authors refers back to the development in the US in the sixties. According to OECD, the late 1960s and early 1970s marked a period in US history of major expansion of health, safety and environmental regulations. Numerous government agencies were set up to protect e.g. the American workplace, the environment, highway travellers, and consumers. However, the first RIA programmes during the Nixon administration were not successful. It was not until the Reagan administration the RIA programme in the US had matured. The Reagan regulatory programme went beyond previous programmes in a number of important aspects. Firstly, it required that agencies not only do cost benefit analyses for major regulations but also that they should issue only regulations that maximize net benefits (social benefits minus social costs). That is, it formulated the first cost-benefit test. Secondly, it required the agencies to send their proposed regulations and cost benefit analyses to Office of Management and Budget (OMB) for approval before the regulations could enter into force. Thirdly, it required agencies to review their existing regulations to see which ones could be withdrawn or scaled back. Finally, the President created The Task Force on Regulatory Relief, chaired by the Vice President to oversee the process and serve as an appeal mechanism if the agencies disagreed with OMB's recommendations. Together these reforms established a centralization of regulatory oversight authority, now often advocated by OECD.

The OECD member countries have been leading the development of RIA. Most OECD Member countries now have systems for RIA in place. On 27 May 1997, ministers of Member countries endorsed the OECD Report on Regulatory Reform, which recommends that governments "integrate regulatory impact analysis into the development, review and reform of regulations".

RIA comes in many forms that reflect various policy agendas of governments and international organizations. Some countries assess business impacts, while others assess administrative

and paperwork burdens. Others use full-fledged cost-benefit analysis based on social welfare theories. Environmental Impact Assessment (EIA) is used to identify potential impacts of regulations on environmental quality. EIA is probably the most widespread form of IA, and according to IAIA, all nations except North Korea and South Sudan have national requirements for EIA. Other regulators assess how proposed rules affect sub-national governments, or groups, or small businesses, or international trade.

According to OECD (1997) the methods used by regulators in OECD countries to reach decisions can be simplified into five categories:

1. Expert – The decision is reached by a trusted expert, either a regulator or an outside expert, who uses professional judgement to decide what should be done.
2. Consensus – The decision is reached by a group of stakeholders who reach a common position that balances their interests.
3. Political – The decision is reached by political representatives based on partisan issues of importance to the political process.
4. Benchmarking – The decision is based on reliance on an outside model, such as international regulation.
5. Empirical – The decision is based on fact-finding and analysis that defines the parameters of action according to established criteria.

All nations and international organizations varies in the mix of these five elements that are used for regulatory decision making, and can be linked to e.g. cultural differences and historical experience. RIA falls clearly in category 5: Empirical, evidence or fact based. However, it should be realized that the other elements always comes into play to a varying degree in all regulatory decision making. Such variations between countries are studied in detail by OECD, and are published in OECD Country reviews. OECD considers EC IA to be state-of-the-art.

7.2 Formal Safety Assessment (FSA)

FSA comes from the tradition of technical risk assessment, where many authors are able to trace the methods used back to the Nuclear Industry and the sixties. Many of the techniques used have their origin in the nuclear industry. The FSA background is typically presented as an evolution from this tradition. The IACS FSA Training course presents the evolution by the following summary:

- Nuclear Industry in 60s: Probabilistic Safety Assessments
- Chemical Industry in 70s: QRA, Seveso Directive I and II
- Offshore Industry in 80s:
    - QRA, Industrial Self-Regulation Regime in Norway, Safety Case Regimes in UK
- Shipping Industry since 90s: FSA
    - 1992, UK House of Lords, Lord Carver Report
    - 1993, MSC 62: UK proposes FSA concept at IMO
    - 1997, MSC 68: FSA Interim Guidelines

- 2001, MSC 74: FSA Guidelines
- 2007, MSC 83: Consolidated Text for FSA Guidelines (including acceptance criteria for safety and FSA review process)
- 2013, MSC 92: Revised FSA Guidelines (including criteria for oil pollution, and separate guidelines for FSA and HEAP)
- 2014, MSC 94: Revised FSA Guidelines, Rev 1 (relation to unplanned output)

In most respect the IMO FSA Guidelines are quite traditional risk assessment guidelines, but with the focus of justifying rules and regulations, and therefore with a similar objective as the EC IA Guidelines. Most other risk assessment guidelines are focused on analysing concrete/specific physical assets or technical systems.

8 COMPARING EC IA AND IMO FSA

Impact Assessment (IA) or more precisely Regulatory Impact Assessment (RIA) as well as IMO FSA is based on the idea that Regulations should be justified by analysis, facts and evidence and be presented in a transparent way.

8.1 Motivation

8.1.1 European Commission - EC

The EC IA Guidelines, EU(2009), makes the fundamental ideas clear by stating that

- Impact assessment is a key tool to ensure that Commission initiatives and EU legislation are prepared on the basis of transparent, comprehensive and balanced evidence.
- Impact assessment is an aid to political decision-making, not a substitute for it.
- While many actors may be involved in an impact assessment, the lead service remains fully responsible for its quality. The Impact Assessment Board provides support and advice, and scrutinizes the quality of all impact assessments.

Each unit/function in each DG is responsible for IA within own field, but is supported by Secretariat General's Impact Assessment Unit (SG.C.2). The Impact Assessment Board (IAB) can also be consulted on methodological issues.

8.1.2 International Maritime Organisation (IMO)

At IMO the motivation for Formal Safety Assessment (FSA) is quite similar. IMO(2013): 'FSA can be used as a tool to help in the evaluation of new regulations for maritime safety and protection of the marine environment or in making a comparison between existing and possibly improved regulations, with a view to achieving a balance between the various technical and operational issues, including the human element, and between maritime safety or protection of the marine environment and costs'. 'The decision makers at IMO, through FSA, will be able to appreciate the effect of proposed regulatory changes in terms of benefits (e.g. expected reduction of lives lost or of pollution) and related costs incurred for the industry as a whole and for individual parties affected by the decision. FSA should facilitate the development of regulatory changes equitable to the various parties thus aiding the achievement of consensus.'

However, the IMO FSA Guidelines also suggest 'The FSA methodology can be applied by, a Committee, or an instructed subsidiary body, to provide a balanced view of a framework of regulations, so as to identify priorities and areas of concern and to analyse the benefits and implications of proposed changes.' The idea of carrying out FSAs by e.g. a Committee has proven to be unrealistic. The way of working in IMO committees does not allow for the type of analysis required in an FSA. All FSAs carried out so far have been carried out by external projects, and submitted to IMO when finalized.

8.2 The key Concepts

8.2.1 EU

The key concept of the EC IA Guidelines is internalizing external costs. Activities give rise to environmental impacts, accidents, negative health effects, and infrastructure wear and tear. In contrast to the benefits, the costs of these effects are not fully borne by

owners/users/industry. Without policy intervention, users do not consider the so-called external costs when they make decisions. Users are thus faced with incorrect incentives, leading to welfare losses.

The internalisation of external costs means making such effects part of the decision making process – external costs are internalized in the decision making process. According to the welfare theory approach, internalisation of external costs with market-based or other instruments may lead to a more efficient use of resources, reduce the negative side effects of activities and improve the fairness between users.

Within the transport sector, internalising the external costs has been an important issue for transport research and policy development for many years in Europe and worldwide. A substantial number of research projects, including projects supported by the European Commission, suggest that implementing market-based instruments inspired by the economic theoretical concept of marginal social cost pricing could yield considerable benefits. Fair and efficient transport pricing has also been advocated in a number of policy documents issued by the European Commission, notably the 2011 White Paper on Transport.

The most concrete useful document for external cost pricing in the transport sector is the Update of the Handbook on External Costs of Transport (Korzhenevych et. al (2014)). This handbook explains the basic concepts well and contains external cost values for many of the important air pollutants and greenhouse gases also from shipping, dependent on area of release and on a per tonne basis.

8.2.2 IMO

The key concept in the IMO FSA Guidelines is risk to life, health, property and the environment. The purpose of the Guidelines is to define a process to reduce the risk to a level that is tolerable and ALARP. ALARP implies that all cost effective RCOs are implemented, and cost effective e.g. for risk to life implies that all RCOs that prevent a fatality at a cost less than VPF should be implemented. On environmental effects the IMO FSA Guidelines only contain criteria or external costs for accidental releases of oil.

8.2.3 Comparison

It might be easy to jump to the conclusion that the two guidelines are totally unrelated, since the basic concepts are so different. This conclusion is not correct. What is correct is that the basic concepts for RIA come from economic theory, the basic concepts for FSA comes from engineering practice.

However, when a RIA is dealing with safety issues, which is often the case, RIA ends up with basing decision on the same parameters as an FSA (cost of preventing fatalities, cost of preventing loss of a life year in good health etc.). The similarity becomes even clearer when the parameters used for decision-making are compared (see below).

The use of the term risk is interesting in this respect. In an FSA, the focus is always a particular ship type (or a system, component or equipment), and all risks are calculated on a per ship-year basis. When analysing the environmental impact of shipping, some of the releases are not referred to as a risk, but as regular releases. However, in the impact assessment such releases ends up as a risk (a risk of premature death, a risk of global heating exceeding the 2ºC target). This illustrates the point that the Handbook on External Costs of Transport has at least partially solved. The method of arriving at a per tonne cost of air pollutants is models that look into

1) The release from e.g. a ship
2) The atmospheric spreading of the pollutants
3) The concentration in Populated Areas
4) The population in the area affected
5) Dose Response Models
6) The estimation of life years lost and
7) The VOLY.

Therefore, by such analysis the VOLY of population ashore is transferred to a cost per tonne of pollutant from the ship. Thereby, per ship-year analysis is trivial, since the cost per tonne can be used directly in an FSA type of analysis. It is not in conflict with the FSA Guidelines to include external cost of pollution in the presentation of the NCAF. However, such an analysis has not been presented to IMO yet.

8.3 The who, what, how and when?

8.3.1 Who carries out IA and FSA?

8.3.1.1 EU

In EU the different units of the DG are responsible for carrying out the IAs. In their work, external consultants may be used, and the EU Joint research Canters contribute to many IAs.

8.3.1.2 IMO

IMO does not have own resources to carry out an FSA. In reality it has always been a Flag state, a NGO or a group of Flag States and NGOs that carry out an FSA. The EU research programmes have also contributed a lot to IMO FSAs. The motivation for those carrying out FSAs is in most cases to increase the chance of success in having a proposed regulation agreed, adopted and implemented.

8.3.2 The questions asked

8.3.2.1 EU

In an EC IA the following questions needs to be answered

- What is the nature and scale of the problem, how is it evolving, and who is most affected by it?
- What are the views of the stakeholders concerned?
- Should the Union be involved?
- If so, what objectives should it set to address the problem?
- What are the main policy options for reaching these objectives?
- What are the likely economic, social and environmental impacts of those options?
- How do the main options compare in terms of effectiveness, efficiency and coherence in solving the problems?
- How could future monitoring and evaluation be organised?

8.3.2.2 IMO

In an IMO FSA the questions asked are:

- What might go wrong?

- How likely is it?
- How bad?
- How can the situation be improved?
- How much better will it become?
- How much will it cost?

8.3.2.3 Comparison

The questions may seem rather different, but in reality, they are not. For example in an FSA stakeholders are involved both in the Hazid and in the identification of risk control options. Similarly, the cost effectiveness evaluation of risk control options that are carried out in an FSA is also carried out in an EC IA, if relevant. The actual decision parameters are the same: Cost must be less that the benefits, to justify a regulation. However, at IMO there is a preference for not converting life saved to its monetary value, as is typically done in an EC IA. The preference is to present the cost effectiveness of each risk control options in terms of $ per life saved. Two parameters are presented to the decision maker, GCAF and NCAF.

GCAF = Cost of RCO/Lives saved = ΔCost/ΔPLL

NCAF = (Cost of RCO – Economic Benefit of RCO)/Lives Saved

= (ΔCost - ΔEconomic Benefit)/ΔPLL

If there are environmental costs or benefits, these should be included in ΔEconomic Benefit. The point is that GCAF and NCAF are properties of the RCOs, and the VPF is only relevant when it is decided to implement the RCO or not.

8.3.3 The Steps

8.3.3.1 EU

The steps of an EC IA are as follows:

1 Identifying the problem
- Describe the nature and extent of the problem.
- Identify the key players/affected populations.
- Establish the drivers and underlying causes.
- Is the problem in the Union's remit to act?
- Does it pass the necessity and value added test?
- Develop a clear baseline scenario, including, where necessary, sensitivity analysis and risk assessment.

2 Define the objectives
- Set objectives that correspond to the problem and its root causes.
- Establish objectives at a number of levels, going from general to specific/operational.
- Ensure that the objectives are coherent with existing EU policies and strategies, such as the Lisbon and Sustainable Development Strategies, respect for Fundamental Rights as well as the Commission's main priorities and proposals.

3 Develop main policy options

- Identify policy options, where appropriate distinguishing between options for content and options for delivery mechanisms (regulatory/non-regulatory approaches).
- Check the proportionality principle.
- Begin to narrow the range through screening for technical and other constraints, and measuring against criteria of effectiveness, efficiency and coherence.
- Draw-up a shortlist of potentially valid options for further analysis.

4 Analyse the impacts of the options
- Identify (direct and indirect) economic, social and environmental impacts and how they occur (causality).
- Identify who is affected (including those outside the EU) and in what way.
- Assess the impacts against the baseline in qualitative, quantitative and monetary terms. If quantification is not possible explain why.
- Identify and assess administrative burden/simplification benefits (or provide a justification if this is not done).
- Consider the risks and uncertainties in the policy choices, including obstacles to transposition/compliance.

5 Compare the options
- Weigh-up the positive and negative impacts for each option on the basis of criteria clearly linked to the objectives.
- Where feasible, display aggregated and disaggregated results.
- Present comparisons between options by categories of impacts or affected stakeholder.
- Identify, where possible and appropriate, a preferred option.

6 Outline policy monitoring and evaluation
- Identify core progress indicators for the key objectives of the possible intervention.
- Provide a broad outline of possible monitoring and evaluation arrangements.

8.3.3.2 IMO

The steps of FSA are as follows:

1. Identification of HAZARDS
2. Risk Analysis
3. Risk Control Options
4. Cost Benefit Assessment
5. Recommendation

8.3.3.3 Comparison

Similarity

Much of what is described in the EC IA step 1 is described according to the introduction to the FSA Guidelines (Some refers to this as step 0 of FSA). In addition, at IMO, the question 'Is it within the remit of IMO to act?' is also asked. However, the most important issues relating to this question is covered by the 'Method of Work' Guidelines (IMO, 2015b), which for example contains the question 'Is the subject addressed by the proposal considered to be within the scope of IMO's objectives and the Strategic Plan for the Organization?' The EC IA criterion:

"Does it pass the necessary added value test?" is similar to the criteria for cost effectiveness at IMO. However, this question is also asked according to the 'Method of Work' Guidelines. The formulation is 'Has the analysis of the issue sufficiently addressed the cost to the maritime industry as well as the relevant legislative and administrative burdens?' The EU principle of proportionality is also similar to cost effectiveness of the RCOs, and a question in the 'Method of Work' Guidelines also relates to proportionality. The formulation is 'Has an analysis been provided that demonstrates and documents the practicality, feasibility and proportionality of the proposed measure?' In this context, it is worth noting that whilst the 'Method of work' Guidelines are mandatory, the IMO FSA Guidelines are not. At IMO there is an ongoing debate on the relationships between the two Guidelines, and IMO may decide that a submitted FSA satisfies all requirements of the 'Method of Work' Guidelines, or that it does not (IMO Secretary General, 2015). An FSA is therefore not a guarantee for having a specific item put on the agenda.

Whilst the steps are described differently, both the EC IA and the IMO FSA (combined with the 'Methods of Work' Guidelines) boils down to the same question: Would society at large be better off with the regulation, than without it?

Difference

The real big difference in the methodology description of the EC IA and the IMO FSA comes from the fact that the EC IA is meant to be used for anything ranging from regulations in the finance to agricultural sector, or from consumer rights to safety. The IMO FSA Guidelines are focused on use for safety regulations and for accidental oil pollution. Therefore, the IMO FSA Guidelines are much more specific in its description of methods. Obviously, the purpose of a safety regulation is to reduce risks to life and health; therefore, the IMO FSA Guidelines are focused on analysing and reducing risks. For the EC IA Guidelines safety regulations are only one of the possible applications, and therefore the EC IA Guidelines are more generic, or less specific.

8.3.4 When is IA or FSA required?

8.3.4.1 EU

The EC IA guidelines do not define which Commission initiatives need to be accompanied by an IA. The Secretariat General/Impact Assessment Board and the departments concerned decide this each year. In general, IAs are necessary for the most important Commission initiatives and those which will have the most far-reaching impacts. This will be the case for all legislative proposals of the Commission's Legislative and Work Programme (CLWP) and for all non-CLWP legislative proposals which have clearly identifiable economic, social and environmental impacts (with the exception of routine implementing legislation) and for non-legislative initiatives (such as white papers, action plans, expenditure programmes, negotiating guidelines for international agreements) which define future policies. This will also be the case for certain implementation, which are likely to have significant impacts.

8.3.4.2 IMO

FSA is not mandated in any way at IMO. Most initiatives to carry out FSAs have come from member states or NGOs, actually only European member states, Japan, IACS, and ICFTU. Some FSAs have also been carried out in EU Research Projects, and the EMSA II and III project initiatives, which are following the IMO FSA Guidelines, were taken by EMSA. The initiative to carry out the FSA on ECDIS came from the IMO NAV Subcommittee, but since IMO does not normally support such initiatives, Norway, Sweden, Denmark, and Finland ended up

funding the various parts of the project activities, and DNV carried out the work. Similarly, there was a requirement to carry out FSAs on the e-navigation strategy. Norway funded this work and DNV carried out the study. The only exceptions, where it seems that IMO funds similar projects, are some fact-finding studies on environmental issues funded by grants from a subset of flag states, on a case-by-case basis.

There was one initiative by IACS to try to set up criteria to mandate FSAs, IACS (2014). IACS suggested the following: 'It is proposed to supplement the criteria in subparagraphs 5, 6 and 7 of paragraph 4.14 of the Committee's Guidelines (MSC-MEPC.1/Circ.4/Rev.2) by adding that the Committee may decide that a comprehensive FSA study needs to be carried out in accordance with the FSA Guidelines (MSC-MEPC.2/Circ.12). In this regard, an FSA study should be carried out if the issue has far-reaching implications, if it is suspected/perceived that a ship type is associated with risks significantly higher than deemed acceptable, or if the cost of a ship type may increase significantly by implementing measures to reduce risks'. This proposal was not supported. Since so few IMO member states are capable or willing to carrying out FSAs, it seems unlikely that FSA will be mandated. However, the success rate for those carrying out FSAs in having their proposal implemented is high; therefore, there are incentives for flag states and NGO to carry out FSAs.

8.4 Procedural Steps

8.4.1 EU

The EC IA is describing the following procedural steps:

1 Planning of impact assessment: Roadmap, integration in the SPP cycle and timetable

2 Work closely with your IA support unit throughout all steps of the IA process.

3 Set up an Impact Assessment Steering Group (IASG) and involve it in all IA work phases.

4 Consult interested parties, collect expertise and analyse the results.

5 Carry out the IA analysis.

6 Present the findings in the IA report.

7 Present the draft IA report together with the executive summary to the Impact Assessment Board (IAB) and take into account the possible time needed to resubmit a revised version.

8 Finalise the IA report in the light of the IAB's recommendations.

9 IA report and IAB opinion(s) go into Inter-Service Consultation alongside the proposal.

10 Submission of IA report, executive summary, IAB opinion(s) and proposal to the College of Commissioners.

11 Transmission of the IA report and the executive summary with the proposal to the other Institutions.

12 Final IA report and IAB opinion(s) published on Europa website by IASG.

13 In the light of new information or on request from the Council or the European Parliament, the Commission may decide to update the IA report.

8.4.2 IMO

There is no quite similar description of procedural steps in the IMO FSA Guidelines, but many of the steps may be found in practice.

Step 1: Since each FSA is planned as a project, such plans will contain budget, timeline, resources, stakeholders to be involved, etc.

Step 2: There is no support unit for FSAs.

Step 3: It is common practice for projects in the maritime area to have a steering group. Steering groups usually consist of more experienced and senior people, and involving the partners that fund the project.

Step 4: Interested parties and stakeholder will normally be involved in the HAZID and in the identification of Risk control Options. Interested parties are normally also funding the project and are involved in the steering committee.

Step 5: Same for FSA as IA.

Step 6: The FSA report is in most cases first presented and accepted by the steering committee prior to submission to IMO.

Steps 7 to 13: There are no such steps for FSA. An FSA report will be made public at the IMODOC website when it is submitted, just like any other IMO submission.

After submission, an FSA is usually first reviewed by IMO EG/FSA. If accepted it is used as basis for recommendations by a subcommittee or a WG in the committee, and possibly agreement and adoption by the committee. Figure 1 describes the process in general.

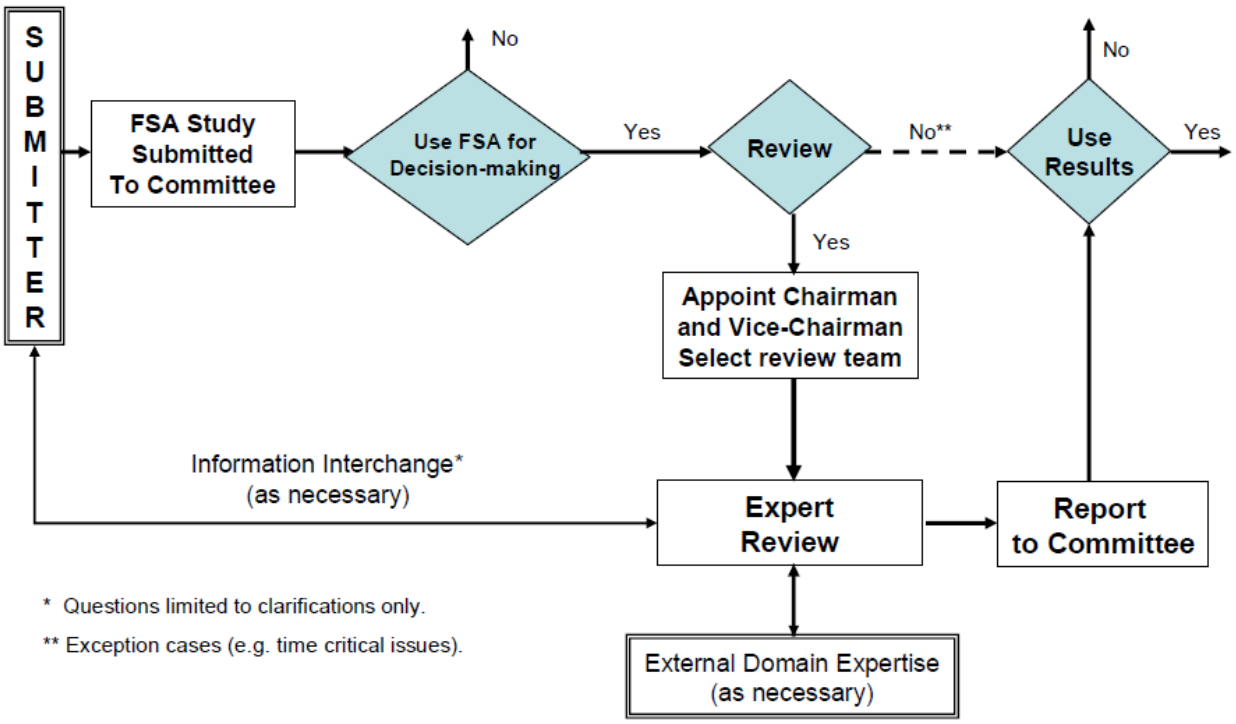

Figure 1: Flow chart for FSA review process

8.5 The Timeline

8.5.1 EU

The Timeline of an EC IA is indicated in Figure 2. This is indicating that an EC IA takes typical one year to carry out – obviously with variations.

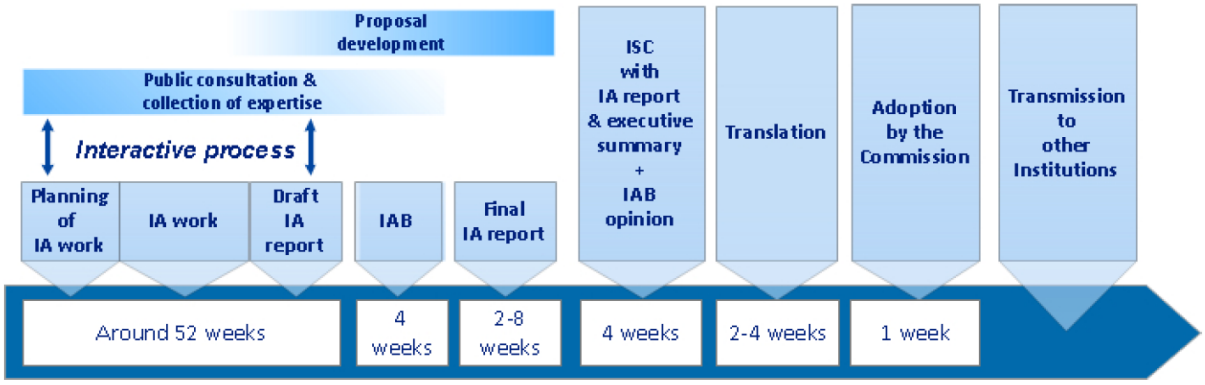

Figure 2: Timeline for an EC IA.

8.5.2 IMO

Similarly a typical FSA takes about a year, maybe more if the issue is complex, or the project involve many organizations.

8.5.3 Comparison

The timelines seem rather similar. However, larger differences are experienced after the EC IA and IMO FSA reports are finalized. At IMO, some processes, despite a conclusive FSA may seem endless. Maybe the most extreme example is the recommendation of 'Free Fall Lifeboat with a Float Free Mode', a recommendation from the FSA-Life Saving Appliances for Bulk Carriers (Norway and ICFTU, 2001). Whilst all other recommendations from the FSA were implemented, 'the free float mode' is still not. The challenge for those involved in the FSA is obviously that it is impossible in practice to follow up such an endless process.

The case of ECDIS was a more positive experience. ECDIS was recommended as a cost effective RCO for passenger ships in Norway (2005) without being followed up at IMO. However, by a number of follow up studies (Denmark and Norway (2006); Denmark et. al (2007a,b)), ECDIS was finally implemented as a mandatory requirement according a schedule starting with passenger ships of 500 gross tonnage and up-wards constructed on or after 1 July 2012; ending with cargo ships, other than tankers, of 10,000 gross tonnage and upwards but less than 20,000 gross tonnage constructed before 1 July 2013, not later than the first survey on or after 1 July 2018.
The implementation took very long, from the first FSA in 2005, until the last implementation date in 2018. On the other hand, the results achieved were much more extensive than initially expected or planned.

For an EC IA the process from finalization of the IA to decision-making is better defined, and in most cases shorter.

8.6 The Report

8.6.1 EU

Figure 3 describes the report requirements of an EC IA.

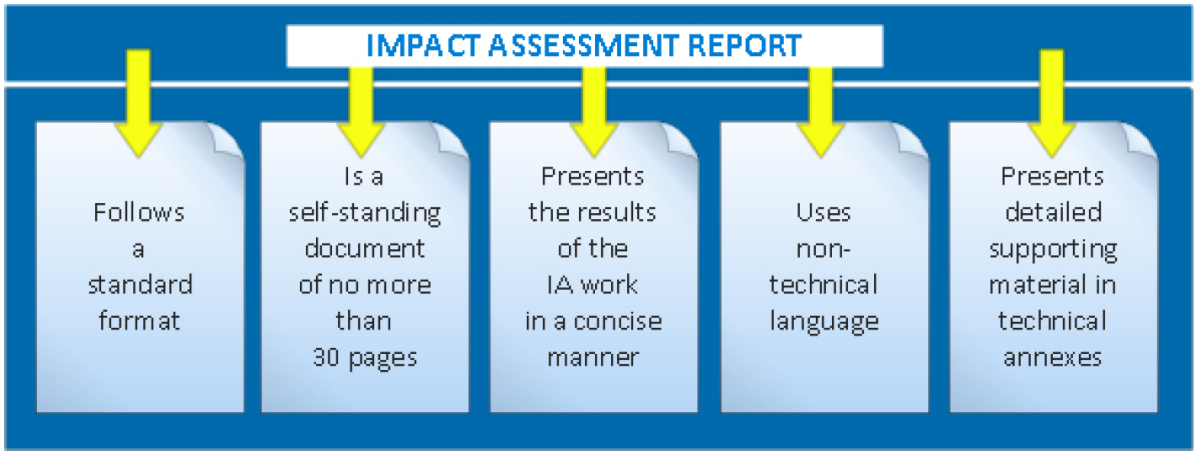

Figure 3: Impact Assessment Report

8.6.2 IMO

The IMO FSA Report is very similar. Also for the IMO FSA report, there is a standard reporting format, even more detailed than the EC IA report format, and the report should not exceed 20 pages. All technical details are in annexes, and the annexes ends up as much more extensive reports, typically hundreds of pages.

8.7 Comparing some standard issues

8.7.1 Facts, politics and the importance of data

The EC IA Guidelines and the IMO FSA Guidelines are based on the same basic ideology with respect to being fact based, and with the purpose of limiting the room for politics. The purpose by both Guidelines is to provide as much factual information and analysis as possible, prior to the 'political' decision making process.

This is made clear by the EC IA Guidelines' in the formulation 'The analysis of political acceptability should however be kept separate from the analysis of substance' and in the section about consultation 'It is important to distinguish evidence from opinions'.

At IMO similar statements are made, for example by the newly elected Secretary General Mr Lim's 'A way forward, means a more proactive IMO where any new regulation is tested and measured against independently verifiable statistics and performance indicators.' This was stated as a response to the activities at IMO related to the underreporting of accidents (ICS et. al, 2014).

8.7.2 The Baseline

Both the EC IA Guidelines and the IMO FSA guidelines specify the need to clearly define the baseline. This is a description of the present situation, and is referred to as the situation with no action, the no-policy change option, the do-nothing option or the zero-option in different IA Guidelines. This is because all Guidelines describe methodologies that are based on estimating (marginal) costs and benefits of the change. In an FSA the baseline is estimated in the FSA Step 2, Risk Assessment. The baseline cannot be established only based on historic data, as there may be new rules and regulations enforced that has not yet materialized as historic data.

8.7.3 Sensitivity Analysis

The EC IA Guidelines specifies 'When the assumptions underlying the baseline scenario might vary as a result of external factors, you need to do a sensitivity analysis to assess whether the impacts of the policy options differ significantly for different values of the key variables. This analysis will have to address the impact of different assumptions on the effectiveness of policy options, and where necessary describe alternative versions of the baseline scenario.' This is obviously the same basic thinking as in the IMO FSA Guidelines, and presumably in most other similar Guidelines and Standards: When assumptions are uncertain and have effect on the final results, there is a need to illustrate such effect by sensitivity analysis. This is done to help the final decision making process, when decisions makers ask questions about the basic assumptions and uncertainties in the data used.

8.7.4 Risk Assessment

The EC IA Guidelines refers to risk assessment, actually using the term 'formal risk assessment' by stating: 'An IA that addresses a problem, in which uncertainty about serious negative outcomes (risk) is an issue, should contain a risk assessment. If these risks may involve irreversible damage or fatalities on an unforeseeable scale, a separate formal risk assessment will have to be carried out on the basis of scientific expertise.' The IMO FSA Guidelines are only about risk assessment, and are therefore more specific and detailed on this topic. In the EC IA Guidelines there are obviously many sectors where the main motivation is to manage risks, from food safety to regulations of the financial markets. Therefore, Risk Assessment will always be a big part of any IA Guideline.

8.7.5 Risk Criteria

Risk criteria in use was reviewed in detail in EMSA(2014). For the 'Value of a Statistical Life', VSL the EC DG Environment (2001) estimates EUR 1.4 million at 2000 prices for accidents (where the average age at death is about 40 years), and a somewhat lower value of EUR 1 million at 2000 prices for a case of environmentally-related premature death (where the average age of fatalities is considerably higher).

The $€_{2000}$ 1.4 million, corresponds to $UD\$_{2012}$ 2.54 million. This is much lower that the criterion used in IMO, which according to the methods described in the FSA Guidelines should be $US\$_{2012}$ 7.66 million (Spouge and Skjong, 2015).

The main difference seems to result from different methods used, and that EU seems not to update the criterion with some acceptable frequency. The EC IA Guidelines also have no reference to such criteria, so presumably different criteria are used in different impact assessment. For example, in the IA on offshore safety (EC, 2011) it is stated that 'the costs related the loss of human life (the statistical value of a life is put at €1-2 million by the European Commission'. In general, whilst it is easy to find the VSL used e.g. in the IAs carried out in the US, the same criteria is difficult to find for EC IAs, although this criteria is often required to be used in an IA. There are many examples where various analyses use different criteria, and where the authors of the studies have had to do separate independent studies to identify such criteria. In such cases, it is somewhat arbitrary what criteria they find in the literature and use. One example where the variation in both VPF and the cost of averting a ton of oil-spill is documented in seven different European studies can be found in Ellis et. al (2012).

8.8 Economic, Social and environmental impact

The EC IA Guidelines specifies that these impacts needs to be analysed, specifically:

- Identify direct and indirect environmental, economic and social impacts and how they occur.
- Identify who is affected by these impacts (including those outside the EU) and in what way.
- Identify whether there are specific impacts that should be examined (fundamental rights, SMEs, consumers, competition, international, national, regional).
- Assess the impacts in qualitative, quantitative and monetary terms or explain in the IA why quantification is not possible or proportionate.
- Consider the risks and uncertainties in the policy choices, including expected compliance patterns.

Since the IMO FSA Guidelines deal mainly with safety and the cost of safety, only these two elements are explicitly accounted for. The economic impacts are also not analysed in any detail, but the basic costs of recommendation will be available in the FSA report, and may be used to estimate e.g. the additional market for yards and equipment manufacturers.

If the FSA Guidelines should consider environmental effects more explicitly this would be an extension of the Guidelines. This would in principle be a logical extension, both sine the FSA Guidelines are a joint work by MSC and MEPC, and because the role of cost-benefit analysis and the principle of internalizing all external costs in the decision making process is even stronger for environmental effects. The lack of criteria for environmental costs is actually problematic in the use of the FSA Guidelines, since there are many cases where there are

conflicts between safety and environmental considerations. Specifically for EMSA III, there are RCOs that result in additional fuel consumption, but the external costs due to the additional release of CO_2. NOx, SOx, NMVOC and Particular Matters are not included in the assessment. In an EC IA, the analysts would presumably refer to the 'Handbook of External Costs', recently updated (Korzhenevych et al., 2014) and providing a comprehensive overview of the approaches for estimating external costs of transport, including air pollution cost from shipping, and recommend a set of methods and default values for use when conceiving and implementing transport pricing policy and schemes. This handbook on the external cost estimation updates the 2008 Handbook (Maibach et al., 2008) with new developments and data generated from research projects and scientific papers in Europe.

In particular for air pollution costs, (Korzhenevych et. al, 2014) report more recent damage costs from the NEEDS project (Preiss et al., 2008). In addition to covering all major pollutants and all Member States, the values provided in NEEDS have several features that are especially relevant for the purpose of policy application. Firstly, they cover all European sea territories. Secondly, they cover not only health effects (that surely correspond to over 90% of the total external effect), but also quantify the side effects of emitted NOx and SO_2 on materials (e.g. buildings), biodiversity and crops. Table 2 reports cost values for all major pollutants calculated for all European sea regions using the EcoSense model (Preiss and Klotz, 2007) in the NEEDS project, updated to the price level of 2010.

Table 2: Damage costs of main pollutants in sea areas, in €$_{2010}$ per tonne

Sea Region	NMVOC	NO_x	$PM_{2.5}$	SO_x
Baltic sea	1100	4700	13800	5250
Black sea	500	4200	22550	7950
Mediterranean	750	1850	18500	6700
North Sea	2100	5950	25800	7600
North-East Atlantic	700	2250	5550	2900

Source: NEEDS (Preiss et al. 2008), updated to year 2010 using EU nominal pro capite GDP (PPP) figures. All values are rounded.

Similarly the cost of averting a ton of CO_2 heating effect (CATCH) was found to be $50 in Skjong (2009), based on IPCC(2008) and the 2^{0}C target. In Korzhenevych et al.(2014), this number is updated to $90 per ton (with an uncertainty band).

The EC IA Guidelines make reference to methods for estimating external effects of transport: 'A handbook with the available estimates and methodologies to assess impacts of noise, air pollution, CO_2 emissions and accidents of transport activities is available on DG TREN website' (The web address is outdated, the new reference is Korzhenevych et al. (2014)).

Actually, the appendix of the EC IA Guidelines contains a detailed description of the principles of internalizing external costs in the decision making process and therefore in an IA by saying:

'Market prices do not reflect the real costs to society: Externalities generate costs ('negative externalities') and benefits ('positive externalities') that are not reflected in market prices. When this happens, the prices of goods and services do not reflect their value to society. In the case of a negative externality, such as pollution, this means that we tend to produce and consume too much of the goods and services that give rise to the externality. The opposite is true of positive externalities.' This is followed by an example of CO_2 emission.

All these well-accepted principles are missing at IMO.

8.9 Competition and free markets

Since EU is concerned about the function of the common market there are a number of issues mentioned (with examples) in the EC IA Guidelines that are not mentioned in the IMO FSA Guidelines. Examples are market access, dominating actors, monopolists, barriers to entry, property rights, imperfect information, split incentives, economy of scale and self-regulation.

8.10 Framework Directives and Goal Based Standards.

The EC IA Guideline describes framework directives as a regulatory option to consider. The point being 'directives should, as far as possible, be general in nature and cover the objectives, periods of validity and essential aspects of legislation, while technicalities and details should be a matter of executive measures or be left to Member States. Framework directives set out general principles, procedures, and requirements for legislation in different sectors. Subsequent 'daughter' directives in each sector must conform to the general requirements of the framework directive. While framework directives offer greater flexibility to Member States, their disadvantage is that, they risk resulting in a diversity of more or less incompatible measures being implemented in different Member States. However, 'daughter directives' should not undo the flexibility gained by being overly prescriptive. In accordance with the Inter-Institutional Agreement on Better Law-making, a proper balance should be struck between general principles and detailed provisions, in a manner that avoids excessive use of Community implementing measures. Example: The National Emissions Ceilings Directive sets out national emissions targets for Member States, without specifying exactly how these are to be achieved.'

The thinking is rather similar to the IMO Goal Based Standard methodology, the definition of which is as follows: Goal-based standards are high-level standards and procedures that are to be met through regulations, rules and standards for ships. GBS are comprised of at least one goal, functional requirement(s) associated with that goal, and verification of conformity that rules/regulations meet the functional requirements including goals. (MSC.1 Circ. 1394. Rev 1)

The EC IA Guidelines also explain the difference between a classical 'Command and Control Policies' and 'performance oriented standards'. According to the definition, most IMO policies belong in the command and control category, although this term is not used at IMO.

8.11 The Steps of Impact Assessment compared to FSA

The EC IA Guidelines specifies three steps

Step 1	**Identification of economic, social and environmental impacts**
Step 2	**Qualitative assessment of the more significant impacts**
Step 3	**In-depth qualitative and quantitative analysis of the most significant impacts**

In an FSA the economic impact will be quantified on a per ship bases, which may be used to identify the impact for the general economy. Purely social impacts are only described in general terms if relevant. For example in connection with e-navigation, there will be such relevant topics, as the changes will affect manning and social life on-board. Environmental impacts are currently not an explicit part of the FSA Guidelines, except accidental oil pollution, but could easily be included if this is decided.

It is also clear that FSA studies are much more focused on quantification than most IAs. At international fora like IMO, this can be understood as resulting from the easier communication of quantified results than qualitative descriptions. In EU there are also larger needs for relating the IA to other political processes, which cannot in general be analysed or described quantitatively.

In any case Table 1 in the EC IA Guidelines demonstrates clearly the much larger scope of an IA than an FSA, when listing all relevant questions relating to economic, social and environmental impacts. Many of the issues are not relevant for an FSA and some are of limited relevance to shipping.

8.12 The Need for Data

Both FSA and IA have an issue with data. Since ideally, everything should be quantified as costs or benefits. In order to identify whether a proposed regulatory change will be associated with more benefits than costs, there will always be a wish to have good data at all levels of analysis.

This may be seen as a 'chicken and egg' issue. What comes first? Some persons seem always willing to claim that analysis cannot be carried out because of lack of data. However, it is clear that both FSA and IA Guidelines are based on the idea that it is better to think through an issue, make (mathematical) models, and if data is missing to populate the models, use expert judgement and well-documented assumptions. This attitude will also increase the value of collecting data, which can be used later to update and improve the analysis and improve the general understanding. Both IA and FSA reuse previous analysis, models and data developed by previous studies to a large degree. This is clearly seen in the reference lists in EMSA III project, but also for example in the EC IA on Offshore safety (EC, 2011), which was heavily reliant on data and reports from the Industry (4 reports) and reports from independent third parties (4 reports). These referenced reports relied on results in a number of other previous reports and studies. Both FSA and IA are clearly influenced by the normal scientific approach, where research builds on previous research and peer reviewed publications.

At IMO there is some unrealistic attitude to the quality of data. The IMO FSA Guidelines say 'Consideration should be given to those data which are already available at IMO (e.g. casualty and deficiency statistics) and to potential improvements in those data in anticipation of an FSA implementation.' The actually situation is that IMO data (GISIS) is almost useless in carrying out FSA. So far, all FSAs have had to rely on data from other sources. GISIS is only used to identify accident investigation reports. Such reports are used in FSAs, but are only available for a fraction of the accidents. This is expected to be improved with the entry into force of the III Code (1/1-2016). It will be an important task in the next few years to improve the reporting in GISIS, in particular to fill in the database entries. Whilst delivering the accident investigation reports is mandated, it is not mandatory to fill in the GISIS database.

The IMO FSA Guidelines also refer to data concerning incident reports, near misses and operational failures that may be very important for the purpose of making more balanced, proactive and cost-effective legislation. Such data must be reviewed objectively and their reliability, uncertainty and validity assessed and reported. In reality, such data are not available in a format that can be practically used in an FSA. Many industry projects have developed databases and data collection schemes that record such data. Such data are used for benchmarking. However, absolute numbers on e.g. equipment reliability cannot be

estimates from such databases, and if this could be done technically, the confidentiality of data would be an additional obstacle.

8.13 Winners and losers

The EC IA guidelines are talking of identifying winners and losers of regulatory changes. In particular, early on in the development of the FSA Guidelines there was a lot of discussion about this, and the need for a 'balance'. This debate has now faded. The reason is that the purpose of safety regulation is not always to find a balance. It can actually be the opposite: To have the safety conscious owners prevail, and the others leave the market. When winners and losers are discussed in an EC IA and the topic may be relevant in an FSA it is because a regulation can have different impacts on e.g. different social groups, income distributional effects on workers, newcomers and established companies etc. Such issues should therefore be analysed when relevant.

8.14 Impacts on the number and the quality of jobs

The effect on job-creation, job-destruction, job-transformation and job-quality is important in an EC IA. This is not an issue in an IMO FSA, although the analysis itself may include information that can be used to estimate the effect on jobs. For example the cost of steelwork used in an FSA to estimate the cost of an RCO, contains an estimate of the amount of work, and therefore the work-hours needed. Similarly, an FSA may recommend a particular equipment to be installed on a ship. The costs are estimated, which could be used to indicate the number of jobs created for the relevant equipment manufacturers, yards etc.

The EC IA is also concerned with the effect on companies, in particular on SMEs. Issues to consider relates to: competitiveness, finance, tax regimes, access to resources and skills, behaviour of competitors, suppliers and consumers, possible loss of competitiveness due to external factors such as the availability of finance, barriers to entry, competition in the market and market structure, impact on innovation, understood as both technological and non-technological innovation (process, marketing, etc.), burden reduction, improved productivity.

These are not issues in an IMO FSA. The reason is mainly the much broader scope of an EC IA.

The EC IA also has a lot of focus on innovation and the competiveness of European industries as compared to non-EU. For obvious reasons, this is not an issue in an IMO FSA. On the other hand, the use of FSA to raise safety standards at international level is generally believed to be an advantage for the innovative industry actors, which in the maritime sector are believed to be predominantly European (at least this is the belief amongst Europeans).

The EC IA even asks the question 'Will a 'first-mover' advantage be generated with other countries likely to follow'. In the European maritime industry, this is always believed to be the case, which is the main reason for continuous investments in research and development and a positive attitude to new regulations.

8.15 Assessing non-market impacts in particular on environment and health

Chapter 9, in the Annex of the EC IA Guidelines, is the only place the EC IA suggest what Norway (2000) referred to as 'Decision parameters and risk acceptance criteria', which later formed the basis for the IMO FSA Guidelines on these matters.

On these matters the EC IA Guidelines, are written more like a review of methods than a guideline, suggesting how the IA should be carried out. The EC IA Guidelines defines the following concepts:

- Quality Adjusted Life Years (QALY)
- Disability Adjusted Life Years (DALY)
- Healthy Life Years (HLY)
- Cost of Illness (COI)
- Human Capital
- Value of Statistical Life (VOSL)
- Value of Statistical Life Year (VOLY)

The methods to arrive at decision parameters are also discussed (willingness to pay, willingness to accept, human capital, stated preferences, revealed preferences, etc.), but the EC IA Guidelines do not conclude with a recommended method or values. This is different from the IMO FSA Guidelines, which result in clear recommendations, which again result in consistent use.

The EC IA Guidelines say 'While there is no uniform methodology for their analysis, it is important to ensure that Commission IAs are backed by sound analysis and that they are consistent'. The problem with this is that there will not be consistency in EC IAs unless the IAs follow the same approach and use the same decision parameters and criteria. The EC IA Guidelines are asking if it is 'more efficient to spend money on reducing air pollution in order to improve health than on improvements in health care'. This is exactly why the same values for e.g. a VOLY should be used in an IA in the Healthcare sector as in the environmental protection area. If not, the use of resources will not be optimum.

Specifically, when it comes to numbers, the EC IA Guidelines just refers to examples, referring to Values of statistical life and life years from the project New Ext (2004)

Table 3: Values of statistical life & life-years

	Value of statistical life (VSL) (€)	Value of life years (VOLY) (€)
Mean	980,000	52,000
Median	2,000,000	120,000

The EC IA suggests using values of €1-2 million for VOSL and €50.000-100.000 for VOLY in Europe. These ranges should be used for the purpose of an Impact Assessment if no more context specific estimates are available.

These numbers are close the proposal by Norway (2000) and used in IMO FSAs. However, the IMO FSA Guidelines provide a method for updating these parameters. The numbers in the EC IA Guidelines now seems outdated. In actual EC IAs carried out at different times, it is also very hard to identify which numbers are actually used. It is therefore extremely difficult to re-use results from previous assessments in a new assessment. For example, it is not known from the report which numbers for a VOLY was used to estimate the cost of a ton of NOx, SOx or PM in the Handbook (Korzhenevych et. al, (2014).

For the CATCH the EC IA is suggesting the following approach: 'ideally greenhouse gas emissions should be valued using the social cost of carbon (SCC). This is the global cost today of an incremental unit of carbon dioxide emitted, summing the full global cost of the damage it imposes over all of its time in the atmosphere. It represents what society should, in theory, be willing to pay now to avoid the future damage caused by additional carbon emissions. The effect of putting a cost on greenhouse gases is to increase the value of options with low carbon impacts relative to those with larger carbon impacts. The question of what value to use for valuing emissions should be discussed with experts in your Impact Assessment Unit. Given uncertainty over the issue, it is likely that a range of values might be best used.'

This approach is not consistent with IPPC (2007) and not consistent with aim of meeting the 2^0 target that has been agreed.

In any case, the IMO FSA Guidelines does not deal with air pollution issues and not with global heating.

8.16 Administrative Burdens

The EC IA Guidelines specifies the need to estimate the cost of administrative burdens in detail. There is also an 'Administrative Burdens Calculator' and an 'EU database on Administrative Burdens' to assist in this respect. Whist administrative burdens are included in the cost of an RCO according to the IMO FSA Guidelines; there is no tools for this available.

8.17 Comparing options

The EC IA guidelines specify that the regulatory options should be compared on the following criteria:

1. Use the following criteria for the comparison of options, and explain how they have been applied:
    - Effectiveness of the option in relation to the objectives
    - Efficiency of the option in achieving the objectives
    - Coherence of the option with overarching EU objectives, strategies and priorities
2. Compare the options against the baseline scenario.
3. Present a summary overview of all positive and negative economic, social, and environmental impacts for the options you have analysed in detail.

In an FSA the effectiveness and efficiency of risk control options shall be presented and quantified by well-defined parameters: Achieved risk reduction (economic and safety), costs, cost-effectiveness etc. Coherence with EU objectives will obviously not be discussed in an IMO FSA, but the coherence with IMO strategic plans needs to be clarified early on in the process in order to have a specific item on the agenda (IMO, 2015b).

Comparing against the baseline scenario is also always done, simply by calculating all changes a risk control option result in compared to the baseline scenario. It is always the change that it the most important decision parameter, not the values (risk) defining the baseline.

Positive and negative effects are summarized, but as indicated previously FSAs normally do not address social effects in any explicit manner, and so far, FSA do not cover environmental effects (except accidental oil pollution).

8.18 Cost-Benefit Analysis

Both the EC IA Guidelines and the IMO FSA Guidelines refers to the use of cost-benefit analysis in a life cycle cost perspective, which generally speaking is the most used method by all institutions that carry out Impact Assessments. There is one very explicit difference between EC IA and IMO FSA Guidelines on one important parameter: the discount rate. In the IMO FSA Guidelines, there is no mentioning of an explicit rate, but 5% has been used in all FSAs. This is a result of the recommendation in Norway (2000). The EC IA Guidelines specifies 4%. Both numbers are too high in the current economic situation, resulting from the problem of keeping such Guidelines up to date. A review carried out in in ISSC (2015), is indicating that about 3% is currently a more correct value, and recommended in various European Governmental Handbooks and Guidelines.

For ship design, the difference does not have much impact when discussing safety measures for ships with a typical lifetime of 20 to 25 years. However, for deciding on the cost of carbon (CATCH above), where the effect of a release now has effects also in thousand year; the so-called depreciation rate of true time preferences has decisive effects. This is discussed in detail in ISSC(2015), and generally in the literature.

8.19 Cost-Effectiveness Analysis

Cost effectiveness analysis is also referenced in both guidelines, and in particular, in the FSA Guidelines cost-effectiveness is a very important decision parameter. The reason for this is actually explained in the EC IA Guidelines 'It is an alternative to cost-benefit analysis in cases where it is difficult to value benefits in money terms.' The point is that when the purpose of a regulation is to save life, decision makers do not like to see 'lives' transformed into $values. Therefore, for each option the cost of averting a fatality, a property of each risk control option is presented to the decision makers and used to rank each option. This is also stated in the EC IA Guidelines 'Cost-effectiveness analysis results in a ranking of regulatory options based on 'cost per unit of effectiveness' of each measure'. The parameters used in the IMO FSA Guidelines are the Net and Gross Cost of averting a Fatality (GCAF/NCAF).

8.20 Ex-ante and Ex-Post IA and FSA

In EU both ex-ante and ex-post IAs are performed regularly, and there are many activities to monitor effectiveness of regulations and to collect data. The EC IA has a final chapter relating to future monitoring and evaluation, and to plan for such monitoring.

At IMO all the FSAs carried out so far have been ex-ante. The only place at IMO where there is some element of thinking of ex-post risk analysis is in GENERIC GUIDELINES FOR DEVELOPING IMO GOAL-BASED STANDARDS, IMO(2011). It is stated under Monitoring that 'Monitoring is a method of evaluating the effectiveness of goals (Tier I), functional requirements (Tier II), rules and regulations (Tier IV) and standards/practices (Tier V) as well as attempting to identify risks not addressed in the initial rules/regulations development. In order to verify that the risk of shipping is kept as low as reasonably practicable, the GBS framework should be continuously monitored and systematically analysed. The degree of detail for the data recording depends on the item to be monitored.' However, so far no such activity has taken place at IMO, and IMO has poor systems for data collection. For example, the situation of reporting accidents is very poor, see ICS et. al (2014). On the other hand, repeated FSA Studies of the same ship types serves the purpose to some degree. However, there is no systematic approach to ex-post analysis at IMO.

9 COMPARISON OF TOOLS#12 AND #27 IN THE 2015 EC IA GUIDELINES WITH THE IMO FSA GUIDELINES

9.1 Tool #12: Risk Assessment and Management

Tool #12 accepts that assessing risks is complex issue and often requires in-depth expertise and specialist knowledge spanning various policy fields. The purpose of tool #12 is therefore to introduce the key concepts rather than to explain how to assess risks and prepare risk management measures. It also provides guidance on how risk assessment may contribute to the Commission's impact assessment process.

This is a very relevant comment, as the methods for risk assessment are extremely varied, and have coexisted within different professions for about half a century. Even within engineering, the methods used are not the same, and this goes down to detailed specifics about the understanding of e.g. the probability concept. This issue is also an issue within IMO and FSA, where most FSAs are based on a classical frequentistic probability concept, whilst structural reliability analysis are based on a Bayesian interpretation of the probability concept, for example in IACS(2006).

The definition of Risk in the EC IA Guidelines is different from in the IMO EU Guidelines "Risk is the chance or probability that a person or something will be harmed or experience an adverse effect if exposed to a hazard". In the IMO FSA Guidelines, risk is the product of probability and consequence, and various parameters for presenting the risk are described in the IMO FSA Guidelines. This difference does not necessarily cause any ambiguity in an EC IA, as long as the consequences are clearly described.

Tool #12 refers to a large variety of permanent bodies that can carry out risk assessment (Decentralised EU Agencies (such as EFSA, ECHA, EMA, ECDC, EASA); Scientific Committees set up by the Commission (such as SCENIHR, SCHER). It is also mentioned that the Joint Research Centre (JRC) can support risk assessments by providing tools and models used in the assessment process as well as validating risk assessment methodologies, and that the JRC can provide expert judgements where risk assessment bodies provide conflicting opinions or in cases where there is large scientific uncertainty.

This demonstrates the large difference in availability of resources in the EC as compared to the IMO. The IMO is very reliant on the resources of the Flag States and NGOs to actually carry out an FSA, and can provide the forum for review, decision and implementation.

The risk assessment process is described differently in the EC IA Guidelines and in the IMO FSA Guidelines. The EC IA Guidelines specifies a three-step process:

1. Identify and characterise the hazard, i.e. identify and characterise the inherent properties of the agent/phenomenon in terms of potential negative effects (on population, environment etc.), establish the causal relationship between the hazard and its effect, describe the negative effect and determine its severity (e.g. occurrence of mutations, changes in the cell structure, etc.). Special attention should be paid to induced or secondary hazards (e.g. contaminated river flood).
2. Assess the likelihood of its occurrence, i.e. estimate the likelihood of the hazard (for the population, environment etc.) to occur.

3. Characterise risk, i.e. on the basis of results from previous steps, determine quantitatively (e.g. death, injury, production loss) and if not possible, qualitatively, the level of risk under given assumptions and uncertainties. Although the level of risk can be difficult to express in monetary terms (e.g. in the case of non-market impacts on environment and health), methods exist that can be used to monetise them.

The process in the IMO FSA Guidelines are described by the following five steps

1. Identification of hazards
2. Risk Analysis
3. Risk Control options
4. Cost Benefit assessment
5. Recommendation for Decision Making

The biggest difference is that the IMO EG/FSA Guidelines emphasize Cost Benefit Assessment (in reality Cost Effectiveness Assessment), contain clear performance indicators for safety (Individual Risk, Potential Loss of Life, FN) and clear cost effectiveness criteria for Value of Preventing Loss of Life or loss of a Life Year in Good Health (QALY).

Presentation of uncertainties and presentations of sensitivities are required according to both Guidelines.

The EC IA Guidelines describes tolerable and intolerable risk with slightly different terminology as compared to the IMO FSA Guidelines. The IMO FSA Guidelines rely on the ALARP principle. The area between intolerable and negligible risk is referred to as the ALARP area. For risk in the ALARP area, all cost-effective measures should be implemented. Clear criteria for intolerable and negligible risks are provided, as well as criteria for cost effectiveness. However, the purpose with this is identical to what is explained in the EC IA Guidelines with the following sentence 'The optimal level of risk reduction is found where the marginal costs of risk reduction equal the marginal reduction in risk'. The real difference is therefore the more explicit criteria for this in the IMO FSA Guidelines, by giving a formula for updating. For a more detailed discussion of this, see Spouge and Skjong (2015).

In conclusion, it might be said that the EC IA Guidelines and the IMO FSA Guidelines are based on very similar ideas, but that the wording and terminology are varying to some degree. This is common amongst risk analysts. It is possible to talk about different 'risk dialects' and an experienced risk analysts is characterized by understanding and being able to communicating using many such dialects.

9.2 Tool #27 Impact on Health

The concepts used under tool #27 of the EC IA Guidelines, are the same as the concepts used in the IMO FSA Guidelines. The key concepts in both guidelines are:

Value of A Statistical Life (VOSL), in the IMO FSA Guidelines this is the cost effectiveness criteria for the NetCAF (The Net Cost of Averting a Fatality).

Value of A Statistical Life year (VOLY). In the IMO FSA Guidelines, this corresponds to the value of preventing a DALY or for gaining a QALY.

The methods to derive these values are different. For example, tool #27 refers to the Cost of Illness method, a method that is not referenced to in the IMO FSA Guidelines, or the background documentation. The EC Tool #27 also refers to the Human Capital Method, a method mentioned as not acceptable in some of the background literature to the IMO FSA Guidelines, but not in the final Guidelines.

The EC IA Tool #27 also specifically mentions some results of analyses of specific treatment options: "For instance, Quality Adjusted Life Years (QALYs, see below), are often used in HTA in relation with reimbursement decisions. In this context, substantial research was conducted on the concept of monetary thresholds for QALYs (i.e. threshold below which an intervention would be cost-effective). Dialysis costs (USD 50,000 / QALY in the USA; GBP 20,000 to 30, 0000 in the UK; and EUR 10,000 to 80,000 in the NL) have been used as a standard to retrospectively analyse reimbursement decisions." Since in practice no such analysis has been carried out according to the IMO FSA Guidelines, such specifics are not known. However, the IMO FSA Guidelines are much more precise on defining criteria, because it refers to specific methods that give specific results when applied. This is discussed in detail in Spouge and Skjong (2015). The methods used at IMO, are referred to in the EC IA Guidelines: Willingness to Accept and Willingness to pay. However, the preferred method at IMO, which is based on revealed preferences (a subgroup of willingness to pay), the Life Quality Index approach, result in a formula for VOSL and VOLY that can easily be updated annually based on easily accessible statistics. Three parameters affect the result: gross domestic product per capita, life expectancy at birth, and the fraction of time spent in economic activity. The IMO FSA Guidelines use the OECD average, which is slightly above the EU average (see Spouge and Skjong (2015)).

The EC IA Tool #27 does not refer to specific values. The reference is to a study undertaken by OECD. It proposed a range for the average adult VOSL for the EU of $1.8 million – 5.4 million (2005-$), with a base value of $3.6 million. These base values and ranges should be updated as new VOSL primary studies are conducted. Converting this to (2012-$) the result is $4.23 million, below the resulting IMO recommended number in 2012, which was $6.92 million. This topic is discussed in detail in Spouge and Skjong (2015), also reviewing available methods to arrive at VOSL values used globally.

The difference between $4.23 million and $6.92 may seem quite large. However, the experience from analysing concrete safety measures, as in an IMO FSA, is that measures are either cost effective and correspond to an NCAF much less than the criterion, or it is not cost effective and with an NCAF much above the criterion. It is only in exceptional cases that the NCAF of a RCO lies between $4 million and $7 million.

In an EC IA about emission to air, this will be different. Most of the contributions to the external cost in Table 2 are due to health effects, and therefore almost directly proportional to the VOLY.

However, the basic idea of IA is the optimum allocation of safety measures in all industries and sectors. This requires in principle that the same criterion is used, otherwise more lives could be saved by reallocation of resources, see Tengs et.al (1995) for an evaluation of the dramatic effects different criteria may have.

Within EU the use of the same criterion for all EU countries is problematic, in particular when the cost of national measures are funded by the member countries themselves. Using the VOSL from the LQI as an indicator, the value for Luxemburg is six times the value for Romania.

10 INCONSISTENCY IN THE EC IA GUIDELINES

The EC IA Guidelines refers to multi-criteria decision-making (MCDM). This is a different decision making process than the Guidelines otherwise advocates, and therefore introduces an inconsistency in the Guidelines.

MCDM is concerned with structuring and solving decision problems involving multiple criteria. The purpose is to support decision makers facing such challenges. For MCDM there will not be any optimum solution. It is necessary to use decision maker's preferences to differentiate between solutions.

The EC IA Guidelines on the other hand builds on the idea of internalizing all external costs, and describes methods and tools to identify such costs. The methods account for the decision makers preferences, and there is therefore no need for MCDM. In principle, an optimum solution can be found, based on the principles otherwise advocated in the EC IA Guidelines.

To rely on decision-makers preferences is clearly problematic, as preferences are subjective and not transparent, whilst transparency is one of the main purposes of IAs.

11 CONCLUSION: POSSIBLE IMPROVEMENTS

11.1 Learning points from EC IA Guidelines for use in the FSA Guidelines

The IMO FSA Guidelines is limited in scope, and has in practice only been used for accidental losses, although criteria are presented in the guidelines that can be used to evaluate both health and injury effects. The FSA Guidelines also contains criteria for accidental oil spill, but no FSA using this criterion for recommended decision-making has been carried out so far.

Since there are often rather concrete conflicts between safety and environmental issues, there would be clear benefits of extending the FSA Guidelines to contain criteria for evaluating the environmental effect of regular releases. The main extension would then relate to proving external cost figures on a per ton basis for the most dominating releases, like in the Handbook (Korzhenevych et al, 2014).

A resent initiative by Jamaica et.al (2015) could in principle result in an IMO Council decision to implement some form of IA at IMO. In particular, the Jamaica et. al (2015) ' believe that when regulatory changes are proposed in the future, emphasis needs to be given to full and effective regulatory impact and feasibility assessments, which take greater account of the economic and social sustainability of maritime transport'.

For application in a FSA it is important that all criteria are defined at the level of the ship, otherwise the analyses would be too demanding for practical use.

11.2 Learning point from FSA Guidelines to the EC IA Guidelines

For the analysts the EC IA Guidelines does not adequately answer the questions relating to decision parameters and acceptance criteria. For example, whilst the Handbook give clear values for the external cost of a ton of NOx released in the North Sea, it is not possible to identify what value of VOLY this is based on. The danger is therefore that there is no consistency between the criteria used between different studies, or even within the same study when health, safety and environmental effects are considered. The criteria are also difficult to keep updated, when the relations between them are not properly documented. The

FSA Guidelines have few criteria, but it is clearly defined how to update them, and they are easily found in the guidelines. It would seem necessary that EC maintain briefer Guidelines with the essential decision parameters and acceptance criteria defined, and have procedures to keep them up to date. Otherwise, the Guidelines will not result in optimum allocation of resources.

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