

# **EHEST SAFETY MANAGEMENT TOOLKIT**

## *STANDARD OPERATING PROCEDURES (SOPs)*

### SOP Development Guidance

1st Edition, December 2015



Courtesy: Elicampiglio  
Photo: Michele Calovi

***European Helicopter Safety Team***

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**SOP DEVELOPMENT GUIDANCE**

*A Template for Industry*

**Edition 1**

December 2015

## **1. ABOUT THIS MANUAL**

This manual has been developed by the Specialist Team Operations & SMS of the European Helicopter Safety Team (EHEST). The EHEST is the European component of the International Helicopter Safety Team (IHST) and the helicopter branch of the European Strategic Safety Initiative (ESSI).

This document is intended to provide the operator additional guidance about development of Company Standard Operating Procedures.

This manual and the procedures therein comply and refer to the applicable EU Regulation and its related AMC's and GM's, in particular:

- SPO.OP.230 standard operating procedures and related AMC
- AMC1 SPO.SPEC.HESLO.100 standard operating procedures
- GM1 SPO.SPEC.HESLO.100 standard operating procedures

**The EHEST tool comes with some risk management data in order to show how to conduct a practical risk management. It is important to understand that the data and the assessments are for example only. The user may use the data but he/she must revise the assessments and make his/her own assessment suitable for his/her real operating environment.**

Even if this guidance is based on the Part SPO (Specialised Operations), it is still a good reference point for the development of the entire set of operator's SOPs, including those addressing operations other than SPO, when applicable.

## **2. TABLE OF CONTENTS**

<b>1.</b>	<b>ABOUT THIS MANUAL .....</b>	<b>3</b>
<b>2.</b>	<b>TABLE OF CONTENTS .....</b>	<b>4</b>
<b>3.</b>	<b>SCOPE OF THE STANDARD OPERATING PROCEDURES.....</b>	<b>5</b>
<b>4.</b>	<b>TERMS AND ACRONYMS .....</b>	<b>5</b>
<b>4.1</b>	<b>General .....</b>	<b>5</b>
<b>4.2</b>	<b>Terminology.....</b>	<b>5</b>
<b>5.</b>	<b>SOP DEVELOPMENT PROCEDURE .....</b>	<b>10</b>
<b>5.1</b>	<b>General .....</b>	<b>10</b>
<b>5.2</b>	<b>Safety Risk Management Process .....</b>	<b>11</b>
<b>5.3</b>	<b>Risk management Complexity.....</b>	<b>13</b>
<b>5.4</b>	<b>Working Group and Task Definition .....</b>	<b>13</b>
<b>5.5</b>	<b>Task and Sub-Task Analysis (Optional).....</b>	<b>13</b>
<b>5.6</b>	<b>MARIA Database (Optional) .....</b>	<b>13</b>
<b>5.7</b>	<b>Hazardous events Identification and Risk Assessment –     HIRA.....</b>	<b>14</b>
<b>5.8</b>	<b>Safety Assessment Document.....</b>	<b>14</b>
<b>5.9</b>	<b>SOP (Standard Operating Procedure) .....</b>	<b>15</b>
<b>5.10</b>	<b>Authority Approval.....</b>	<b>15</b>
<b>5.11</b>	<b>SOP implementation .....</b>	<b>15</b>
<b>5.12</b>	<b>SOP Revisions .....</b>	<b>15</b>
<b>6.</b>	<b>EHEST TOOL CONCEPT .....</b>	<b>15</b>
	<b>ANNEX A - EHEST TOOL VS. EU REG. &amp; BOWTIE.....</b>	<b>20</b>

### 3. SCOPE OF THE STANDARD OPERATING PROCEDURES

The Standard Operating Procedures are developed to standardise all the operating procedures used by an operator.

Before commencing a normal operation, a specialised operation, or after the introduction of any changes; in the Company operating procedures the operator shall conduct a risk analysis, assessing the complexity of the activity to determine the hazards and related risks inherent in the operation and to establish risk mitigation measures.

Based on the risk assessment, Standard Operating Procedures (SOP) will be established appropriate to the activity and aircraft used. The SOPs are collected in the Company's SOP Manual. SOPs will be regularly reviewed and updated, as appropriate.

It is required that pilots and all other personnel perform operations in accordance with SOPs.

SOPs are not the only form of risk control available within a Company, but it is a vital part of the wider operator's safety management system.

### 4. TERMS AND ACRONYMS

#### 4.1 General

Many terms used in the SMS framework have different meanings depending of the context (EU Regulation, ICAO, BowTie, etc.). The Specialist Team made an effort in order to use as much standard terminology as possible, but sometimes we had to opt for a specific term or meaning. In some cases, the Specialist Team had to select a term so as to avoid confusion with other concepts or to differentiate between words used for similar concepts.

It is suggested to carefully read the following terms and related meanings in order to better understand the concepts used in the EHSET tool.

#### 4.2 Terminology

Cause	<p>Actions, omissions, events, conditions, or a combination thereof, which led to the accident or incident. The identification of causes does not imply the assignment of fault or the determination of administrative, civil or criminal liability (cf. ICAO Annex 13).</p> <p>In the EHEST SOP and Risk Assessment tools context, Cause includes:</p> <ul style="list-style-type: none"> <li>- Hazard, as defined in the BowTie environment (see Hazard)</li> <li>- Threat (see Threat)</li> <li>- Contributing Factor (see Contributing Factor)</li> </ul>
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	<p>CAUSE is a condition that produces an effect and can be a normal operational conditions (Hazard as for BowTie), a triggering event (Threat) or something that is partly responsible for the development of a Hazardous Event but that is not yet an unwanted state or event (i.e. Hazardous Event).</p>
Consequence	<p>A potential event resulting from the release of a Hazardous Event, which directly results in loss or damage. It describes the undesirable events (usually accidents and safety related) that may potentially result from the Hazardous Event, if that event is not effectively managed with Recovery Barriers.</p> <p>Consequences should be expressed in operational terms (e.g. 'collision on the runway') so that the scenario being controlled is clear to the reader.</p> <p>It should be noted, Consequences are events not the actual loss or damage.</p> <p>The loss or damage is the 'outcome' against which severity is usually gauged. In certain circumstances it can be desirable to include some brief information on the outcome within the consequence description, in order to clarify the issue for the reader (e.g. mid-air collision resulting in the loss of both aircraft).</p> <p>If the Hazardous Event is not controlled, it should be capable of resulting in any of the consequences. (cf. UK CAA - <a href="http://www.caa.co.uk/default.aspx?catid=2796&amp;pageid=16078">http://www.caa.co.uk/default.aspx?catid=2796&amp;pageid=16078</a>)</p>
Contributing factor	<p>Action, omission, events, condition, or a combination thereof, which, if eliminated, avoided or absent, would have reduced the probability of the accident or incident occurring, or mitigated the severity of the consequences of the accident or incident. The identification of contributing factors does not imply the assignment of fault or the determination of administrative, civil or criminal liability (cf. ICAO Annex 13).</p> <p>CONTRIBUTING FACTOR is a condition that influences the effect by increasing its likelihood, accelerating the effect in time, affecting severity of the consequences, etc.</p>
Hazard	<p>Conditions which could cause or contribute to unsafe operation of aircraft or aviation safety-related equipment, products and services. (cf. ICAO Doc. 9859 – SMM – 2.13.2)</p> <p>The term HAZARD can have different "technical" meanings depending in which context we operate.</p> <p>Sometimes HAZARD is intended as an "unwanted situation" , i.e. something already happened that puts me in an unwanted state and that could lead to an incident or accident (Consequence):</p>

	<p>Hazard (H). An undesirable condition or situation which may lead to unsafe event(s) or occurrence(s). (cf. ICAO Doc. 9859 – SMM – Appendix 2 to Chapter 2)</p> <p>The identification of aviation safety hazards entailed by the activities of the operator, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness; (cf. ORO.GEN.200 Management system (a) (3))</p> <p>This kind of HAZARD is referred to, in the EHEST SOP and risk assessment tools, as HAZARDOUS EVENTS.</p> <p>Some other times HAZARD describes a normal situation, condition or operation but that can have the potentiality to develop threats and lead to unwanted situations or states (Hazardous Events), as for BowTie methodology:</p> <p style="padding-left: 40px;">The condition, object or activity with the potential of causing injuries to personnel, damage to equipment or structures, loss of material or reduction of ability to perform a prescribed function.</p> <p style="padding-left: 40px;">This describes the potential source of harm under consideration. It will often describe a 'normal' aspect within the operating environment and sets the context and scope of the bowtie, for example driving a car on a busy motorway – this is an activity where risks are present.</p> <p style="padding-left: 40px;">A hazard can be focused on:</p> <ul style="list-style-type: none"> <li>• a condition (e.g. icing conditions),</li> <li>• an object (e.g. another vehicle) or</li> <li>• an activity (e.g. driving).</li> </ul> <p style="padding-left: 40px;">Hazards are often part of normal business activities and not necessarily something that can or should be eliminated. There is also the possibility to have more than one top event (i.e. Hazardous Event for the EHEST tool) from one hazard as, for example, there would be a number of risk events associated in driving on a motorway.</p> <p style="padding-left: 40px;">(cf. UK CAA  <a href="http://www.caa.co.uk/default.aspx?catid=2796&amp;pageid=16075">http://www.caa.co.uk/default.aspx?catid=2796&amp;pageid=16075</a>)</p> <p style="padding-left: 40px;">Those conditions which could cause or contribute to unsafe operation of aircraft or aviation safety-related equipment, products and services. (cf. ICAO Doc. 9859 – SMM – 2.13.2)</p> <p>This kind of HAZARD is referred to, in the EHEST SOP and risk assessment tools, as CAUSE.</p>
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	For this reason, the EHEST SOP and risk assessments tools do not use the term HAZARD, but CAUSE and HAZARDOUS EVENT in order to reduce the possible confusion. The term HAZARDOUS EVENT has been chosen in order to be closer, in wording, to the EU Regulation, but retaining the concept of TOP EVENT as for BowTie methodology.
Hazardous Events	See Hazard
Hazardous Events identification	Formal process used to identify Hazardous Events that may contribute to aviation safety-related occurrences. (cf. ICAO Doc. 9859 – SMM – 5.3.42)  Hazardous Events identification is based on a combination of reactive, proactive and predictive safety data collection methods (cf. ICAO Doc. 9859 – SMM – 5.3.43).
Outcome	The loss or damage related to a Consequence (see Consequence)
Outcomes	The outcome is the loss or damage against which severity is usually gauged. Consequences are events not the actual loss or damage. In certain circumstances it can be desirable to include some brief information on the outcome within the consequence description, in order to clarify the issue for the reader (e.g. mid-air collision resulting in the loss of both aircraft). (cf. UK CAA - <a href="http://www.caa.co.uk/default.aspx?catid=2796&amp;pageid=16078">http://www.caa.co.uk/default.aspx?catid=2796&amp;pageid=16078</a> )
Proactive Barrier	Proactive Barrier (PB). A mitigating action/mechanism/defence to block or prevent a Cause from escalating into an unsafe event or ultimate consequence. (Also referred to as Preventive Control, by ICAO Doc. 9859 – SMM – Appendix 2 to Chapter 2)
Recovery Barrier	Specific action, control or measure put in place to prevent the realization or escalation of a Hazardous Event into a Consequence by reducing the likelihood and/or the severity of the outcome/consequence.
Risk analysis	Part of the risk management process that use the available information to analyse the risks in terms of likelihood and severity.  Risk analysis provides the basis for risk evaluation and decisions about risk treatment.
Risk assessment	Part of the risk management process that compares the results of risk analysis with risk acceptability criteria to determine whether the risk level is acceptable or tolerable. Risk evaluation assists in the decision about risk treatment. Also called Risk Evaluation.
Risk evaluation	See Risk Assessment



Risk Management	A process used in aviation activities used to control the safety risks encountered. This process includes hazard identification, safety risk assessment and the implementation of appropriate safety Barriers. (cf. ICAO Doc. 9859 – SMM – 5.3.39)
Safety	The state in which risks associated with aviation activities, related to, or in direct support of the operation of aircraft, are reduced and controlled to an acceptable level (cf. ICAO Annex 19).
safety assessment	<p>Safety assessment is a document that contains hazard descriptions, the related consequences, the assessed likelihood and severity of the safety risks, and required safety risk controls (safety Barriers). Existing safety assessments should be reviewed whenever new Hazardous Events are identified and proposals for further safety risk controls (safety Barriers) are anticipated (cf. ICAO Doc. 9859 – SMM – 5.3.47).</p> <p>Safety Assessment documents are commonly referred to as Risk Assessment documents. In order not to confuse the Risk Assessment document with the assessment of the tolerability of the risk (risk assessment – risk evaluation), it is recommended that this document is called a Safety Assessment.</p>
Safety risk	<p>Safety risk is the projected likelihood and severity of the consequence or outcome from an existing hazard or situation. (cf. ICAO Doc. 9859 – SMM – 2.14.2)</p> <p>Important note, the risk is a measure, not an event or situation.</p>
Safety Risk Likelihood	<p>Safety risk likelihood is defined as the probability or frequency that a safety consequence or outcome might occur. (cf. ICAO Doc. 9859 – SMM – 2.14.3)</p> <p>Likelihood can be defined, determined, or measured objectively or subjectively and can be expressed either qualitatively (expert judgement) or quantitatively (using mathematical data).</p>
Safety Risk severity	Safety risk severity is defined as the extent of harm that might reasonably occur as a consequence or outcome of the identified Hazardous Event. (cf. ICAO Doc. 9859 – SMM – 2.14.7)
Threats	Factors which, in isolation or in combination with other threats, could be the triggering element of a Hazardous Event, but, in isolation, it is not yet an unwanted state or event (i.e. Hazardous Event).

## **5. SOP DEVELOPMENT PROCEDURE**

### **5.1 General**

The SOP development procedure complements the SPO.OP.230 and related AMC and GM.

The SOP development follows these steps:

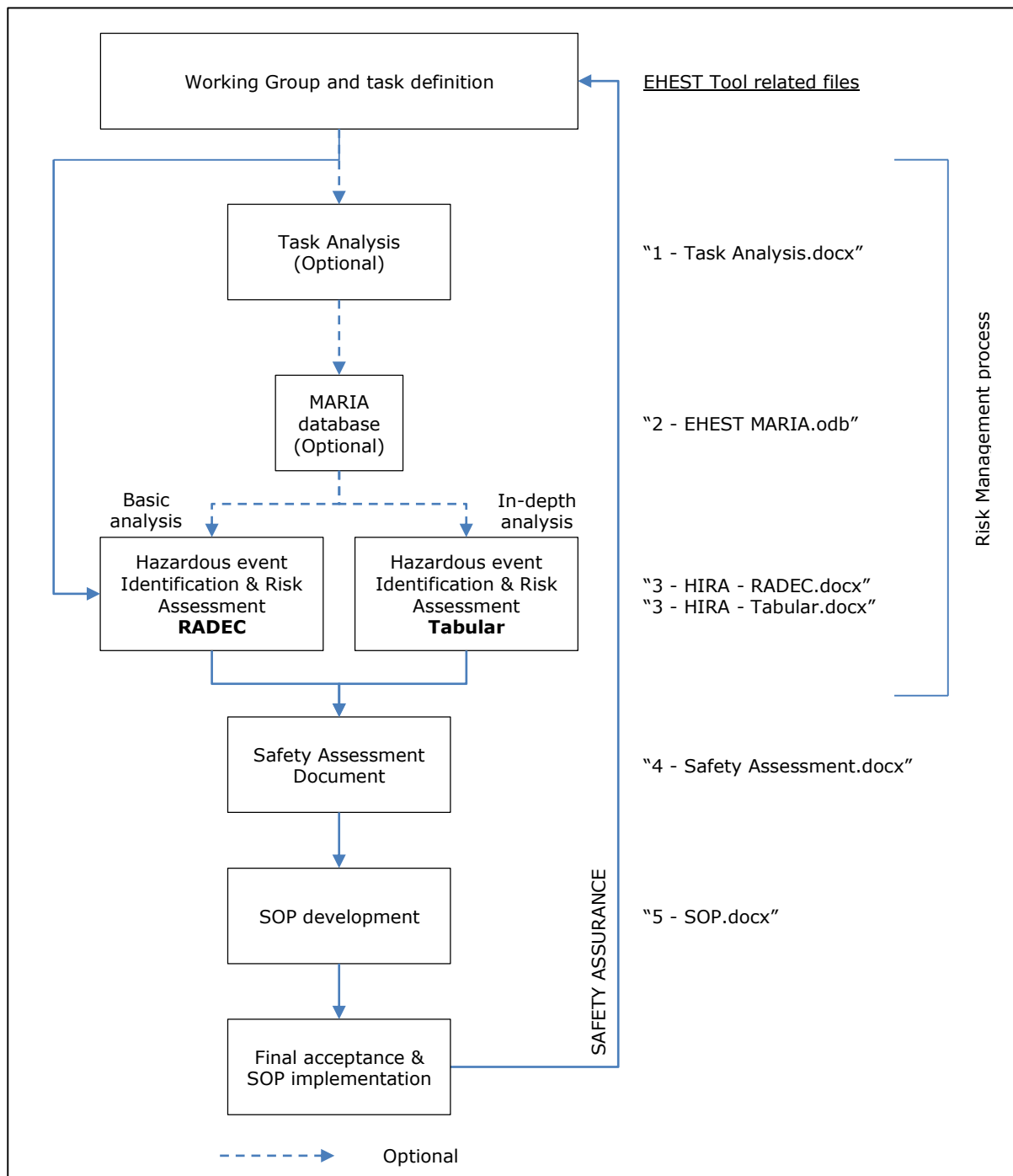
1. Task and sub-tasks are analysed<sup>1</sup>.
2. The safety risk management is performed (hazard identification, risk analysis, risk assessment and control of the safety risks associated with identified Hazardous Events).
3. A SOP is developed based on the previous safety risk study.
4. If required, an Authority approval is requested.
5. The SOP is implemented.

SOP will then be revised based on implementation feedback.

Figure 1 shows the logical flowchart of the SOP development using the EHEST tool and the related files.

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<sup>1</sup> This is optional. Regulation does not require this step. This will anyway help the operator to better focus on the Hazardous Events.

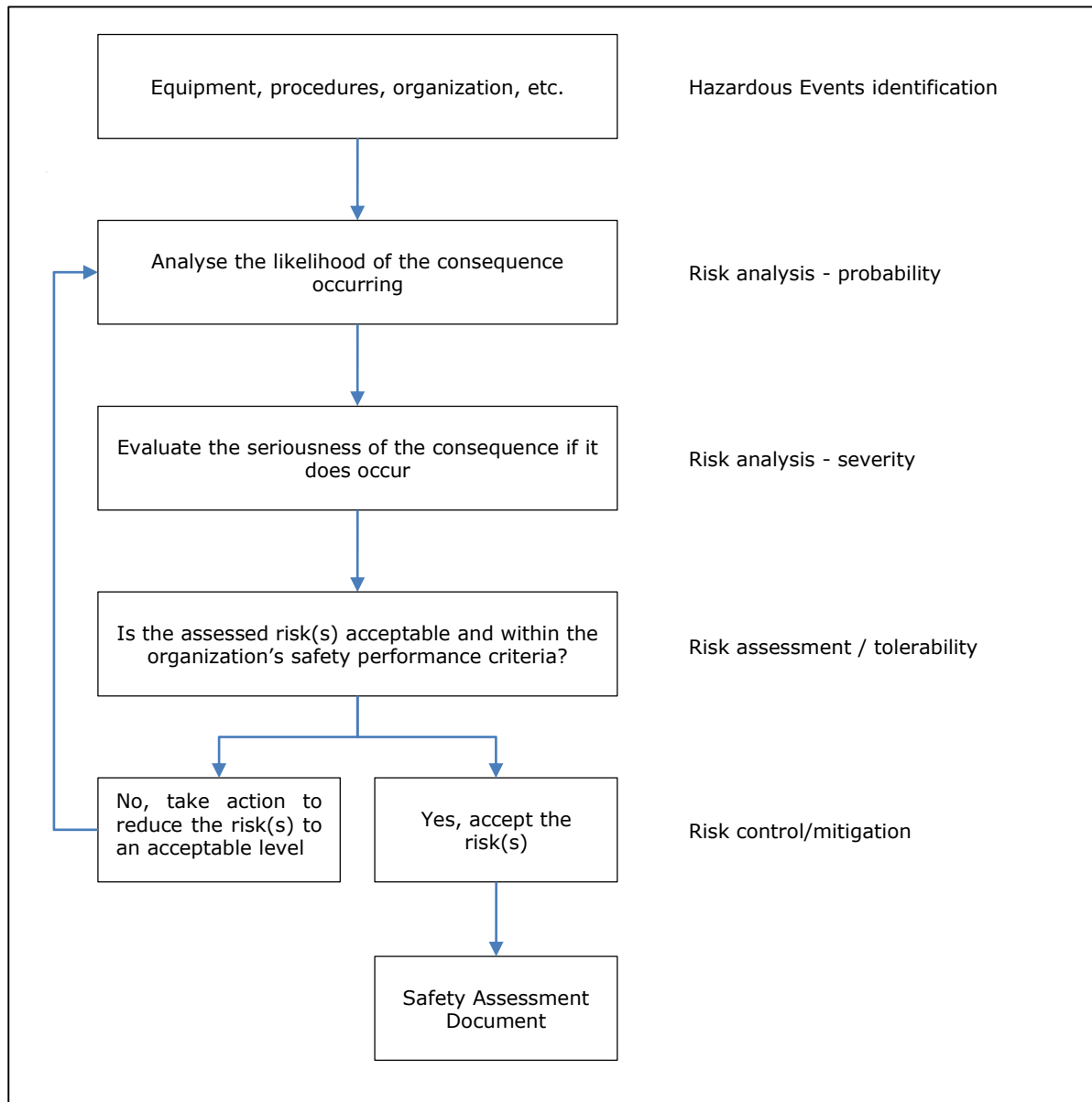


**Figure 1 – SOP development procedure flowchart**

## 5.2 Safety Risk Management Process

Operators should ensure that the safety risks encountered in aviation activities are controlled in order to achieve their safety performance targets. This process is known as safety risk management and includes Hazardous Events identification, safety risk assessment and the

implementation of appropriate remediation measures (safety Barriers). The safety risk management process is illustrated in Figure 2 (cf. ICAO Doc. 9859 – SMM – 5.3.39).



**Figure 2 – The safety risk management process**

### **5.3 Risk management Complexity**

The EHEST tool comes with two methods of risk management (RADEC<sup>2</sup> and tabular). The two proposed methods have different complexity and can be used for basic or in-depth risk management. These are two of the possible methods, but the operator can elect to use different methods at its discretion (BowTie<sup>3</sup>, fault-tree – event-tree, ARMS<sup>4</sup>, checklists, etc.).

### **5.4 Working Group and Task Definition**

Before commencing the SOP development, the Company should set up a multi-functional working group. In addition, the scope of the SOP and operation to be analysed must be defined at this stage.

### **5.5 Task and Sub-Task Analysis (Optional)**

The operation being analysed may be divided into simple tasks or sub-tasks in order to better identify and analyse the related Hazardous Events (events that we want to prevent or impede from deteriorating into incidents or accidents, see Section 6, page 11). These sub-parts can then be used to list the Hazardous Events for each part of the flight. The defined Hazardous Events are the base of the subsequent risk analysis.

Task analysis is not required by EU Regulation and can be omitted, especially for simple risk management processes and safety studies.

### **5.6 MARIA Database (Optional)**

The MARIA database (My Assessment of Risks for Incidents and Accidents) helps the user to keep track of the various elements of the risk assessment, and also the links between the elements.

The tool is a support to the risk management. The user can use the database or manually insert his/her analysis in the risk management documents.

Please refer to the MARIA Guidance Manual for further information.

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<sup>2</sup> Cf. EHEST - Safety Management Manual for Non-Complex Operators

<sup>3</sup> Cf. UK CAA - <http://www.caa.co.uk/default.aspx?catid=2786&pagetype=90>

<sup>4</sup> Cf. ECAST - <http://easa.europa.eu/essi/ecast/main-page-2/sms/>

## 5.7 Hazardous events Identification and Risk Assessment – HIRA

This document is used to perform the Hazardous Events identification, safety risk assessment and the implementation of appropriate remediation measures (safety Barriers) for the operation being studied. For each Hazardous Event, the Causes and the consequences are defined and the related barriers are sought.

The final goal of this document is to verify the safety barriers already in place, define the actual level of risk per each top event, develop further barriers if deemed necessary and then to decide if the residual risk is considered acceptable.

This is the base for the Safety Assessment document.

There are two documents available for the Safety Assessment:

- The tabular method is the more comprehensive way to analyse the risk. It allows the user to split the Cause for each Hazardous Event, and to list the Proactive Barriers in order to prevent the Cause to become a Hazardous Event. Similarly, this document lists the possible consequences of each Hazardous Event and its related recovery barrier.

When studying complicated operations, this tabular list can become quite long and the relations between Causes, Hazardous Events, Consequences and Barriers can become quite complicated. For this reason, the use of the MARIA database is recommended.

- The RADEC form is a simplified way to list Hazardous Events, Causes, Consequences and Barriers. This document represents the results in a simpler manner, but it does not show the relations between the elements in the same amount of detail.

The MARIA database can produce various forms that can be easily used for both the tabular and the RADEC analysis.

NOTE: In order to reduce the complexity of the risk management process and subsequent description (Safety Assessment document), only the right part of the MARIA tool needs to be used, i.e. (see Figure 4):

CAUSES → HAZARDOUS EVENTS → CONSEQUENCES

In this case the safety Barriers will include Proactive and Recovery Barriers.

## 5.8 Safety Assessment Document

The Hazardous events Identification and Risk Assessment (HIRA) document is a technical working document that can become quite long and complicated, and it is potentially not easily understandable for non-safety-experts.

The Safety Assessment Document is a more general document that describes the studied operation, the environment, the personnel, the aircraft and other important information. It includes the conclusions of the risk study performed with the previous documents.

## **5.9 SOP (Standard Operating Procedure)**

Finally, the SOP is developed.

The SOP shall integrate the barriers identified in the Hazardous event & Risk Assessment document (HIRA).

The document must show evidence for the conclusions of the Risk management, but needs not report the full explanation of the risk study.

### **5.10 Authority Approval**

If required by the Authority, approval must be received before implementing the SOPs.

If requested by the Authority, the Risk Assessment Document and the other working documents can be presented to demonstrate the consistency of the studies and of the residual risk level.

### **5.11 SOP implementation**

Only the SOP document is required to be distributed to personnel.

However, it can be useful to explain to the users what risk barriers are incorporated in the SOP and explain why certain procedural steps (cross-checks, for instance) have been implemented. This will reduce the possibility of having certain steps by-passed or modified by the users (procedural non-compliance).

### **5.12 SOP Revisions**

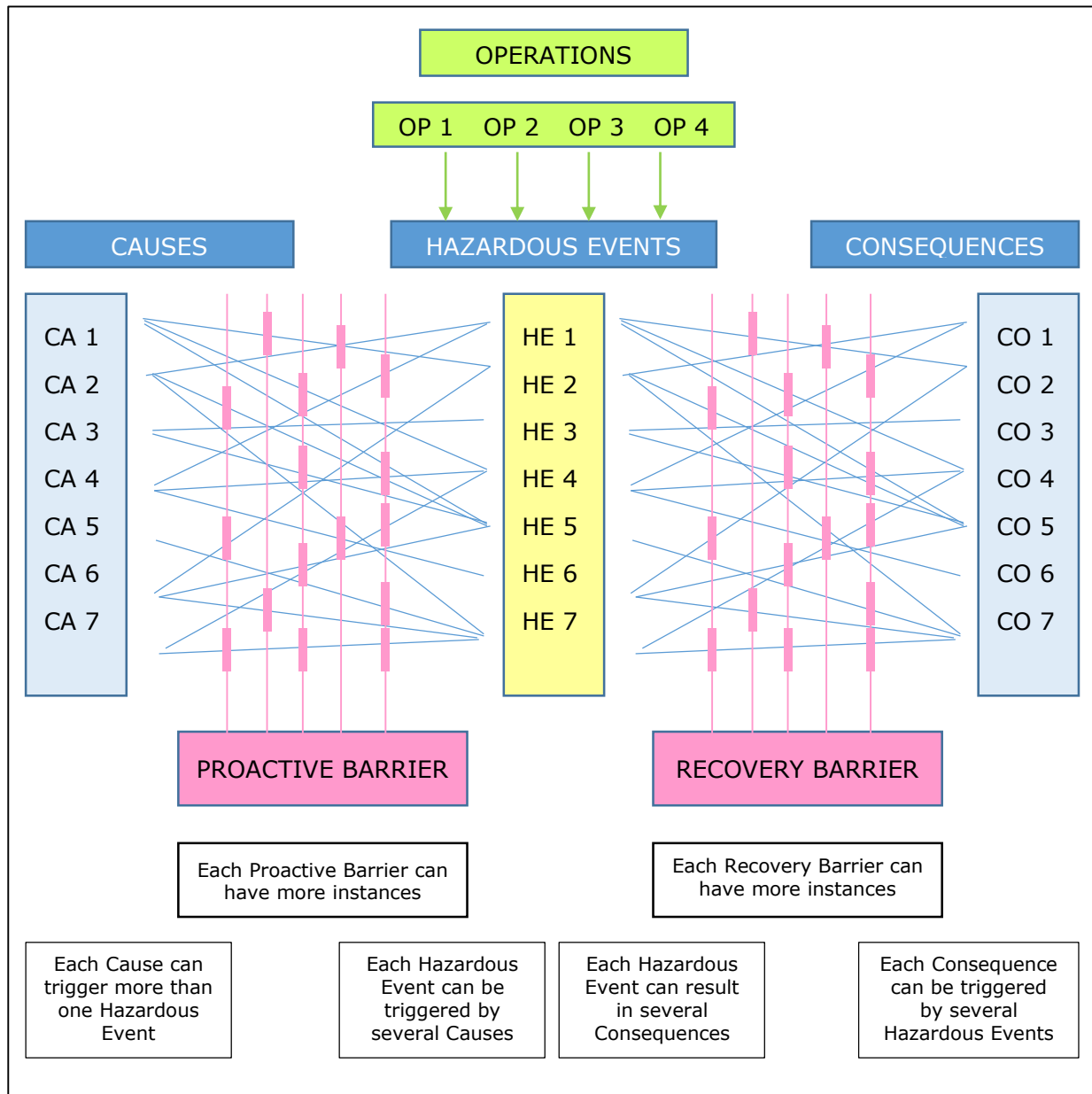
The SOP and its related risk management must be reviewed for effectiveness and reliability:

- on a regular basis,
- based on feedback from operations, and
- when conditions change in the operations (change of area of operation, helicopters, etc.).

Revision number and date shall be included in the front cover of the document.

## **6. EHEST TOOL CONCEPT**

The concept used throughout this EHEST tool is depicted in figure 3.

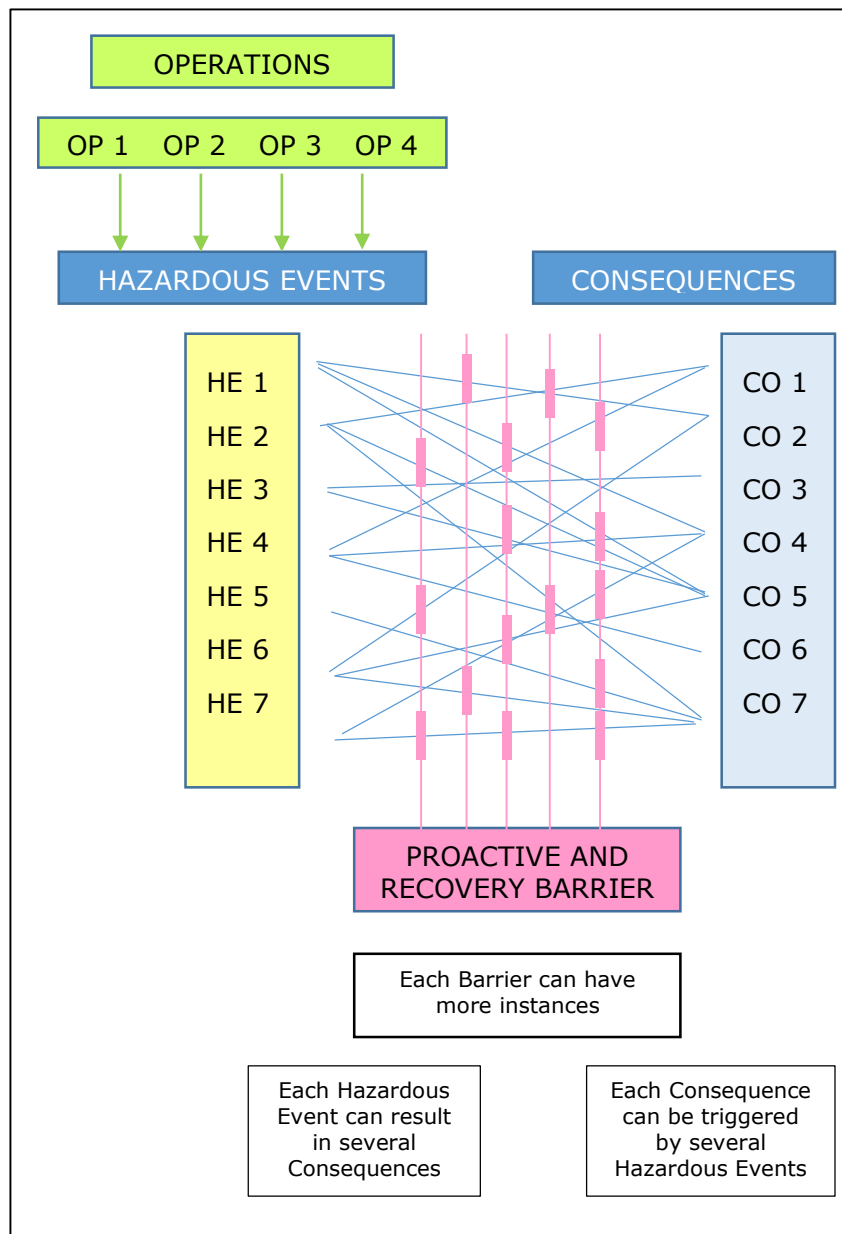


**Figure 3 – The EHEST tool concept**

The risk management study can be eventually simplified using only the right part of MARIA. (see Figure 4). In this case the triggering events and the contributing factors will not be evident. Regardless, the risk management will be consistent as long as the user is able to define the two most important elements of the risk management:

- the definition of effective risk control actions (safety Barriers); and
- the correct assessment and the acceptance of the final risk level.





**Figure 4 – The simplified EHEST tool concept**

The operation we want to study is defined as **Operation**.

The operation can have some Causes (flight in a thunderstorm area, cold weather operations, confined area operations, etc.) that are able to trigger an unwanted event or unwanted state called Hazardous Event (reduced separation with obstacles, flight in heavy turbulence, inadvertent IMC, reduced power availability, etc.).

A Hazardous Event is not a catastrophic situation, yet, but it must be recovered before it turns into an incident or an accident, called **Consequence**.

Both the aviation industry and each operator have already developed several ways (procedures, systems, controls, etc.), called Proactive Barriers, to avoid making a normal operation escalate into an adverse situation (Hazardous Event, e.g. inadvertent IMC). In case a Hazardous Event is triggered, several other elements (Recovery Barriers) are in place

to recover from this unusual situation (e.g. IFR training, IFR certified aircraft, etc.). These are called Barriers. They can be subdivided into **Proactive Barriers** if they are used to avoid the triggering of the Hazardous Event, or **Recovery Barriers** if they are used to come back from an unwanted situation.

The aim of the Risk management is to predict the possible Hazardous Events and verify which Barriers (Proactive and Recovery) are already in place, and determine the resulting risk level. After that, an evaluation is made in order to determine whether the risk is acceptable. If not, barriers are added, or modified (avoiding some operations, add controls, add technology, train personnel, etc.), or eventually removed until the risk is considered acceptable.

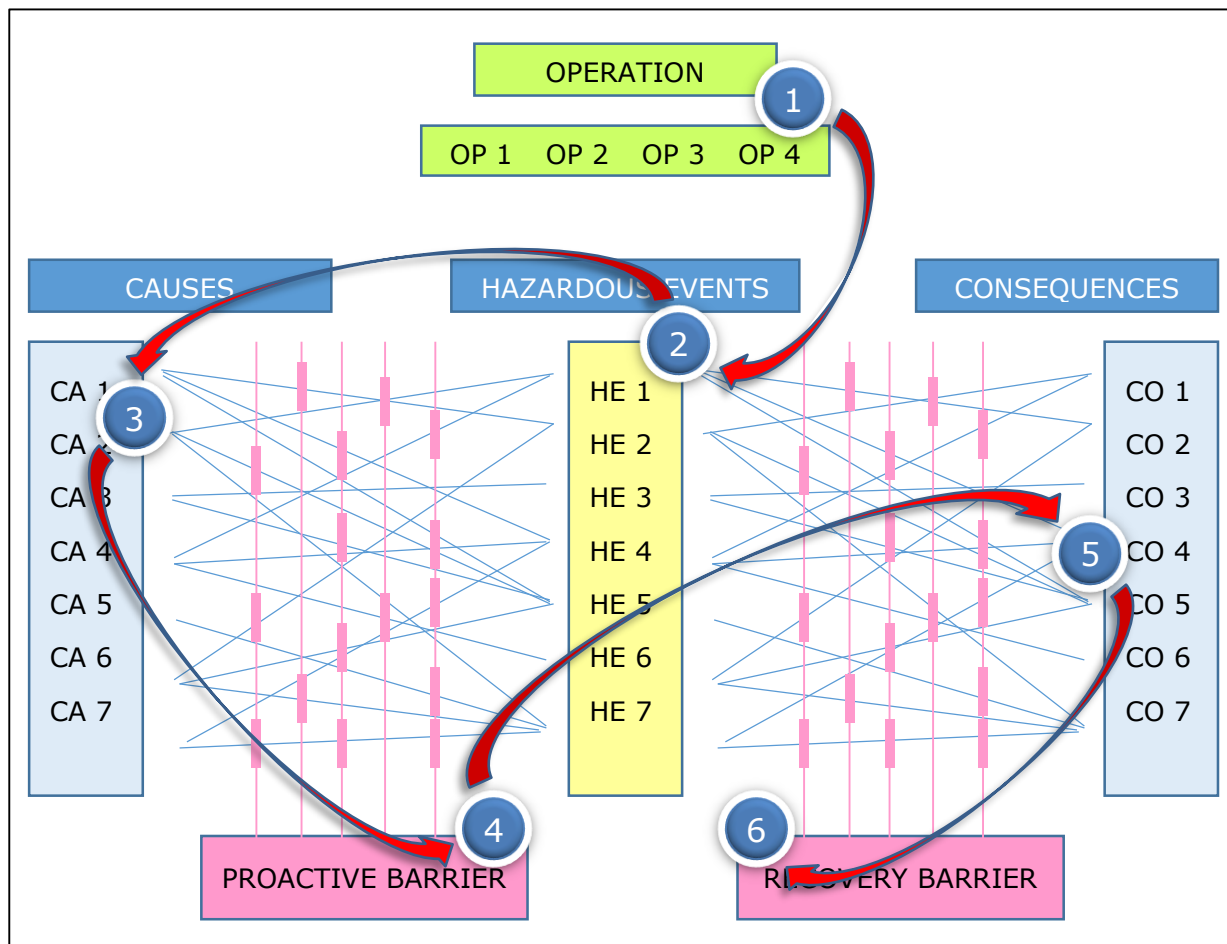
Risk Transfer check: It should be verified that any new, modified or removed barriers do not create new hazards or increase other risks in an unacceptable manner.

Generally, a Risk Matrix is used to help define and evaluate the level of risk.

**No matter the system used or the tools put in place, there is a final output that must be sought:**

- **determine and assess the level of risk for the specific Operation; and,**
- **develop efficient barriers to keep the final risk acceptable.**

The risk assessment flow used in this EHEST tool is illustrated in the figure below:



**Figure 3 – Typical risk management procedure**

1. Define the **Operation** and set up a working group
2. List the possible **Hazardous Events** with the use of the **Task and Sub-Task Analysis (optional)** and link them to the Hazardous Events (MARIA tool only)
3. List the **Causes** related to the operation being considered and link them to the related Hazardous Event (MARIA tool only)
4. List the **Proactive Barriers** already in place and the additional barriers. Link the Proactive Barriers with the related Causes (MARIA tool only)
5. List the possible **Consequences** of each Hazardous Event and link them to the related Hazardous Events (MARIA tool only)
6. List the **Recovery Barriers** already in place and the additional barriers that will help in further reducing the likelihood and/or the magnitude of the Consequences, and link them with the related Consequences (MARIA tool only)

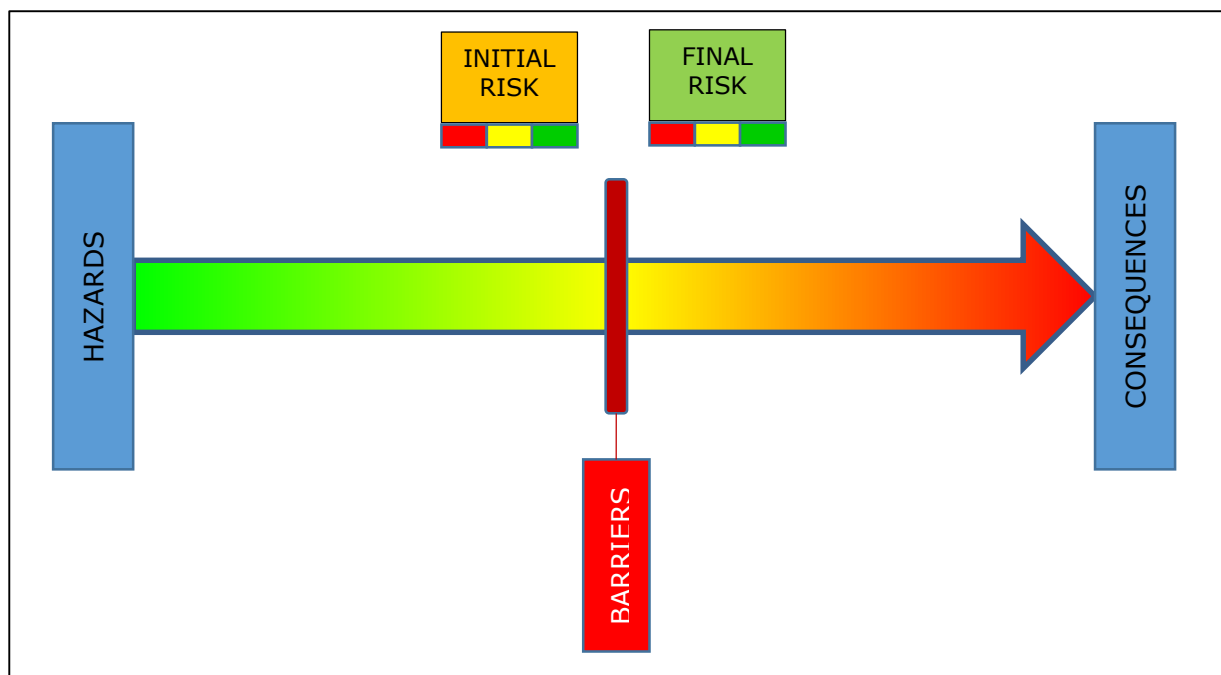
## EHEST TOOL VS. EU REG. & BOWTIE

This EHEST tool is a simplified version of the Bowtie methodology, but it lacks of some of its elements. For this reason no reference is made to the Bowtie in the tool. Anyway, provision has been made in order to be as much as possible consistent with the Bowtie methodology. In particular the guidance provided by UK CAA has been taken as reference. As a result, the studies inserted in the MARIA tool can be exported into the full Bowtie methodology without too much difficulty.

Even if some parts are missing, the value of the studies made with the MARIA tool, or manually with the other documents, remain valid and consistent. The missing parts do not reduce the value of the two most important results of the risk management procedure: **the development of barriers** and the **awareness of a residual risk level**, which the operator shall evaluate and consider acceptable.

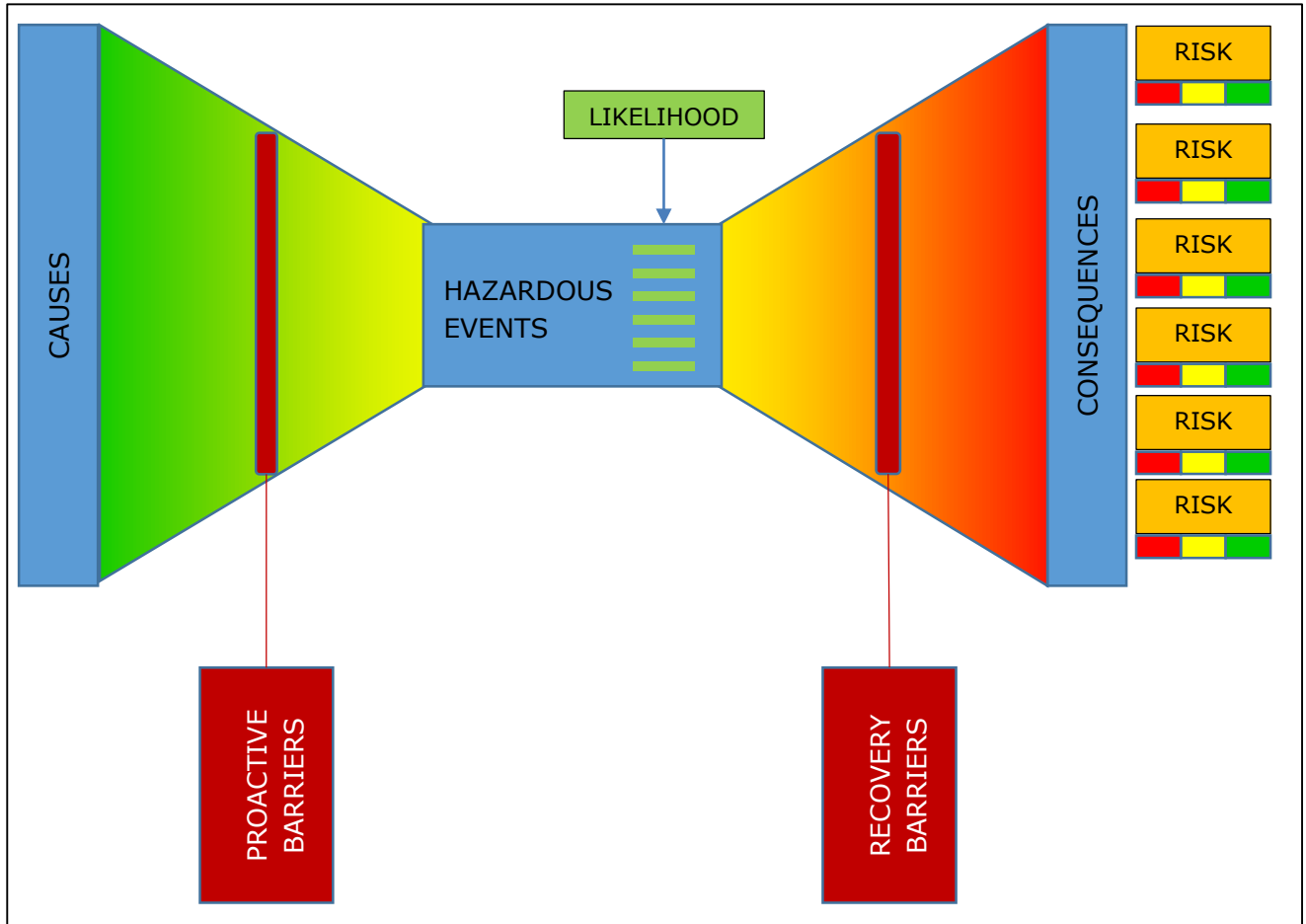
Illustrated below is a depiction of the risk management as reported in the ICAO and EU Regulation, in a classical Bowtie methodology and in the EHEST toolkit.

### ICAO & EU REGULATION

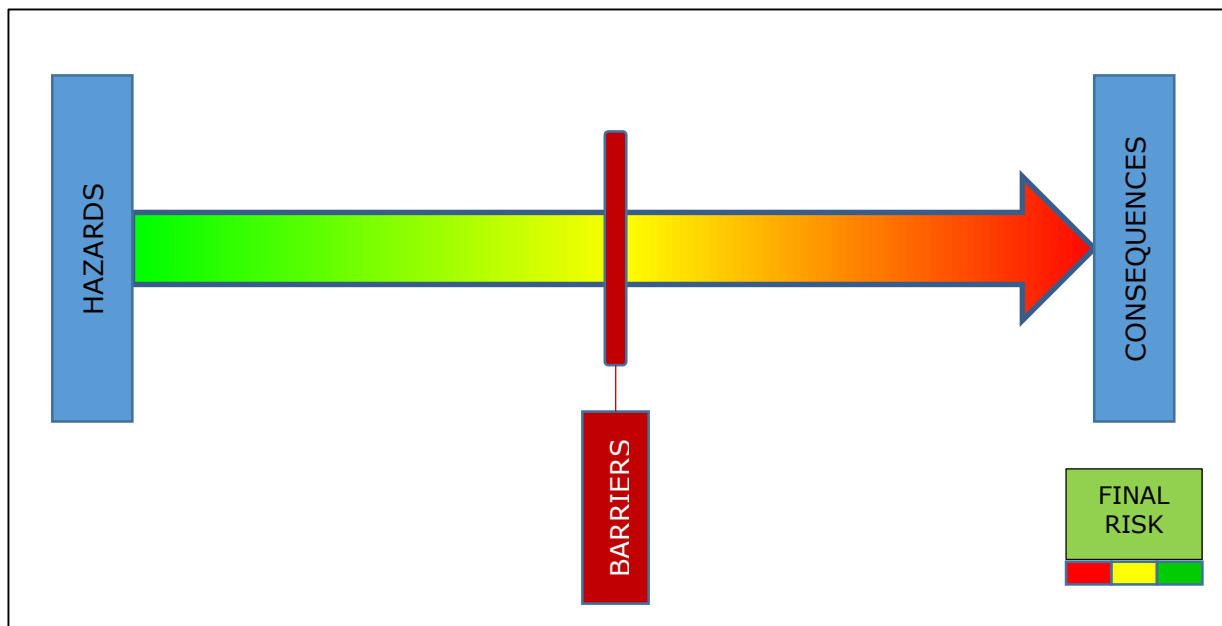


## EHEST TOOL

The MARIA tool



The Hazard and Risk Analysis – RADEC



## TYPICAL BOWTIE METHODOLOGY

