

Standard Operation Procedures	SOP_058 AI Use Case Registration
Effective Date: 11/03/2026	Public

AI Use Case Registration and Risk Assessment

Special Requirements	This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls. Please note that this document becomes uncontrolled once printed. Make sure by always referring only to the Repository that you have the right version in use. Deviations from the provision of this document need to be recorded in the relevant tool. The procedure should be updated when there are changes in EFSA with respect to what is stated in the document (e.g. Relevant Standards, legislation, and documents, change in procedure, etc.). The person responsible for maintaining this procedure up to date is the Lead author with the support of the QM.
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Process Responsibility	Process owners and/or Head of Units are accountable for this procedure being adhered to within their respective process or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document
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SCOPE AND OBJECTIVES

This Standard Operating Procedure outlines the process adopted by EFSA for the registration of Artificial Intelligence (AI) Use Cases. A use case is defined as the intended deployment for a specific process related goal within EFSA's production environment of an artificial intelligence system, or a system incorporating an AI component, whether developed internally or procured externally. This can be interpreted that a use case needs to be registered if it fits the three conditions:

1. The tool serves a specific process goal (*i.e.* it is a use case)
2. The tool is paid for by EFSA
3. The tool is made available to EFSA staff

To govern the use of AI at EFSA, the Authority has elected to register all corporate AI intended use cases fitting the above definition in the AI Register, including where applicable, high risk activities.

The AI Register also contributes to ensure compliance with the applicable legal requirements by integrating in the procedure the analysis of legal and ethical risks and identification of mitigating actions (AI Compliance Risk Assessment) by the AI Ethics & Data Protection Compliance Function. It also supports EFSA in the interaction with the European Data Protection Supervisor (EDPS), offering a tool that provides a comprehensive and up-to-date overview of AI use at EFSA and facilitates its monitoring.

This SOP specifies the steps from the registration request to the relevant assessments required, through to the validation and, where necessary, the identification of conditions and mitigating actions addressed to the proponent. The SOP indicates the change of state in the AI Register of a given request as far it advances through the procedure. In order for an AI Use Case to be considered validated, 3 conditions are set out in this SOP:

1. AI&I Board endorse the Use Case
2. AIE&DP Function review Risk Log positively and
3. Process Owner accepts ongoing management of the AI risks.

EFSA Process Architecture

In the framework of the EPA 3 Process Architecture, this SOP covers the AI Registration part of the EPA 13.04 Innovation Implementation process charter.

Ownership of this SOP lies in the Explore team in KNOW.

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

The following legislation and documents apply:

- The Artificial Intelligence (AI) Act (EU) 2024/1689 and associated guidelines of the Commission
- European Data Protection Regulation (EU) 2018/1725 (GDPR)
- EDPS Guidance



The following EFSA documents are related to this process because Registered AI Use Cases must deliver artefacts which are required for transition to operations or live use¹:

- SOP_10_Procurement and grants, Planning, Launch, Evaluation, Award and Implementation ([link](#))
- SOP_050_Enhance Products and Services ([link](#))
- SOP_052_Delivery via Programmes and Projects ([link](#))
- Change Advisory Board (CAB) Transition Checklist
- EFSA AI Code of Conduct
- AI Risk Taxonomy and Risk Log Template
- AI Registration form

ABBREVIATIONS AND DEFINITION

AI	Artificial Intelligence
AI&I Board	Artificial Intelligence and Innovation Board
AI Use Case	The intended deployment for a specific process related goal within EFSA' s production environment of an artificial intelligence system, or a system incorporating an AI component, whether developed internally or procured externally.
AIE&DP	Artificial Intelligence Ethics and Data Protection Compliance Function
AI Compliance Risk Assessment	The analysis of legal and ethical risks and identification of mitigating actions to be carried out by the Artificial Intelligence Ethics and Data Protection Compliance Function
CORSER	Corporate Services Unit
DW	Digital Workplace team of the CORSER Unit
EDPS	European Data Protection Supervisor
POC	Proof of Concept
SMU	Subject Matter Unit
R	Responsible. Executes the task under the supervision of the A. Is obliged to implement the feedback from the A. Is not obliged to implement the feedback from the C. On the other hand, R must present relevant feedback from the C to the A before the endorsement decision.
A	Accountable. Must ensure quality and timeliness of delivery by managing appropriately the R. Takes the endorsement decision for the deliverables of the task.
S	Supporting. Collaborates with the R in the execution of the task. May modify the deliverable under the instructions of the R.

¹ Additional documentation will be referenced here as they are created which will cover AI adoption through citizen development, product development or other emerging mechanisms under discussion.



C	Consulted. Gives feedback about the requirements, the intermediate deliverables, and the final deliverable of the task.
I	Informed. Receives information about the task and the deliverable at appropriate points in time.
PROCEDURE	
TRIGGER	
	• A Process Owner (or a delegated staff member) has identified a novel AI Use Case OR • A Project has identified a novel AI Use Case (SOP 52) OR • A Fusion Team has identified a novel AI Use Case (SOP YYY) OR • A grant/procurement/service level agreement initiative - sponsored by a Process Owner - has identified a novel AI Use Case (SOP 10) OR • A Process Improvement Initiative implies the identification of a novel AI Use Case (SOP 50 Enhance products and services) OR • An IT enhancement implies the identification of a novel AI Use Case (SOP 50) Identification of an AI Use Case to be registered by a Process Owner/Business Manager/Fusion Team Product Owner/Project Officer/PII leader or request for change proponent supported by the Service Manager (hereinafter referred to as 'proponent')
Step 1	Registration of an AI Use Case
Proponent AI Register Manager AI&I Board	Step 1. Register an AI Use Case • The proponent identifies an AI Use Case for registration in the AI Register. It reviews already registered AI use cases to identify whether their case is new or not². In case of uncertainty, the proponent contacts the AI&I Board for advice. • If it is confirmed that the AI Use Case is not new, no further action is required in terms of registration. • If it is confirmed that the AI Use Case is new (i.e. not yet present in the AI Register), the proponent completes the AI Registration form which triggers (i)/ creation of a row item in the AI Register (state becomes 'active') and (ii)/ notification to the AI Register Manager.

² New can mean a different use of existing AI capability, e.g. in a different process, adoption of a different AI system or AI capability or adoption of a changed AI system or AI capability.



	<table><tr><th>Input</th><th>RASCI</th><th>Output</th></tr><tr><td rowspan="5">AI Use Case idea</td><td>Proponent (R)</td><td>AI Register record</td></tr><tr><td>AI Register Manager (S, C, I)</td><td>Updated AI Register state</td></tr><tr><td>13.04 Process Owner (A)</td><td>Notifications</td></tr><tr><td>All Staff (I)</td><td></td></tr><tr><td>AI & I Board (I)</td><td></td></tr></table>	Input	RASCI	Output	AI Use Case idea	Proponent (R)	AI Register record	AI Register Manager (S, C, I)	Updated AI Register state	13.04 Process Owner (A)	Notifications	All Staff (I)		AI & I Board (I)	
Input	RASCI	Output													
AI Use Case idea	Proponent (R)	AI Register record													
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	All Staff (I)														
	AI & I Board (I)														
Step 2	Evaluation of an AI Use Case and advice to proponents														
AI Register Manager AI & I Board AI Ethics & Data Protection Function Proponent Process Owner (13.04)	Step 2 Evaluate an AI Use Case - Step 2.1 AI Register Manager invites the proponent to the next available AI&I Board Evaluation meeting or via written procedure,³ to share further details of their idea and propose an AI Risk Tier on the basis of the risk classification of the AI Act (high risk, limited risk or minimal risk). - Step 2.2 AI&I Board discuss the idea and provide advice including but not limited to: ✓ Confirmation or change to the proposed AI Risk Tier. If necessary, the AIE&DP provide advice on the correct AI Risk Tier categorisation; once the AI Risk Tier is confirmed the row in the AI Register becomes 'Risk Tier validated'; ✓ Advice regarding the proposed AI technology solution; once this advice is provided the row in the AI Register becomes 'Adequate'. AI Register Manager records the input above in the AI Register within 2 working days which triggers an automated notification to the proponent and the AIE&DP. AI Compliance Risk assessment can start. The state in the AI Register becomes 'AI Compliance risk assessment in progress'. - Step 2.3 The AIE&DP contact the proponent and, where necessary, request information additional to the one collected under steps above via a dedicated AI Compliance Risk Assessment Form made available to the proponent. - Step 2.4 The proponent provides the required information, where applicable through the dedicated AI Compliance Risk Assessment Form, resulting in the AI Compliance Risk Log. - Step 2.5 The AIE&DP review the AI Compliance Risk Log provided by the proponent. If necessary, they contact the														

³ Meetings are scheduled every 2 weeks and extra meetings can be convened in case of many use cases pending evaluation. AI&I Board may also adopt written procedure as an alternative.



	proponent again for further clarifications or amendments to the AI Compliance Risk Log. - Step 2.6 The AIE&DP conclude the review of the AI Compliance Risk Log within 15 working days, with one of the following outcomes: i. Favourable advice (with mitigating actions if need be), ('favourable advice') ii. Preliminary favourable advice subject to the need for additional analysis when the initiative is more advanced ('preliminary favourable advice'), iii. The indication that further assessments are necessary and to be coordinated by the Process Owner (e.g. Data Protection Impact Assessment, Fundamental Rights impact assessment) ('further assessment pending'), iv. Unfavourable advice ('unfavourable advice') - Step 2.7 The AI register manager updates the register with the outcome of the review and informs the AI & Innovation Board and the proponent.						
	<table><tr><th>Input</th><th>RASCI</th><th>Output</th></tr><tr><td>Registered AI Use Case</td><td>AI Register Manager (R) 13.04 process Owner (A) All Staff (I) AI Ethics & Data Protection Function (C, I) AI & I Board (C, I)</td><td>Updated AI Use Case Register record Notifications</td></tr></table>	Input	RASCI	Output	Registered AI Use Case	AI Register Manager (R) 13.04 process Owner (A) All Staff (I) AI Ethics & Data Protection Function (C, I) AI & I Board (C, I)	Updated AI Use Case Register record Notifications
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Step 3	Transition to Operations or Live Use of AI Use Case						
AI Register Manager DW Change Manager Process Owner AI & I Board	Step 3 Update Status of AI Register Use Case Trigger 1: Change request is received by Digital Workplace team of the CORSER Unit (DW) DW Change Manager verifies that the Change Request includes an AI Register AI Use Case record, an AI Compliance Risk Log, which has been reviewed by AIE&DP and named Process Owner, who accepts ongoing management of the AI Risk Log.						



AI Ethics & Data Protection Function	If these conditions are not met, DW informs Change requester that transition cannot proceed. - If these conditions are met, DW Change Manager informs AI Register Manager that an AI Use Case has been approved for transition to Operations according to SOP 050 Enhance Products and Services. - AI Register Manager updates the AI Register AI Use Case's status to 'Live'.												
All Staff	Trigger 2: Process Owner accepts ownership of AI Use Case Risk Log which was reviewed by AIE&DP, accepting the live use of a Registered AI Use Case. - Process Owner informs AI Register Manager that an AI Use Case has been accepted into live use. - AI Register Manager verifies the existence of an AI Register Use Case record, an AI Risk Log which has been verified by AIE&DP function and named Process Owner who accepts ongoing management of the AI Risk Log. If these conditions are not met, AI Register Manager informs Process Owner that transition to live use cannot proceed. - If these conditions are met, AI Register Manager updates the AI Register Use Case's status to 'Live' . <table><tr><th>Input</th><th>RASCI</th><th>Output</th></tr><tr><td>CAB Transition Checklist complete for Reviewed AI Risk Log</td><td>DW Change Manager (R) Process Owner (R)</td><td rowspan="4">Updated AI Use Case Register record</td></tr><tr><td>OR</td><td>AI Register Manager (R)</td></tr><tr><td>Process Owner accepts ownership of Reviewed AI Risk Log</td><td>13.04 Process owner (A) All Staff (I)</td></tr><tr><td></td><td>AI & I Board including AI Ethics & Data Protection Function representation (I)</td></tr></table>	Input	RASCI	Output	CAB Transition Checklist complete for Reviewed AI Risk Log	DW Change Manager (R) Process Owner (R)	Updated AI Use Case Register record	OR	AI Register Manager (R)	Process Owner accepts ownership of Reviewed AI Risk Log	13.04 Process owner (A) All Staff (I)		AI & I Board including AI Ethics & Data Protection Function representation (I)
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Step 4	Maintenance of AI Register												
AI Register Manager	Step 4 Maintain AI Register AI Use Case records												



All Staff	- AI Register Manager makes AI Register records visible to all staff through AI Hub and invites all staff to provide update information through functional mailbox AI.Hub@EFSA.europa.eu. - AI Register Manager sends periodic reports of AI Use Cases to stakeholders including but not limited to Process Owners, Heads of Units, Programme Managers, Product Managers, Fusion Teams, IT Governance Committee, AI&I Board, AIE&DP and Data Protection Function, and upon specific request, to the EDPS. - Based on any feedback received, AI Register Manager updates the AI Register Use Case records.						
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RECORDS

Reference	Title	Source or Link/Location
AIReg	AI Register	AI Register in Sharepoint Lists

ANNEXES

See next page.



ANNEX 1 : RASCI MATRIX FOR AI REGISTER

Tasks	AI INN Board	AI Ethics & Data Protection Compliance function	IDATA / KNOW HoUs	MT	CORSER DW	Procurement	Process Owners	Programme Managers	Contract Managers
First Iteration									
The first roll out of the AI Register	R	A	C	I	S	S	I	I	I
Populate the AI register	S	C	I	I	C	C	A	R	R
Review and risk tiering	C	R/A					C/I	C/I	C/I
Final report back to contacts for completion of process	R	A							
EDPS report	C	R/A							
Updates									
Insert new entries for new use cases	C	A			R	R	R	R	R
Review and risk tiering	C	R/A			C	C	C	C	C
Report back to contacts	R	A			I	I	I	I	I