

	<p align="center">Standard Operating Procedure</p> <p align="center">Management of competing interests</p>
Public	

Scope	<p>This SOP lays down the steps of initiation, assessment, validation and publication of the Declarations of Interests (i.e. Annual and Oral) completed or declared by members of the Management Board, former members of the Management Board for two years after their mandate expired, members of the Advisory Forum, Networks, candidates having applied to the call for expression of interest published by EFSA pursuant to Article 28(5) of Regulation (EC) No 178/2002, Scientific Committee, Scientific Panels, Working Groups, participants in peer review meetings, staff of EU Institutions, bodies or other agencies participating in EFSA's scientific meetings in their private capacity, the Executive Director, EFSA statutory staff, candidates placed in reserve lists for EFSA statutory staff vacant positions, Seconded National Experts and National Experts in Professional Training, tenderers and participants to grants awarding procedures. It also covers the procedures regarding PI/non-PI classification, omission of declarable interests and breaches of EFSA's rules as well as granting waivers.</p> <p>In addition, pursuant to Article 19 of the Executive Director Decision on Competing Interest Management, EFSA performs a systematic and regular check of the compliance and veracity of a sample of Declarations of Interests screening processes submitted by experts who participated in either a Plenary, Working Group or Peer Review meeting held within a specified reporting period. The relevant responsibilities, roles and steps of this check are described in the WIN/SOP039A/02.</p> <p>Concerning staff DoIs, monitoring compliance with DoI submission requirements applicable to staff members is monthly ensured by LA and followed up when necessary with the responsible individual.</p>
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Special Requirements	<p>This procedure is a controlled document maintained by Quality Management. It may not be deleted without comparable controls.</p>
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Responsibilities	<p>Concerned individual – individual required to submit a DoI LA – validation of ADoIs and PI/non-PI classification Head of Local Unit or delegated officer – assessment of ADoIs, PI/non-PI pre-classification and validation of OdoIs</p>
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Abbreviations and definitions

AA	Assurance Adviser
ABAC	Accrual Based Accounting
AdoI	Annual Declaration of Interest
AC	Assurance Council
ACo	Audit Committee

AF	Advisory Forum
AO	Authorising Officer
Article 36 List	List drawn up by EFSA's MB pursuant to Article 2 of Commission Regulation (EC) No 2230/2004, implementing Article 36 of Regulation (EC) No 178/2002
BuS	Business Services Department
CIM	Competing Interest Management
CoI	Conflict of Interest
COMCO	Communication Engagement & Cooperation Department
DoI	Declaration of Interest
DoI group	Group of experts (e.g. Management Board, Advisory Forum, Networks, SC, SP, WGs, peer review meetings, etc.)
Downgrading	A CoI risk preventing measure consisting in the change of the role of an expert being chair or vice-chair to member or to the dismissal of the expert from the relevant scientific group.
DMS	Document Management System
ED	Executive Director
EFSA staff	Officials, Temporary and Contract Agents
EU	European Union
Extraordinary mitigating measures	Any measure adopted by the ED in cases not falling under the 'ordinary mitigating measures'
FP	Focal Points
HoD	Head of Department
Local Unit	EFSA Unit responsible for managing the DoI group, assessment and validation of ADoIs and ODoIs
LA	Legal and Assurance Services
MB	EFSA Management Board
MS	Member State
HoU	Head of Unit
NEPT	National Experts in Professional Training
ODoI	Oral Declaration of Interest
Ordinary mitigating measures	<p>For the purpose of this SOP, in the context of DoI validation process related to staff members or candidates placed in reserve lists for EFSA statutory staff vacant positions, the CoI mitigating measures delegated to the signature of the BuS HoD pursuant to the Decision of the ED on the delegation of powers conferred by the Staff Regulations on the Appointing Authority and by the Conditions of Employment of Other Servants on the Authority responsible for concluding contracts of employment when consisting either of:</p> <ul style="list-style-type: none"> • selling, freezing or disposal of stocks and shares, stock options, equities, bonds and or partnerships interest in the capital of a company holding an interest in EFSA's activities; or • resigning from, or suspending, an activity, membership or

	affiliation with an entity holding an interest in EFSA's activities; or <ul style="list-style-type: none"> for positions regarding the appointment of AST or from AD5 to AD8 temporary agents, or contract agents, establishing short term limitations during the probationary phase of their contract with respect to the handling of dossiers for which the potential CoI has been identified.
Operational Management Team	Executive Director and Heads of Department
PI	Public institution
RASA	Risk Assessment & Scientific Assistance Department
REPRO	Scientific Evaluation of Regulated Products Department
SOP	Standard Operating Procedure
SC	Scientific Committee
SP	Scientific Panel
SNE	Seconded National Experts
WG	Working Group

Procedure 1 – ADoIs (Article 37 of Regulation (EC) No 178/2002 and Articles 3, 4, 6, 7, 8(1), 9(1, 2), 10, 11, 12, 13(1, 3, 4, 5, 6), 14, 15, 16, Annex 1 and 2 of the ED Decision on CIM ; Article 11 and 11a of the Staff Regulations and Articles 19 and 20 of the ED Decision on Declarations of Interest of 31 July 2014)

Person Responsible	
Local Unit	1.1 Trigger 1.1.1 Local Unit initiates the request for ADoI submission.
Candidates having applied to the call for expression of interest published by EFSA pursuant to Article 28(5) of Regulation (EC) No 178/2002, members of the SC, SPs, WGs, peer review meetings, staff of EU Institutions, bodies or other agencies participating in EFSA's scientific meetings in their private capacity,	1.2 Submission of ADoIs 1.2.1 Concerned individuals submit an ADoI in the following circumstances: <ul style="list-style-type: none"> when they are pre-selected for the reserve list from which the candidates to be appointed as members of the SC or SPs are drawn; When they become member of a DoI group; Spontaneously whenever the expert has new interests to declare and in any case within 45 calendar days following any change in the expert interests; or At least once a year, at the expiration of the previously submitted ADoI. When they take part in EFSA's public procurement and grant awarding procedures. 1.2.2 EFSA staff submit the ADoI in the following circumstances: <ul style="list-style-type: none"> Spontaneously whenever the staff member has new interests to declare; At least once a year, at the expiration of the previous submitted ADoI.

<p>Networks, MB, AF, FPs, EFSA staff, candidates placed in reserve lists for EFSA statutory staff vacant positions, SNE and NEPT, tenderers and participants to grant awarding procedure. Hearing experts participating in meetings of the SC, SPs WGs, peer review meetings, MB, AF, FPs and Networks.</p>	<p>1.2.3 Candidates placed in reserve lists for EFSA statutory staff vacant positions and selected to fill in a post pursuant to Article 11 of the Staff Regulations submit the ADoI before employment in EFSA starts.</p> <p>1.2.4 SNEs and NEPTs submit the ADoI before the period of secondment in EFSA starts.</p> <ul style="list-style-type: none"> • Spontaneously whenever an SNE or an NEPT has new interests to declare; • At least once a year, at the expiration of the previous submitted ADoI. <p>1.2.5 The ADoI is submitted via the DoI IT tool, or in case this is not available, in hard copy using the template available in Appendix I. In this event, the Local Unit shall keep appropriate records of the outcome of the assessment and validation and of its underlying rationale.</p> <p>1.2.6 Observers are not required to submit ADoIs.</p>
<p>Local Unit and LA</p>	<p>1.3 Assessment and validation of ADoIs</p> <p>1.3.1 The Local Unit and LA respectively carry out the assessment and the validation of ADoIs.</p> <p>1.3.2 The HoU may delegate the assessment of the ADoI to one or more officers of his/her Unit. In this case a formal delegation shall be signed and recorded in the Unit DMS. The delegation may be written in an email or in a note to the file electronically scanned or on paper, it should be dated and should indicate a time period of validity and the person or function to which the task is delegated.</p> <p>1.3.3 The workflow for the assessment and validation of ADoIs of candidates having applied to the call for expression of interest published by EFSA pursuant to Article 28(5) of Regulation (EC) No 178/2002, of members of the SC, SPs, WGs, peer review meetings and staff of EU Institutions, bodies or other agencies participating in EFSA's scientific meetings in their private capacity is outlined in Annex I; the workflow for the assessment and validation of ADoIs of MB members is outlined in Annex III; the workflow for the submission and publication of ADoIs of MB members after their mandate has expired is outlined in Annex IV; the workflow for the assessment and validation of ADoIs of the ED is outlined in Annex V; the workflow for the assessment and validation of ADoIs of EFSA staff members is outlined in Annex VI; the workflow for the assessment of ADoIs of candidates placed in reserve lists for EFSA statutory staff vacant positions and selected to fill in a post, SNEs and NEPTs is outlined in Annex VII; No assessment and validation is performed on ADoIs submitted by the AF members, members of Networks, FPs, and hearing experts whose applicable workflow is outlined in Annex VIII; the workflow for the assessment and validation of ADoIs of tenderers and participants to grant awarding procedures is outlined in Annex IX; the workflow for the process regarding omission of declarable interests and breaches of EFSA's rules is described in Annex XI; and the workflow for granting waivers is outlined in Annex XII.</p>

Procedure 2 – Assessment and validation of ADoIs – sub-process for PI/non-PI classification (Article 2(1) (litt.m) of the ED Decision on CIM)

Person Responsible	
Local Unit and LA	<p>2.1 Process for PI/non-PI classification</p> <p>2.1.1 During the ADoI assessment phase described in step 1.3, Local Unit pre-classifies newly declared organizations.</p> <p>2.1.2 Pursuant to the ED Decision on CIM:</p> <ul style="list-style-type: none"> • All organisations included in the Article 36 List are to be considered PIs. Organisations not included in the Article 36 List may be considered as PIs only if they are classified in ABAC by the European Commission as public legal entities or if they meet the following three cumulative criteria: <ul style="list-style-type: none"> ○ carries out tasks related to EFSA’s remit; ○ pursues public interests objectives; and ○ receives more than 50% of its budget from public entities. <p>2.1.3 Local Unit may consult with the concerned individual for additional details, indicating the information that is needed in order to conclude the classification of the organisation, or may ask LA to send to the organisation in question the form available in Appendix IV.</p> <p>2.1.4 Every week, LA assesses and classifies new organisations notified via email by the DoI tool and, if appropriate, changes how an organisation had been already classified beforehand.</p> <p>2.1.5 The workflow for the PI/non-PI classification is outlined in Annex II.</p>

Procedure 3 - ODoIs (Articles 5, 8(2), 13(2) and Annex 1 of the ED Decision on CIM)

Person Responsible	
Local Unit, Members of the SC, SPs, WG, peer review meetings, staff of EU Institutions, bodies or other agencies participating in EFSA's scientific meetings in their private capacity MB and AF members.	3.1 Submission of ODoIs 3.1.1 ODoIs are made when the concerned individuals realise that relevant interests, or particulars thereof, have not been declared previously in ADoIs or that new interests have emerged in the meantime. 3.1.2 Upon request of the Local Unit who places the item on the agenda of the relevant meeting, ODoIs are made orally at the beginning of each meeting, before the discussion of the items on the agenda commences.
Local Unit	3.2 Assessment and validation of ODoIs 3.2.1 ODoIs from SC, SPs WGs, peer review meetings and AF members, and staff of EU Institutions, bodies or other agencies participating in EFSA's meetings in their private capacity are screened by the responsible officer from the Local Unit supporting the meeting pursuant to the delegation received from the responsible HoU. ODoIs are recorded in the minutes of the meeting they refer to. 3.2.2 ODoIs from the MB members are screened by the MB collegially, with the exclusion of the member declaring the interest. This is recorded in the MB meeting minutes. 3.2.3 If the interest is considered prejudicial to the independence of the expert in relation to one or more items in the agenda, the expert or member is required to leave the meeting room when the agenda item(s) is/are discussed or excluded from participating in the specific meeting. This is recorded in the meeting minutes. 3.2.4 The workflow for the assessment of ODoIs is outlined in Annex X.

Procedure 4 – Monitoring (Article 19 of the ED Decision on CIM)

Person Responsible	
LA COMCO, RASA and REPRO Department representatives , BuS representative	4. Monitoring of compliance 4.1 Twice a year, LA coordinates a compliance and veracity check exercise on a random sample of DoI screening processes, within the specified reporting period, regarding experts who participated in either a Plenary, Working Group or Peer Review meeting as well as on a sample of DoIs submitted, within the specified reporting period, in the context of procurement and grant awarding procedures concerning EFSA's scientific activities. 4.2 COMCO, RASA and REPRO Department representatives perform the compliance and veracity checks on the random sample of scientific DoI

	<p>screening processes.</p> <p>4.3 The BuS representative performs the compliance and veracity checks on the random sample of DoI screening processes identified in outsourcing procedures.</p> <p>4.4 The findings resulting from the compliance and veracity checks exercises are submitted to the AC for endorsement.</p> <p>4.5 Every month, LA follows up on findings identified for EFSA staff members by the automated reporting system embedded in the DoI IT tool by reminding concerned EFSA staff members to either update their DoIs or to validate pending DoIs.</p>
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Procedure 5 – Transparency (Article 24 (b) of the ED Decision on CIM)

LA	<p>5. Reporting</p> <p>5.1 Every year, by end of January of year n+1, LA submits for validation by the AC a report on the highlights of independence related findings, facts and figures.</p> <p>5.2 Such report includes the outcome of the two compliance and veracity checks exercises, breach of the rules identified in the course of the year, number of waivers granted, number of CoIs prevented, number of ADoIs validated, number of hearing experts invited to EFSA’s meetings as well as any policy or regulatory development occurred in the reference period.</p> <p>5.3 After endorsement by the AC, EFSA makes the report available on its website and annex it to its Consolidated Annual Report.</p>
	Following SOP in the process: N/A