Standard Operation Procedures	SOP_020
Effective Date: 16/12/2022	**Public**

Confidentiality assessment, implementation and publication of documents

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Process Responsibility	Process owners are accountable this procedure being adhered to within their respective or unit. All relevant staff is responsible for the correct implementation of the procedure. Responsibilities for performing specific steps are outlined in the document.

SCOPE AND OBJECTIVES

This Standard Operating Procedure (SOP) lays down the steps to be followed by EFSA to implement process 2.3, 3.3, 4.3 Confidentiality Assessment and 5.9 Content Sanitization, when processing a request for confidential treatment, with the aim of ensuring a coherent and sound processing of these files.

This SOP was developed to implement Articles 38-39e of Regulation (EC) No 178/2002, Article 30 of Regulation (EC) No 1829/2003, Article 18 of Regulation (EC) No 1831/2003, Article 15 of Regulation (EC) No 2065/2003, Article 20 of Regulation (EC) No 1935/2004, Article 12 of Regulation (EC) No 1331/2008, Article 63 of Regulation (EC) No 1107/2009, MRL Regulation (EC) No 396/2005, Article 23 of Regulation (EU) 2015/2283 and Article 25 of Directive 2001/18/EC as amended by the Transparency Regulation, as well as EFSA's Practical Arrangements on Transparency and Confidentiality and EFSA's Practical Arrangements in accordance with Articles 7 and 16 of Regulation 1107/2009. This SOP applies to all EFSA Units and staff who are processing confidentiality requests, implementing them, publishing resulting documents, or who are handling documents, data or information claimed confidential.

RELEVANT STANDARDS, LEGISLATION AND DOCUMENTS

- *Treaty on the Functioning of the European Union;*
- *Charter of Fundamental Rights of the European Union;*
- *Articles 39 – 39(e) of Regulation (EC) No 178/2002;*
- *Article 30 of Regulation (EC) No 1829/2003,*
- *Article 18 of Regulation (EC) No 1831/2003,*
- *Article 15 of Regulation (EC) No 2065/2003,*
- *Article 20 of Regulation (EC) No 1935/2004,*
- *Article 12 of Regulation (EC) No 1331/2008,*
- *Article 63 of Regulation (EC) No 1107/2009,*
- *Article 12 and 13 of Commission Implementing Regulation (EU) 2020/1740,*
- *Article 23 of Regulation (EU) 2015/2283 and*
- *Article 25 of Directive 2001/18/EC*
- *Regulation (EC) No 1107/2009;*
- *Regulation (EU) 2018/1725;*
- *IMPRUL_108_PAs-confidentiality-Art-7-and-16-of-regulation-1107-2009*
- *IMPRUL_109_PAs-transparency-and-confidentiality*
- *EFSA Code of Good Administrative Behaviour.*
- *EFSA administrative guidance for regulated products*
- *Staff Regulations of the European Union*

ABBREVIATIONS AND DEFINITION

Appian	Appian confidentiality workflow processing confidentiality requests in accordance with EFSA's Practical Arrangements
Applicant	• any natural or legal person submitting an application or notification under Union law; • any natural or legal person submitting scientific data and information for evaluation to the Authority pursuant to established sectoral Union law procedures; • where permitted under sectoral Union law procedures and/or in the absence thereof, any natural or legal person submitting information voluntarily to the Authority upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the General Food Law Regulation; • any natural or legal person who has produced information supporting a request from the European Parliament, the Commission and the Member States for a scientific output and therefore having a direct interest with respect to the closed list of information items for which confidentiality treatment can be requested; This definition also covers a natural or legal person having provided data to the European Commission, the European Parliament, other Union Institutions, bodies, offices or agencies, Union Member States, or third countries' public authorities, if these institutions, bodies, offices or agencies transmit said data to EFSA.
Application	Applications of so-called "Regulated product" means the claim, process, product, substance or organism which is the subject matter of an intended or submitted given application for which Union law contains provisions for EFSA to provide a scientific output, including a scientific opinion. In the context of this SOP, the word 'application' is also considered as covering notifications under the Novel Food legislation.
A.S.	Active Substance

CBI	Confidential Business Information is information which concerns or relates information, data, documents, processes, operations, or to the manufacturing process, regulatory data, production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses of any legal or natural person, or other information of commercial value, the disclosure of which is likely to have the effect of causing substantial harm to the competitive position of the person from whom the information was obtained, in accordance with Article 39-39de of Regulation EC No 178/2002.
Case handler / CH	LA team member in charge for the assessment and processing of a set of confidentiality requests.
Confidentiality request / CR	Request submitted by the applicant pursuant to EFSA's Practical Arrangements on Transparency and Confidentiality or EFSA's Practical Arrangements in accordance with Articles 7 and 16 of Regulation 1107/2009 to maintain certain elements of the application dossier, document or dataset confidential.
DAR	Draft Assessment Report pursuant to Regulation (EC) No 1107/2009
DMS	EFSA's Document Management System, irrespective of the actual technical solution deployed.
EC	European Commission
ED	Executive Director
EFSA	European Food Safety Authority
EMS	Evaluating Member State under Regulation (EC) No 396/2005
ESFC	The E-Submission Food Chain platform – the 'ESFC' – is the main tool with which the applicants can create and manage their dossiers. Using the ESFC platform, all the main stakeholders (Applicant, Commission and EFSA) interact from the start to the end of the authorisation process. While compiling their dossiers, applicants can request confidentiality on data elements (sections of documents) within their dossiers. Consequently, EFSA carries out the confidentiality assessments for most domains. Only non-confidential information is disseminated on the OpenEFSA portal
Evidence Log	Tool used to upload supporting documents (e.g., mandates, mandate acceptance letters, deadline extension requests, annexes, additional data requests) for possible dissemination through the OpenEFSA Portal.
EU	European Union
FDP	Front-Desk & Workforce Planning unit responsible for interacting with applicants
FMB	Functional Mailbox
GFL	General Food Law - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
GM	Genetically Modified
HoD	Head of Department
HoU	Head of Unit

IUCLID	International Uniform Chemical Information Database
LA	Legal Affairs Services or unit housing confidentiality team or function responsible for handling confidentiality requests and sanitizsing relevant documents to implement a confidentiality decision.
NCA	National competent authority: authority in charge of advisory or regulatory tasks under the respective sectoral Union law. Under Directive 2001/18/EC this is called "notified Member State".
Open EFSA Portal	This portal is the single public interface for all information related to EFSA's scientific work. It allows to follow the risk assessment process from receipt of the mandate to adoption/ endorsement/approval of the resulting output, and integrates information coming from different platforms, such as Case Management Tool, Customer Portal or Talent Management Tool, making available the documents produced and used in the process.
Practical Arrangements	Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning transparency and confidentiality
PC	Public Consultation performed pursuant to Article 32c of Regulation EC No 178/2002 or on the DAR or RAR pursuant to Regulation (EU) No 1107/2009.
Portalino	e-submission portal allowing applicants to submit confidentiality requests in sectors not covered by ESFC or IUCLID.
RAL	Risk Assessment Logistics, unit in charge for the provision of logistical functions to SMUs.
RAR	Renewal Assessment Report pursuant to Regulation (EC) No 1107/2009
RMS	Rapporteur Member State under Regulation (EC) No 1107/2009
TL	Team Leader(s) in charge for the coordination of the confidentiality assessment process
Transparency Regulation	Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance.) OJ L 231, 6.9.2019, p. 1–28
SMU	Subject Matter Unit - EFSA Unit or function in charge of performing or coordinating the scientific evaluation on any "dossier", document, data or information on which a confidentiality request is submitted
SOP	Standard Operating Procedure – Detailed, written instructions aiming at achieving uniformity in the performance and quality of a specific process. The instructions usually cover more than one task or area within EFSA, the Department, the Unit or the team.
UUID	Universally unique identifier
WIN	Working Instruction
	Previous SOPs in the process:n/a
PROCEDURE 1	STANDARD CONFIDENTIALITY DECISION-MAKING ON CONFIDENTIALITY REQUESTS SUBMITTED BY APPLICANTS

Step 1	1.0 Submission and compliance of confidentiality requests
Applicant	1.1 For the purpose of this procedure, in accordance with Article 9 of EFSA's Practical Arrangements on Transparency and Confidentiality, an applicant submits (either via Portalino or ESFC) a confidential and a non-confidential version of its application dossiers or datasets. The confidential version of the application includes all information submitted by the applicant, including any written request for confidential treatment of certain items to be evaluated by EFSA by using the tools indicated by EFSA on its website ("EFSA user guide on confidentiality")
SMU, FDP	1.2 In the alternative to step 1.1, a confidentiality request may be submitted in the context of a mandate submitted under Article 29 or 31 of the GFL[1], or of a call for data. Deadlines for the assessment and adoption of confidentiality decisions in this procedure are not applicable to confidentiality requests submitted in the context of a mandate or of a call for data.
	1.3 The SMU and FDP comply with the submitted confidentiality request(s) ensuring that information claimed confidential by the applicant is consistently identified as such to experts, staff or contractors responsible for its handling. Compliance with the confidentiality requests may be waived only after the rejection of a confidentiality request pursuant to a decision adopted under Procedures 1, 2, 3, 4, 7 or 8, of this SOP.
Step 2	2.0 Completeness check of the dossier, or receipt of a mandate pursuant to Article 29 of the GFL
FDP	2.1 For processes which require a completeness step (e.g. see SOP12), FDP informs RAL and LA of the presence of confidentiality request(s) in the dossier already at the moment in which the application is considered complete. For confidentiality requests received in the context of a mandate under Article 29 and 31 of the GFL, such communication shall take place when the mandate is accepted by EFSA.
FDP	
	2.2 In the course of the completeness check, FDP for ESFC and Portalino carries out an additional verification, randomly based, on pre-defined practical requirements of the dossier relevant to the confidentiality assessment process (so called "light check"). The aim is to detect before publication the most impacting and recurrent shortcomings of the non-confidential version of the dossier as prepared by the applicant.
SMU	2.3 FDP requires at least on two occasions the applicant to submit a compliant version and keeps the records of such requests.
	2.4 In case a confidentiality request is received in the context of a call for data, SMU informs LA when the call is closed and assigns a Question Number to Portalino submissions.
FDP	2.5 Upon finding a dossier suitable or valid, FDP ensures it is made publicly available on OpenEFSA.

[1] Procedure 1 shall apply to any generic mandate, including sector-specific mandates sent to EFSA based on Article 29 and 31 of the GFL via the applicable sectorial legislation (e.g., Article 21(2) of Regulation (EC) No 1107/2009 or Article 43 of Regulation (EC) No 396/2005).

Step 3	3.0 First check of confidentiality request
LA	3.1 LA acknowledges receipt of the CRs to FDP, asking FDP to provide the NoS extraction relevant for the application dossier, if not done already by FDP. In case an extraction exists, the CH sends the encrypted NoS extraction to the applicant asking whether they want to submit any confidentiality request on the NoS extraction, giving them 5 working days to reply. Any CR submitted in this context is processed in accordance with Procedure 1 of this SOP, with the exception that the acceptance of all CRs may be communicated by EFSA via an ordinary email from the TL, without the need of issuing a formal decision. 3.2 If the applicant submits confidentiality requests on items other than the NoS extraction, LA performs a first check of the confidentiality request to verify in accordance with Articles 9 and 10 of EFSA's Practical Arrangements concerning transparency and confidentiality whether it: i) was submitted in writing, using the appropriate tool. ii) allows the precise identification of the information to be kept confidential and is accompanied by a link to and detailed reference to the exact paragraph, page and line where this information is located; iii) provides justification supporting each confidentiality request; iv) is made on information that is not in the public domain. 3.3 If the screening of step 3.2 reveals that the confidentiality request does not comply with the elements in point 3.2., and this is allowed by the relevant IT system, LA may request the applicant in writing to submit a compliant request, setting a five (5) working days deadline to reply. If the request remains unanswered after the expiry of the deadline, the CH proceeds to the assessment of the confidentiality request as it is, drafting where relevant a negative decision highlighting non-compliance with the relevant procedural requirement. 3.4 If LA confirms compliance with all elements in 3.2, it moves to the assessment of the confidentiality request (step 4).
Step 4	4.0 Assessment of the confidentiality request
LA, SMU where needed	4.1 LA analyses the confidentiality request in its entirety, including the merits of the verifiable justification submitted by the applicant as per Article 10 of EFSA's Practical Arrangements on Transparency and Confidentiality. 4.2 In case of doubts whose clearance requires expertise not available within LA, the CH in LA consults with the SMU by indicating clearly the input required and by setting a deadline of up to 20 (twenty) working days for the more numerous requests. 4.3 If it needs clarifications on certain elements of the confidentiality request, the CH in LA contacts the applicant in writing, setting a deadline for them to reply within five (5) working days. Upon receipt of the requested clarifications from the applicant and/or reply to SMU consultation, if any, the CH in LA completes the Template Decision provided in the relevant IT tool or in the available Working Instructions.

Step 5	5.0 Consultation of the applicant on the draft decision
LA	5.1 In case the draft decision accepts all the confidentiality requests submitted by the applicant, the CH moves to step 6 without notifying the draft decision pursuant to step 5.2. 5.2 The CH in LA shares the draft decision with the applicant informing them that they may submit comments or withdraw the application no later than two (2) calendar weeks from the receipt of the draft decision. 5.3 Where relevant, this deadline is extended automatically by the number of days during which EFSA was closed for business.
Step 6	6.0 Decision on the confidentiality request
LA	6.1 Within seven (7) weeks from the start of the confidentiality decision making process as per Step 2.2, and upon consideration of all relevant elements, including verifiable justification submitted by the applicant, the CH in LA considers and addresses any comment received by the applicant, finalises and prepares the decision on the confidentiality requests for signature.
TL	6.2 By default, the draft decisions and decisions are issued in English. Draft decisions and decisions are issued in the official language of the Union in which they are received only upon explicit request by the applicant. Applicants may do so by writing to confidentialityrequestassessment@efsa.europa.eu within the time limits foreseen in the EFSA information management policy. In this event, the applicant receives a translation into the requested language of the Union by two months from the receipt of their request. The English version remains the authentic one, and the request of a translation does not impact on any applicable deadline.
CH	6.3 Within ten (10) calendar weeks from the start of confidentiality decision making as per Step 2.2, the draft decision on the confidentiality request is signed off by the responsible TL of LA.
CH	6.4 Once the decision is signed, and no later than the next working day, the CH in LA shares the decision with the SMU and RAL and notifies it to the applicant, either via Appian, Portalino or, in case of unavailability of the relevant IT tool, by email in a secure manner. The notification includes a notice about the applicant's right to submit a confirmatory application within two (2) calendar weeks from receipt of the notification as per Procedure 2.
LA	6.5 The decision is to be recorded in the tool made available by EFSA, where present, or in LA DMS files.
	6.6 The CH triggers the implementation / sanitisation by sharing the decision with the FMB confidentialitysanitisation@efsa.europa.eu.
RAL	6.7 LA performs the sanitisation in accordance with Procedure 5. 6.8 Upon completion of Procedure 5, LA informs the SMU and RAL when the implementation of the relevant decision is completed by writing to the respective FMBs, thereby triggering publication pursuant to Procedure 10.
	6.9 RAL communicates the reasoned decision on the confidentiality request to the Commission and the Member States' competent authorities and/or the EU Reference Laboratory involved in the risk assessment process, as appropriate.

PROCEDURE 2	CONFIDENTIALITY DECISION MAKING ON CONFIRMATORY APPLICATIONS ON DECISIONS ADOPTED UNDER PROCEDURE 1
Step 1	1.0 Submission of the confirmatory application
Applicant	1.1 In accordance with Article 12 of EFSA's Practical Arrangements on Transparency and Confidentiality, the applicant files a confirmatory application asking EFSA to reconsider its decision made under the Step 6 of Procedure 1 or Procedure 8. 1.2 The confirmatory application referred to in paragraph 1.1. is submitted via ESFC or Portalino, or in the unavailability thereof to confidentialityconfirmatoryappication@efsa.europa.eu, to the attention of the ED within two (2) calendar weeks of the notification of the contested decision to the applicant 1.3 The submission of a confirmatory request has a suspensive effect on Procedure 5 concerning the implementation of the decision on which the confirmatory request is made.
Step 2	2.0 Completeness check of the dossier, or receipt of a mandate pursuant to Article 29 of the GFL
LA	2.1 The CH in LA verifies compliance with the two (2) calendar weeks legislative timeline for submitting the confirmatory application and assigns the confirmatory application to a CH who has not worked on the decision subject to the confirmatory application. 2.2 The CH informs the SMU and RAL about the receipt of the confirmatory application and the need to suspend the implementation of the decision on which the confirmatory application is submitted. 2.3 Where the Appian workflow is available, the CH clicks on the button "suspend publication".
Step 3	3.0 Assessment of confirmatory application
LA	3.1 The CH in LA firstly examines compliance with the procedural requirements set out in Article 12 of the Practical Arrangements on Transparency and Confidentiality. 3.2 The CH in LA then analyses the confirmatory application in its entirety as per Article 12 of EFSA's Practical Arrangements on Transparency and Confidentiality. 3.3 In case of doubts whose clearance requires expertise not available within LA, the CH in LA consults with the SMU by indicating clearly the input required and by setting a deadline for the reply (indicatively 3 working days). If it needs clarifications on certain elements of the confirmatory application, the CH in LA may contact in writing the applicant, setting a deadline for them to reply within three (3) working days.
Step 4	4.0 Decision on confirmatory application
LA	4.1 The CH in LA drafts the decision on the confirmatory application by using the template Decision provided in the available Working

	Instructions. By default, the decisions are issued in English. Decisions are issued in the official language of the Union in which the confidentiality requests are received only upon explicit request by the applicant. Applicants may do so by writing to confidentialityrequestassessment@efsa.europa.eu in accordance with the timeline set out in this regard by the EFSA information management policy. In this event, the applicant receives a translation into the requested language of the Union. The English version remains the authentic one, and the request of a translation does not impact on any applicable deadline.
	4.2 Upon consideration of all relevant elements, the CH prepares the decision on the confirmatory application for signature and shares it with the LA HoU indicatively not later than three (3) working days before the expiry of the timeline for the adoption of the decision on the confirmatory application.
HoU LA	4.3 The decision on the confirmatory application is signed off by the HoU LA on behalf of EFSA's Executive Director no later than three (3) calendar weeks from receipt of the confirmatory application.
LA	4.4 Once signed, the decision is notified to the applicant not later than the next working day, either via Appian, Portalino or, in case of unavailability of the respective IT tool, by email in a secure manner.
	4.5 The notification of the decision on the confirmatory application or the decision itself indicates the possibility for the concerned individual to withdraw the application or have recourse to legal remedies.
	4.6 The CH in LA records the signed decision in the tool made available by EFSA, where present, or in LA DMS files.
	4.7 The CH in LA shares the decision on the confirmatory application with the SMU as well as RAL.
	4.8 The CH triggers the implementation / sanitisation by sharing the decision with the FMB confidentialitysanitisation@efsa.europa.eu.
	4.9 LA performs the sanitisation in accordance with Procedure 5 and informs RAL and SMU once it is finalised by writing to the respective FMBs, thereby triggering publication pursuant to Procedure 10.
RAL	Upon finalisation of Procedure 5, RAL communicates the reasoned decision on the confirmatory application to the Commission and the Member States' competent authorities and/or EU Reference Laboratory involved in the risk assessment process, as appropriate, and makes the dossier implementing the decision publicly available on OpenEFSA pursuant to Procedure 10.

PROCEDURE 3	CONFIDENTIALITY DECISION MAKING ON CONFIDENTIALITY REQUESTS REGARDING DATA SUBMITTED DURING THE SCIENTIFIC EVALUATION PROCESS
Step 1	1.0 Submission of confidentiality requests
Applicant	1.1 This procedure applies to confidentiality requests submitted to EFSA through the tools indicated by EFSA by an applicant with

	regard to additional or supplementary information, documents or data submitted to EFSA at its request or at the request of the RMS or in the context of the updated dossier that may be submitted following the commenting round on the draft output with the applicant pursuant to Article 13(4) of Regulation (EU) 2020/1740 for evaluation during the risk assessment or scientific evaluation process after the application was considered valid/ admissible or the mandate was accepted. This does not apply where (i) an explicit legal provision requires the assessment of the confidentiality request earlier in the process, or (ii) in exceptional cases, it may be decided to depart from this principle and assess the confidentiality requests earlier in the process in combination with the original submissions.
Step 2	2.0_Processing of confidentiality requests submitted during the scientific evaluation process
TL LA	2.1 The TL in LA groups all confidentiality requests submitted under Step 1 and keeps them on hold until the SMU informs LA that the scientific output is adopted/approved/endorsed. 2.2 Upon receipt by the SMU of the information that the scientific output is adopted/approved/endorsed, LA processes the confidentiality request in accordance with Procedure 1, or, where applicable, Procedures 2, 4, 5, 6 and 8, with the exception of the relevant timelines.
Step 3	3.0_Publication
RAL	3.1 Following approval of the output, and upon conclusion of the confidentiality assessment regarding confidentiality requests on the additional information, RAL makes proactively available the final non-confidential version of the updated dossier received from the applicant . No publication of the versions submitted by the applicant in reply to ADR, or of the version that may be submitted in the framework of Art 13(4) of Regulation (EU) 2020/1740 and prior to the confidentiality is performed.

PROCEDURE 4	REVIEW OF PREVIOUSLY ADOPTED CONFIDENTIALITY DECISIONS UNDER PROCEDURES 1, 2, 3, 7 OR 8
Step 1	1.0 Review of confidentiality decisions adopted under Procedure 1, 2, 3, 7 or 8 and confidentiality decisions taken by a competent national authority pursuant to Directive 2001/18/EC.
SMU RAL	1.1 As soon as a scientific output containing information relating to foreseeable effects on human health, animal health or the environment related to information that has been granted confidential status pursuant to Procedure 1, 2, 3, 7 or 8 is adopted, approved or endorsed, as appropriate for the output in question, the SMU informs LA by using the tool made available by EFSA (Appian) or, in case of its unavailability, writing to FMB confidentialityrequestassessment@efsa.europa.eu by identifying clearly which items that were granted confidential status form part of the safety concerns, environmental or animal health concerns. 1.2 Where necessary in view of the urgency to publish to comply with the deadline for publication as per SOP14, RAL publishes a

	provisional version of the adopted output keeping confidential the items initially granted confidential status. This is done in combination with a legal notice on the relevant webpage
LA	1.3 The CH in LA may consult with the SMU to clarify aspects of scientific relevance in the scientific output, underlying confidentiality request or information claimed confidential.
	1.4 The CH in LA reviews the decision issued pursuant to Procedure 1, 2, 3, 4, or 8 , or the decision issued by national authority for application received under Directive 2001/18/EC Part C, where applicable, to establish whether they considered confidential information, documents or data, which: a. forms part of conclusions of scientific outputs, including scientific opinions; and b. relates to foreseeable effect on human health, animal health or the environment.
	1.5 If the requirements in 1.4 are met, by twenty (20) working days of the adoption of the scientific output, the CH in LA issues a decision pursuant to Procedure 1, stating which of the elements previously considered confidential must be made public pursuant to Article 39c of Regulation (EC) No 178/2002.
	1.6 As the timelines for the Article 39c review procedure is short (20 working days) and the internal deadlines have not been specified in the Transparency Regulation or Practical Arrangements, it has been decided to adopt the approach that for mandatory consultations on draft decisions carried out as part of Procedure 1, a deadline of two (2) weeks be granted to the applicant whereas for requests for clarification and consultations of the SMU a deadline of three (3) working days will apply. The timeline of two (2) weeks to submit a confirmatory application applies.
LA	1.7 If the applicant submits a confirmatory application against the decision issued pursuant to Step 1.4, the CH in LA applies Procedure 2. In this event, the deadline for adopting the decision on the confirmatory application is ten (10) working days from the receipt of the confirmatory application, and the deadline for requests for clarification or SMU consultation is three (3) working days from the sending of the request by LA.
	1.8 Without delay the CH in LA shares the review decision(s) with the SMU via the FMB and RAL (ral@efsa.europa.eu) or via the tool made available by EFSA.
	1.9 The CH in LA triggers the sanitisation of the dossier by sharing the decision with the FMB confidentialitysanitisation@efsa.europa.eu.
SMU, LA RAL	1.10 LA sanitises the dossier and the SMU sanitises the scientific output and its background documents, if any, implementing the confidentiality decision in accordance with Procedure 5 and RAL makes the output available online replacing the previous version of the document in accordance with Procedure 10.

PROCEDURE 5	IMPLEMENTATION / SANITISATION OF EFSA'S DECISIONS UNDER PROCEDURES, 1, 2, 3, 4 OR
Step 1	1.0 Implementation of the Authority's decisions pursuant to Procedures 1, 2 3, 4 or 8
LA, Applicant	1.1 LA implements the EFSA confidentiality decisions on the application dossiers, generic mandates and calls for data without delay and in any event immediately after two (2) weeks from the notification of the decision adopted pursuant to Procedures 1, 2, 3, 4 or 8. By the following working day at the latest, LA informs the RAL, SMU and FDP FMBs once the implementation process has been finalised.
SMU	1.2 SMU implements EFSA's decisions pursuant to Procedures 1, 2, 3 and 4 on the minutes of EFSA's Scientific Committee, Scientific Panels and Working groups, as well as on the Authority's scientific outputs and background documents, including the opinions of the Scientific Committee and the Scientific Panels, minority opinions, seeking where appropriate clarifications from LA.
	1.3 To implement EFSA's confidentiality decisions, LA and the SMU must ensure that information or data granted confidential status is blocked out in an unreversible and permanent manner in the version of the document meant for public disclosure and that information or data for which a confidentiality request has been rejected are visible. These operations must be done using the technical tool made available by EFSA (nuance pdf or comparable).
RAL, SMU	1.4 RAL, SMU as well as all concerned EFSA staff members comply with the confidentiality decision ensuring that information acknowledged as confidential by EFSA, the EC or the RMS/EMS is consistently identified as such to Member States involved in the scientific evaluation process, experts, staff or contractors responsible for its handling. To do so, experts and staff receive via the relevant IT tool (Dossier Viewer, Evidence Log or IUCLID, or DMS) earmarked versions of the documents, information or data on which confidentiality requests are submitted identifying information initially claimed confidential in the documents. SMU also shares via the relevant IT tool (Dossier Viewer, Evidence Log or IUCLID, or DMS) with the experts the documents, data or information with regard to which the confidentiality decision has been implemented, as soon as they are made available by LA or by the SMU, depending on who is in charge for performing the sanitisation.
	1.5 The submission of a confirmatory application or the receipt of an Order from the General Court of the EU shall put on hold the implementation of the relevant decision until a final determination is issued.
LA, SMU	1.6 For dossiers other than those submitted via IUCLID, LA and SMU may share the documents resulting from the implementation of confidentiality decisions under Step 1.1 and 1.2 with the applicant in order to verify the consistency between the confidentiality decisions and the way they have been implemented by EFSA.
	1.7 For documents in Step 1.1., LA triggers the publication of the sanitised documents on the OpenEFSA portal at the expiry of a two (2) weeks' timeline after notification of the EFSA's decision pursuant to Procedure 1, 2, 3, 4 or 8).

	1.8 For the next Step regarding dissemination, please refer to Procedure 10 below.

PROCEDURE 6	WITHDRAWAL OF AN APPLICATION BY THE APPLICANT
Step 1	1.0 Withdrawal of an application by the applicant
SMU	1.1 This process only applies to applications submitted under the scope of the Transparency Regulation. In case the applicant withdraws its application prior to the adoption of EFSA's output, SMU informs LA, RAL and FDP of the withdrawal.
	1.2 Upon receipt of the withdrawal request from the applicant, all processes in SOP020 reach an end and SMU deletes all the information made publicly available in relation to this dossier, except, where relevant, EFSA's scientific outputs with background documents, which always remain publicly available.
RAL	1.3 RAL deletes all withdrawn application dossiers, from the dissemination portal. Administrative information on the question number, mandate acceptance and stop the clock cover letters shall not be deleted.
SMU	1.4 The SMU stores for at least seven years one copy of the withdrawn dossiers, information, documents or datasets in its archives for auditing reasons. Where relevant, the same applies to files held by LA in the context of the confidentiality decision making.
RAL	1.5 RAL communicates the notification of withdrawal to the Commission, Member States' competent authorities and EU reference laboratories.

PROCEDURE 7	CONFIDENTIALITY DECISION-MAKING, IMPLEMENTATION AND DISSEMINATION IN RELATION TO NEW ACTIVE

	SUBSTANCE (NAS) AND AMENDMENT TO THE CONDITIONS OF AN APPROVAL DOSSIERS
Step 1	1.0 Light check
RMS FDP	1.1 In the course of the check on admissibility, RMS carries out an additional, randomised verification based on pre-defined practical requirements of the dossier relevant to the confidentiality assessment process (so called "light check"). The aim is to detect the most impactful and recurrent shortcomings of the initial public version of the initial dossier, as prepared by the applicant, before publication. 1.2 FDP performs its own light check prior to publication and the applicant is asked to notify LA (confidentialityrequestassessment@efsa.europa.eu) once the initial dossier has been re-submitted and to provide the corresponding UUID.
Step 2	2.0 From admissibility to public consultation
RMS TL LA LA, SMU RMS, Applicant FDP	2.1 No later than four (4) calendar weeks after receipt of confidentiality requests on the initial dossier and prior to finalizing its confidentiality decision, EFSA (LA confidentialityrequestassessment@efsa.europa.eu) is consulted by the RMS within the approval procedure under Article 7 of Regulation (EC) No 1107/2009 by sharing the draft decision in an electronic format and via the tool made available by EFSA. The RMS also shares the corresponding UUID of the initial dossier. 2.2 The TL in LA assigns the case to an available CH, without delay. 2.3 By an indicative timeline of ten (10) working days from the receipt of the draft decision, the CH in LA comments on the draft decision received from the RMS by verifying its compliance with its Practical Arrangements concerning Articles 7 and 16 of Regulation (EC) No 1107/2009 as well as applicable Union law and case law. In case there is a related MRL dossier concerning intended uses specified in the A.S dossier, LA should ensure alignment in the confidentiality assessments on the MRL and A.S. dossier. Furthermore, to the extent possible, the timelines for the two linked confidentiality assessments should be kept aligned. 2.4 Where necessary, the CH in LA consults with the SMU (PREV.confidentialityPostTR@efsa.europa.eu) by giving them an indicative timeline of four (4) working days for commenting on the draft decision. 2.5 Once the confidentiality decision has been adopted, the RMS requests the applicant to implement the decision by re-submitting the initial dossier in IUCLID modified in accordance with the decision. The RMS communicates the decision and the UUID to the EC/MS, EURLs and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu). FDP makes available on the OpenEFSA Portal the final public version of the initial dossier implementing the confidentiality decision in IUCLID as well as the (sanitised) extract from the NoS database.
Step 3	3.0 From public consultation to approval of output

RAL	3.1 Upon automated closure of the public consultation (PC) on the final public version of the initial dossier, RAL ensures dissemination of comments received in the PC on the OpenEFSA Portal.
FDP, Applicant	3.2 Upon receipt of the complete initial DAR from the RMS, FDP shares the initial DAR with the applicant who has two (2) weeks to submit confidentiality requests along with a non-confidential, sanitised version as well as a confidential version thereof via Portalino (https://confportal.efsa.europa.eu/) informing EC/MS and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu) by e-mail.
LA, RAL	3.3 Upon receipt of confidentiality requests on the complete initial DAR, if any, LA carries out a confidentiality assessment applying Procedure 1, Steps 3-6 *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, if any. If no confidentiality requests are received within the two (2) weeks period, upon indication from LA to RAL (RAL@efsa.europa.eu), RAL publishes the complete initial DAR on the OpenEFSA Portal without delay.
LA	3.4 If applicable, LA notifies the confidentiality decision on the initial DAR in accordance with Procedure 1, Step 6.4, applicable *mutatis mutandis*. LA implements the decision applying Procedure 5 *mutatis mutandis*. In case a confirmatory application is received on the decision, LA processes the confirmatory application applying Procedure 2 *mutatis mutandis*. RAL notifies the decision applying Procedure 1, Step 6.9 *mutatis mutandis*.
RAL	3.5 If applicable, RAL makes available the final non-confidential version of the initial DAR on the OpenEFSA Portal without delay upon indication from LA to RAL (RAL@efsa.europa.eu), unless an Order from the General Court of the EU has been received to suspend implementation of the decision in the meantime. 3.6 Upon the automated closure of the PC on the DAR, RAL ensures dissemination of comments received in the PC on the OpenEFSA Portal. 3.7 RAL sanitises personal data as well as information subject to pending confidentiality requests or which was awarded confidentiality treatment in the EFSA cover letter, if any, requesting additional information from the applicant and uploads it in the evidence log for dissemination on the OpenEFSA Portal. Following the experts meeting, if any, a high-level report of the experts meeting is published on the EFSA website by RAL without delay after having ensured that no information for which a confidentiality decision is pending or having been awarded confidential status is contained therein.
Step 4	4.0 Post-approval of output
	4.1 If the approved EFSA output identifies foreseeable effects on human health, animal health or the environment related to information that has been granted confidential status, Procedure 4 shall apply *mutatis mutandis*.
RAL, Applicant	4.2 When notifying the applicant of the approved output, RAL also shares the final DAR and the peer review report with the applicant who, considering any relevant confidentiality decisions, has two (2) weeks to (i) submit confidentiality requests on the final DAR along with a non-confidential, sanitised version and a confidential version thereof via Portalino (https://confportal.efsa.europa.eu/) and (ii) to

	submit justified requests for removal on the output and peer review report along with non-confidential, sanitised versions and confidential versions of these documents via the DMS link made available for that purpose informing EC/MS and EFSA (LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu) by e-mail.
LA, RAL	4.3 Upon receipt of the confidentiality requests on the final DAR, if any, LA assesses the confidentiality requests on the final DAR (i.e. the confidentiality requests regarding all the updates, if any, to the initial DAR) applying Procedure 1, Steps 3-6 *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, including in particular the Article 39c review decision, if any. If no confidentiality requests are received within the two (2) weeks period, upon indication from LA to RAL (RAL@efsa.europa.eu), RAL publishes the final DAR on the OpenEFSA Portal without delay at the same time as the other documents referred to under step 4.4.
SMU, LA, RAL	4.4 If necessary to ensure implementation of relevant confidentiality decisions and confidentiality of items subject to pending confidentiality requests, SMU performs a sanitisation check of the output[2] and publishes it with the support of RAL in accordance with SOP014. Upon indication from SMU (peer review report) and/or LA[3] (final DAR) to RAL (RAL@efsa.europa.eu), the sanitised/public version of the peer review report and the sanitised/public version of the final DAR is also published by RAL on the OpenEFSA portal, as provided by the applicant. If relevant, a legal notice is made available on the EFSA webpage indicating that the documents concerned may be re-published due to the need to unblacken certain information following conclusion of relevant confidentiality assessments that were ongoing at the time of first publication.
	4.5 In case there are 39c requests steps 4.6 to 4.7 are to be followed. If there are no 39c request but there are confidentiality requests on additional information, proceed from step 4.8. If there are neither 39c requests nor confidentiality requests on additional information but there are confidentiality requests on the final DAR, proceed from step 4.10, or, if there are also no confidentiality requests on the final DAR but there is a peer review report, proceed from step 4.11. Otherwise, the procedure ends here.
LA, RMS	4.6 Before notification of the Article 39c review decision to the applicant, LA verifies with RMS where there are confidentiality requests concerning the updated dossier including additional information ('updated dossier') and the confidentiality assessment on the additional information still needs to be concluded **a.** where there are confidentiality requests concerning the additional information and the confidentiality assessment on the additional information still needs to be concluded: **i.** upon adoption of the Article 39c decision, LA notifies the decision to relevant actors, including the RMS for consideration in the confidentiality assessment on the additional information, applying Procedure 1, Step 6.4 *mutatis mutandis*. The decision is to specify that the

[2] While the confidential and confidential version of the output submitted by the applicant may serve as useful point of reference for the sanitization check of the output, the SMU is to sanitise the version of the output that was subject to editorial checks and corrections by EFSA's publisher.

[3] Only in case there are confidentiality requests on the final DAR, otherwise RAL is to autonomously proceed with the publication upon receipt of the complete final DAR.

	applicant shall await the notification of the confidentiality decision on the additional information before re-submitting the updated dossier in order to be able to implement changes flowing from the Article 39c review decision and the confidentiality decision on additional information via a single re-submission
RMS, Applicant	**ii.** upon adoption and notification of the confidentiality decision on the additional information[4], and once the applicant has re-submitted the updated dossier modified in compliance with the confidentiality decision on additional information, RMS communicates the decision and the relevant UUID to the EC/MS, EURLs and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu)
LA	**iii.** LA performs systematic quality checks on the sanitisation performed by the applicant to implement the Article 39c decision
LA, RAL	**iv.** once the two (2) weeks timeline to submit a confirmatory application has expired and the applicant correctly implemented the decision, upon notification from LA to RAL (RAL@efsa.europa.eu) of the completion of the implementation of the decision in accordance with Procedure 5, Step 1.1, applicable *mutatis mutandis*, RAL notifies the decision to other relevant actors, applying Procedure 1, Step 6.9 *mutatis mutandis*. LA requests FDP to publish the public version of the updated dossier on the OpenEFSA Portal providing the relevant UUID, unless an Order from the General Court of the EU has been received to suspend implementation of the decision in the meantime
FDP	**v.** FDP makes available on the Open EFSA portal the public version of the updated dossier in IUCLID.
	b. where there were no confidentiality requests on additional information or the confidentiality assessment on additional information has already been concluded[5]:
LA, Applicant	**i.** upon adoption of the Article 39c decision, LA notifies the decision applying Procedure 1, Step 6.4 *mutatis mutandis*. LA requests the applicant to re-submit the (updated) dossier in IUCLID within two (2) weeks of notification of the decision thereby applying Procedure 8a, Step 2.3 *mutatis mutandis*[6]

[4] The confidentiality decision on the additional information shall specify that the applicant shall implement both the confidentiality decision on additional information and the 39c decision simultaneously via a single re-submission, if possible.

[5] In case the confidentiality assessment on the additional information is concluded before the 39c review, the RMS should check with EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu) whether the confidentiality decision on the 39c requests is still ongoing and, if so, the RMS should specify in its confidentiality decision on additional information that the applicant shall await the notification of the confidentiality decision on the 39c decision before re-submitting the dossier in order to be able to implement changes flowing from the Article 39c review decision and the confidentiality decision on additional information via a single re-submission.

[6] In case the confidentiality assessment on the additional information was concluded before the 39c review, the 39c decision shall specify that the applicant shall implement both the confidentiality decision on additional information and the 39c decision simultaneously via a single re-submission, if possible.

LA	**ii.** LA performs systematic quality checks on the sanitisation performed by the applicant to implement the Article 39c decision
LA, RAL	**iii.** once the two (2) weeks timeline to submit a confirmatory application has expired and the applicant correctly implemented the confidentiality decision, upon notification from LA to RAL (RAL@efsa.europa.eu) of the completion of the implementation of the decision in accordance with Procedure 5, Step 1.1, applicable *mutatis mutandis*, RAL notifies the decision to other relevant actors applying Procedure 1, Step 6.9 *mutatis mutandis*. LA requests FDP (FDP@efsa.europa.eu) to publish the public version of the (updated) dossier on the OpenEFSA Portal providing the relevant UUID, unless an Order from the General Court of the EU has been received to suspend implementation of the decision in the meantime
FDP	**iv.** FDP makes available on the Open EFSA portal the public version of the (updated) dossier in IUCLID.
SMU, RAL	4.7 SMU implements the Article 39c decision on the initial DAR applying Procedure 5 *mutatis mutandis* and, upon notification from SMU to RAL (RAL@efsa.europa.eu), RAL re-publishes the initial DAR on the OpenEFSA Portal.
RMS, Applicant	4.8 If applicable, once the confidentiality decision on the additional information has been adopted, the RMS requests the applicant to implement the decision by re-submitting the updated dossier in IUCLID modified in accordance with the decision. The RMS communicates the decision and the UUID to the EC/MS, EURLs and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu).[7]
FDP	4.9 FDP makes available on the OpenEFSA Portal the public version of the updated dossier.[8]
LA, RAL	4.10 If applicable, the confidentiality decision regarding the final DAR is notified by LA in accordance with Procedure 1, Step 6.4, applicable *mutatis mutandis*. LA implements the decision applying Procedure 5 *mutatis mutandis* (in case a confirmatory application is received, LA processes the confirmatory application applying Procedure 2 *mutatis mutandis*). RAL notifies the decision to other relevant actors applying Procedure 1, Step 6.9 *mutatis mutandis*.
SMU, Applicant, LA	4.11 Considering the finalisation of (i) the Article 39c review decision, (ii) the confidentiality decisions on the final DAR and (iii) the confidentiality decision on the additional information, if applicable, and provided these decisions were not available at the time of the first publication of the EFSA output, SMU may ask the applicant to upload new non-confidential, sanitised versions and confidential versions of the peer review report and of the output along with new justified requests for removal thereon via the DMS link made available for that purpose. The SMU verifies and ensures compliance with relevant confidentiality decisions[9]. As for the peer review

[7] In light of the procedural autonomy of the RMS, this step can also happen earlier or later in this procedure.
[8] In light of the procedural autonomy of the RMS, this step can also happen earlier or later in this procedure.
[9] While the confidential and confidential version of the output submitted by the applicant may serve as useful point of reference for the sanitization check of the output, the SMU is to sanitise the version of the output that was subject to editorial checks and corrections by EFSA's publisher.

SMU, LA, RAL	report, if any, if the applicant insists on submitting confidentiality requests, SMU is to verify with the applicant if it contains new information on which the applicant could not have previously submitted confidentiality requests[10]. 4.12 If applicable, upon indication from SMU[11] and/or LA[12] to RAL (RAL@efsa.europa.eu), RAL makes the final version of the EFSA output, peer review report and final DAR publicly available on the OpenEFSA portal after having notified the applicant, unless an Order from the General Court of the EU has been received to suspend implementation of an relevant confidentiality decision in the meantime. If relevant, the legal notice is removed from the EFSA webpage.

PROCEDURE 8	CONFIDENTIALITY DECISION-MAKING, IMPLEMENTATION AND DISSEMINATION IN THE CONTEXT OF THE RISK ASSESSMENT ON AN APPLICATION FOR RENEWAL OF APPROVAL OF A PESTICIDE ACTIVE SUBSTANCE OR AN MRL APPLICATION
Step 1	1.0 Light check
RMS/EMS, FDP	1.1 During the course of the check on admissibility, RMS/EMS carries out an additional, randomised verification based on pre-defined practical requirements relevant to the confidentiality assessment process (so called "*light check*") with regard to the initial public version of the initial dossier. The aim is to detect the most impactful and recurrent shortcomings of the initial public version of the initial dossier, as prepared by the applicant, before publication.
FDP	FDP performs its own light check prior to publication and the applicant is asked to notify LA (confidentialityrequestassessment@efsa.europa.eu) once the initial dossier has been re-submitted and to provide the corresponding UUID.
Step 2	2.0 From admissibility/validity to public consultation

[10] If so, without prejudice to the publication of the final version of the output and other background documents, the applicant is given two (2) weeks to submit confidentiality requests on this information in the peer review report along with a non-confidential, sanitised version and a confidential version thereof via Portalino (https://confportal.efsa.europa.eu/). Upon receipt of the confidentiality requests on the peer review report, if any, LA assesses the confidentiality requests applying Procedure 1, Steps 3-6 mutatis mutandis thereby taking account of all relevant confidentiality decisions. The confidentiality decision is notified by LA in accordance with Procedure 1, Step 6.4, applicable mutatis mutandis. LA implements the confidentiality decision applying Procedure 5 mutatis mutandis (in case a confirmatory application is received, LA processes the confirmatory application applying Procedure 2 mutatis mutandis). RAL notifies the decision to other relevant actors applying Procedure 1, Step 6.9, mutatis mutandis.

[11] For EFSA output and peer review report in case LA has not adopted a confidentiality decision thereon.
[12] For final DAR and peer review report in case LA has adopted a confidentiality decision thereon.

FDP, LA	2.1 FDP notifies LA (confidentialityrequestassessment@efsa.europa.eu) in case an initial dossier containing confidentiality requests was declared admissible/valid without delay from the date FDP was informed of the admissibility/validity of the initial dossier. In that context FDP also (i) informs LA of the UUID of the admissible/valid initial dossier, (ii) and forwards the relevant extract from the NoS database, if available. For MRL dossiers, LA verifies whether there is a related NAS or renewal dossier, including by retrieving the UUID of the related NAS or renewal dossier.
LA	2.2 LA assesses confidentiality requests on the initial dossier and, if available, on the extract from the NoS database applying Procedure 1 *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, if any. As for MRL dossiers, in case there is a related NAS or renewal dossier, LA should ensure substantive alignment in the confidentiality assessments on the NAS, MRL and the renewal dossier. Furthermore, to the extent possible, the timelines for the two linked confidentiality assessments should be kept aligned.
LA, Applicant	2.3 When notifying the applicant of its confidentiality decision on the initial dossier applying Procedure 1, Step 6.4, *mutatis mutandis*, LA requests the applicant to re-submit the initial dossier in IUCLID within two (2) weeks of notification of the decision by removing the relevant confidentiality flags and corresponding redactions/earmarking in the attachments concerned. The applicant is called on to notify LA (confidentialityrequestassessment@efsa.europa.eu) once the initial dossier has been re-submitted and to provide the corresponding UUID. In case a confirmatory application is received on the decision, LA processes the confirmatory application applying Procedure 2 *mutatis mutandis*.
LA	2.4 LA performs systematic quality checks on the sanitisation performed by the applicant to implement the decision.
LA, RAL	2.5 Once the two (2) weeks timeline to submit a confirmatory application has expired and the applicant correctly implemented the decision, upon notification from LA to RAL (RAL@efsa.europa.eu) of the completion of the implementation of the decision in accordance with Procedure 5, Step 1.1, applicable *mutatis mutandis*, RAL notifies the decision to other relevant actors applying Procedure 1, step 6.9 *mutatis mutandis*. LA requests FDP (FDP@efsa.europa.eu) to publish the final public version of the initial dossier providing the relevant UUID as well as the (sanitised) extract from the NoS database on the OpenEFSA Portal, unless an Order from the General Court of the EU has been received to suspend implementation of the decision in the meantime.
FDP	2.6 FDP makes available on the OpenEFSA Portal the final public version of the initial dossier in IUCLID as well as the (sanitised) extract from the NoS database.
Step 3	3.0 From public consultation to approval of output
RAL	3.1 Upon automated closure of the PC on the final public version of the initial dossier, RAL ensures dissemination of comments received in the PC on the OpenEFSA Portal.
FDP	3.2 **a. For MRLs only:** having received the Evaluation Report (ER) from the Evaluating Member State (EMS), and upon receipt of the EC mandate, FDP publishes the sanitised mandate and acceptance

	letter on the Open EFSA Portal via Evidence log **b. For renewals only:**
FDP, Applicant, LA, RAL	**i.** Upon receipt of the complete initial RAR from the RMS, FDP shares the initial RAR with the applicant who has two (2) weeks to submit confidentiality requests along with a non-confidential, sanitised version and a confidential version thereof via Portalino (https://confportal.efsa.europa.eu/) informing EC/MS and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu) by email.
LA, RAL	**ii.** Upon receipt of confidentiality requests on the complete initial RAR, if any, LA carries out a confidentiality assessment on the confidentiality requests concerning the initial RAR applying Procedure 1, Steps 3-6 *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, if any. If no confidentiality requests are received within the two (2) weeks period, upon indication from LA to RAL (RAL@efsa.europa.eu), RAL publishes the complete initial RAR on the OpenEFSA Portal without delay.
LA, RAL	**iii.** If applicable, the confidentiality decision regarding the initial RAR is notified by LA in accordance with Procedure 1, Step 6.4, applicable *mutatis mutandis*. LA implements the decision applying Procedure 5 *mutatis mutandis.* In case a confirmatory application is received, LA processes the confirmatory application applying Procedure 2 *mutatis mutandis*. RAL notifies the decision to other relevant actors applying Procedure 1, Step 6.9, *mutatis mutandis*.
LA, RAL	**iv.** If applicable, RAL makes available the final non-confidential version of the initial RAR on the OpenEFSA Portal without delay upon indication from LA to RAL (RAL@efsa.europa.eu), unless an Order from the General Court of the EU has been received to suspend implementation of the decision in the meantime.
	v. Upon the automated closure of the PC on the initial RAR, RAL ensures dissemination of comments received in the PC on the OpenEFSA Portal.
RAL	**3.3** RAL sanitises personal data as well as information subject to pending confidentiality requests or which was awarded confidentiality treatment in the EFSA cover letter, if any, requesting additional information from the applicant and uploads it in the evidence log for dissemination on the OpenEFSA Portal. Following the experts meeting, if any, a high-level report of the experts meeting is published on the EFSA website by RAL without delay after having ensured that no information for which a confidentiality decision is pending or having been awarded confidential status is contained therein.
Step 4	4.0 Post-approval of output
	4.1 Once output has been approved **a.** if the approved EFSA output identifies foreseeable effects on human health, animal health or the environment related to information that has been granted confidential status, Procedure 4 shall apply *mutatis mutandis*.
SMU, LA	**b.** upon indication from SMU to LA (confidentialityrequestassessment@efsa.europa.eu) that the

	output has been approved, LA starts the assessment of confidentiality requests on the additional information submitted with regard to the initial dossier in accordance with Procedure 3 applicable *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, including in particular the Article 39c review decision, if any.
RAL, Applicant	4.2 When notifying the applicant of the approved output, RAL also shares **a.** (**for renewals only**) the final RAR and the peer review report, or **b.** (**for MRLs only**) the final ER, the Member states consultation report and experts meeting report (if any) ('MRL background documents') with the applicant. Considering any relevant confidentiality decisions, the applicant has **a.** (**for renewals only**) two (2) weeks (i) to submit confidentiality requests on the output and final RAR along with non-confidential, sanitised versions and confidential versions of these documents via Portalino (https://confportal.efsa.europa.eu/) and (ii) to submit request for removal and a non-confidential, sanitised version and a confidential version regarding the peer review report via the DMS link made available for that purpose informing EC/MS and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.peerreview@efsa.europa.eu. and RAL RAL@efsa.europa.eu) by e-mail , or **b.** (**for MRLs only**) one (1) week to submit justified requests for removal on the output and MRL background documents along with the non-confidential, sanitised versions and confidential versions of the output and MRL background documents via the DMS link made available for that purpose informing EC/MS and EFSA (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, SMU pesticides.mrl@efsa.europa.eu and RAL RAL@efsa.europa.eu) by e-mail.
LA, RAL	4.3 **For renewals only**: Upon receipt of the confidentiality requests on the final RAR (i.e. the confidentiality requests regarding all the updates) and the EFSA output, if any, LA assesses the confidentiality requests applying Procedure 1, Steps 3-6 *mutatis mutandis* thereby taking account of all relevant confidentiality decisions, including in particular the Article 39c review decision, if any. If no confidentiality requests are received within the two (2) weeks period, upon indication from LA to RAL (RAL@efsa.europa.eu), RAL publishes the final RAR and/or the output on the OpenEFSA Portal at the same time as the other documents referred to under step 4.4.
SMU, LA, RAL	4.4 If necessary to ensure implementation of relevant confidentiality decisions and confidentiality of items subject to pending confidentiality requests, SMU (**for MRLs only**) or LA (**for renewals only**) performs a sanitisation check of the output[13] based on the justified requests for removal (**for MRLs only**) or the confidentiality requests (**for renewals only**) as well as the confidential and non-confidential version of the output and publishes the output with the support of RAL in accordance with the SOP014. Upon indication from SMU (peer review report and MRL background documents) and/or LA (final RAR) to RAL (RAL@efsa.europa.eu), the sanitised/public version of the peer review report and the sanitised/public version of

[13] While the confidential and confidential version of the output may serve as useful point of reference for the sanitization check of the output, SMU/LA is to sanitise the version of the output that was subject to editorial checks and corrections by EFSA's publisher.

	the final RAR (**for renewals**) or the sanitised/public version of MRL background documents (**for MRLs**) are also published by RAL on the OpenEFSA portal, as provided by the applicant. If relevant, a legal notice is made available on the EFSA webpage indicating that the documents concerned may be re-published due to the need to unblacken certain information following conclusion of relevant confidentiality assessments that were ongoing at the time of first publication. 4.5 In case there are 39c requests steps 4.6 to 4.7 are to be followed. If there are no 39c request but there are confidentiality requests on additional information, proceed from step 4.8. **a. For renewals only**: If there are neither 39c requests nor confidentiality requests on additional information but there are confidentiality requests on the final RAR, proceed from step 4.12, or, if there are also no confidentiality requests on the final RAR but there is a peer review report, proceed from step 4.13 a. Otherwise, the procedure ends here. **b. For MRLs only**: If there are neither 39c requests nor confidentiality requests on additional information, the procedure ends here. 4.6 Before notification of the Article 39c review decision to the applicant, LA verifies whether there are confidentiality requests concerning additional information and, if so, whether the confidentiality assessment on additional information still needs to be concluded **a.** where there are confidentiality requests concerning the additional information and the confidentiality assessment on the additional information still needs to be concluded: **i.** upon adoption of the Article 39c decision, LA notifies the decision applying Procedure 1, Step 6.4, *mutatis mutandis*. The decision is to specify that the applicant shall await the notification of the confidentiality decision on additional information before re-submitting the updated dossier including additional information ('updated dossier') in order to be able to implement changes flowing from the Article 39c review decision and the confidentiality decision on additional information via a single re-submission
LA	**ii.** upon adoption of the confidentiality decision on the additional information LA notifies the decision applying Procedure 1, Step 6.4, *mutatis mutandis* and requests the applicant to re-submit the updated dossier in IUCLID within 2 (two) weeks of notification of the decision thereby applying Procedure 8a, Step 2.3 *mutatis mutandis*[14] **iii.** LA performs systematic quality checks on the sanitisation performed by the applicant to implement the decisions
LA, Applicant	**iv.** once the two (2) weeks timeline to submit a confirmatory application has expired and the applicant correctly implemented the 39c decision and the confidentiality decision on additional information, upon notification from LA to RAL (RAL@efsa.europa.eu) of the completion of the implementation of the decisions in accordance with Procedure 5, Step 1.1, applicable *mutatis mutandis*, RAL notifies the decisions to other relevant actors applying Procedure 1, Step 6.9, *mutatis mutandis*. LA requests FDP

[14] The confidentiality decision on the additional information shall specify that the applicant shall implement both the confidentiality decision on additional information and the 39c decision simultaneously via a single re-submission.

LA	(FDP@efsa.europa.eu) to publish the public version of the updated dossier on the OpenEFSA Portal providing the relevant UUID, unless an Order from the General Court of the EU has been received to suspend implementation of the decisions in the meantime
RAL, LA	**v.** FDP makes available on the Open EFSA portal the public version of the updated dossier in IUCLID.
	b. where there were no confidentiality requests on additional information or the confidentiality assessment on additional information has already been concluded[15]:
	i. upon adoption of the Article 39c decision, LA notifies the decision applying Procedure 1, Step 6.3, *mutatis mutandis* and requests the applicant to re-submit the (updated) dossier in IUCLID within 2 (two) of notification of the decision thereby applying Procedure 8a, Step 2.3 *mutatis mutandis*[16]
	ii. LA performs systematic quality checks on the sanitisation performed by the applicant to implement the Article 39c decision and, if applicable, the confidentiality decision on additional information
FDP	**iii.** once the two (2) weeks timeline to submit a confirmatory application has expired and the applicant correctly implemented the 39c decision and, if applicable the confidentiality decision on additional information, upon notification from LA to RAL (RAL@efsa.europa.eu) of the completion of the implementation of the decision(s) in
LA, Applicant	accordance with Procedure 5, Step 1.1, applicable *mutatis mutandis*, RAL notifies the decision(s) to other relevant actors applying Procedure 1, Step 6.9, *mutatis mutandis*. LA requests FDP (FDP@efsa.europa.eu) to publish the public version of the (updated) dossier on the OpenEFSA Portal providing the relevant UUID, unless an Order from the
LA	General Court of the EU has been received to suspend implementation of the decision(s) in the meantime
	iv. FDP makes available on the Open EFSA portal the public version of the (updated) dossier in IUCLID.
LA, RAL	4.7 **For renewals only**: SMU implements the Article 39c decision on the initial RAR applying Procedure 5 *mutatis mutandis* and, upon indication from SMU to RAL (RAL@efsa.europa.eu), RAL re-publishes the initial RAR on the OpenEFSA Portal.
	4.8 If applicable, LA notifies the confidentiality decision on the additional information applying Procedure 1, Step 6.4, *mutatis mutandis* and requests the applicant to re-submit the updated dossier in IUCLID within two (2) weeks of notification of the decision thereby applying Procedure 8a, Step 2.3 *mutatis mutandis*.
	4.9 LA performs systematic quality checks on the sanitisation performed by the applicant to implement the decision.
	4.10 If applicable, once the two (2) weeks timeline to submit a confirmatory application has expired and the applicant correctly

[15] In case the confidentiality assessment on the additional information is concluded before the 39c review, the confidentiality decision on the additional information is to specify that the applicant shall await the notification of the confidentiality decision on the 39c decisions before re-submitting the dossier in order to be able to implement changes flowing from the Article 39c review decision and the confidentiality decision on additional information via a single re-submission.

[16] In case the confidentiality assessment on the additional information was concluded before the 39c review, the 39c decision shall specify that the applicant shall implement both the confidentiality decision on additional information and the 39c decision simultaneously via a single re-submission.

FDP SMU, RAL LA, Applicant	implemented the decision, upon notification from LA to RAL (RAL@efsa.europa.eu) of the completion of the implementation of the decision in accordance with Procedure 5, Step 1.1, applicable *mutatis mutandis*, RAL notifies the decision to other relevant actors, including the RMS, applying Procedure 1, step 6.9, *mutatis mutandis*. LA requests FDP (FDP@efsa.europa.eu) to publish the public version of the updated dossier on the OpenEFSA Portal providing the relevant UUID, unless an Order from the General Court of the EU has been received to suspend implementation of the decision in the meantime.
	4.11 FDP makes available on the Open EFSA portal the public version of the updated dossier in IUCLID including the additional information.
LA LA, RAL	4.12 **For renewals only**: The confidentiality decision regarding the final RAR and/or output, if any, is notified by LA in accordance with Procedure 1, Step 6.4, applicable *mutatis mutandis*. LA implements the decision regarding the final RAR applying Procedure 5 *mutatis mutandis* (in case a confirmatory application is received, LA processes the confirmatory application applying Procedure 2 *mutatis mutandis*). RAL notifies the decision(s) to other relevant actors applying Procedure 1, Step 6.9, *mutatis mutandis*.
FDP LA, RAL	4.13 **a.** **For renewals only**: Considering the finalisation of (i) the Article 39c review decision, (ii) the confidentiality decision on the output and (iii) the confidentiality decision on the additional information, if applicable, and provided these decisions were not available at the time of the first publication of the peer review report, SMU may ask the applicant to upload a new non-confidential, sanitised version and confidential version of the peer review report along with new justified requests for removal via the DMS link made available for that purpose. The SMU verifies and ensures compliance with relevant confidentiality decisions. As for the peer review report, if the applicant insists on submitting confidentiality requests, SMU is to verify with the applicant if it contains new information on which the applicant could not have previously submitted confidentiality requests[17].
SMU, Applicant, LA SMU, Applicant	**b.** **for MRLs only**: Considering the finalisation of the Article 39c review decision and the confidentiality decision on the additional information, if applicable, and provided these decisions were not available at the time of the first publication of the EFSA output, SMU may ask the applicant to upload new non-confidential, sanitised versions and confidential versions of the output and the MRL background documents along with new justified requests for removal thereon via the DMS link made available for that purpose. The SMU verifies and ensures

[17] If so, without prejudice to the publication of the final version of the output and other background documents, the applicant is given two (2) weeks to submit confidentiality requests on this information in the peer review report along with a non-confidential, sanitised version and a confidential version thereof via Portalino (https://confportal.efsa.europa.eu/). Upon receipt of the confidentiality requests on the peer review report, if any, LA assesses the confidentiality requests applying Procedure 1, Steps 3-6 mutatis mutandis thereby taking account of all relevant confidentiality decisions. The confidentiality decision is notified by LA in accordance with Procedure 1, Step 6.4, applicable mutatis mutandis. LA implements the confidentiality decision applying Procedure 5 mutatis mutandis (in case a confirmatory application is received on the confidentiality decision, LA processes the confirmatory application applying Procedure 2 mutatis mutandis). RAL notifies the decision to other relevant actors applying Procedure 1, Step 6.9, mutatis mutandis.

SMU, LA, RAL	compliance with relevant confidentiality decisions.[18] **4.14** If applicable, upon indication from SMU[19] and/or LA[20] to RAL (RAL@efsa.europa.eu), RAL makes the final version of the output and background documents publicly available on the OpenEFSA portal after having notified the applicant, unless an Order from the General Court of the EU has been received to suspend implementation of any relevant confidentiality decision in the meantime. If relevant, the legal notice is removed from the EFSA webpage.

PROCEDURE 9	CONFIDENTIALITY DECISION MAKING RELATED TO DIRECTIVE 2001/18/EC
Step 1	1.0 Confidentiality decision on requests concerning a dossier pursuant to Article 25 of Directive 2001/18/EC.
FDP, SMU	1.1 When receiving from a national competent authority an application dossier submitted under Directive 2001/18/EC, FDP obtains a copy of the confidentiality decision by the NCA (in the Directive: "notified Member State").
All units	1.2 All concerned units comply with the confidentiality decision taken by the national competent authority by informing all staff and experts about the items of the dossier which must be kept confidential.
SMU	1.3 Upon adoption of an EFSA scientific output, SMU verifies if conditions set out in step 1.1 of Procedure 4 apply. If this is the case, Procedure 4 applies.
LA	1.4 Upon receipt of the documents sanitised in accordance with the NCA decision pursuant to step 1.2, Procedure 10 applies. In case Procedure 4 applies, LA ensures the implementation of the Article 39c Decision in accordance with Procedure 5.

PROCEDURE 10	PUBLICATION OF A DOCUMENT INCLUDING CONFIDENTIAL ITEMS
Step 1	1.0 Publication of document(s) which includes items claimed confidential or awarded confidential status (This procedure is also applied after Procedure 4 unless the applicant withdraws the application)
FDP/RAL	1.1 Upon receipt of a non-confidential version of a document to be made proactively available pursuant to Article 6 of EFSA's Practical Arrangements concerning transparency and confidentiality, FDP for application dossiers including all updated dossiers in IUCLID or

[18] While the confidential and confidential version of the output submitted by the applicant may serve as useful point of reference for the sanitization check of the output, the SMU is to sanitise the version of the output that was subject to editorial checks and corrections by EFSA's publisher.

[19] For MRL output, MRL background documents and peer review report in case LA has not adopted a confidentiality decision on the peer review report

[20] For renewal output, final RAR and peer review report in case LA has adopted a confidentiality decision on the peer review report.

	general mandates after acceptance, RAL for dossiers post-validity, , and for scientific outputs, background documents or meeting minutes, stores or uploads the public version of the document to Dossier veiwer or Evidence Log triggering its publication on/to Open EFSA Portal.
RAL LA, FDP, SMU	1.2 For ESFC or Portalino dossiers, in case LA, RAL, FDP or SMU receives a complaint that confidential business information (not personal data) have accidentally been disclosed to the public via the OpenEFSA portal or another technical solution, the unit in charge of the step that led to the accidental dissemination opens a ticket with Service Desk to remove the application dossier containing confidential data, informs LA and the applicant and, where appropriate, submits a non-conformity report.
	1.3 For IUCLID dossiers, in case LA, RAL, FDP or SMU receives a complaint that confidential business information (not personal data) have accidentally been disclosed to the public via the OpenEFSA portal or another technical solution, the unit in charge of the step that led to the accidental dissemination asks FDP to remove the link leading to the IUCLID public instance of the relevant application dossier containing confidential data. FDP follows up by removing the link to the dossier on the public instance of IUCLID as well as by removing the link from OpenEFSA, informs the applicant and, where appropriate, submits a non-conformity report.
LA	1.4 In case EFSA receives a complaint from an external actor (applicant, data subject, NGOs, etc) that personal data has been published with a dossier as a result of this SOP, LA assesses whether the personal data in question falls under one of the categories under Article 39e(1) of Regulation EC No 178/2002, and if it is not the case, it takes down the dossier by opening a ticket with Service Desk.
SMU/FDP	1.5 Upon completion of Procedure 5, LA for application dossiers, FDP for IUCLID dossiers or SMU for generic mandates, replaces the public version disseminated under Step 1.1 above with the version resulting from the implementation of EFSA's confidentiality decision.
	1.6 Upon completion of Procedure 7, RAL replaces the public version disseminated under Step 1.1. above with the version resulting from the implementation of the RMS' confidentiality decision and from EFSA's confidentiality decision on requests submitted on the DAR, if any.
RAL	1.7 When receiving from a national competent authority a notification submitted under Directive 2001/18/EC, FDP and SMU comply with the confidentiality decision taken by the national competent authority by disseminating without delay the documents sanitised by the authority or by the applicant.
FDP/SMU LA	1.8 If a confirmatory application has been received by EFSA pursuant to Procedure 2, or an order of the General Court of the European Union has been served on EFSA ordering it to suspend the publication of the documents, LA informs the SMU//RAL, which puts the dissemination on hold until the final determination is issued.

	Following SOP in the process: SOP_014_Publishing a scientific output in the EFSA Journal