SME CONNECT / BETTER REGULATION FORUM

RCC PRACTICAL CASES HANDBOOK

Twelve European regulatory dossiers through the lens of Regulatory Chain Control

Eight documented cases | Four prospective assessments

A companion to Better Regulation as Regulatory Chain Control (RCC), the October 2026 Working Paper by the members of the SME Connect Better Regulation Forum.



OCTOBER 2026 | ANALYTICAL EDITION

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Navigate by case. Each dossier uses the same four-page structure and distinguishes the documented record from proposed RCC action.

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HOW TO USE A CASE

Page 1 identifies the legal and practical problem; page 2 shows a decision-ready RCC workflow; page 3 sets out the evidence and verification record; page 4 visualises the real task, handover and performance test.

Executive introduction

THE CORE PROPOSITION

Better Regulation is not a choice between more or less law. A legitimate EU policy goal should remain evidence-based, proportionate, enforceable and workable as obligations move from proposal through secondary measures and implementation to real tasks.

Why twelve cases – and what they can establish

This companion handbook applies a consistent RCC method to twelve selected EU dossiers. **Eight documented cases** identify existing regulatory situations and possible points for earlier scrutiny. **Four prospective assessments** define tests for ongoing files; their risks are not reported as proven failures. The selection is purposeful, not representative of the EU acquis.

Documented	IVDR, EU Guarantee Label, EFSA Transparency/Novel Foods, EUDR, PPWR, CBAM, CSRD and Late Payments.
Prospective	AI Act, Digital Product Passport / ESPR, European Biotech Act and vitamin/mineral maximum levels.

The mechanism tested in every dossier

1. Trace the task. Identify the authoritative legal duty, its addressee, secondary and national requirements, technical systems and any private requests. **2. Screen a material residual risk.** Review what existing scrutiny already covers, whether a competent decision is still open and whether extra analysis is worth its cost. **3. Produce one decision record.** Link trigger, evidence, owner, options, reasoned response and review. **4. Verify the actual result.** Measure compliance work, the regulatory benefit, burden migration and the cost of RCC itself.

How governance can help – without becoming mandatory

Stewardship keeps an obligation, its unresolved questions and follow-up accessible across stages. **Steering** can consolidate overlapping signals when several competent actors need to coordinate. **Activation** is a separate, selective decision by the authorised sponsor. A single Implementation Readiness Check or SME user test remains possible without any central RCC structure. Human-validated AI assistance is optional.

NO INVENTED IMPACT OR NEW POWERS

A dossier may illustrate where a check could help, but not prove that RCC caused a past correction, savings or institutional outcome. Existing Commission, Parliament, Council, national and agency mandates remain intact. A widened mandate or binding new right requires its own legal basis.

Main Paper: §7 (pp. 15–23); §8 (pp. 24–30); §12 (pp. 45–57); Annexes II–III (pp. 64–65).

Executive introduction | How to read the findings

EVIDENCE IS NOT ADVOCACY

The Handbook distinguishes binding legal obligations, Commission and agency data, representative operational evidence, stakeholder testimony and forward-looking test scenarios. Reported difficulties do not establish illegality. Announced simplification does not automatically establish realised cost savings.

READING A CASE FROM A POLITICAL DECISION TO A COMPANY TASK

1 | REGULATORY CHAIN

The legal objective, implementing layers and concrete obligation are mapped together. What matters is the real task, not only the title of the legal act.

2 | DECISION HANDOVER

A material gap leads to a named actor and a reasoned response. Legislative choices remain for the co-legislators; administrative matters stay within the competent mandate.

3 | VERIFICATION

Any correction is checked against time, cost, legal certainty, regulatory benefits and new burdens transferred elsewhere. The incremental costs of RCC also count.

THE PRINCIPAL ANALYTICAL CAUTION

No case proves retrospectively that RCC would have prevented an outcome. Cases with enacted corrective measures show that EU processes can respond. The narrower added-value question is whether an earlier, better-connected assessment would help reveal a material risk, enable a lawful decision or make a result independently verifiable.

WHAT A SUCCESSFUL PILOT SHOULD DEMONSTRATE

A bounded dossier pilot should generate usable evidence before an important choice becomes difficult to reverse; identify gaps that existing assessment did not resolve; obtain a proportionate institutional answer; and verify actual results without creating excessive procedural workload.

REFERENCE TO THE MAIN DOCUMENT

For institutional proposals, legal limits, national precedents and the full RCC control architecture, consult the SME Connect Better Regulation Forum Working Paper (October 2026), especially sections 7–9 and 12

FOUR WAYS TO READ THE TWELVE CASES

DECISION QUESTION	EXAMPLE CASE
Is the system ready before application?	IVDR / AI Act / DPP
Does formal scope match the actual SME burden?	CSRD / EUDR / PPWR
Are procedures and enforcement effective?	EFSA / Late Payments
Is the regulatory instrument proportionate?	CBAM / Biotech Act / Vitamins

INTERPRETATION OF THE PILOT LANGUAGE

"Activate" means a competent sponsor chooses a **selective, voluntary test** after checking an unresolved material issue, ordinary scrutiny, legal decision point and net value. It does not imply an automatic trigger, committee veto, extended statutory period or operational RCC programme.

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WORKING PAPER PP. 18-19 AND 22 / THE EXISTING REGULATORY PROCESS

Eight EU stages, eight RCC checkpoints

RCC is a risk-based overlay on existing decisions - not eight compulsory new approvals.

1 Preparation

REGULAR RESPONSIBILITY
Commission

RCC CHECK 1
RCC Scoping Note

WHEN:
Before the option is fixed

->

2 Proposal

REGULAR RESPONSIBILITY
Commission

RCC CHECK 2
Consultation / Impact Review

WHEN:
Before College adopts proposal

->

3 Scrutiny

REGULAR RESPONSIBILITY
EP / Council

RCC CHECK 3
Amendment Impact Assessment

WHEN:
Before committee / Council position

->

4 Negotiations

REGULAR RESPONSIBILITY
EP / Council

RCC CHECK 4
Trilogue Note / Updated IA

WHEN:
Before a material compromise

->

5 Adoption

REGULAR RESPONSIBILITY
EP / Council

RCC CHECK 5
Adoption Checklist

WHEN:
Before adoption; track follow-up

->

6 Secondary rules

REGULAR RESPONSIBILITY
Commission + lawful scrutiny

RCC CHECK 6
Delegated/Implementing Review

WHEN:
Before the secondary measure

->

7 Application

REGULAR RESPONSIBILITY
Member States / services

RCC CHECK 7
Implementation Report

WHEN:
Before real-world application

->

8 Evaluation

REGULAR RESPONSIBILITY
Commission / competent actors

RCC CHECK 8
Evaluation + Follow-up

WHEN:
At review; before next revision

Two distinctions that keep RCC institutionally lawful

Commission: a service may pilot checks within its remit. EP / Council: optional scrutiny under their own procedures.

Which check produces what?

1-2	Scoping, consultation and impact evidence
3-4	Amendment impact and compromise note
5	Adoption checklist / unresolved implementation risks
6	Proportionate review of secondary measures
7	Role-by-role implementation and readiness record
8	Outcome review and realised burden account
A	Operational fix within lawful remit
B / C	Coordination or legislative referral when needed

Always the same five-field handover

TRIGGER > EVIDENCE > RESPONSIBLE ACTOR > CONSEQUENCE > REVIEW

Cross-cutting safeguards: legal traceability and the Burden-Migration Test; stop if the added work outweighs the benefit.

Source: RCC Main Working Paper (27 October 2026), pp. 18, 19, 22 and 42. Stage checks are proposed RCC additions, not current mandatory legal stages.

EIGHT CHECKPOINTS ARE OPTIONS, NOT A COMPULSORY SEQUENCE

The diagram identifies where specific RCC instruments may help. Each may be used individually within existing powers. Combined dossier stewardship and selective activation could link their outputs, but neither is a legal prerequisite for using a single tool. Main Paper §8 / Annex II.

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WORKING PAPER §§7 AND 11.2-11.4 / INSTITUTIONAL ACTIVATION

Who starts RCC - and who decides?

A file lead uses an existing decision point; a material finding becomes a short evidence-and-options note.

01 COMMISSION / BEFORE PROPOSAL

WHO ACTIVATES
DG management agrees a bounded pilot and names a dossier lead.

WHEN / BEFORE WHICH DECISION
Before the service finalises the proposal or a material drafting choice.

WHO RECEIVES / DECIDES
DG manager / competent decision point; the College adopts the proposal.

PUBLISHABLE OUTPUT
Scoping or Consultation & Impact Review note.

02 PARLIAMENT / COUNCIL SCRUTINY

WHO ACTIVATES
Each co-legislator chooses whether to use supplementary analysis.

WHEN / BEFORE WHICH DECISION
Before the relevant committee, Council position or substantial compromise.

WHO RECEIVES / DECIDES
The committee or Council team entitled to decide; no RCC veto.

PUBLISHABLE OUTPUT
Amendment Impact Assessment / Trilogue Note.

03 SECONDARY RULES / IMPLEMENTATION

WHO ACTIVATES
Competent Commission service or national owner agrees a targeted technical/user test.

WHEN / BEFORE WHICH DECISION
Before delegated/implementing adoption, system release or application milestone.

WHO RECEIVES / DECIDES
The legally empowered adoption, scrutiny or enforcement actor.

PUBLISHABLE OUTPUT
Delegated Act Review / Implementation Report.

04 EVALUATION / NEXT REVISION

WHO ACTIVATES
Evaluation owner uses a material risk or unresolved follow-up item.

WHEN / BEFORE WHICH DECISION
At a defined review milestone, before a future reform choice.

WHO RECEIVES / DECIDES
Competent service and, when legal change is needed, legislative route.

PUBLISHABLE OUTPUT
Evaluation Report with realised costs, benefits and burden migration.

The seven-step RCC operating logic (Working Paper p. 18)

1	2	3	4	5	6	7
Stage	**Risk**	**Instrument**	**Owner**	**Evidence**	**Consequence**	**Verify**

No automatic stop-right, new RSB mandate or obligation on co-legislators. Any binding new duty needs the appropriate legal route.

Source: RCC Main Working Paper (27 October 2026), pp. 18, 22, 40-44. The four routes are a proposed operating arrangement within lawful competences.

RESPONSIBILITY WITHOUT NEW INSTITUTIONAL POWERS

An RCC finding is useful only if a competent actor can respond and results can be checked. Possible coordination by the lead Commission DG and Secretariat-General remains one option; Parliament, Council and national authorities retain their mandates. RSB-initiated RCC screening would require an explicit mandate change.

Method and evidence standard

Case selection is deliberately risk-based. It is not a statistically representative assessment of EU regulation. Each dossier has a clear legal anchor and at least one useful operational test, with uncertainty disclosed.

EVIDENCE LADDER

MATERIAL	ROLE IN THIS HANDBOOK
EU acts and official legal documents	Confirm legal obligations, dates, powers and adoption status.
Commission, EU agencies and observatories	Provide institutional evidence and administrative estimates, subject to their limitations.
IVSH, Coppens and other stakeholder records	Identify actual user questions and potential burden channels; allegations remain attributed.
Proposed RCC test scenarios	Show what should be measured prospectively; never presented as completed pilots.

WHAT MAKES A CREDIBLE CASE

MATERIALITY AND ATTRIBUTION

A defined obligation or practical step, traceable to a specific legal or administrative source, with a meaningful SME or implementation effect.

LAWFUL CONSEQUENCES

A competent actor, realistic corrective options, proportionate burden, preservation of the regulatory benefit and a measurable verification point.

METHODS CARRIED ACROSS ALL TWELVE CASES

The unit of analysis is a practical obligation and the actor facing it. Case files separate the basic act from secondary rules, national implementation and private requests. Alternative explanations are considered explicitly. A reduction is treated as realised only if work or cost actually disappears rather than migrating to a new interface or business partner.

CUT-OFF AND COUNTERFACTUAL BOUNDARY

The analytical reference date is 27 October 2026. The 2026 Working Paper, RCC Case Inventory and Coppens and IVSH material supply the project context. Each case provides links to legal or institutional material. Where later verification is needed, the required evidence is specified rather than silently assumed.

SOURCE AND INSTITUTIONAL STATUS

The Handbook accompanies the October 2026 RCC Working Paper by members of the SME Connect Better Regulation Forum. SME Connect acts as a politically neutral convening platform; members retain responsibility for the analysis and their independent positions. EU Transparency Register: 465361845122-87.

ACTIVATION STANDARD FOR A CREDIBLE CASE PILOT

Signal: evidence from a DG, competent parliamentary or Council channel, national authority or affected user. **Triage:** test materiality, what existing scrutiny has settled, which lawful decision can still be informed, and expected extra cost. **Ownership:** the authorised service chooses whether to proceed; consolidate duplicate signals. **Output:** one source-level obligation map and Issue-and-Options Note with a human-verified legal handover. **Evaluation:** compare against ordinary procedures, policy outcomes, SME burden and staff time. Stop where added value is absent.

RCC method-to-case map | Twelve dossiers

Eight lifecycle checkpoints in the Main Working Paper (p. 22) identify potential decision points. The seven-step control logic (p. 18) describes a selected check; five fields retain its trigger, evidence, actor, consequence and review. The principal control below is a **proposed test**, not an automatic procedure.

Primary decision point and relevant RCC instruments

DOSSIER	CHECKPOINT	MAIN SECTIONS	USER TASK / OUTPUT
01 IVDR	7 · readiness	§§9.7, 12.4	Notified-body capacity; class-specific readiness
02 Guarantee label	6 · secondary	§§9.8, 9.11	Label usability on shelf and online
03 EFSA / Novel Foods	8 · review	§§9.2, 10.9	Attribute dossier-validation delays
04 EUDR	7 · implementation	§§9.7, 12.6	Map source of cocoa supply-chain requests
05 PPWR	6 · secondary	§§9.11–9.12	One packaging SKU; EU, national and buyer rules
06 CBAM	8 · evaluation	§§9.4, 10.4	Threshold and actual burden outcomes
07 CSRD	7 · implementation	§§7.1, 12.2	Supplier questionnaire vs legal scope
08 Late Payments	8 · evaluation	§§10.9, 12.2	Entitlement vs usable recovery
09 AI Act	7 · readiness	§§9.7, 12.6	SME high-risk classification and tools
10 DPP / ESPR	6 · technical	§§9.8, 10.3	Textile data fields and reuse
11 Biotech Act	3 · scrutiny	§§9.1–9.2	Clinical-trial approval option and evidence
12 Vitamins	1 · front-end	§§9.1, 9.3	Scope and instrument choice

ONE OPERATING RULE IN EVERY CASE

TRIGGER (material residual risk) → **EVIDENCE** (representative user task) → **ACTOR** (competent decision-maker) → **CONSEQUENCE** (correct, refer, explain or do not intervene) → **REVIEW** (actual outcomes and extra RCC effort).

Reading rule: The cited instruments are selected points of relevance, not a claim that each is already operational in that dossier. Main Paper §7.1 (pp. 16–19), §9 (pp. 31–38) and §§12.2–12.4 (pp. 47–52).

01 / DOCUMENTED CASE / REGULATORY PROCESS AND PROBLEM

IVDR: How a Legal Transition Became a Capacity Decision

In-vitro diagnostics | Regulatory process, implementation readiness and lawful institutional response

THE GOVERNANCE QUESTION

Who knew what, at which institutional stage, and where could a timely capacity forecast have changed the available options?

REGULATORY SEQUENCE: LEGAL DECISIONS AND OPERATIONAL CONDITIONS

Stage / timing	Existing institutional mechanism	What matters in practice
2017: adoption	Parliament and Council adopt the IVDR (EU) 2017/746.	Risk-based conformity requirements; more devices require notified-body assessment.
2022: transition	Regulation (EU) 2022/112 revises transitional arrangements.	Some legacy devices obtain more time, subject to conditions.
Oct 2023: monitoring	Commission draws on applications, certificates and notified-body capacity.	1,378 applications; 677 certificates; 12 designated bodies (not comparable cohorts).
Jan–Jul 2024: correction	Commission proposes changes; Parliament and Council adopt Regulation 2024/1860.	Further conditional transition dates protect continuity without waiving safety rules.

HOW THE OBLIGATION REACHED THE BUSINESS

A manufacturer must classify its diagnostic device, maintain appropriate quality management and technical evidence, engage a notified body where required, and meet applicable transition conditions. Notified-body assessment capacity and manufacturer dossier readiness jointly determine whether certification can be completed on time.

THE CAUSAL CHAIN MUST REMAIN ATTRIBUTED

Regulatory choice	Operational dependency	RCC early-warning variable
Expanded third-party assessment	Notified-body availability + valid manufacturer files	Forecast demand / throughput for comparable risk-class cohorts
Conditional transition pathway	QMS, filing and agreement milestones	Share of eligible devices meeting each required step

OBSERVED CONTROL PRESSURE

The Commission itself identified a risk of shortages; the EU institutions acted in 2024. RCC cannot claim that no existing monitoring or political correction occurred.

THE CONTROL QUESTION MISSED BY A LAW-ONLY NARRATIVE

The useful unit of scrutiny is a risk-class-specific certification cohort linked to its legal deadline, application quality, available assessment capacity and the availability of critical tests. An aggregate backlog cannot identify which actor must change what.

Working Paper link: §7 (chain traceability and five-field control logic), §9.7 (Implementation Readiness Gate), and §12 (bounded dossier pilot).

01 / DOCUMENTED CASE / EXISTING CONTROLS VERSUS RCC

IVDR: How a Legal Transition Became a Capacity Decision

In-vitro diagnostics | Regulatory process, implementation readiness and lawful institutional response

WHAT ALREADY HAPPENS - AND WHAT RCC WOULD ADD

Existing safeguard / actor	Observed limitation or open question	Incremental RCC function
IVDR / legislators	A legal transition date alone cannot guarantee assessment capacity.	Connect a cohort forecast to the next relevant political or administrative decision.
Commission / MDCG / survey evidence	Data exist, but aggregate counts do not by themselves attribute the bottleneck.	Single risk record distinguishes valid demand, application quality, review queues and critical-device exposure.
Notified bodies / national designation	Assessments and capacity supervision are distributed across actors.	Named issue-and-options note routes capacity and procedural findings to the lawful owner.
Parliament and Council	May change statutory transition conditions through legislation.	Use the reasoned evidence note; RCC neither orders an amendment nor delays the procedure.

FIVE-FIELD RCC OPERATING RECORD AT THE CAPACITY CONTROL POINT

Trigger	Evidence	Actor	Consequence	Review
Projected cohort mismatch	Demand, valid files, capacity and criticality	Commission / national authorities; lawmakers for dates	Capacity support, guidance or legislative referral	Queue time, supply and protection

THE ACTUAL HANDOVER AND THE COUNTERFACTUAL

ILLUSTRATIVE DECISION WINDOW (not an actual 2023-24 RCC process): Before DG SANTE policy leadership considers capacity support or a Commission proposal, it could authorise a single risk-class cohort test using existing notified-body and manufacturer evidence. The team would send a dated Capacity and Readiness Options Note to that policy lead. The response could be operational coordination, a Commission legislative proposal for co-legislators to decide, or no further measure. The additional value must be tested against the ordinary Commission monitoring that already led to the 2024 response.

WHAT A DECISION-READY NOTE WOULD CONTAIN

Question for the institution	Responsible route
Does a capacity shortage affect designated notified bodies?	National designation authorities and Commission coordination, within existing powers.
Would guidance or procedural coordination solve the verified blockage?	Competent services, competent national authorities and notified bodies.
Is a statutory transition change necessary?	Commission proposal if appropriate; Parliament and Council decide.

ADDED VALUE TO TEST

Not “RCC would have prevented the 2024 amendment”, but whether a connected early-warning record would have improved timing, attribution, option quality or the subsequent verification of results.

01 / DOCUMENTED CASE / EVIDENCE, DECISIONS AND VERIFICATION

IVDR: How a Legal Transition Became a Capacity Decision

In-vitro diagnostics | Regulatory process, implementation readiness and lawful institutional response

DECISION-READY EVIDENCE AND MEASUREMENT

Question	Minimum evidence	How the result is checked
Can eligible devices finish in time?	Risk-class application cohorts, QMS status, written agreements and assessment milestones.	Median and upper-percentile time from valid application to certification.
What causes the queue?	Notified-body personnel and capacity; completeness and correction cycles in manufacturer files.	Attribute delay to capacity, file preparation or other documented causes.
Is public health protected?	Critical-device availability reports and clinical-risk categorisation.	Track verified availability issues without equating delays with proven shortages.
Did RCC add value?	Date of issue note, competent actor response, institutional and SME effort.	Compare with regular monitoring and report RCC's additional workload.

INSTITUTIONAL CHOICES MUST REMAIN LAWFUL

Commission services can coordinate implementation support and propose legislation; national authorities retain designation and enforcement roles; notified bodies perform conformity assessments; Parliament and Council change binding deadlines where law requires. A decision not to amend is a possible outcome if evidence and risks justify it.

BASELINE BEFORE INTERVENTION AND AFTER CORRECTION

Retain the same risk-class cohorts before and after the competent decision. Report valid applications, processing-time distribution, withdrawn/incomplete files, actual review capacity, critical-device availability and public-health protection. Record when the RCC note reached DG management and whether it changed information, options or timing compared with normal Commission monitoring; disclose RCC staff effort.

TIMELINE AND EVIDENTIARY CAUTION

Regulation 2024/1860 extended eligible legacy-device transition dates to 31 December 2027 (class D), 2028 (class C) and 2029 (class B and sterile class A), subject to detailed statutory conditions. These are not blanket extensions for every device. The 2023 counts measure different populations and cannot be presented as a certification success rate.

PUBLISHABLE RCC OUTPUT

Risk-class Capacity & Readiness Note | Named Institutional Response | Follow-up Cohort Verification

SOURCE REGISTER (PRIMARY SOURCES)

COM(2024)43, explanatory memorandum and capacity data: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52024PC0043

Regulation (EU) 2024/1860: https://eur-lex.europa.eu/eli/reg/2024/1860/oj/eng

Regulation (EU) 2017/746 and Working Paper §9.7 Commission IVDR transitional-provisions guidance.

01 / DOCUMENTED CASE / INTEGRATED PROCESS GRAPHIC

IVDR: How a Legal Transition Became a Capacity Decision

In-vitro diagnostics | Regulatory process, implementation readiness and lawful institutional response

RCC CONTROL MAP / CASE 01

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	7 APPLICATION — MAIN RCC CHECK	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before a Commission decision on a transition-law proposal (historical 2024 decision window)

Status: DOCUMENTED CORRECTION; RCC HISTORICAL SIMULATION

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

Commission and MDCG already monitored applications, certificates and notified-body capacity; co-legislators amended deadlines in 2024.

MATERIAL GAP TO TEST

Counts alone do not join valid class-specific application cohorts, assessment capacity, legal deadlines and critical-device supply.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A risk-class cohort cannot realistically complete conformity assessment before its applicable transition deadline. Proposed lead: Illustrative DG SANTE-led check with notified bodies, national designation authorities and manufacturer cohorts.

DELIVERABLE AND DECISION ROUTE

Class-specific Capacity and Readiness Issue-and-Options Note to DG SANTE before its policy choice. Commission: coordinate practical support or propose a change; Parliament and Council: decide any statutory deadline.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Valid-file queue time; certified cohort; availability of essential tests; assessment and RCC review workload.

IMPORTANT LIMIT

RCC did not cause or precede the actual 2024 amendment. Treat this as a counterfactual process test.

Reading key: the upper timeline is historical. The RCC control and verification path is a proposed test, not a claim of actual deployment.

CASE 02 / DOCUMENTED CASE / THE REGULATORY SITUATION

EU Guarantee Label: Design Rules Meet Retail Reality

Consumer goods and sales channels | SME Reality Check and Secondary-Measure Screen

CASE IN ONE SENTENCE

A harmonised label is only effective if it works across actual products and selling channels.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
Consumer aim	Label design > Physical / online POS > Manufacturer–retailer > Customer clarity	Physical / online POS

POLICY PURPOSE

The EU guarantee information reform aims to improve consumer understanding of statutory rights and commercial guarantees of durability. A harmonised label can strengthen comparability if it is clear and usable at the point of sale.

WHAT THE RECORD ESTABLISHES

Directive (EU) 2024/825 requires a harmonised durability label only where the producer makes available to the trader information on a free commercial guarantee for the entire good lasting more than two years. A separate harmonised notice explains the statutory guarantee. Implementing Regulation (EU) 2025/1960 sets the two designs and applies from 27 September 2026. The IVSH submission records specific retail and online layout questions, which are stakeholder evidence rather than verified EU-wide costs.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

A seemingly straightforward horizontal label interacts with product models, component configurations, packaging, retailer shelf space, digital interfaces and manufacturer-to-retailer information flows. Technical clarification can arrive after firms have built costly local interpretations.

SME EXPOSURE

Smaller manufacturers and retailers must update labels, product data, displays and online sales templates without the same capacity as large chains. The IVSH survey evidence describes practical constraints, but its estimates are not representative measures of the EU retail sector.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

Stakeholder questions prove the existence of implementation uncertainty, not that each interpretation was unlawful or that every identified problem persisted after guidance. Reported withdrawal of commercial guarantees needs independent verification.

THE DECISION POINT

Before a DG JUST clarification or lawful design revision, which presentation works across a small item, a multi-part product and an online listing?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 6 (formal stage 6); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 02 / DOCUMENTED CASE / RCC AT THE EXISTING DECISION POINT

EU Guarantee Label: Design Rules Meet Retail Reality

Consumer goods and sales channels | SME Reality Check and Secondary-Measure Screen

WHAT WOULD BE DECIDED?

Before a DG JUST clarification or lawful design revision, which presentation works across a small item, a multi-part product and an online listing?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	A documented product-and-channel scenario produces conflicting feasible interpretations of the adopted label presentation requirements.
2 Evidence	Directive (EU) 2024/825, Implementing Regulation (EU) 2025/1960, guidance, sample SKUs, shelf/mock-up and online checkout tests.
3 Responsible actor	DG JUST for Commission guidance and lawful implementing action; national consumer authorities for enforcement; legislators for basic-duty changes.
4 Consequence	Clarify permitted layouts and reuse templates if consistent with law; formally amend a binding design only via its authorising procedure.
5 Review	Same test SKUs: proportion with a legally clear display, retailer hours, clarification requests and tested consumer comprehension.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Map the exact label duty for three product-and-sales scenarios.
02 Test the user workflow	Let SME retailers execute the design on shelves and in an online listing, recording barriers by legal source.
03 Refer and verify	Issue a channel-tested Layout Options Note to DG JUST before its next clarification decision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION: DG JUST could commission a retail reality check only for a confirmed forthcoming clarification or legally available design review. WHEN: before that identified DG JUST decision, not automatically because the rules applied on 27 September 2026. TEST OWNER: DG JUST implementation staff with retailers, manufacturers and consumer authorities. OUTPUT/RECIPIENT: an Eligibility and Label Workability Note to the clarification owner. DECISION: explain an already valid application, consider a lawful design revision, or conclude that targeted retailer training is sufficient.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE WITHOUT RCC: Directive 2024/825 already defines which producer guarantees qualify; Implementing Regulation 2025/1960 fixes the label and notice; Commission guidance and national enforcement already operate. INCREMENTAL TEST: classify one eligible and one ineligible SKU first, then test eligible shelf and online layouts against current guidance. RCC is warranted only if the existing guidance leaves a material, repeatable unanswered question that could change the next competent decision; otherwise stop at training.

CASE 02 / DOCUMENTED CASE / OUTPUT, EVIDENCE AND VERIFICATION

EU Guarantee Label: Design Rules Meet Retail Reality

Consumer goods and sales channels | SME Reality Check and Secondary-Measure Screen

EVIDENCE BASELINE AND SOURCES

Directive (EU) 2024/825, Article 22a and consumer-information duties; Implementing Regulation (EU) 2025/1960 (applies 27 September 2026). Distinguish the mandatory general legal-guarantee notice from the conditional commercial-durability label. IVSH examples are attributed observations, not verified market-wide losses; no confirmed next DG JUST decision date is claimed.

Directive (EU) 2024/825 | View primary source

Implementing Regulation (EU) 2025/1960 | View primary source

Commission harmonised guarantee label material | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); IVSH Guarantee Label submission.

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Operational baseline	Qualifying commercial guarantee, non-qualifying control and online listing; document the conditional label and separate statutory-guarantee notice.
Test of options	Compare permitted common display or digital variants with measured setup time and consumer comprehension.
Review after clarification	Retest identical SKUs, note remaining ambiguous scenarios and whether compliance work has shifted to retailers.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Scenarios legally resolved	Share of sample product/channel scenarios with a clear legally valid layout.
SME deployment time	Person-hours for manufacturer information, shelf/POS and online configuration.
Consumer comprehension	Accuracy of test shoppers identifying statutory rights versus commercial guarantees.

A CREDIBLE ALTERNATIVE EXPLANATION

If the label is not legally triggered for that SKU, do not classify its absence as non-compliance. If the rule and Commission instructions already permit a clear valid layout, offer retailer training rather than a second regulatory review.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: legal acts and harmonised design. Medium: documented stakeholder uncertainties. Low: economy-wide costs and behavioural claims.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If tested layouts already meet the adopted rule without ambiguity, classify the issue as training rather than regulatory failure; stop extra RCC scrutiny.

CASE 02 / DOCUMENTED CASE / VISUAL CASE EXPLANATION

EU Guarantee Label: Design Rules Meet Retail Reality

Consumer goods and sales channels | SME Reality Check and Secondary-Measure Screen

RCC CONTROL MAP / CASE 02

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES — MAIN RCC CHECK	7 APPLICATION	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before a verified DG JUST clarification or lawful revision of the harmonised label rules

Status: ADOPTED RULE; CLARIFICATION TEST CONDITIONAL

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

Directive (EU) 2024/825 defines eligibility; Implementing Regulation (EU) 2025/1960 fixes design; guidance and national enforcement exist.

MATERIAL GAP TO TEST

Retail shelf and online layouts may be difficult even where producer-to-retailer information exists; first determine legal eligibility.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A verified eligible SKU cannot be displayed consistently across shop and online channels under the current instructions. Proposed lead: DG JUST owner if it authorises a test; retailers, manufacturers and consumer authorities provide practical cases.

DELIVERABLE AND DECISION ROUTE

Eligibility-screened Label Workability Note, with tested mock-ups and specific clarification requests. DG JUST clarifies within law; formal design changes follow proper procedure; retailers adapt where rules already suffice.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Eligible/non-eligible SKUs correctly classified; compliant layouts; staff time; consumer understanding.

IMPORTANT LIMIT

The label concerns a free producer durability guarantee for the whole good lasting more than two years, if made known to the trader.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 03 / DOCUMENTED CASE / THE REGULATORY SITUATION

EFSA Transparency and Novel Foods: Time Lost Before Assessment

Food innovation and authorisation | Procedural-Effect and Outcome Review

CASE IN ONE SENTENCE

Procedural transparency must be assessed alongside reliability, scientific scrutiny and applicant workability.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
Study planning	Study notification > Validation > EFSA review > Market entry	Validation

POLICY PURPOSE

The Transparency Regulation strengthens public confidence, access to risk-assessment information and integrity of studies. Novel foods remain subject to scientific safety assessment and authorisation before market access.

WHAT THE RECORD ESTABLISHES

EFSA requires notification of studies before they start and operates a formal validation and scientific-review workflow. SWD(2026) 450 reports 47 invalid applications linked to study-notification non-compliance in 2021-24, many involving novel foods. In European Ombudsman case 2372/2023/KW, the six-month treatment of a late-notification resubmission was examined; the Ombudsman found no maladministration. This documents a lawful but potentially difficult applicant pathway, not a proven unlawful EFSA delay.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

Pre-submission compliance and validity checking precede the substantive risk assessment. A missed notification, repeated validation exchanges or requests for new information can extend time-to-market even where the scientific safety standard itself is unchanged.

SME EXPOSURE

Food-technology start-ups and smaller ingredient developers may carry financing, consultancy and regulatory staffing costs during uncertain pre-revenue periods. Their exposure should be measured rather than inferred from the number of all EFSA applications.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

The Coppens submission alleges overly broad interpretation, confidentiality costs and long validation times. These are stakeholder claims unless independently confirmed. Not all clock stops are unnecessary; many reflect missing scientific evidence or dossier quality.

THE DECISION POINT

Before EFSA revises its applicant guidance or practical arrangements, which validation and study-notification failures are attributable to rules, applicants or agency workflow?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 8 (formal stage 8); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 03 / DOCUMENTED CASE / RCC AT THE EXISTING DECISION POINT

EFSA Transparency and Novel Foods: Time Lost Before Assessment

Food innovation and authorisation | Procedural-Effect and Outcome Review

WHAT WOULD BE DECIDED?

Before EFSA revises its applicant guidance or practical arrangements, which validation and study-notification failures are attributable to rules, applicants or agency workflow?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	A statistically or operationally material cluster of study-notification invalidities, repeated validation cycles or stop-clock events.
2 Evidence	Sample anonymised event logs, study-notification reason codes, completeness, applicant correspondence and the applicable EFSA Practical Arrangements.
3 Responsible actor	EFSA for lawful practical arrangements and guidance; Commission for policy follow-up; co-legislators if statutory disclosure or notification duties change.
4 Consequence	Clarify submission instructions, improve pre-submission guidance or workflow within legal powers; refer statutory questions by the proper route.
5 Review	Similar application cohorts: first-valid-submission rate, correction cycles, time by cause, assessment integrity and incremental RCC workload.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Choose one defined Novel Foods application cohort and classify invalidity reason codes.
02 Test the user workflow	Reconstruct each validation/stop-clock event by applicant omission, binding rule or agency workflow.
03 Refer and verify	Deliver a Procedural Delay Attribution Note to the actual guidance owner before revision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION: EFSA procedure management could approve a bounded clarity/usability check only before a confirmed guidance or practical-arrangements revision. OWNER: EFSA validation team, with the Commission service responsible for legal validity decisions and an anonymised applicant cohort. OUTPUT/RECIPIENT: Late-Study-Notification Guidance Options Note to the EFSA guidance owner. DECISION: improve lawful guidance or tools, refer any rule change through proper channels, or leave the current procedure unchanged. No unverified revision date is assumed.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE WITHOUT RCC: EFSA already explains study notification, validation and pre-submission advice, while the Commission determines application validity. In case 2372/2023/KW the Ombudsman accepted the disputed six-month practice and found no maladministration. INCREMENTAL TEST: attribute repeated misunderstandings to unclear instructions, missed applicant steps or administrative workflow; test clearer examples only if an existing guidance decision would benefit. RCC cannot dispense with the lawful six-month consequence.

CASE 03 / DOCUMENTED CASE / OUTPUT, EVIDENCE AND VERIFICATION

EFSA Transparency and Novel Foods: Time Lost Before Assessment

Food innovation and authorisation | Procedural-Effect and Outcome Review

EVIDENCE BASELINE AND SOURCES

SWD(2026) 450 reports notification-related invalidity; EFSA publishes the novel-food submission workflow. European Ombudsman decision 2372/2023/KW found no maladministration in applying a six-month interval to a resubmitted late-study-notification case. A procedure-useability test must not imply that this legal outcome was reversed. Official Ombudsman case: 2372/2023/KW

European Biotech Act staff working document SWD(2026) 450 | View primary source

EFSA novel food application procedure | View primary source

Transparency Regulation (EU) 2019/1381 | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); Coppens Cases.

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Procedure baseline	Validation decisions, reasons for invalidity, rework requests and stop-clock logs by same application cohort.
Decision options	EFSA guidance/template and pre-submission workflow changes versus statutory questions for DG SANTE.
Outcome review	Measure first-valid-submission share and attributable validation time while maintaining scientific scrutiny.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
First-valid-submission rate	Share accepted as valid at first submission, by cohort and required-study complexity.
Validation time by cause	Calendar days allocated to applicant rework, authority processing and legal waiting periods.
Scientific safeguards	Whether assessment completeness, confidentiality rules and scientific quality are preserved.

A CREDIBLE ALTERNATIVE EXPLANATION

If delays predominantly arise from poor scientific evidence, redesign should focus on applicant preparation and clear guidance; faster administrative acceptance must not weaken safety assessment.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: statutory workflow and documented 47 non-valid applications. Medium: aggregate causes. Low: unsupported average-delay and confidentiality cost claims.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If delays are explained by incomplete applicant submissions or mandatory safety information and guidance changes would not help, do not attribute a regulatory failure to EFSA.

CASE 03 / DOCUMENTED CASE / VISUAL CASE EXPLANATION

EFSA Transparency and Novel Foods: Time Lost Before Assessment

Food innovation and authorisation | Procedural-Effect and Outcome Review

RCC CONTROL MAP / CASE 03

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	7 APPLICATION	8 REVIEW — MAIN RCC CHECK

1 THE DECISION IN THE EXISTING PROCEDURE

Only before a confirmed EFSA applicant-guidance or practical-arrangements review

Status: DOCUMENTED ADMINISTRATIVE PRACTICE; NO OMBUDSMAN MALADMINISTRATION

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

The legal study-notification rule, Commission validity decisions and EFSA practical arrangements already apply. Ombudsman case 2372/2023/KW found no maladministration.

MATERIAL GAP TO TEST

Applicants may misunderstand timing and re-submission consequences; aggregate delay figures do not allocate fault by source.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

Repeated same-type invalidity or late-notification misunderstandings appear in a comparable application cohort. Proposed lead: EFSA procedural lead, coordinated with the competent Commission food-law service for legal changes.

DELIVERABLE AND DECISION ROUTE

Validation Attribution and Applicant-Guidance Note, separating applicant errors from agency workflow. EFSA improves lawful guidance/tools; Commission handles its validity role; no unsupported reduction of mandatory waiting time.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Invalidity reason by cohort; repeated questions; administrative clarification time; applicant comprehension.

IMPORTANT LIMIT

The European Ombudsman accepted the six-month practice in the individual case; RCC cannot present it as an unlawful delay.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 04 / DOCUMENTED CASE / THE REGULATORY SITUATION

EUDR: Digital Readiness and Downstream Data Requests

Deforestation-free supply chains | Digital Readiness and Burden-Migration Test

CASE IN ONE SENTENCE

Digital reporting should be usable and information demands must be assigned to their true legal source.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
EUDR duty	EU information system > National checks > Trade chain > SME work	EU information system

POLICY PURPOSE

The EU Deforestation Regulation seeks to reduce the EU market contribution to deforestation through product-specific due diligence. Its effectiveness depends on reliable traceability, functional information systems and precise allocation of duties.

WHAT THE RECORD ESTABLISHES

The Commission announced July 2026 updates to product scope and the EUDR Information System, including an amended implementing act, technical updates, reopened systems and new training. It announced application dates of 30 December 2026 for the main operator categories and 30 June 2027 for other micro and small operators, subject to the relevant legal distinctions.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

Formal duties are expressed in the basic act but completed through digital statements, role-specific forms, technical interfaces, national enforcement and customer requests. Downstream actors can be asked for substantially similar data through multiple channels, some statutory and others contractual.

SME EXPOSURE

Smaller traders and suppliers may depend on external software or larger customers to handle data exchanges. Repeated data requests create potential time and cost exposure, but generic claims about EU-wide duplicate requests must not be presented as measured EUDR outcomes.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

This is a documented implementation-readiness process, not proof that the information system failed generally. A private customer request is not automatically an EU legal requirement, nor is it necessarily national gold-plating.

THE DECISION POINT

Before the next specified EUDR Information System release or Commission implementation guidance decision, which data must the selected downstream operator legally provide?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 7 (formal stage 7); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 04 / DOCUMENTED CASE / RCC AT THE EXISTING DECISION POINT

EUDR: Digital Readiness and Downstream Data Requests

Deforestation-free supply chains | Digital Readiness and Burden-Migration Test

WHAT WOULD BE DECIDED?

Before the next specified EUDR Information System release or Commission implementation guidance decision, which data must the selected downstream operator legally provide?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	A downstream SME repeatedly receives data requests not clearly mapped to its own legal role or cannot complete the official submission route.
2 Evidence	Regulation (EU) 2023/1115 as amended, role-by-role duties, system screen steps, data fields and actual private buyer requests.
3 Responsible actor	Commission for EU system/guidance, national authorities for lawful enforcement; contractual parties for discretionary extra data; lawmakers for statutory changes.
4 Consequence	Clarify roles, reduce duplicate official fields, enable lawful reuse; separately seek voluntary changes to private templates.
5 Review	Pilot cocoa chain: duplicate fields and requests per shipment, completion time, legal traceability and deforestation safeguards.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Trace one real cocoa-product shipment through operator, trader, national authority and buyer roles.
02 Test the user workflow	Label each requested field: EU obligation, national enforcement practice, system need or private contract.
03 Refer and verify	Send a Data Attribution & System Readiness Note before the defined release/guidance decision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION AND LEAD: DG ENV implementation management could authorise a narrowly scoped digital and obligation-map check. DG ENV information-system/implementation team, with competent national authorities and volunteer cocoa-chain traders. WHEN: Attach the pilot to a documented next system-release or guidance approval; no unverified release date is assumed. HANDOVER: DG ENV system or guidance owner; relevant national authorities for enforcement practice; private buyers for voluntary template alignment. OUTPUT: EUDR Role-by-Role Obligation and Data-Flow Note.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE WITHOUT RCC: EUDR legal duties, Commission Information System and guidance, national enforcement and buyer templates already have distinct owners. INCREMENTAL TEST: for one cocoa shipment, tag each data field with its legal source and the actor able to change the form. Before a verified DG ENV system release or guidance sign-off, forward only unresolved EU-system defects to DG ENV, national procedural problems to the competent Member State, and contractual requests to buyers. Stop if existing guidance resolves the issue.

CASE 04 / DOCUMENTED CASE / OUTPUT, EVIDENCE AND VERIFICATION

EUDR: Digital Readiness and Downstream Data Requests

Deforestation-free supply chains | Digital Readiness and Burden-Migration Test

EVIDENCE BASELINE AND SOURCES

Commission 13 July 2026 implementation announcement and Information System documentation; historical readiness risks must be checked against actual system releases.

Commission EUDR implementation update, 13 July 2026 | View primary source

Commission EUDR Information System | View primary source

Regulation (EU) 2023/1115 | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Role-level baseline	The legal addressee and purpose of each field; official submission steps and customer request samples.
Test of corrective options	Re-use of authoritative data versus clear guidance versus optional standard buyer template, respecting lawful access.
Verified follow-up	Count repeat requests and manual entries; record legal traceability, costs and environmental control quality.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Duplicate data fields	Same field asked more than once per role and shipment, attributed to request origin.
Submission time	Minutes and retries for the lawful EUDR Information System task.
Due diligence integrity	No loss of required risk assessment, traceability or enforcement information.

A CREDIBLE ALTERNATIVE EXPLANATION

If a request reflects a legitimate traceability need or sector-specific fraud risk, it should not be removed mechanically; equivalent verification and controlled reuse may be the better option.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: legal duty, system arrangements and dates. Medium: usability risk. Low: quantified recurring duplicate requests across EU SMEs.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If requests are necessary for legally distinct roles or mandatory due diligence, preserve them and stop claiming administrative duplication.

CASE 04 / DOCUMENTED CASE / VISUAL CASE EXPLANATION

EUDR: Digital Readiness and Downstream Data Requests

Deforestation-free supply chains | Digital Readiness and Burden-Migration Test

RCC CONTROL MAP / CASE 04

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	**7 APPLICATION — MAIN RCC CHECK**	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before an identified DG ENV system change or implementation-guidance sign-off

Status: IMPLEMENTATION / DIGITAL WORKFLOW TEST

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

EU due-diligence duties, the Information System, Commission guidance and Member State controls already have separate owners.

MATERIAL GAP TO TEST

The same cocoa shipment can generate EU data requests and additional private-buyer fields whose legal source is unclear.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

One data field is repeatedly requested across EU system, buyer template and local procedure without a traceable basis. Proposed lead: DG ENV digital owner with a competent national authority and volunteer cocoa-chain operators.

DELIVERABLE AND DECISION ROUTE

Cocoa Shipment Role-by-Role Obligation and Data-Flow Note, field by field. DG ENV changes lawful tools/guidance; Member States adjust their practices; private buyers decide voluntary templates.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Unique required fields; duplicate entry hours; accepted submission rate; preserved due-diligence effectiveness.

IMPORTANT LIMIT

Buyer requests must not automatically be described as EU obligations or unlawful duplication.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

05 / DOCUMENTED CASE / REGULATORY PROCESS AND PROBLEM

PPWR: One EU Regulation, Several Compliance Channels

Packaging and Packaging Waste Regulation | Obligation traceability, secondary rules and burden migration

THE GOVERNANCE QUESTION

How can a direct EU requirement remain legally traceable when technical measures, national practice and private customer demands determine the task faced by a smaller firm?

FROM LEGISLATION TO THE TASK PERFORMED BY AN SME

Layer	Legal or operational source	Practical issue to test
EU political agreement	Regulation (EU) 2025/40 adopted in 2024 and applicable in phases from 12 August 2026.	Harmonised packaging policy objectives and actor-specific duties.
EU specification	Implementing/delegated acts, standards and Commission guidance.	Which technical format or interpretation is mandatory at which date?
National application	Competent-authority enforcement and EPR-related systems within applicable EU rules.	Which procedure is EU-derived, nationally determined or redundant?
Market transmission	Retailer, platform or customer packaging-data requests.	Is the requested test or certificate legally required or privately stipulated?

ONE TRACEABLE EXAMPLE, NOT AN EU-WIDE FAILURE CLAIM

Consider an SME selling one kitchen product in a specified retail packaging SKU to a retailer in two Member States. First map exact PPWR product and economic-operator obligations, including phased dates. Article 12 harmonised material labels are generally required no earlier than 12 August 2028 or the relevant later implementing-act timetable, not simply on the general 2026 application date. Then distinguish technical documentation, national procedures and voluntary customer questionnaires. No independent producer-register case is examined.

WHY A SINGLE PRODUCT FILE BECOMES SEVERAL TASKS

SME activity	Potential origin
Prepare packaging composition and conformity data	EU legal provisions and applicable technical specifications.
Repeat or reformat that information for different recipients	National procedure, customer system design or voluntary private contracting.
Obtain a specified accredited laboratory test	Needs independent legal-source check; cannot be presumed a general PPWR requirement.

IMPORTANT DISTINCTION

A directly applicable Regulation is not “transposed” like a Directive. National implementation practices, legally permitted national choices and private requests are different sources and require different corrective routes.

Working Paper link: §7 (traceability and burden migration); §9.8 (Material-Impact Screen); §§9.11–9.12 (secondary / national controls).

05 / DOCUMENTED CASE / EXISTING CONTROLS VERSUS RCC

PPWR: One EU Regulation, Several Compliance Channels

Packaging and Packaging Waste Regulation | Obligation traceability, secondary rules and burden migration

THE DISTINCT REGULATORY CONTROL MECHANISMS

Existing mechanism	Question not necessarily answered by that mechanism	Incremental RCC contribution
Basic act and legal definitions	Can an SME classify its roles correctly across packaging configurations?	Role-by-role obligation map tied to the precise EU provision and date.
Commission implementing acts and guidance	Are the combined technical steps operationally workable?	Material-impact and usability check of the cumulative compliance route.
National competent authorities and EPR processes	Is a request mandated by EU law, allowed nationally or administratively duplicated?	Source attribution, structured coordination and lawful national correction.
Business customer questionnaires	Are extra test reports legally necessary or commercial risk controls?	Burden-Migration Test separating legitimate checks from duplicative over-collection.

CONTROL RECORD FOR ONE PACKAGING CONFIGURATION

Trigger	Evidence	Actor	Consequence	Review
Material duplication or ambiguity	Legal-source map; task and field tests	Commission, national authority or private requester	Clarify, reuse data, coordinate; amend only lawfully	Staff time, duplicate fields, compliance outcomes

THE INSTITUTIONAL HANDOVER MAKES THE DIFFERENCE

ILLUSTRATIVE COMMISSION PILOT: Before a specific Article 12 implementing measure or lawful guidance decision, DG ENV management could authorise a one-SKU test. The team would compare an existing Commission impact/guidance baseline with exact EU fields, national administrative requests and retailer data demands, then submit a Packaging Compliance Cascade Options Note to the competent Commission lead. Any national simplification is for the relevant national authority; retailer-form changes are voluntary. An unresolved difference alone does not justify another RCC review unless it alters a lawful forthcoming decision.

SOURCE ATTRIBUTION DETERMINES THE REMEDY

If the requirement originates in …	Then RCC forwards the issue to …
EU basic act or binding secondary measure	Competent EU service; legal change follows the relevant EU procedure.
National administrative workflow	National competent authority, with cooperation on consistent application.
Customer or platform policy	Private requester; voluntary standard forms or acceptance of equivalent proof.

WHY THIS IS SYSTEM STEWARDSHIP

Each actor owns its own decision, but no single stage necessarily sees the cumulative SME task. RCC creates a shared issue record and closes the loop by checking what burden actually disappears.

05 / DOCUMENTED CASE / EVIDENCE, DECISIONS AND VERIFICATION

PPWR: One EU Regulation, Several Compliance Channels

Packaging and Packaging Waste Regulation | Obligation traceability, secondary rules and burden migration

TEST ONE PACKAGING DATA OBJECT END-TO-END

Observed request / activity	Source to verify	Possible response and outcome metric
Identify manufacturer, importer or distributor role	PPWR Articles 15–21 and the precise commercial configuration.	Clear role allocation; fewer contradictory declarations.
Provide technical documentation and declaration	Articles 15, 38–39 and Annex VII, as applicable.	Proportionate reusable evidence package; elapsed staff time.
Use relevant national/EPR processes	PPWR Chapter VIII and applicable national arrangements.	Avoid duplicate entry where legally possible; count repeated fields.
Supply retailer-requested accredited laboratory report	Check actual EU duty first; record commercial contract and risk rationale.	Accept equivalent evidence where possible; no assumption of blanket EU testing rule.

THREE VERIFICATIONS ACROSS THE CHAIN

Legal fidelity	Implementation functionality	Actual burden
Did any actor add a requirement without appropriate legal basis?	Can a typical SME complete the workflow with current instructions and systems?	What time and outside cost remains after clarification?

WHAT THE PILOT CANNOT ESTABLISH WITHOUT ADDITIONAL DATA

One retailer chain cannot prove EU-wide gold-plating or a quantified regulatory cost. A Commission FAQ is not a binding new requirement; it cannot amend the Regulation. The presence of a private test request does not automatically mean it is unlawful or unnecessary. Benefits of packaging sustainability must remain part of the outcome account.

ADDITIONAL BURDEN TEST AND REGULATORY BENEFIT

Count an administrative saving only when the same product-level data field genuinely disappears from the whole selected chain, not when it is shifted from an EU form to a national or private request. Record legal purpose, actor, staff hours and sustainability safeguard before and after any clarification. A request serving a separate lawful purpose is not automatically redundant.

PUBLISHABLE RCC OUTPUT

Packaging-Role Obligation Map | EU / National / Private Source Register | Duplicate-Request and Outcomes Review

SOURCE REGISTER (PRIMARY + ATTRIBUTABLE STAKEHOLDER EVIDENCE)

Regulation (EU) 2025/40: https://eur-lex.europa.eu/eli/reg/2025/40/oj

Commission PPWR Guidance (C/2026/3084): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52026XC03084

Commission PPWR implementation; IVSH material (stakeholder observations); Working Paper §§7, 9.8 and 9.11–9.12.

05 / DOCUMENTED CASE / INTEGRATED PROCESS GRAPHIC

PPWR: One EU Regulation, Several Compliance Channels

Packaging and Packaging Waste Regulation | Obligation traceability, secondary rules and burden migration

RCC CONTROL MAP / CASE 05

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES — MAIN RCC CHECK	7 APPLICATION	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before a specified packaging label implementing measure or Commission guidance decision

Status: PHASED IMPLEMENTATION; PRODUCT-SPECIFIC TEST

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

Regulation (EU) 2025/40 sets phased obligations; Commission technical acts, Member State enforcement and private supply chains have distinct roles.

MATERIAL GAP TO TEST

One packaged household product can be documented repeatedly for legal compliance, nationally required information and retailer forms.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

The same material/compliance fact is collected through several channels with no clear data owner or legal attribution. Proposed lead: Commission PPWR implementing team, national authority, packaging supplier and retailer if a pilot is authorised.

DELIVERABLE AND DECISION ROUTE

One-SKU Packaging Obligation and Data-Reuse Map showing mandatory, national and contractual requirements. Commission fixes lawful technical formats; national authority handles national practice; buyer changes private forms voluntarily.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Unique fields and repeat requests; SME hours; errors; unchanged recyclability and safety obligations.

IMPORTANT LIMIT

Article 12 labelling is phased (2028 or later as prescribed); this is not a separate producer-register case.

Reading key: source attribution determines who may act. The same business request can have a legal, national-administrative or contractual origin.

CASE 06 / DOCUMENTED CASE / THE REGULATORY SITUATION

CBAM: Proportionality for Small-Volume Importers

Carbon border administration | Ex-Post Threshold Outcome Review

CASE IN ONE SENTENCE

A well-calibrated scope can protect the regulatory objective while avoiding marginal fixed administrative costs.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
Climate objective	Original scope > SME cost test > 50-tonne rule > Emissions review	SME cost test

POLICY PURPOSE

The Carbon Border Adjustment Mechanism addresses carbon-leakage risk and supports EU climate policy. It must balance credible emissions coverage against reporting, authorisation and compliance costs for importers.

WHAT THE RECORD ESTABLISHES

The October 2025 enacted simplification introduced an annual 50-tonne exemption for eligible CBAM goods. The Commission estimated that around 182,000 importers, largely SMEs or individuals, would be exempt while over 99% of embedded emissions remained covered. These are policy forecasts, not audited realised savings.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

A large number of low-volume importers can face fixed setup and reporting duties while representing only a small share of embedded emissions. The later scope adjustment demonstrates how evidence about distributions changes the proportionality assessment.

SME EXPOSURE

For occasional importers, compliance system setup, supplier emissions data and declarant administration may be relatively expensive per tonne. Exemption can reduce formal tasks but does not prove all customs or supply-chain information demands disappear.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

The initial design should not be labelled unlawful or ineffective solely because it was later amended. Simplification figures describe anticipated coverage, not ex-post measured business time. Avoid treating tonne thresholds as identical for every product circumstance.

THE DECISION POINT

At the next CBAM implementation review, does the adopted 50-tonne exemption preserve emissions coverage while reducing burdens on small-volume importers?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 8 (formal stage 8); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 06 / DOCUMENTED CASE / RCC AT THE EXISTING DECISION POINT

CBAM: Proportionality for Small-Volume Importers

Carbon border administration | Ex-Post Threshold Outcome Review

WHAT WOULD BE DECIDED?

At the next CBAM implementation review, does the adopted 50-tonne exemption preserve emissions coverage while reducing burdens on small-volume importers?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	A threshold or exemption materially changes importer coverage or creates unforeseen fixed-cost effects.
2 Evidence	Actual annual imported tonnage per operator, emissions covered, customs-authorisation administration, declaration costs and SME cohorts.
3 Responsible actor	Commission/national competent authorities apply the adopted rules; statutory scope changes require EU legislative procedure.
4 Consequence	Explain/clarify administration, improve data reuse or propose a scoped legal revision if evidence supports it.
5 Review	Measure actual exempt importers, retained embedded-emissions coverage, hours/cost per active filer and enforcement integrity.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Define before/after importer cohorts around the adopted annual 50-tonne threshold.
02 Test the user workflow	Calculate the actual emissions share and compliance work for small versus large importers.
03 Refer and verify	Give DG TAXUD a Proportionality Review Note before the next implementation decision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION: DG TAXUD could ask for a supplementary importer-cost analysis as part of a defined Article 2a threshold assessment or follow-up, not a retrospective Front-End Gate. WHEN: before the next actually scheduled threshold/guidance choice; the Commission assessment published 30 September 2026 already found 0.87% of embedded emissions would be exempt for 1 April 2025-31 March 2026. OUTPUT: a linked Emissions Coverage and Importer-Cost Note. DECISION: apply the statutory threshold-adjustment rule if triggered, refine lawful guidance, or record no additional RCC need.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE WITHOUT RCC: the 2025 adopted CBAM changes and the Commission assessment of 30 September 2026 already address emissions coverage; the latter reports 0.87% under the 50-tonne exemption for the measured period. INCREMENTAL TEST: a small importer/broker cohort measures actual admin hours, costs and any shifted supplier work beyond the statutory emissions metric. If the ordinary assessment already captures those costs adequately, RCC should not duplicate it or imply that RCC influenced the enacted reform.

CASE 06 / DOCUMENTED CASE / OUTPUT, EVIDENCE AND VERIFICATION

CBAM: Proportionality for Small-Volume Importers

Carbon border administration | Ex-Post Threshold Outcome Review

EVIDENCE BASELINE AND SOURCES

The adopted Regulation (EU) 2025/2083 and Commission reform estimates are historical baseline evidence. Under Article 2a(3), the Commission published a threshold assessment on 30 September 2026 finding 0.87% exempted embedded emissions for 1 April 2025-31 March 2026. Actual importer hours, broker fees and supplier work still require independent measurement; the 2025 reform was not RCC-driven. Official assessment: DG TAXUD, 30 Sep 2026

Regulation (EU) 2025/2083 | View primary source

Commission CBAM simplification announcement, 20 October 2025 | View primary source

Commission CBAM review COM(2025) 783 | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Actual coverage baseline	Matched customs and CBAM records: imported mass, product coverage, associated embedded emissions by firm size.
Review options	Keep threshold, improve administrative templates or propose a legislative adjustment if outcomes warrant it.
Observed impacts	Importer participation, emissions coverage, processing time, private broker costs and enforcement signals.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Importers in/out of scope	Count distinct importers by annual tonnes using the enacted threshold and correct product scope.
Covered embedded emissions	Share of in-scope embedded emissions retained after exemption, not importer headcount.
Compliance cost per filer	Verified person-hours and external broker charges for active SMEs, using consistent periods.

A CREDIBLE ALTERNATIVE EXPLANATION

A threshold may create incentives for splitting transactions or shifting intermediaries; monitoring and anti-circumvention controls remain necessary.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: enacted law and Commission scenario. Medium: proportionality inference. Low: verified long-run administrative cost and emissions outcomes.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If observed emissions coverage and burden reductions meet the objectives without unexplained adverse effects, record success of existing reform; do not claim RCC caused it.

CASE 06 / DOCUMENTED CASE / VISUAL CASE EXPLANATION

CBAM: Proportionality for Small-Volume Importers

Carbon border administration | Ex-Post Threshold Outcome Review

RCC CONTROL MAP / CASE 06

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	7 APPLICATION	8 REVIEW — MAIN RCC CHECK

1 THE DECISION IN THE EXISTING PROCEDURE

At a statutory or scheduled DG TAXUD threshold-implementation assessment, not a past front-end gate

Status: EX-POST ASSESSMENT OF ENACTED 50-TONNE THRESHOLD

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

The adopted threshold exists; Commission assessed embedded emissions on 30 September 2026 under Article 2a(3).

MATERIAL GAP TO TEST

The legal emissions-coverage test does not alone prove that small importers saved work rather than paid brokers or suppliers.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

Threshold coverage stays within law but importer/broker data indicate residual or migrated fixed costs. Proposed lead: DG TAXUD CBAM team with customs and importer evidence; threshold changes require the applicable legal procedure.

DELIVERABLE AND DECISION ROUTE

CBAM Threshold Outcome Review Note linking measured exempted emissions and actual small-importer costs. DG TAXUD refines guidance/administration; Commission follows statutory adjustment rules if triggered.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Commission 0.87% embedded-emissions finding for Apr 2025-Mar 2026; broker fees; importer hours.

IMPORTANT LIMIT

An adopted 2025 reform is not evidence of an RCC intervention; 0.87% is a dated official assessment.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 07 / DOCUMENTED CASE / THE REGULATORY SITUATION

CSRD: Sustainability Data Passed Down the Value Chain

Reporting and supplier information | Burden-Migration and Supply-Chain Test

CASE IN ONE SENTENCE

Formal SME exclusion is not enough if equivalent data demands continue through the value chain.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
Reporting company	ESRS requests > Protected supplier > Private contracts > Actual effort	Private contracts

POLICY PURPOSE

EU sustainability reporting seeks comparable and reliable information on business impacts and sustainability risks. Reporting companies must gather relevant information while respecting proportionality for smaller suppliers.

WHAT THE RECORD ESTABLISHES

Directive (EU) 2026/470 narrowed mandatory CSRD reporting to companies exceeding both 1,000 employees and EUR 450 million net turnover under the stated conditions. It introduced a protected-undertaking framework: qualifying value-chain firms generally may decline information requests exceeding the voluntary standard for CSRD reporting purposes, subject to legal qualifications.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

The legal reporting perimeter is narrower than the network of business-to-business requests created by customers, lenders, certification systems and contractual practices. The same SME may be outside scope yet field overlapping questionnaires from multiple partners.

SME EXPOSURE

Smaller suppliers may face fragmented data demands and bargaining pressure, even where the formal legislative obligation is directed at a larger enterprise. Private requests may also serve legitimate commercial or other regulatory purposes.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

The value-chain safeguards are legally specific. They should not be described as banning every customer sustainability request. A comparison must isolate requests made for CSRD reporting from those arising under other rules or voluntary contracts.

THE DECISION POINT

Before a competent national authority issues guidance or reviews application of the value-chain safeguards, are out-of-scope SMEs still asked for data beyond the legally protected standard?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 7 (formal stage 7); §7 / §12 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 07 / DOCUMENTED CASE / RCC AT THE EXISTING DECISION POINT

CSRD: Sustainability Data Passed Down the Value Chain

Reporting and supplier information | Burden-Migration and Supply-Chain Test

WHAT WOULD BE DECIDED?

Before a competent national authority issues guidance or reviews application of the value-chain safeguards, are out-of-scope SMEs still asked for data beyond the legally protected standard?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	Repeated supplier questionnaires cite CSRD but appear to demand data not required of the out-of-scope supplier.
2 Evidence	Directive 2022/2464 as amended by Directive 2026/470, relevant voluntary standard and actual supplier requests, contracts and cost logs.
3 Responsible actor	National authorities oversee domestic application, Commission addresses EU policy/standards where empowered; private customers decide their non-statutory questionnaires.
4 Consequence	Clarify the protected scope, remove unsupported official requirements, promote a standard request template and consider lawful follow-up.
5 Review	Count non-required fields per supplier, request frequency, response hours and reporting-company information quality.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Collect two buyer questionnaires received by one out-of-scope supplier and trace each field to legal source.
02 Test the user workflow	Separate required reporting-company evidence from excess or contract-specific requests.
03 Refer and verify	Issue a Supplier Data Protection Note before the national guidance or supervisory decision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION AND LEAD: Competent national administration, optionally with DG FISMA evidence coordination, would approve a limited value-chain request audit. National reporting-policy/supervisory owner; DG FISMA liaises on EU interpretation; sample buyers and small suppliers contribute data. WHEN: Attach a pilot to a confirmed national transposition/guidance or supervisory-review milestone; no uniform EU national date is assumed. HANDOVER: National authority for enforcement/guidance; DG FISMA for EU-level implementation feedback; reporting firms for voluntary request revisions. OUTPUT: CSRD Supplier-Request Attribution and Safeguard Note.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE: Directive (EU) 2026/470 protects qualifying suppliers against CSRD-purpose data requests beyond the voluntary standard. RCC ADDITION: For one verified protected supplier, identify excessive fields and their business purpose. Submit a short note only before a confirmed national guidance or supervisory choice; unrelated lawful commercial requests remain outside this test. Verify removed work, not merely shifted questionnaires.

CASE 07 / DOCUMENTED CASE / OUTPUT, EVIDENCE AND VERIFICATION

CSRD: Sustainability Data Passed Down the Value Chain

Reporting and supplier information | Burden-Migration and Supply-Chain Test

EVIDENCE BASELINE AND SOURCES

Directive (EU) 2026/470 and accompanying EU sustainability-standard measures; future observed requests must be collected against a dated baseline.

Directive (EU) 2026/470 | View primary source

Council explanation of corporate sustainability changes | View primary source

Commission CSRD implementing acts | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Supplier-request baseline	Requested fields, frequency, provenance and buyer purpose; legal thresholds and the applicable voluntary standard.
Institutional decision	National guidance/enforcement options and EU implementation feedback; separately invite buyers to narrow requests.
Post-guidance review	Supplier time per questionnaire and out-of-scope excess fields; verify reporting completeness is maintained.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Excess data requests	Fields demanded of a protected out-of-scope supplier beyond applicable requirements, classified by legal basis.
Supplier response time	Hours per reporting period spent by a matched group of smaller suppliers.
Reporting usefulness	Information quality for reporting undertakings and legal compliance after narrowing duplicate requests.

A CREDIBLE ALTERNATIVE EXPLANATION

Some information may be sought under separate due diligence, finance or product regimes. The remedy must reflect the correct legal basis and not nullify lawful requests.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: legal scope and protection. Medium: plausible burden transmission. Low: representative quantitative effects after the new rules.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If a buyer genuinely requires information for a separate lawful purpose, distinguish that demand from a CSRD obligation; do not treat it as proven gold-plating.

CASE 07 / DOCUMENTED CASE / VISUAL CASE EXPLANATION

CSRD: Sustainability Data Passed Down the Value Chain

Reporting and supplier information | Burden-Migration and Supply-Chain Test

RCC CONTROL MAP / CASE 07

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	**7 APPLICATION** MAIN RCC CHECK	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before a participating Member State guidance or supervisory decision on value-chain requests

Status: ENACTED PROTECTION; NATIONAL APPLICATION TEST

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

Directive (EU) 2026/470 provides a value-chain cap and protected suppliers a right to decline excessive CSRD-purpose requests.

MATERIAL GAP TO TEST

Smaller suppliers may still receive questionnaires without a clear statement of reporting purpose or limits.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A documented request exceeding the applicable voluntary standard is addressed to a legally protected supplier. Proposed lead: Named national reporting/supervision authority only if it accepts a pilot; DG FISMA can exchange EU-level evidence.

DELIVERABLE AND DECISION ROUTE

Protected-Supplier Request and Legal-Source Note for authority guidance plus a buyer feedback template. National authority clarifies/enforces applicable law; buyer changes request practice; DG FISMA considers EU guidance.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Request fields beyond standard; supplier hours; correct self-declarations; reporting quality preserved.

IMPORTANT LIMIT

First establish supplier eligibility and that the request is made for CSRD reporting, not another lawful business purpose.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 08 / DOCUMENTED CASE / THE REGULATORY SITUATION

Late Payments: Legal Entitlement Versus Actual Payment

Commercial transactions and enforcement | Ex-Post Outcome and Enforcement Feedback

CASE IN ONE SENTENCE

A right written in law is not an effective Single Market outcome unless businesses can exercise it in practice.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
EU payment rights	National rules > Contract practice > Collection effort > Liquidity result	Collection effort

POLICY PURPOSE

Directive 2011/7/EU seeks to protect creditors in business-to-business and public-authority transactions through payment-time safeguards, statutory late interest and recovery-cost rights. Payment culture and enforceability remain central to actual SME liquidity.

WHAT THE RECORD ESTABLISHES

The EU Payment Observatory 2025, drawing on 2024 evidence and survey inputs, reports that firms spent an average 9.85 hours per week pursuing overdue invoices. Thirty-seven per cent of surveyed businesses considered sanctions ineffective; roughly one-third reported inconsistent enforcement. The 2023 proposal for a replacement regulation remained in the legislative process at the October 2026 cut-off.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

The legal right to payment and interest is mediated by contract terms, national enforcement, costs of litigation, commercial bargaining power and creditor reluctance to challenge customers. Aggregate payment-performance statistics may reveal an effectiveness gap without proving any single state violated EU law.

SME EXPOSURE

SMEs have less liquidity cushion and may be commercially dependent on larger buyers or public contracts. Pursuing unpaid invoices consumes administrative time and may transmit delays to their own suppliers.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

Survey averages are not verified EU-wide population means; they vary by country and sector. The Commission does not establish that every reported delay breached Directive 2011/7/EU. The unadopted 2023 proposal is not current law.

THE DECISION POINT

Before a named national late-payment enforcement reform or Commission policy review, which remedy actually reduces the time SMEs spend collecting overdue invoices?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 8 (formal stage 8); §10 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 08 / DOCUMENTED CASE / RCC AT THE EXISTING DECISION POINT

Late Payments: Legal Entitlement Versus Actual Payment

Commercial transactions and enforcement | Ex-Post Outcome and Enforcement Feedback

WHAT WOULD BE DECIDED?

Before a named national late-payment enforcement reform or Commission policy review, which remedy actually reduces the time SMEs spend collecting overdue invoices?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	Documented late-payment incidence and weak use of statutory interest or recovery remedies, especially among small suppliers.
2 Evidence	Directive 2011/7/EU, national transposition, invoice/payment cohorts, reminder and enforcement actions, Observatory survey results.
3 Responsible actor	National courts and authorities apply remedies; Commission monitors EU framework; co-legislators only for binding EU changes.
4 Consequence	Improve accessible remedy information, standard recovery forms, enforcement coordination or propose lawful national legislative changes.
5 Review	Median days overdue, successful claims, staff time spent collecting and debtor/payment risk; account for commercial power differences.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Recruit a comparable SME invoice cohort and classify contractual terms, payment delay and actual remedies used.
02 Test the user workflow	Trace bottlenecks in claiming interest or recovery costs, including fear of losing customers.
03 Refer and verify	Present a National Enforcement Options Note before the participating authority chooses a remedy.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION AND LEAD: A competent national justice/economic administration could commission a pilot, with DG GROW sharing EU Payment Observatory evidence. National authority responsible for debt recovery or late-payment enforcement; SME sample and DG GROW evidence liaison. WHEN: Before a scheduled national enforcement-review or Commission Observatory follow-up; the participating authority must first confirm the decision calendar. HANDOVER: National justice/economic ministry or competent enforcement authority; Commission for broader EU policy findings. OUTPUT: Late-Payment National Enforcement Issue-and-Options Note.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE: Directive 2011/7/EU, national remedies and the Payment Observatory already exist. RCC ADDITION: Only if a named national authority accepts a pending review, trace one documented unpaid SME invoice through reminder, interest and enforcement to actual recovery. Compare a specific procedural option with ordinary practice and measure creditor cost. No confirmed Member State pilot or decision date is claimed.

CASE 08 / DOCUMENTED CASE / OUTPUT, EVIDENCE AND VERIFICATION

Late Payments: Legal Entitlement Versus Actual Payment

Commercial transactions and enforcement | Ex-Post Outcome and Enforcement Feedback

EVIDENCE BASELINE AND SOURCES

2025 EU Payment Observatory Annual Report (observations predominantly for 2024), Commission directive implementation material and the pending 2023 legislative dossier.

Late Payment Directive 2011/7/EU | View primary source

EU Payment Observatory Annual Report 2025 | View primary source

Legislative file COM(2023) 533 | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Transaction baseline	Matched invoice dates, contractual payment terms, actual receipts and claim filing rates.
National options	Compare reminder templates, accessible complaint routes and enforcement coordination with unchanged legal rights.
Ex-post outcome	Days overdue, collection staff time, SME cost and remedy uptake, controlling for sector and debtor type.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Actual days overdue	Distribution of days past contractual/statutory due date on paid and unpaid SME invoices.
Remedy use and success	Share of eligible invoices with interest/recovery claim, with outcomes and attrition.
Collection staff time	Verified weekly staff-hours spent following up overdue payments, by company size.

A CREDIBLE ALTERNATIVE EXPLANATION

Long contract terms and late payment are not the same; distinguish agreed terms, illegal terms and unpaid overdue balances before allocating responsibility.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: Directive and Observatory report. Medium: observed enforcement gap. Low: attributing individual payment failures to a specific EU rule.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If delay mainly reflects commercial disputes, insolvency or debtor concentration not addressed by the proposed administrative fix, do not count a guidance change as proof of RCC effectiveness.

CASE 08 / DOCUMENTED CASE / VISUAL CASE EXPLANATION

Late Payments: Legal Entitlement Versus Actual Payment

Commercial transactions and enforcement | Ex-Post Outcome and Enforcement Feedback

RCC CONTROL MAP / CASE 08

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	7 APPLICATION	8 REVIEW MAIN RCC CHECK

1 THE DECISION IN THE EXISTING PROCEDURE

Before a participating national authority reviews a named payment-enforcement or recovery measure

Status: RIGHTS EXIST; NATIONAL PILOT DECISION NOT YET SELECTED

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

Directive 2011/7/EU confers late-payment rights through national law; national remedies and the EU Payment Observatory exist.

MATERIAL GAP TO TEST

EU-wide survey indicators do not show which practical step deters an SME from using a national legal remedy.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A documented sample of overdue B2B invoices shows persistent, identifiable barriers to lawful recovery. Proposed lead: Competent national justice/economic authority to be confirmed, with SME evidence and DG GROW observatory data.

DELIVERABLE AND DECISION ROUTE

National SME Payment-Recovery Pathway Note with an enforceable-option comparison. National authority improves procedures within mandate; lawmaker changes any legal entitlement; Commission monitors trends.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Time to recovery; creditor legal costs; use of statutory interest; SME staff hours after intervention.

IMPORTANT LIMIT

Choose a specific Member State and actual review date before claiming an operational pilot.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 09 / PROSPECTIVE ASSESSMENT / THE REGULATORY SITUATION

AI Act: Stress-Testing High-Risk SME Compliance

Ongoing high-risk AI implementation | Prospective Implementation Readiness Gate

CASE IN ONE SENTENCE

The remaining transition should be used to test whether a small provider can complete a defensible compliance route.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
High-risk category	Standards / guidance > Conformity route > National bodies > SME readiness	Standards / guidance

POLICY PURPOSE

The AI Act introduces risk-based obligations to protect safety and fundamental rights while supporting an EU market for trustworthy AI. Technical documentation, harmonised standards, conformity procedures and supervisory capacity shape how high-risk providers comply.

VERIFIED STATUS AND THE PROSPECTIVE CONCERN

Regulation (EU) 2026/1744 expressly cited delayed availability of standards, guidance and national competent authorities. It moved specified high-risk obligations under Annex III to 2 December 2027 and Annex I to 2 August 2028. The delays are documented; future SME readiness is not yet established.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

Statutory requirements depend on technical and institutional inputs delivered later. Firms can prepare general quality systems while awaiting final standard pathways, detailed guidance or local authority contact points.

SME EXPOSURE

A small developer of recruitment-related AI is an illustrative test user, not an observed infringement. Compliance may require external legal and conformity expertise, but its actual resource use needs a measured walk-through.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

The case is prospective: it must not claim that the AI Act is defective or that a future deadline will be missed. Additional regulatory adjustments associated with the 2026 amendment are part of adopted law, not a substitute for evidence of actual compliance capacity.

THE DECISION POINT

Before 2 December 2027 for Annex III systems, can an SME provider of a recruitment-screening AI system complete the lawful conformity route with available support?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 7 (formal stage 7); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 09 / PROSPECTIVE ASSESSMENT / RCC AT THE EXISTING DECISION POINT

AI Act: Stress-Testing High-Risk SME Compliance

Ongoing high-risk AI implementation | Prospective Implementation Readiness Gate

WHAT WOULD BE DECIDED?

Before 2 December 2027 for Annex III systems, can an SME provider of a recruitment-screening AI system complete the lawful conformity route with available support?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	A tested high-risk system lacks a usable documentation, classification or conformity-assessment step despite its approaching legal application.
2 Evidence	Regulation 2024/1689 as amended by 2026/1744, available standards/common specifications, legal alternative routes, provider task log.
3 Responsible actor	Commission/AI Office and national authorities act within their mandates; co-legislators change statutory duties or dates.
4 Consequence	Clarify lawful alternative routes, coordinate instructions and technical support; refer binding-law changes separately.
5 Review	Task completion by route, missing mandatory tools, provider cost and preservation of fundamental-rights and safety protection.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Select one Annex III recruitment-related high-risk SME use case and legally classify it.
02 Test the user workflow	Walk through risk management, documentation, conformity, registration and available standards or lawful alternatives.
03 Refer and verify	Submit a High-Risk SME Readiness Note to the named Commission/national guidance owner before their decision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION AND LEAD: Commission AI Office/DG CNECT management and a willing national market-surveillance authority could authorise a targeted readiness test. AI Office implementation team and national competent authority, with a volunteer smaller recruitment-AI provider. WHEN: A dated pilot review well before 2 December 2027; choose a concrete Commission guidance or national-authority readiness milestone rather than inventing an automatic RCC deadline. HANDOVER: AI Office/Commission guidance owner and national authority for their respective implementation decisions. OUTPUT: Annex III SME Compliance Readiness & Options Note.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE: The AI Act, standards, Commission support and national authorities already govern high-risk systems. Regulation (EU) 2026/1744 sets Annex III application for 2 December 2027 and Annex I product systems for 2 August 2028. RCC ADDITION: Before a verified guidance or readiness choice, test one recruitment-AI SME provider workflow; refer unresolved blockers to the competent owner only. No new legal deadline.

CASE 09 / PROSPECTIVE ASSESSMENT / OUTPUT, EVIDENCE AND VERIFICATION

AI Act: Stress-Testing High-Risk SME Compliance

Ongoing high-risk AI implementation | Prospective Implementation Readiness Gate

EVIDENCE BASELINE AND SOURCES

Regulation (EU) 2026/1744 sets 2 December 2027 for Annex III high-risk AI and 2 August 2028 for Annex I product AI. The recruitment-provider case is a proposed SME reality check, not a recorded violation.

AI Act, Regulation (EU) 2024/1689 | View primary source

Amending Regulation (EU) 2026/1744 | View primary source

Commission AI Act implementation guidance | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Provider baseline	One small recruitment-AI provider scenario; legal classification, needed documents, available standards and lawful fallback.
Guidance decision	Categorise blockers as missing explanation, technical standard, national practice or binding legal requirement.
Readiness review	Time and cost to complete each step, with rights/safety safeguards and extra RCC test workload.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Route-step completion	Percentage of legally mandatory compliance steps fully executable in the defined test scenario.
Support instrument availability	Count required tools and legally valid alternatives available before the Annex III date.
SME compliance effort	Observed staff/expert hours for the full scenario without weakening fundamental-rights controls.

A CREDIBLE ALTERNATIVE EXPLANATION

Requirements might be feasible through alternative legally valid compliance routes despite absent harmonised standards; test those routes rather than equating missing standard with non-compliance.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: enacted timing and stated readiness concerns. Prospective: practical readiness and remedy effectiveness.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If the selected provider can lawfully comply using existing standards or alternatives, do not interpret absent preferred guidance as a demonstrated legal blockage.

CASE 09 / PROSPECTIVE ASSESSMENT / VISUAL CASE EXPLANATION

AI Act: Stress-Testing High-Risk SME Compliance

Ongoing high-risk AI implementation | Prospective Implementation Readiness Gate

RCC CONTROL MAP / CASE 09

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	**7 APPLICATION — MAIN RCC CHECK**	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before a named Annex III readiness decision in advance of 2 December 2027

Status: PROSPECTIVE BEFORE ANNEX III HIGH-RISK APPLICATION

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

AI Act high-risk obligations, standards/guidance and national market surveillance are established through separate channels.

MATERIAL GAP TO TEST

An SME recruitment-screening provider may lack an end-to-end route through documented obligations and support tools.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A sample provider cannot complete a required Annex III conformity step using available standards, instructions or contacts. Proposed lead: Commission AI Office/DG CNECT and consenting national market-surveillance authority, with one SME provider.

DELIVERABLE AND DECISION ROUTE

Annex III Provider Journey and Readiness Note, naming unresolved tools and the lawful owner. Competent Commission service clarifies support; national authority fixes its interface; statutory dates remain binding.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

End-to-end time; missing support steps; consistent classification; compliance without reduced safeguards.

IMPORTANT LIMIT

Do not conflate 2 Dec 2027 (Annex III) with 2 Aug 2028 (Annex I product systems).

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 10 / PROSPECTIVE ASSESSMENT / THE REGULATORY SITUATION

Digital Product Passport: Once-Only Data by Design

ESPR and product-specific roll-out | Interoperability and Secondary-Measure Screen

CASE IN ONE SENTENCE

A digital passport simplifies compliance only if it replaces repetition instead of adding a parallel data silo.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
ESPR framework	Sector acts > Registry / identifiers > Data exchange > Product lifecycle	Registry / identifiers

POLICY PURPOSE

Regulation (EU) 2024/1781 (ESPR) provides a horizontal framework; digital product passport duties arise product by product under later delegated acts. Textiles are a priority group, with a future product-specific delegated act and DPP rules envisaged.

VERIFIED STATUS AND THE PROSPECTIVE CONCERN

The Commission textile DPP page describes indicative adoption of the textile ESPR delegated act in Q4 2027, subject to change. No adopted textile-specific passport field list is assumed. This proposed RCC test targets one illustrative apparel SKU before the draft rules are settled.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

The framework, registry, service providers, sector acts and industry data systems are separate design layers. Without source attribution and interoperability, the same material or compliance evidence could be entered and verified repeatedly.

SME EXPOSURE

Smaller suppliers may need to obtain data from customers, suppliers and external providers. New passport obligations could generate one-time data preparation costs and recurring maintenance work; such costs should not be asserted before the product-specific duties exist.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

A risk of duplicated reporting is prospective, not proof of a failed DPP. The 20 July registry milestone does not mean all product categories already require a passport.

THE DECISION POINT

Before the planned textile ESPR delegated act is finalised, which product data fields and passport transfers are actually needed and reusable for an SME apparel supplier?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 6 (formal stage 6); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 10 / PROSPECTIVE ASSESSMENT / RCC AT THE EXISTING DECISION POINT

Digital Product Passport: Once-Only Data by Design

ESPR and product-specific roll-out | Interoperability and Secondary-Measure Screen

WHAT WOULD BE DECIDED?

Before the planned textile ESPR delegated act is finalised, which product data fields and passport transfers are actually needed and reusable for an SME apparel supplier?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	Draft textile DPP schema requires repeated entry of existing product data or imposes unsupported interface obligations on smaller supply-chain actors.
2 Evidence	Regulation (EU) 2024/1781, ESPR working plan, draft textile requirements if available, sample material-origin data, test API/schema paths.
3 Responsible actor	Commission acts within ESPR delegated powers and scrutiny by Parliament/Council; national authorities implement and enforce adopted requirements.
4 Consequence	Adjust the proposed data schema within delegated powers, clarify access roles, reuse authoritative fields and schedule system-readiness tests.
5 Review	Number of duplicate fields, test time, successful handovers and data accuracy once textile DPP requirements eventually apply.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Select a real textile product and map its existing bill-of-materials and traceability data.
02 Test the user workflow	Prototype one data journey: upstream supplier -> SME brand -> future passport -> regulator/customer.
03 Refer and verify	Present a Textile DPP Interoperability Note before the Commission drafts or adopts its delegated requirements.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION AND LEAD: Relevant Commission ecodesign/DPP service management could authorise a textile-sector schema test during preparatory analysis. Responsible Commission ESPR drafting team with JRC technical support, DPP architecture experts and representative apparel SMEs. WHEN: Before adoption of the future textile-specific delegated act (Commission indicative plan: Q4 2027, subject to change). HANDOVER: Commission delegated-act preparation owner; other actors only for their own interoperability/system responsibilities. OUTPUT: Textile DPP Draft-Data & Interoperability Options Note.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE: ESPR, JRC studies, stakeholder input and horizontal DPP specifications already support drafting. A textile delegated act is provisionally planned for Q4 2027; no final textile data fields are presumed. RCC ADDITION: Test a draft apparel field list against actual SME and supplier systems and submit only verified, avoidable duplication to the Commission drafting owner before that act is settled.

CASE 10 / PROSPECTIVE ASSESSMENT / OUTPUT, EVIDENCE AND VERIFICATION

Digital Product Passport: Once-Only Data by Design

ESPR and product-specific roll-out | Interoperability and Secondary-Measure Screen

EVIDENCE BASELINE AND SOURCES

ESPR Regulation (EU) 2024/1781, its 2025-2030 working plan and Commission Textile Apparel DPP page (indicative Q4 2027 delegated act); any field list used in testing is a prototype until lawfully adopted.

ESPR Regulation (EU) 2024/1781 | View primary source

Commission Digital Product Passport roadmap | View primary source

Commission ecodesign framework | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Product-data baseline	One apparel SKU, current supplier records and an illustrative future textile DPP field list (marked draft).
Drafting decision	Use once-only mapping and role-based access to propose proportionate fields before the delegated act is finalised.
Later verification	Transfer success, duplicate entry counts, issuer access burden and product sustainability information quality.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Fields re-entered	Count same identifiers or data elements typed again in the proposed textile passport flow.
Data handover success	Share of test supply-chain transfers accepted with correct permission and provenance.
SME integration effort	Hours and cost to map one textile SKU; distinguish draft assumptions from enacted law.

A CREDIBLE ALTERNATIVE EXPLANATION

Some duplicated fields may have different lawful verification, confidentiality or security purposes. Only unnecessary duplication should be removed.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: legal and roadmap architecture. Prospective: firm-level cost, interoperability effects and sector outcomes.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If no product-specific textile DPP content is yet defined, treat the exercise as a design prototype, not as measurement of legal compliance.

CASE 10 / PROSPECTIVE ASSESSMENT / VISUAL CASE EXPLANATION

Digital Product Passport: Once-Only Data by Design

ESPR and product-specific roll-out | Interoperability and Secondary-Measure Screen

RCC CONTROL MAP / CASE 10

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES — MAIN RCC CHECK	7 APPLICATION	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before the planned Q4 2027 textile delegated act is finalised (Commission timetable indicative)

Status: PROSPECTIVE TEXTILE-SPECIFIC DELEGATED ACT

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

ESPR sets horizontal architecture; future delegated acts determine actual textile obligations; JRC study and consultations already exist.

MATERIAL GAP TO TEST

A draft data requirement may duplicate supplier ERP records, sector standards or other existing information systems.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

One candidate textile passport field has unclear purpose, owner, collection cost or interoperable reuse. Proposed lead: Commission ecodesign/DPP drafting service and JRC, with representative SME apparel supply-chain users.

DELIVERABLE AND DECISION ROUTE

Textile Draft-Data Necessity and Reuse Matrix as input to the competent delegated-act drafting team. Commission evaluates the delegated-act design; no textile DPP legal data fields are presumed already final.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Required vs optional draft fields; one-time entry rate; inter-system transfer errors; data-production costs.

IMPORTANT LIMIT

The future textile act will determine actual requirements and transition; this remains a prospective design test.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 11 / PROSPECTIVE ASSESSMENT / THE REGULATORY SITUATION

European Biotech Act: A Verifiable Innovation Path

Prospective health-biotechnology framework | Front-End and Procedural Workability Check

CASE IN ONE SENTENCE

A promise of faster innovation must be mapped to one real regulatory route and measured against the existing baseline.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
Biotech start-up	Regulatory route > Trials / assessment > Authorisation > Market pathway	Trials / assessment

POLICY PURPOSE

The proposed European Biotech Act seeks to strengthen health biotechnology and biomanufacturing through better regulatory conditions, stronger ecosystems and support for start-ups and SMEs. The proposed act is not yet binding legislation.

VERIFIED STATUS AND THE PROSPECTIVE CONCERN

COM(2025) 1022, procedure 2025/0406(COD), proposes changes to the Clinical Trials Regulation (EU) No 536/2014. The proposal describes reducing the maximum multinational initial authorisation timeline from 106 to 75 days, including validation and ethics assessment. These are proposed time limits, not measured savings or enacted outcomes.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

For a multinational trial, CTIS submission, reporting-Member-State coordination, requests for information and ethical assessment share the authorisation clock. A shorter statutory limit is useful only if each handover remains legally and operationally feasible.

SME EXPOSURE

A smaller biotech sponsor faces trial funding and preparation costs when authorisation timing is uncertain. Any reduction must be compared using similar trial complexity and full clinical safeguards; no general faster-market-access claim follows from the draft alone.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

Do not amalgamate food Novel Foods proceedings with health-biotech authorisations. This prospective case should test a health-biotech route to avoid duplicating Case 03. The proposal can change during ordinary legislative negotiations.

THE DECISION POINT

Before a co-legislator position on COM(2025)1022, should the proposed multinational clinical-trial authorisation timeline be shortened from a stated 106 to 75 days?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 3 (formal stage 3); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 11 / PROSPECTIVE ASSESSMENT / RCC AT THE EXISTING DECISION POINT

European Biotech Act: A Verifiable Innovation Path

Prospective health-biotechnology framework | Front-End and Procedural Workability Check

WHAT WOULD BE DECIDED?

Before a co-legislator position on COM(2025)1022, should the proposed multinational clinical-trial authorisation timeline be shortened from a stated 106 to 75 days?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	A material proposed change to Regulation (EU) 536/2014 alters the maximum multinational trial authorisation route and reporting-Member-State coordination.
2 Evidence	COM(2025)1022 clinical-trials amendment, current CTR 536/2014 and CTIS workflows, real sponsor submissions, requests for information, ethical safeguards.
3 Responsible actor	Parliament/Council decide amendments; Commission supports or clarifies its proposal; Member States perform trial authorisation under existing law.
4 Consequence	Retain, adjust or condition the proposed 75-day route; require an evidence plan or implementation guidance, without weakening patient safety.
5 Review	Comparable clinical-trial cohorts after any adoption: median and upper-percentile authorisation time, request cycles, patient safety and sponsor effort.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Isolate the proposal to shorten multinational trial authorisation from 106 to 75 days (Commission proposal, not enacted law).
02 Test the user workflow	Test a multinational SME-led clinical-trial dossier with reporting Member State, CTIS timing and ethics assessment.
03 Refer and verify	Provide the committee or Council a Clinical Trial Amendment Impact Note before its position is fixed.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION: the joint SANT/ITRE committee working on file 2025/0406(COD) could voluntarily request a narrow amendment-impact check through its own parliamentary services; Council may independently evaluate its position. DOCUMENTED FILE: draft joint report PE789.987 (16 June 2026) and amendments tabled on 13 July 2026; no final committee decision is presumed. WHEN: before the actual committee choice on the clinical-trials text, if such a check is accepted. OUTPUT: a CTIS and Member-State Timeline Options Note to the authorised committee owner. Binding text remains for co-legislators.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE WITHOUT RCC: Commission proposal COM(2025)1022, the joint SANT/ITRE draft report PE789.987 and July 2026 amendments already provide political/legal scrutiny. INCREMENTAL TEST: simulate a representative multinational SME clinical-trial application under the current CTIS coordination path and the proposed 106-to-75-day model, including requests for information, ethics and safety steps. A short note should identify specific feasible legislative options, not repeat the existing impact evidence or prejudge the committee position.

CASE 11 / PROSPECTIVE ASSESSMENT / OUTPUT, EVIDENCE AND VERIFICATION

European Biotech Act: A Verifiable Innovation Path

Prospective health-biotechnology framework | Front-End and Procedural Workability Check

EVIDENCE BASELINE AND SOURCES

COM(2025)1022 proposes changes to Regulation (EU) 536/2014, including a stated multinational trial authorisation timetable of 106 to 75 days. The European Parliament joint SANT/ITRE procedure 2025/0406(COD) has draft report PE789.987 (16 June 2026) and amendment packages (13 July 2026). This is proposed law, not an enacted statutory entitlement or demonstrated reduction in approval time. Parliamentary procedure: EP 2025/0406(COD)

Commission European Biotech Act portal | View primary source

COM(2025) 1022 legislative file | View primary source

SWD(2026) 450 | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); SME Connect Better Regulation Forum Working Paper (October 2026).

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Current-law comparator	Present authorisation timetable, reporting-Member-State interaction, RFI cycles and practical CTIS processing for comparable trials.
Concrete amendment test	Commission proposal: up to 106 -> 75 days for multinational initial authorisation; model which procedural steps actually change.
Future verification	After adoption only: comparable trial time, sponsor hours, procedural completeness, ethics and patient safeguards.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Multinational trial decision time	Submission-to-authorisation distribution under the current regime versus a specified future cohort.
RFI cycles and deadlines	Requests for information, sponsor response time and assessment time by responsible actor.
Participant protection	Evidence that ethics, safety assessment and data reliability are not weakened by quicker decisions.

A CREDIBLE ALTERNATIVE EXPLANATION

Faster approval may reflect poorer submissions or unequal case mix; analyse complexity and product class before making causal claims.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: existence and scope of proposal. Prospective: effects on approval time and SME investment.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

If an illustrative fast-track scenario requires skipping mandatory ethics or assessment steps, reject the option; if no valid data can be supplied, mark the amendment test indeterminate.

CASE 11 / PROSPECTIVE ASSESSMENT / VISUAL CASE EXPLANATION

European Biotech Act: A Verifiable Innovation Path

Prospective health-biotechnology framework | Front-End and Procedural Workability Check

RCC CONTROL MAP / CASE 11

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION	2 COMMISSION PROPOSAL	3 EP / COUNCIL MAIN RCC CHECK	4 NEGOTIATION
5 ADOPTION	6 SECONDARY RULES	7 APPLICATION	8 REVIEW

1 THE DECISION IN THE EXISTING PROCEDURE

Before the next relevant joint SANT/ITRE committee decision on clinical-trials provisions

Status: PROSPECTIVE ORDINARY LEGISLATIVE PROCEDURE 2025/0406(COD)

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

The Commission proposed COM(2025)1022; SANT/ITRE joint draft report PE789.987 and July 2026 amendments already exist.

MATERIAL GAP TO TEST

The proposed shorter multinational trial route must be tested against reporting-Member-State coordination, CTIS and ethics review.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A material proposed change from a 106-day to 75-day maximum merits an end-to-end practicability assessment. Proposed lead: Joint SANT/ITRE parliamentary services if commissioned by committee; DG SANTE and trial authorities supply evidence by consent.

DELIVERABLE AND DECISION ROUTE

Multinational Clinical-Trial Amendment Impact Note delivered before committee position is settled. SANT/ITRE committee and Council decide negotiating positions; co-legislators decide binding legislative text.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Representative elapsed days; RFI loops and time by actor; ethics/participant protection; SME trial resources.

IMPORTANT LIMIT

16 June draft report and 13 July amendments are real documents; no final enacted 75-day entitlement is claimed.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

CASE 12 / PROSPECTIVE ASSESSMENT / THE REGULATORY SITUATION

Vitamin and Mineral Maximum Levels: A Front-End Choice

Food supplements and fortified foods | Necessity, Mutual-Recognition and SME Gate

CASE IN ONE SENTENCE

The necessity and design of harmonised limits must be tested against public health, mutual recognition and real SME reformulation effects.

THE REGULATORY CHAIN

POLICY / LAW	OPERATIONAL CHAIN	TEST POINT
Divergent national rules	Health evidence > EU options > SME reformulation > Market outcomes	EU options

POLICY PURPOSE

EU legislation envisages maximum permitted levels of vitamins and minerals in supplements and fortified foods. The policy challenge is to protect consumers while addressing divergent national rules and avoiding unjustified Single Market fragmentation.

VERIFIED STATUS AND THE PROSPECTIVE CONCERN

The Commission describes extensive earlier consultation and divergent views, with no EU maximum-level proposal yet presented on its public information page. The Coppens submission alleges that a newer technical phase lacked meaningful stakeholder participation and could impose costly reformulation. These competing accounts cannot be reconciled without phase-specific documents.

HOW A CONCRETE BURDEN EMERGES

THE MECHANISM

Member State limits and mutual-recognition practices may already create trade barriers. A future EU harmonisation measure could reduce fragmentation, but its precise numerical limits and implementation periods would determine reformulation costs and safety benefits.

SME EXPOSURE

Smaller supplement manufacturers may be sensitive to multiple national product versions and to expensive EU-wide reformulation. Numerical cost, public-health and product-removal claims in the stakeholder submission remain forecasts, not established outcomes.

IMPORTANT EVIDENCE BOUNDARY

DO NOT OVERSTATE

Do not assert that no consultation ever occurred, that a particular maximum is already adopted or that lawful national health measures systematically violate mutual recognition. These issues require document-specific evidence and legal review.

THE DECISION POINT

Before the Commission finalises a draft maximum-level measure, should the identified nutrients be harmonised or should existing lawful market-access mechanisms be improved?

DIRECT LINK TO THE WORKING PAPER

Working Paper p. 22, RCC Check 1 (formal stage 1); §9 The check is a proposed, risk-based pilot, not an automatic gate or new competence.

CASE 12 / PROSPECTIVE ASSESSMENT / RCC AT THE EXISTING DECISION POINT

Vitamin and Mineral Maximum Levels: A Front-End Choice

Food supplements and fortified foods | Necessity, Mutual-Recognition and SME Gate

WHAT WOULD BE DECIDED?

Before the Commission finalises a draft maximum-level measure, should the identified nutrients be harmonised or should existing lawful market-access mechanisms be improved?

CONTROL RECORD: TRIGGER TO REVIEW

CONTROL	APPLIED TO THE DOSSIER
1 Trigger	Demonstrated trade barriers or divergent exposure rules plus an identified EU-level measure with material effects on existing SMEs.
2 Evidence	Relevant directives, EFSA scientific upper levels/intake scenarios, national rules, reasoned trade refusals, sample products and reformulation costs.
3 Responsible actor	Commission and applicable committee actors within empowering legislation; Member States for lawful national measures; EFSA for scientific advice.
4 Consequence	Publish a necessity/proportionality comparison of market-access enforcement, targeted cooperation and scientifically justified harmonisation.
5 Review	If measure adopted: product availability, adverse health signals, lawful cross-border access and actual SME reformulation costs.

THE THREE TASKS FOR AN AUTHORISED PILOT

01 Scope one real obligation	Choose three named nutrients/products and compare their present legally applicable national limits.
02 Test the user workflow	Test scientific safety and a verified cross-border market-access barrier, separating claims from legal findings.
03 Refer and verify	Send a Nutrient Levels Scoping & Options Note before a documented EU drafting decision.

ACTIVATION, HANDOVER AND DECISION POINT

AUTHORISATION AND LEAD: DG SANTE food-policy management could approve a narrow front-end options comparison within the applicable procedure. DG SANTE dossier service, supported by EFSA science and Member State evidence with balanced stakeholder participation. WHEN: Only once the responsible Commission team identifies an actual upcoming drafting or PAFF decision point; the public record does not establish a final draft. HANDOVER: Competent Commission decision-maker and, where applicable, the responsible Member State committee under the relevant legal procedure. OUTPUT: Vitamin/Mineral Harmonisation Scoping & Options Note.

EXISTING MECHANISM VS RCC ADDED LINK

BASELINE: EU food law, EFSA advice, national limits and earlier Commission consultations already exist. No final new EU nutrient-level proposal or confirmed vote is publicly established. RCC ADDITION: Only when DG SANTE specifies a nutrient, a draft and a decision window, compare safety evidence, verified cross-border barriers and SKU-level costs. Until then this is a scoping scenario, not an authorised RCC intervention.

CASE 12 / PROSPECTIVE ASSESSMENT / OUTPUT, EVIDENCE AND VERIFICATION

Vitamin and Mineral Maximum Levels: A Front-End Choice

Food supplements and fortified foods | Necessity, Mutual-Recognition and SME Gate

EVIDENCE BASELINE AND SOURCES

Directive 2002/46/EC, Regulation (EC) 1925/2006, Commission food-supplements page and identifiable consultation documents. A specific new draft or PAFF decision must be verified; Coppens allegations remain attributed.

Commission food supplements and vitamin levels | View primary source

Directive 2002/46/EC | View primary source

Regulation (EC) 1925/2006 | View primary source

Additional project evidence: RCC Case Inventory (12 October 2026); Coppens Cases.

WHAT AN EVALUATOR WOULD ACTUALLY COLLECT

EVIDENCE / TEST	DECISION USE OR VERIFICATION
Evidence comparator	Scientific risk by nutrient/population, present national limits and substantiated refusals to market products.
Decision options	Existing-law enforcement, justified national differentiation and legally empowered EU harmonisation, with transition options.
Review if adopted	Health protection, access outcomes, number of affected SME SKUs and realised reformulation cost.

THREE HEADLINE INDICATORS

INDICATOR	HOW TO CHECK IT
Safety and exposure evidence	Compare proposed levels with EFSA evidence and intake of relevant population groups.
Cross-border market access	Count independently documented market refusals and their stated legal reasons by Member State.
SME reformulation cost	Price and staff-hours per sample SKU under each specified (not hypothetical final) option.

A CREDIBLE ALTERNATIVE EXPLANATION

Different national limits can reflect justified risk-management choices. Harmonisation is not automatically better and mutual recognition may not apply identically to each national measure.

STRENGTH OF THE PRESENT EVIDENCE

CONFIDENCE AND LIMITATIONS

High: EU framework and divergent views. Medium: fragmentation concern. Low: allegations about new proposal content, health impacts and consultation failure.

WHAT WOULD INVALIDATE THE RCC INTERVENTION?

Without an identifiable Commission decision or a legally/scientifically grounded draft, record a prospective screening only; do not manufacture a consultation failure.

CASE 12 / PROSPECTIVE ASSESSMENT / VISUAL CASE EXPLANATION

Vitamin and Mineral Maximum Levels: A Front-End Choice

Food supplements and fortified foods | Necessity, Mutual-Recognition and SME Gate

RCC CONTROL MAP / CASE 12

EIGHT-STAGE REFERENCE

The highlighted point is the main proposed test. Other stages remain under normal institutional ownership.

1 PREPARATION MAIN RCC CHECK	**2 COMMISSION PROPOSAL**	**3 EP / COUNCIL**	**4 NEGOTIATION**
5 ADOPTION	**6 SECONDARY RULES**	**7 APPLICATION**	**8 REVIEW**

1 THE DECISION IN THE EXISTING PROCEDURE

Only after DG SANTE identifies a specific nutrient/measure and a genuine upcoming drafting decision

Status: PROSPECTIVE FRONT-END SCOPING; NO VERIFIED DRAFT

2 WHAT THE NORMAL PROCESS DOES - AND WHAT RCC WOULD ADD

EXISTING EU / NATIONAL ROUTE

Directive 2002/46/EC, Regulation 1925/2006, EFSA advice, national rules and past Commission consultations exist.

MATERIAL GAP TO TEST

Options for EU limits versus existing lawful market access may lack a linked SKU-level impact and safety comparison.

3 THE SPECIFIC RCC TASK AND INSTITUTIONAL HANDOVER

TRIGGER AND TASK

A dated, scoped proposed EU level or specific nutrient choice appears; unsourced stakeholder concerns alone do not suffice. Proposed lead: DG SANTE food-policy lead, EFSA science, relevant Member States and balanced stakeholder participation.

DELIVERABLE AND DECISION ROUTE

Nutrient-Specific Necessity, Safety and Mutual-Recognition Scoping Note. Commission examines the legally applicable procedure; Member States act within their competence; no draft inferred.

4 VERIFIED OUTCOME AND EVIDENCE BOUNDARY

MEASURE AND COMPARE WITH EXISTING PRACTICE

Nutrient exposure risk; actual cross-border refusals; SKU reformulation cost under specified options.

IMPORTANT LIMIT

Public evidence does not confirm a final draft; this pilot must not proceed without a real decision point.

Reading key: the highlighted EU checkpoint shows a proposed RCC test, never an automatic approval or proven RCC intervention. The named institution retains the decision.

Cross-case findings | What the cases can test

These twelve deliberately selected dossiers identify possible control points and learning questions. They do **not** measure the frequency of regulatory failure across the EU or demonstrate that RCC changed any legislative result.

Four recurring problems, four proportionate responses

Readiness	IVDR, EUDR, Guarantee Label	Test real application tasks, system interfaces and supporting capacity before material duties bite.
Indirect burdens	PPWR, CSRD, CBAM	Attribute EU, national and private information demands; measure repeated work rather than assume savings.
Procedural friction	EFSA / Novel Foods	Distinguish applicant, administrative and legal causes of delay before proposing any remedy.
Real-world outcomes	Late Payments	Contrast formal rights with actual enforcement, firm liquidity and proportionate remedies.

Where connected stewardship could add extra value

A material SME observation can remain unresolved when the relevant legal provision, secondary measure, national procedure and private request are assessed separately. An **Obligation Map** preserves their origin; **stewardship** keeps the finding, its owner and review point visible; **selective steering** links competent actors only when ordinary routes leave a coordination gap. A single Issue-and-Options Note then goes to the lawful decision-maker. The additional value must be tested against the time and cost of doing this work.

Prospective dossiers remain prospective

The AI Act, DPP/ESPR, European Biotech Act and vitamin/mineral maximum levels may be suitable for readiness, data-reuse, instrument-choice and innovation tests. They are opportunities for a voluntary, source-verified assessment, not documented failures or authorised RCC pilots.

THREE SAFEGUARDS AGAINST OVERSTATING THE EVIDENCE

Attribution: enacted changes such as IVDR or CBAM corrections do not prove prior neglect. **Competence:** EU, national and private obligations require distinct remedies. **Net result:** measure retained safety, consumer, environmental and other legitimate benefits alongside SME costs and all RCC workload.

Reference: Main Working Paper §8 (pp. 24–30), §§12.2–12.7 (pp. 47–57) and Annex II (p. 64).

A bounded three-dossier RCC pilot | Design, not result

A pilot is justified only if an existing EU procedure leaves a **material, unresolved question** that a competent actor can still address. The suggestions below are candidate tests, not authorised programmes or demonstrated outcomes.

Three complementary tracks

A · Readiness	AI Act high-risk compliance or product-specific DPP: test whether a representative smaller operator can follow a complete route with available guidance and interfaces.
B · Migration	EUDR or CSRD: identify which downstream requests are legally required, which arise from national practice and which are private duplications.
C · Effectiveness	Late Payments: compare formal entitlement with actual use of national recovery mechanisms and observed payment outcomes.

An executable charter for one selected dossier

Question & source	One obligation, legal status, representative task, verified evidence and a dated unresolved risk.
Authority & timing	Named sponsor and actual upcoming decision or review; a Commission lead DG may be supported by the SG if cross-DG coordination is needed.
Bounded method	Use ordinary assessments first; user-test the remaining gap and issue one map and one short Issue-and-Options Note.
Recorded exit	The competent decision-maker may respond, refer, request further evidence or decline action; do not invent a statutory delay or veto.

Comparable pilot scorecard

For each test, record **baseline** and source accuracy; **decision value** and response time; **policy benefits** and rights protected; **SME effort** and burdens transferred; and **incremental RCC hours, IT and stakeholder costs**. Compare the same task without RCC. A negative outcome is a valid reason to discontinue the check.

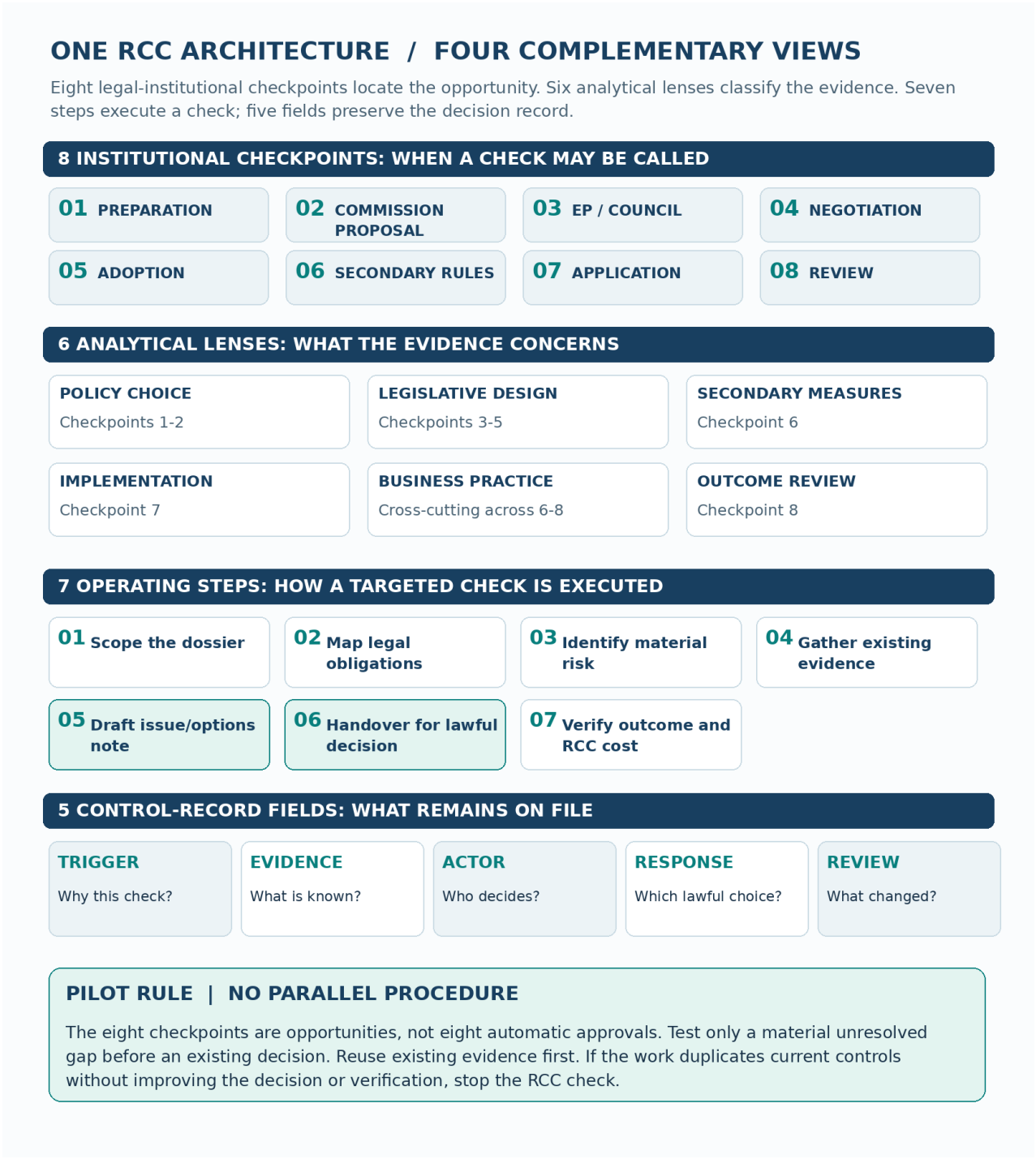
OPTIONAL AI IS A SEPARATE, BOUNDED COMPARISON

Test only an authorised, source-linked document task against the manual baseline. Record missing sources, wrong citations, false alerts, human verification time, confidentiality and total costs. AI cannot determine legal meaning, activate a pilot or replace an institution. RCC must work without it.

Main Paper: §§12.2–12.5 (pp. 47–54), Annex II (p. 64) and Annex III (p. 65).

RCC visual reference | The complete chain

The Working Paper has eight institutional checkpoints. Six analytic lenses group the same obligations by subject; seven operating steps perform one targeted check, and five fields preserve the decision. The figure reconciles all four views rather than introducing another procedure.



READING THE DIAGRAM | INDEPENDENT COMPONENTS, POSSIBLE INTEGRATION

The pictured checkpoints, analytic lenses, control steps and decision record describe complementary views, not extra procedural stages. Individual controls can run without an RCC steering model. The proposed activation / stewardship route connects them only where a material gap, a competent decision and a credible net gain justify the added work. See Main Paper §8 and Annex II.

RCC in action | A filled Issue-and-Options Note

A completed, explicitly simulated IVDR Issue-and-Options Note shows a pending decision, existing evidence, the incremental RCC test, three lawful options, the recipient, a review criterion and the formal non-authorised status. No real RCC pilot or institutional decision is represented.

RCC ISSUE-AND-OPTIONS NOTE / FILLED SPECIMEN

SIMULATED / NO RCC PILOT, INSTITUTIONAL APPROVAL OR DECISION

FILE ID	DATE	STATUS	DECISION RECORDED
RCC-IVDR-SIM-01	27 OCT 2026	ILLUSTRATIVE	NOT APPLICABLE

EXISTING DECISION AND POSSIBLE RECIPIENT
DG SANTE policy lead would decide whether ordinary implementation support is enough or a Commission proposal merits consideration. Statutory changes require Parliament and Council.

MATERIAL TRIGGER / EU LIFECYCLE CHECKPOINT 7
The 2023 data showed a risk-class certification-capacity and deadline mismatch. This is a retrospective example, not a claim that RCC existed during that decision.

BASELINE: REUSE THE EVIDENCE ALREADY AVAILABLE
COM(2024)43 and notified-body survey results already informed EU monitoring. Use valid-file cohorts, capacity, processing time and device availability; no duplicate collection without a defined gap.

SPECIFIC RCC ADDITION TO TEST
Join risk-class demand, usable notified-body capacity and applicable legal deadlines in one dated cohort-by-decision table. Separate manufacturer-file problems from assessment bottlenecks.

LAWFUL OPTIONS FOR THE COMPETENT DECISION-MAKER

A | ADMINISTRATIVE
Coordinate lawful capacity guidance, authorities and assessment information.

B | LEGISLATIVE
Commission may propose an amendment; co-legislators decide any statutory change.

C | NO ADDED CONTROL
If normal monitoring suffices, record no material RCC gap and do not expand the pilot.

DELIVERABLE AND INSTITUTIONAL HANDOVER
Issue-and-Options Note for an authorised DG SANTE manager before the policy choice; include source attribution, lawful options, counter-arguments, date and responsible reviewer.

MEASURE ACTUAL EFFECT AND ADDITIONAL RCC COST
Track valid-file waiting time, class-specific certification, essential test availability, safety and SME hours; compare with ordinary monitoring outcomes and extra RCC staff effort.

FORMAL CLOSURE / FALSIFICATION RULE
No signed authorisation, response or completed RCC evaluation exists. If the existing process already produced equally usable and timely evidence, close the proposed RCC control without claiming an added benefit.

SOURCE: Regulation (EU) 2017/746; COM(2024)43; Regulation (EU) 2024/1860; RCC Working Paper (2026), sections 7, 8 and 11.

SIMULATION AND INSTITUTIONAL STATUS

This note is a methodological illustration, **not** a completed intervention or authorised EU pilot. A prospective use would first require competent approval and a proportionate activation screen. A human reviewer validates applicable law and the final note; AI assistance is optional and cannot trigger the test or decide the response.

Supporting Members of the SME Connect Better Regulation Forum

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Note on SME Connect's institutional role

Responsibility for the content of this handbook rests with the members of the SME Connect Better Regulation Forum. SME Connect acts solely as a politically neutral network, moderator and convening platform; it does not adopt common positions on legislation, intervene in political negotiations or advocate on behalf of its members.

Members remain independent in the positions and interests they advance.

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AI assistance

MILA X Intelligence, based on ChatGPT, was used as an AI-assisted tool in preparing this document.