REACH COMPLIANCE ROADMAP

First-Time EU Importer — Specialty Chemical Substance

A structured REACH assessment for an SME importing a specialty substance into the EU for the first time. It determines the company's role and obligations under Regulation (EC) No 1907/2006, screens for restrictions and Substances of Very High Concern, maps the registration pathway, and delivers a prioritised, time-phased action plan.

SCENARIO	OBJECTIVE
An EU-based SME plans to import ~40 t/year of a mono-constituent organic additive from a non-EU manufacturer. No prior REACH registration exists for their supply route.	Establish legal route to market: who must register, what data is required, what it costs in time, and the fastest compliant path.
FRAMEWORKS APPLIED	**OUTCOME**
REACH (EC) 1907/2006 · Candidate List / Annex XIV · Annex XVII · POP (2019/1021) · Annexes VII–IX	A defensible decision (importer registration vs. Only Representative) and a 9-month compliance timeline.

- **Illustrative reference sample.** Company, volumes and substance identity are fictional but realistic. Prepared by Chemply to demonstrate assessment methodology.

Assessment & Action Plan

(EC) No 1907/2006
Rev. 1.0 · 2025-06

EXECUTIVE SUMMARY

Importing ≥ 1 tonne/year of a substance into the EU triggers a **registration obligation** under REACH Article 6. At ~40 t/year the substance falls in the **10–100 t/year band**, requiring information to Annexes VII–IX and a Chemical Safety Report under Article 14. The importer has two compliant routes: **(a)** register directly, or **(b)** have the non-EU manufacturer appoint an **Only Representative (OR)**, which removes the registration burden from the importer. Route (b) is recommended where the manufacturer supplies multiple EU customers.

01 Role & obligation determination

The company purchases from a non-EU manufacturer and brings the substance across the EU border — it is therefore an **importer** under REACH Article 3(11), with the same obligations as an EU manufacturer. The pivotal decision is whether the importer carries the registration itself or whether the non-EU manufacturer appoints an Only Representative.

Route A — Importer registers

Importer becomes registrant, joins the existing joint submission, obtains a Letter of Access to the shared data, and holds the registration. Suitable where the importer wants control and volumes are stable.

Route B — Only Representative RECOMMENDED

Non-EU manufacturer appoints an OR who registers on behalf of all EU importers. The importer is reclassified as a **downstream user** — no registration burden, lower cost, faster route to market.

02 Substance identification & scope

Substance type	Mono-constituent organic substance
Identifiers required	`EC / CAS · IUPAC name · molecular formula · structural formula`
Import volume	≈ 40 t/year → **10–100 t/year** registration band
Data requirement	Annexes VII–IX · Chemical Safety Report (CSR) under Article 14 (required > 10 t/y)
Analytical evidence	Spectral data (UV/IR/NMR/MS) + purity/impurity profile from manufacturer

03 SVHC & restriction screening

Screen	Source	Result
Candidate List (SVHC)	ECHA Candidate List	Not listed — clear
Authorisation	Annex XIV	Not listed — no authorisation
Restriction	Annex XVII	Monitor — verify use conditions
Persistent Organic Pollutants	(EU) 2019/1021 (POP)	Not listed — clear
CLH (harmonised classification)	Annex VI CLP	No entry — self-classify

04 Registration pathway

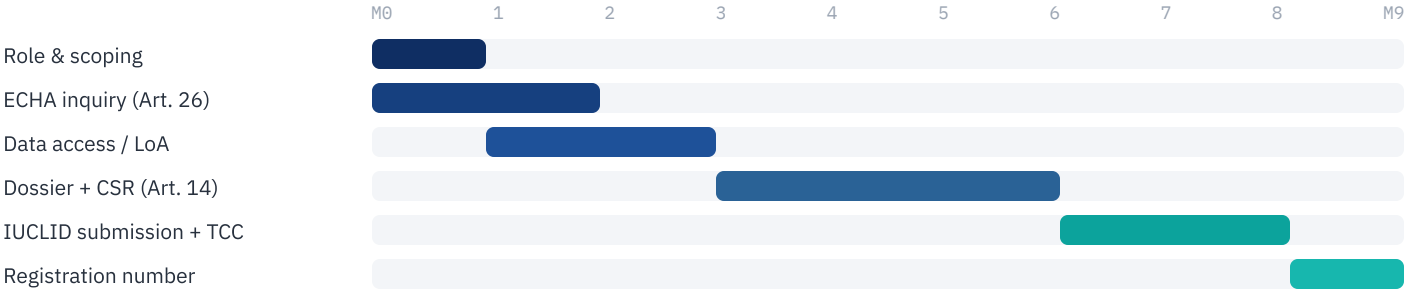
1. Submit an inquiry to ECHA (Article 26, where applicable) to determine existing registrations and identify co-registrants for data sharing.
2. Confirm whether a joint submission already exists and contact the lead registrant; obtain access to the jointly submitted data through a **Letter of Access (LoA)** for the 10–100 t band. Data sharing is governed by Articles 27 and 30.
3. Compile the substance identity dossier and any importer-specific data.
4. Prepare the Chemical Safety Report (CSR) under Article 14 with exposure scenarios for the identified uses.
5. Submit the member registration dossier in IUCLID via REACH-IT; clear the ECHA technical completeness check (TCC).
6. Receive the registration number — the legal basis to place the substance on the EU market.

05 Supply-chain & downstream obligations

Provide a compliant extended SDS (with exposure scenarios where a CSR exists) to customers, communicate registered uses, and ensure the actual use falls within the registered exposure scenarios. If the importer becomes a downstream user under Route B, it must keep its use within the OR's registered scope or file a downstream-user report (Article 38).

06 Indicative timeline

Indicative critical path assuming a co-operative lead registrant and available data. Actual timelines depend heavily on consortium negotiations and data availability.



07 Prioritised action plan

Action	Owner	Timing	Priority
Confirm role & decide OR vs. importer registration	Importer + Chemply	Month 0–1	High
Obtain substance identity & analytical data from manufacturer	Manufacturer	Month 0–2	High
Confirm joint submission; obtain Letter of Access	Chemply	Month 1–3	Medium
Prepare CSR & exposure scenarios	Chemply	Month 3–6	Medium
Submit dossier, clear completeness check	Chemply	Month 6–8	Medium

08 Indicative cost & effort

Item	Typical range	Notes
Letter of Access	€10k – €150k+	Set by the data owner; varies by endpoint coverage and tonnage band
IUCLID dossier preparation	Variable	Depends on data completeness and substance complexity
Chemical Safety Report	Variable	Driven by the number of identified uses / exposure scenarios
ECHA registration fee	SME-reduced	Depends on tonnage band and verified SME status

Indicative ranges for scoping only — not a quotation. Letter-of-Access costs are set by the data owner and vary widely.

09 Key risks & mitigation

Risk	Mitigation
Substance already registered by others	Confirm the joint submission early; join as a member registrant
Manufacturer unwilling to appoint an OR	Fall back to Route A (importer registration)
Missing / incomplete analytical data	Obtain substance identity & spectral data before the ECHA inquiry
Use outside the registered exposure scenario	Extend the CSR or file a downstream-user report (Article 38)
Lead-registrant / consortium delays	Build slack into the timeline; use the ECHA data-sharing dispute route if negotiations stall

Assessment summary

Company role	**Importer (Art. 3(11))**
Recommended route	**Only Representative**
Registration band	**10–100 t/year**
CSR required	**Yes (Article 14)**
Estimated duration	**~9 months (data-dependent)**

Annexes VII / VIII / IX	**Required**
Candidate List (SVHC)	**Clear**
Annex XIV (Authorisation)	**Clear**
Annex XVII (Restriction)	**Review completed**
POP (EU) 2019/1021	**Clear**

Prepared to demonstrate assessment methodology. Timelines are indicative and depend on consortium negotiations and data availability. Prepared by Chemply · chemply.co