

Agrochemical Formulation Science: Development, Quality, and Sustainability

¹Ajay Kumar Singh, ²Akhilesh Kumar Pandey

^{1,2} *Mycological Research Laboratory, Department of Biological Sciences, Rani Durgawati University, Jabalpur 482001, Madhya Pradesh, India*

Abstract—Agrochemical formulations are fundamental determinants of the efficacy, safety, environmental compatibility, and commercial viability of modern crop protection products. The global pesticide formulation market, valued at approximately US\$12.4 billion in 2023, continues to expand in response to intensifying food production demands and evolving regulatory requirements (Mordor Intelligence, 2024). This review critically examines the complete agrochemical formulation development lifecycle, encompassing major formulation types—Emulsifiable Concentrates (EC), Suspension Concentrates (SC), Wettable Powders (WP), Water-Dispersible Granules (WG), Capsule Suspensions (CS), and Oil Dispersions (OD)—alongside structured New Product Development (NPD) stage-gate frameworks, global regulatory compliance strategies, dossier preparation methodologies aligned with CIPAC and FAO standards (CIPAC, 2023), post-market quality management systems, and market-driven innovation approaches. Emerging technologies including nanoformulations, controlled-release encapsulation, biodegradable polymers, and AI-assisted formulation design are evaluated with respect to their regulatory trajectories and sustainability credentials (Kah et al., 2018). The review synthesizes current scientific understanding and industrial practice to provide an integrated reference for formulation scientists, regulatory professionals, and product development managers engaged with the challenges of twenty-first century agrochemical innovation.

Index Terms—agrochemical formulations; suspension concentrate; emulsifiable concentrate; water-dispersible granules; capsule suspension; new product development; regulatory dossier; CIPAC methods; controlled-release; sustainable crop protection

I. INTRODUCTION

The global agrochemical industry stands at the intersection of pressing scientific, commercial, and societal imperatives. With the world population projected to reach 9.7 billion by 2050, sustaining food security demands not merely the discovery of novel active ingredients (AIs) but also their

translation into commercially applicable, regulatory-compliant, and environmentally responsible formulated products (FAO, 2023). Formulation science occupies this translational role: a technically complex discipline that transforms laboratory-grade chemical entities into products capable of withstanding the rigours of manufacturing, storage, transport, and field application under diverse agroclimatic conditions.

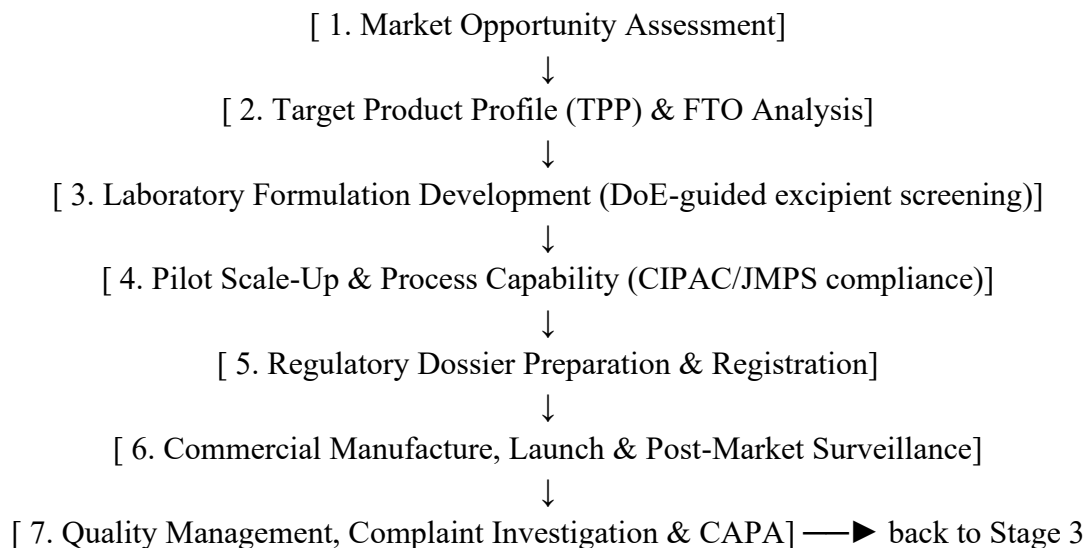
Formulations are engineered delivery systems designed to optimize the biological activity of AIs while minimizing risks to human health and the environment. The formulation type profoundly influences a product's physicochemical stability, bioavailability at the target site, uptake kinetics, leaching potential, and fate in non-target ecosystems (van Emden & Peakall, 2024). A poorly formulated product may fail at the registration stage due to inadequate stability data, exhibit inferior field performance compared with competitors, or generate unacceptable environmental residues—even if the underlying AI possesses excellent intrinsic biological activity (Knowles, 2008).

The landscape of formulation development has changed substantially over the past two decades. Regulatory authorities worldwide—including the United States Environmental Protection Agency (US-EPA), the European Food Safety Authority (EFSA), Canada's Pest Management Regulatory Agency (PMRA), India's Central Insecticides Board and Registration Committee (CIBRC), and the Australian Pesticides and Veterinary Medicines Authority (APVMA)—have implemented increasingly stringent data requirements governing product chemistry, stability, toxicology, ecotoxicology, and environmental fate (European Commission, 2009). Simultaneously, market dynamics driven by generic AI competition, digital agriculture platforms, and growing farmer demand for precision-application solutions compel manufacturers to differentiate through formulation innovation rather than AI novelty alone (CropLife International, 2023).

Sustainability considerations have become non-negotiable in modern formulation strategy. The European Green Deal and its Farm-to-Fork Strategy mandate a 50% reduction in overall pesticide use by 2030 (European Commission, 2020). These policy trajectories are catalysing the development of low-solvent formulations, biodegradable encapsulation systems, biological hybrid products, and nanoformulation platforms. Concurrently, the rapid adoption of machine learning (ML) tools in formulation research is accelerating excipient screening, predictive stability modelling, and regulatory dossier generation (Wink et al., 2022).

This review synthesizes current knowledge and practice across the complete agrochemical formulation development lifecycle. It provides an integrated account of major formulation types and their physicochemical rationale, structured NPD stage-gate processes, global regulatory framework navigation, dossier preparation requirements, quality management and complaint resolution systems, and market-driven product differentiation strategies. Emerging frontiers including nano- and bioformulation technologies, AI-assisted design, and digital agriculture integration are also critically assessed (Fig 1).

Figure 1 — Integrated Agrochemical Formulation Development Lifecycle



Cross-cutting disciplines: Chemistry · Toxicology · Regulatory Affairs · Quality · IP · Marketing

Figure 1. *Schematic representation of the integrated agrochemical formulation development lifecycle. Each stage feeds into the next, while quality management and complaint investigation provide a continuous feedback loop to formulation development. CAPA = Corrective and Preventive Action; DoE = Design of Experiments; FTO = Freedom-to-Operate; CIPAC = Collaborative International Pesticides Analytical Council; JMPS = Joint Meeting on Pesticide Specifications.*

II. MAJOR AGROCHEMICAL FORMULATION TYPES

The selection of formulation type is among the earliest and most consequential decisions in product development. It must reconcile the physicochemical properties of the AI with the requirements of the target application, anticipated environmental conditions, regulatory constraints, and cost-of-goods objectives. Table 1 and Fig 2 provides a comparative overview of principal formulation types, their codes as defined by CropLife International and GIFAP, their key advantages, and primary application domains (CropLife International, 2023).

Table 1. *Comparative overview of major agrochemical formulation types, their physicochemical characteristics, key advantages, and primary applications. Formulation codes follow CropLife International (2023) nomenclature. VOC = volatile organic compound; AI = active ingredient.*

| Formulation Type | Code | Continuous Phase | Key Advantages | Primary Applications |
|---------------------------|------|---------------------------|---|---|
| Emulsifiable Concentrate | EC | Organic solvent | High efficacy, easy manufacture, good tank-mix compatibility | Insecticides, fungicides, herbicides requiring rapid foliar uptake; log KOW > 3 AIs |
| Suspension Concentrate | SC | Water | Reduced VOC, improved operator safety, no fire hazard, broad AI compatibility | Water-insoluble AIs; soil- and foliar-applied fungicides, insecticides, herbicides |
| Wettable Powder | WP | Solid carrier | Simple manufacture, thermally stable, cost-effective for commodity AIs | Sulfur- and copper-based fungicides; heat-sensitive AIs in water-scarce markets |
| Water-Dispersible Granule | WG | Solid granule | Dust-free handling, superior storage stability, improved user safety vs WP | Herbicides, fungicides, insecticides in dry climates; modern premium products |
| Capsule Suspension | CS | Water (encapsulated) | Controlled release, reduced mammalian toxicity, odour masking, reduced phytotox | Pyrethroid insecticides, organophosphate replacements, pheromone systems |
| Oil Dispersion | OD | Oil phase | Enhanced cuticular penetration, superior rainfastness, anti-drift, better hot/dry performance | Post-emergence herbicides, curative fungicides, crop oil adjuvant-integrated products |
| Suspo-Emulsion | SE | Water + emulsified oil | Combines SC and EW benefits; multi-AI co-formulation possible in one product | Co-formulation products; adjuvant-integrated solutions |
| Emulsion in Water | EW | Water-continuous emulsion | Lower solvent content vs EC; reduced flammability; acceptable environmental profile | Pyrethroid and azole fungicide products replacing legacy EC formulations |

2.1 Emulsifiable Concentrates (EC)

EC formulations remain among the most widely manufactured pesticide product types globally, accounting for approximately 25–30% of formulated products in major crop protection markets (CropLife International, 2023). An EC consists of a technical-grade AI dissolved in one or more organic solvents with a blend of emulsifiers selected to produce a stable oil-in-water emulsion upon dilution in spray water (Knowles, 2008). The Hydrophilic-Lipophilic Balance (HLB) of the emulsifier blend is a primary determinant of emulsion droplet size and stability; HLB values of 8–16 are typically targeted for agricultural emulsions (Tadros, 2013).

Key physicochemical requirements include spontaneous emulsification upon addition to water and persistent emulsion stability over 2 hours per CIPAC Method MT 36 (CIPAC, 2023). ECs must demonstrate acceptable cold storage stability (0°C, 7 days) and accelerated thermal stability (54°C, 14 days) without phase separation, AI crystallization, or significant viscosity changes (FAO,

2010). Despite high biological efficacy and excellent tank-mix compatibility, ECs carry inherent limitations: high volatile organic compound (VOC) content, potential phytotoxicity from solvents, and worker exposure risks during handling of concentrated product (Tadros, 2013). Regulatory pressure under REACH Regulation (EC) No 1907/2006 is driving replacement of aromatic and naphthalenic solvents with aliphatic or ester-based alternatives (European Commission, 2009).

2.2 Suspension Concentrates (SC)

SC formulations represent the predominant water-based alternative to ECs, with substantial market growth over the past decade driven by environmental and occupational safety advantages (van Emden & Peakall, 2024). In an SC, the AI exists as a finely milled solid suspended in an aqueous continuous phase, stabilized by polymeric dispersants (e.g., lignosulfonates, polycarboxylates, or nonionic block copolymers) and anti-settling agents such as xanthan gum or attapulgite (Knowles, 2008).

Critical quality attributes include particle size distribution (D90 typically $<5\ \mu\text{m}$), suspensibility ($\geq 70\%$ per CIPAC MT 15.1), absence of irreversible sedimentation or hard caking, and maintenance of particle size and polymorphic form during storage (Tadros, 2013). Freeze-thaw stability (three cycles of -10°C to $+20^\circ\text{C}$) is particularly important for temperate markets, as crystal growth and particle aggregation under these conditions can irreversibly compromise product performance (Knowles, 2008). Rheological control—targeting shear-thinning behaviour to enable easy pourability at high shear rates, combined with sufficient low-shear yield stress to prevent static sedimentation—is a sophisticated aspect of SC development (Tadros, 2013). Zeta potential measurement ($|\zeta| > 30\ \text{mV}$) combined with oscillatory rheology provides the primary toolkit for early stability prediction (Rosen & Kunjappu, 2012).

2.3 Wettable Powders (WP)

WP formulations comprise the AI dispersed on an inert filler (kaolin, talc, or silica) with wetting agents and dispersants to ensure rapid re-suspension in spray water (Knowles, 2008). Despite their manufacturing simplicity—typically blending, pin-milling, and air classification—WPs present significant occupational exposure challenges due to dust generation during tank preparation (van Emden & Peakall, 2024). Performance criteria include wettability (CIPAC MT 53.3, $\leq 60\ \text{s}$), suspensibility (MT 15.1, $\geq 60\%$ after 30 min), and wet sieve retention (MT 59.1, $< 0.6\%$ on 75 μm sieve) (CIPAC, 2023). WPs retain commercial relevance for commodity fungicides (sulfur, copper-based) and in markets where infrastructure for liquid formulations is limited.

2.4 Water-Dispersible Granules (WG)

WG formulations address the primary safety limitation of WPs by delivering the same chemical functionality in a dust-free, free-flowing granular form that disperses to a fine suspension upon addition to spray water (Knowles, 2008). Manufacturing routes include fluid-bed granulation, extrusion-spheronization, and spray drying, each producing granules with distinct morphological characteristics influencing dispersibility, attrition resistance, and bulk density (CropLife

International, 2023). Fluid-bed granulation typically produces the most uniform and free-flowing product, with granule size distributions of 150–2000 μm optimal for handling and dispersibility (Knowles, 2008). Dispersibility (CIPAC MT 174, $\geq 90\%$) and wettability (MT 170, ≤ 60 s) are the primary functional quality metrics, with long-term ambient and accelerated stability studies confirming AI content, granule integrity, and polymorphic form over the product shelf-life (FAO, 2010).

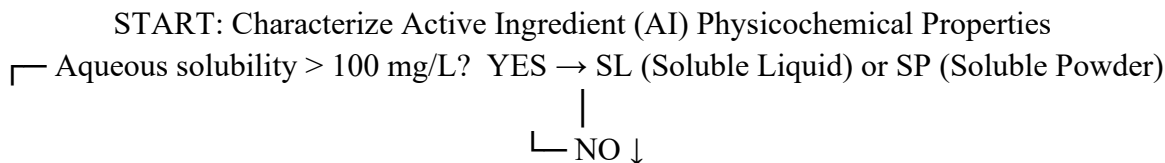
2.5 Capsule Suspensions (CS)

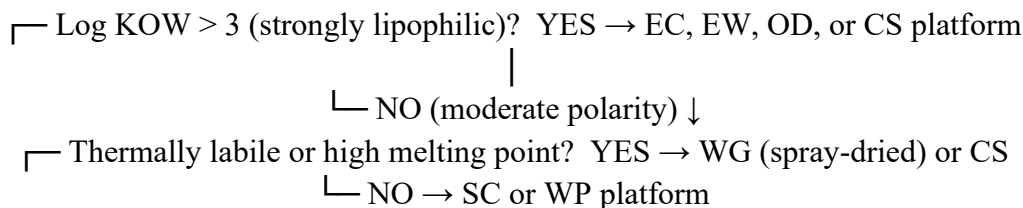
CS formulations encapsulate the AI within a polymeric shell—formed by interfacial polymerization of polyurea or polyurethane, or by coacervation of gelatin or starch derivatives—with the resulting microcapsules (typically 5–100 μm) suspended in an aqueous phase (Peng et al., 2022). The primary benefits are modulation of AI release rate, reduction of acute mammalian toxicity through barrier effects, odour suppression, and mitigation of phytotoxicity (Grillo et al., 2021). Shell thickness, crosslink density, and polymer molecular weight collectively govern release kinetics (Campos et al., 2020). Encapsulation efficiency ($\geq 85\%$ per CIPAC MT 184) and retention of release profile following accelerated storage are the primary quality benchmarks (CIPAC, 2023). CS technology has found particular traction in pyrethroid insecticide products, chlorpyrifos alternatives, and pheromone-based mating disruption systems (Jaber & Ownley, 2018).

2.6 Oil Dispersions (OD)

OD formulations disperse finely milled AI particles within an oil-continuous phase, typically comprising vegetable oil (soybean, canola, or rapeseed methyl ester) or mineral oil blended with appropriate dispersants and anti-settling agents (Knowles, 2008). The oil phase imparts superior cuticular penetration by dissolving epicuticular wax barriers, enhanced rainfastness through increased adhesion to leaf surfaces, and improved performance under high-temperature and low-humidity conditions (van Emden & Peakall, 2024). OD products must demonstrate spontaneous dispersibility in water (CIPAC MT 180, $\geq 90\%$), physical stability at 54°C/14 days and 0°C/7 days, and viscosity within approved specification limits over the shelf-life (CIPAC, 2023). Bioaccumulative or non-biodegradable oils are increasingly restricted; formulation using low-viscosity ester oils or NExBTL-class renewable paraffinic hydrocarbons is an active area of industrial research (European Commission, 2009).

Figure 2 — Decision Framework for Agrochemical Formulation Type Selection Based on AI Physicochemical Properties





Sustainability / operator safety priority? → Prefer SC, WG, CS (low-solvent, dust-free, water-based)

Environmental restrictions (EU, REACH)? → Exclude aromatic solvents; prioritize ester/aliphatic oil EC or EW

Final selection integrates: regulatory acceptability · cost-of-goods · application equipment · climatic conditions

Figure 2. *Decision framework for selection of agrochemical formulation type based on AI physicochemical properties, sustainability requirements, and regulatory constraints. SL = Soluble Liquid; SP = Soluble Powder; EW = Emulsion in Water. Properties at each decision node are indicative; integration of multiple factors is required for final selection.*

III. NEW PRODUCT DEVELOPMENT (NPD) IN AGROCHEMICAL FORMULATION

NPD in the agrochemical sector is a structured, stage-gated process designed to channel technical resources from concept ideation through commercial launch while managing financial risk, regulatory uncertainty, and market timing (Cooper, 2011). The typical NPD timeline for a new formulated agrochemical product spans five to seven years when novel regulatory data are required, or two to four years for reformulation of existing AIs (CropLife International, 2023). Table 2 maps the stage-gate framework applied in modern agrochemical NPD.

Table 2. *Stage-gate NPD framework for agrochemical formulation development, showing gate criteria, key activities, and deliverables at each stage. Adapted from Cooper (2011) and CropLife International (2023). COGS = cost of goods sold; VoC = voice of customer; FTO = freedom-to-operate.*

| Stage | Gate Criteria | Key Activities | Deliverables / KPIs |
|--------------------------------------|--|--|--|
| Stage 1 Ideation & Opportunity | Market gap confirmed; regulatory feasibility screened; FTO clear | Literature review; competitor landscape; farmer VoC surveys; preliminary COGS modelling; IP landscape review | Target Product Profile (TPP); concept brief; preliminary FTO opinion; go/no-go recommendation |
| Stage 2 Feasibility & Lab Dev | Prototype ≥70% efficacy vs reference; | Excipient screening via DoE; solubility/compatibility studies; accelerated stability (54°C, 14 d); CIPAC method identification | Laboratory formulation code; physicochemical data package; preliminary COGS; stability summary |

| | | | |
|---------------------------------------|--|--|--|
| | preliminary stability pass | | |
| Stage 3 Optimization & Pilot Scale | Batch-to-batch CV <5%; 2-year equivalent stability pass; CIPAC compliance | DoE-guided optimization; pilot batches (10–500 L); full CIPAC test panel; process capability analysis; tox pre-screen | Pilot batch reports; draft product specification; analytical method draft; preliminary regulatory strategy |
| Stage 4 Regulatory Submission | Complete dossier accepted by lead authority; pre-submission feedback positive | Regulatory study generation; dossier assembly per Annex III / OECD HT; CIPAC/JMPS method validation; pre-submission meetings | Registration dossier; analytical method package; draft SDS; draft label; authority correspondence log |
| Stage 5 Commercial Launch | First commercial batch released; quality audit passed; field performance confirmed | Manufacturing scale-up; supply chain qualification; commercial batch validation; field demonstration trials; sales training | Batch release certificate; post-launch monitoring plan; complaint protocol; annual stability commitment |

3.1 Market Opportunity Assessment and Target Product Profiling

The NPD process commences with a rigorous market opportunity assessment integrating agronomic intelligence, competitive landscape analysis, and regulatory feasibility screening (Cooper, 2011). Identification of unmet farmer needs—whether for improved spectrum of control, greater rainfastness, compatibility with precision agriculture platforms, or reduced resistance risk—provides the commercial rationale for development investment. Market sizing methodologies including bottom-up acreage analysis and willingness-to-pay surveys establish the minimum viable market threshold justifying development budget (Mordor Intelligence, 2024). Concurrent freedom-to-operate (FTO) analysis ensures that the intended formulation type and composition do not infringe existing formulation patents—a significant challenge in novel technologies such as nanoencapsulation or polymer-controlled release (van Emden & Peakall, 2024). The Target Product Profile (TPP)—specifying desired and minimum acceptable values for all critical quality attributes, regulatory parameters, and commercial characteristics—is established at Stage 1 and serves as the benchmark against which development candidates are evaluated throughout all subsequent stage gates (FAO, 2010).

3.2 Formulation Design and Laboratory Development

Formulation design integrates knowledge of AI physicochemical properties (aqueous solubility, log K_{OW} , melting point, vapour pressure, polymorphic behaviour) with target application requirements and identified excipient options (Knowles, 2008). Design of Experiments (DoE) methodologies—D-optimal, central composite, and mixture designs—are routinely applied to screen multi-component excipient systems efficiently, reducing experimental runs required to locate the optimal formulation space by up to 70% compared with one-factor-at-a-time approaches (Wink et al., 2022).

Compatibility studies evaluate potential physicochemical interactions between formulation excipients and the AI (polymorphic conversion, complex formation, catalytic degradation), and between the formulation and primary packaging materials (migration, permeation, container corrosion) (Knowles, 2008). Accelerated storage studies at 54°C/14 days and under freeze-thaw cycling conditions, with analysis of AI content, physical appearance, and functional performance metrics at each time point, provide the primary stability data package supporting early regulatory interactions (FAO, 2010).

3.3 Scale-Up and Process Validation

The translation from laboratory-scale prototype to pilot-scale manufacturing (10–500 L batch) introduces process engineering challenges frequently underestimated in agrochemical NPD programs (Cooper, 2011). Scale-up of SC and CS formulations demands careful attention to mill energy input and recirculation time, as particle size distribution is highly sensitive to tip speed, chamber geometry, and bead fill ratio in bead mill operations (Tadros, 2013). Process capability analysis (C_{pk}) at pilot and commercial scale demonstrates that the manufacturing process consistently delivers product within specification with adequate statistical margin (ICH Q8, 2009). Batch-to-batch variability data for key quality attributes—AI content, particle size, pH, viscosity, and physical stability outcomes—must be generated as part of the GMP documentation package underpinning both internal quality release and regulatory submissions (European Commission, 2009).

IV. REGULATORY REQUIREMENTS IN AGROCHEMICAL FORMULATION DEVELOPMENT

Regulatory compliance is an integral element of formulation development, not merely a terminal step before market entry. Modern regulatory frameworks require formulation scientists to engage in regulatory strategy from the earliest development stages, ensuring data generation programs are aligned with current and anticipated requirements of all target registration jurisdictions (van Emden & Peakall, 2024). Table 3 summarizes the principal global regulatory authorities, their legislative frameworks, primary data requirements, and official resources.

Table 3. *Major global regulatory authorities for agrochemical products, primary enabling legislation, required data domains, and official information resources. CIPAC = Collaborative International Pesticides Analytical Council; JMPS = Joint Meeting on Pesticide Specifications.*

| Regulatory Body | Region | Key Legislation | Primary Data Requirements | Official Resource |
|----------------------------|----------------|---------------------------|---|--------------------------------|
| US-EPA / OCSPP | United States | FIFRA (7 U.S.C. § 136) | Product chemistry, acute/subchronic/chronic toxicology, environmental fate, residue data, efficacy data | epa.gov/pesticide-registration |
| EFSA / European Commission | European Union | Regulation (EC) 1107/2009 | Full Annex II/III dossier; endocrine disruptor | efsa.europa.eu |

| | | | | |
|----------------------|---------------|-----------------------------------|---|----------------------|
| | | | screening; nano-specific assessments under review | |
| PMRA (Health Canada) | Canada | PCPA (S.C. 2002, c.28) | Chemistry, tox, environmental fate, efficacy; Canadian crop-specific residue data | canada.ca/pesticides |
| CIBRC (MoAFW) | India | Insecticides Act 1968 + CIB Rules | Bioefficacy trials on Indian crops, acute toxicology, residue data, local environmental fate | cibrc.nic.in |
| APVMA | Australia | APVMA Act 1992 (Agvet Code) | Chemistry, safety, environment, trade and efficacy; Australian crop registration trials | apvma.gov.au |
| FAO/WHO (JMPS) | International | FAO Spec Guidelines (2010) | CIPAC methods compliance, impurity limits, packaging and labelling; prerequisite for UN procurement | fao.org/agriculture |

4.1 Product Chemistry Requirements

Product chemistry data constitute the foundation of every formulation registration dossier. All major regulatory frameworks require a complete declaration of composition—specifying AI content as weight/weight (w/w) or weight/volume (w/v), identity, function, and concentration of each co-formulant, and nature and level of impurities in both the AI and formulated product (US-EPA, 2022). Impurity profiling is particularly demanding under European Regulation (EC) 1107/2009, which requires characterization of all impurities ≥ 0.1 g/kg in the technical AI and assessment of their toxicological and ecotoxicological significance (European Commission, 2009). Analytical method validation for AI content determination in the formulated product—following CIPAC Method MT 191 and SANCO/3030/99 guidance—must demonstrate specificity, linearity, precision, accuracy, and robustness (CIPAC, 2023). Methods intended for enforcement must be validated in an independent laboratory. The analytical method package typically includes: the validated method procedure, validation data summary, reference standards documentation, and certificate of analysis (European Commission, 2013).

4.2 Physical and Chemical Properties Testing

Regulatory authorities require comprehensive physicochemical characterization of the formulated product using standardized CIPAC or equivalent internationally recognized methods (CIPAC, 2023). Core tests across most liquid and suspension formulations include: pH determination (MT 75), viscosity (MT 192), density (MT 3), suspensibility (MT 15.1, for SC/WG/WP), spontaneous emulsification and emulsion stability (MT 36, for EC/EW), particle size distribution (MT 170/187, for SC/CS), and flash point for flammability classification (Knowles, 2008). Packaging compatibility testing—demonstrating no reaction, corrosion, or migration between the formulation

and the intended container system—is required for all liquid formulations, with containers tested under accelerated conditions representative of the product's intended shelf-life (FAO, 2010).

4.3 Toxicological and Ecotoxicological Requirements

For formulated products, a tiered toxicological assessment is required, comprising at minimum: acute oral toxicity (OECD TG 423 or 425), acute dermal toxicity (OECD TG 402), acute inhalation toxicity (OECD TG 403), primary skin and eye irritation (OECD TG 404/405), and skin sensitization (OECD TG 406 or 429) (OECD, 2022). In many jurisdictions, formulated product toxicological data can be bridged from the AI data package using read-across approaches where excipients present no additional toxicological concern (European Commission, 2009).

Ecotoxicological data for formulated products—including acute toxicity to fish (OECD TG 203), *Daphnia magna* (OECD TG 202), and aquatic algae (OECD TG 201)—are required in most major markets to assess environmental hazard of the as-marketed product in addition to AI-level ecotoxicological characterization (OECD, 2022). Co-formulants with known aquatic toxicity or endocrine-disrupting potential receive particular scrutiny under the EU regulatory framework (EFSA, 2021).

V. DOSSIER PREPARATION AND REGISTRATION SUPPORT

The assembly of a complete, scientifically defensible, and jurisdictionally compliant registration dossier is among the most demanding deliverables in the formulation development program (Fig 3). A typical new product dossier for a major market such as the EU comprises several hundred to over one thousand pages, organized according to the data format requirements of the relevant authority (European Commission, 2009). The formulation scientist's contributions extend beyond product chemistry to include active participation in the manufacturing process description, quality control specifications, analytical method package, stability study reports, and packaging specifications (van Emden & Peakall, 2024). In the EU, the dossier format follows EPPO PP 1/181 guidelines and OECD harmonized templates, structured across Product Chemistry (Annex III, Part A), Toxicology (Part B), and Ecotoxicology (Part C) (OECD, 2020).

Figure 3 — Registration Dossier Structure for EU Regulation (EC) 1107/2009 (Annex III, Formulated Product)

REGISTRATION DOSSIER — FORMULATED PRODUCT (Annex III)

PART A: Product Chemistry

- ├— A.1 Applicant Identity & Registration History
- ├— A.2 Composition: AI content, co-formulants, impurities, packaging

- └─ A.3 Physical & Chemical Properties (CIPAC methods)
- └─ A.4 Analytical Methods (validated per CIPAC MT 191 / SANCO/3030/99)
- └─ A.5 Stability Studies (accelerated 54°C/14d + long-term 24 months)
- └─ A.6 Packaging, Labelling & SDS

PART B: Efficacy & Resistance Management

- └─ B.1 Biological Activity Trials (Good Experimental Practice)
- └─ B.2 Field Efficacy Trials (≥2 years, geographically representative)
- └─ B.3 Resistance Risk Assessment & Anti-Resistance Strategy

PART C: Toxicology | PART D: Ecotoxicology | PART E: Environmental Fate

(Formulated product acute tox, irritation, sensitization; aquatic + non-target organism tox; soil degradation, KOC adsorption, leaching modelling per FOCUS guidance)

Figure 3. Schematic representation of the EU Annex III registration dossier structure for formulated plant protection products under Regulation (EC) 1107/2009. The Product Chemistry module (Part A) is primarily the responsibility of the formulation science team. SDS = Safety Data Sheet; KOC = soil organic carbon-normalized partition coefficient; FOCUS = Forum for the Co-ordination of Pesticide Fate Models and Their Use.

5.1 Stability Studies and Documentation

Stability studies form the core scientific evidence base for establishing product shelf-life and storage recommendations. The FAO/WHO JMPS stability testing protocol requires accelerated studies at 54°C for 14 days and long-term studies at ambient temperature for 24 months for solid formulations and 18 months for liquid formulations (FAO, 2010). All stability samples are analyzed for AI content by the validated analytical method and for the full suite of relevant physicochemical properties at each time point. Table 4 summarizes the CIPAC test methods, stability conditions, and acceptance criteria applicable to each major formulation type.

Table 4. CIPAC/FAO stability test methods, conditions, and acceptance criteria for major agrochemical formulation types, as required for registration dossier preparation. Methods referenced are from the CIPAC Handbook (CIPAC, 2023) and FAO Specifications Manual (FAO, 2010).

| Formulation Type | CIPAC / FAO Test Method | Test Conditions | Acceptance Criterion |
|-----------------------------|----------------------------------|---|--|
| SC (Suspension Concentrate) | MT 15.1 – Suspensibility; MT 170 | 54°C / 14 days; –10°C freeze-thaw (×3); ambient 24 months | Suspensibility ≥70%; D90 increase <20%; no irreversible caking; pour time within specification |

| | | | |
|---------------------------------------|--|--|--|
| | – Particle size; MT 180 – Pour/sedimentation | | |
| EC (Emulsifiable Concentrate) | MT 36 – Emulsification character; MT 175 – Emulsion stability | 54°C / 14 days; 0°C / 7 days cold stability | Cream + sediment ≤2 mL per 100 mL; no persistent flocs; AI content ±5% of nominal |
| WG (Water- Dispersible Granule) | MT 170 – Wettability; MT 174 – Dispersibility; MT 46.3 – Attrition resistance | 40°C / 12 weeks (accelerated); ambient 24 months (long-term) | Wettability ≤60 s; dispersibility ≥90%; dust content ≤1%; AI content ±5% |
| WP (Wettable Powder) | MT 53.3 – Wettability; MT 15.1 – Suspensibility; MT 59.1 – Wet sieve | 40°C / 12 weeks; ambient 24 months | Wettability ≤60 s; suspensibility ≥60% after 30 min; wet sieve retention <0.6% on 75 µm |
| CS (Capsule Suspension) | MT 184 – Encapsulation efficiency; MT 170 – Particle size; release profile testing | 54°C / 14 days; 0°C / 7 days; UV stability where relevant | Encapsulation efficiency ≥85%; particle size within specification; release profile ±15% of nominal |
| OD (Oil Dispersion) | MT 180 – Spontaneous dispersibility; viscosity (Brookfield); particle size | 54°C / 14 days; 0°C / 7 days | Spontaneous dispersibility ≥90%; viscosity within ±20% of initial; no irreversible sedimentation |

The stability study report must document batch number, composition, manufacturing date, analytical method reference, results at each time point with statistical summary, and a conclusion on conformance with the proposed product specification (FAO, 2010). Statistically significant AI degradation must be explained in terms of degradation pathway and characterized for identity and quantity of degradation products, with toxicological assessment where required (European Commission, 2009).

5.2 CIPAC and FAO Method Compliance

CIPAC methods provide the internationally recognized standard analytical and performance testing procedures for agrochemical formulated products. Compliance is required or strongly recommended by virtually all major regulatory authorities including FAO, WHO, the EU, EPA, and most national authorities in Asia, Latin America, and Africa (CIPAC, 2023). Where no validated CIPAC method exists for a specific AI in a specific formulation type, the applicant must develop and validate a new method, conduct an interlaboratory collaborative study, and submit for CIPAC publication—a process that can add 12–24 months to the development timeline.

FAO Specifications, prepared by JMPS and published in the Manual on the Development and Use of FAO Specifications for Plant Protection Products, define minimum purity requirements, impurity limits, and performance criteria for formulated products using internationally agreed CIPAC test methods (FAO, 2010). FAO-compliant products are eligible for procurement by United Nations agencies and development banks—an important market access requirement for manufacturers targeting developing country markets.

VI. QUALITY MANAGEMENT AND CUSTOMER COMPLAINT INVESTIGATION

Post-commercialization quality management is the mechanism by which the performance promises embedded in the development program and registration dossier are consistently delivered to end users throughout the product's commercial life. A robust quality management system (QMS) encompasses raw material qualification, in-process controls, finished product release testing, stability monitoring, and systematic investigation and resolution of customer complaints (ICH Q10, 2008).

6.1 Classification and Triage of Customer Complaints

Customer complaints for agrochemical formulated products are broadly classified into four categories: (i) physical complaints (sedimentation, caking, phase separation, abnormal viscosity or colour change); (ii) chemical complaints (off-odour, AI content out-of-specification, impurity formation); (iii) performance complaints (reduced biological efficacy, phytotoxicity, crop damage); and (iv) packaging complaints (leakage, container deformation, seal failure, label deterioration) (van Emden & Peakall, 2024). Performance complaints are typically the most commercially significant but also the most challenging to investigate, due to the multiplicity of field variables—weather, application equipment condition, tank-mix interactions, pest population dynamics, resistance status—that can confound attribution to formulation quality (Knowles, 2008).

Complaint triage protocols incorporating complaint severity classification (safety-critical vs. performance vs. cosmetic), regulatory notification requirements (mandatory reporting thresholds vary by jurisdiction), and sample retention policies must be established as part of the QMS and documented in the Quality Manual (ICH Q10, 2008). Regulatory authorities require immediate notification of any product safety incidents and may mandate market withdrawal actions pending investigation (US-EPA, 2022).

6.2 Root Cause Investigation Methodologies

Systematic root cause investigation employs a hierarchy of analytical and process investigation tools. First-line investigations involve analytical verification of the complaint sample against retained reference standards and batch release data, using the validated CIPAC method for AI content and the full physicochemical test panel relevant to the formulation type. Comparison of complaint sample particle size distribution, rheological profile, and stability parameters against batch release data enables discrimination between manufacturing deviations and storage/transport-related degradation (ICH Q10, 2008).

For manufacturing-related deviations, Failure Mode and Effects Analysis (FMEA), Fishbone (Ishikawa) causal analysis, and 5-Why techniques provide structured frameworks for identifying root causes in raw material variations, process parameter deviations, equipment performance anomalies, or operator errors (Cooper, 2011). Statistical Process Control (SPC) charts for key in-process parameters enable early detection of process drift not apparent from batch release data

alone (ICH Q10, 2008). Corrective and Preventive Actions (CAPA) generated from root cause investigation must be documented with implementation timelines, effectiveness verification criteria, and linkage to regulatory authority if specification changes are required.

VII. MARKET-ORIENTED FORMULATION DEVELOPMENT AND PRODUCT DIFFERENTIATION

The intensification of generic AI competition in major crop protection markets—a consequence of expiring patents on second-generation pyrethroids, strobilurins, and triazole fungicides—has shifted competitive differentiation increasingly toward formulation innovation, service excellence, and digital agriculture integration (Mordor Intelligence, 2024). Formulation scientists must command not only deep technical expertise but also understanding of commercial strategy, farmer psychology, and competitive intelligence.

7.1 Farmer-Centric Value Proposition Development

Market-driven formulation development commences with systematic capture of farmer, agronomist, and distributor insights through structured voice-of-customer (VoC) research—encompassing focus group discussions, in-field demonstrations, conjoint analysis surveys, and digital sentiment monitoring of agricultural platforms (Mordor Intelligence, 2024). Key performance attributes valued by farmers include ease of tank preparation, rainfastness within 30–60 minutes of application, crop safety under heat and stress conditions, compatibility with commonly co-applied products, and product longevity under ambient storage (van Emden & Peakall, 2024). These attributes translate directly into formulation development targets: optimal droplet size distribution for rainfastness, buffered pH for tank-mix compatibility, low foam generation, and acceptable spray pattern from diverse nozzle types (Knowles, 2008).

7.2 Benchmarking and Competitive Intelligence

Competitive benchmarking studies comparing the candidate formulation against market leaders across a standardized panel of physicochemical, biological, and user-experience metrics provide objective evidence of product differentiation at each stage gate (Cooper, 2011). Metrics of commercial relevance include spray deposit distribution uniformity (fluorescent tracer methodology), cuticular retention under simulated rainfall events, canopy penetration efficiency, and operator exposure during mixing and loading (van Emden & Peakall, 2024). Intellectual property differentiation through formulation patents—covering novel excipient combinations, particle size ranges, encapsulation technologies, or application methods—provides a mechanism for maintaining product exclusivity beyond AI patent expiry (CropLife International, 2023).

7.3 Economic Evaluation and Commercialization Strategy

Economic evaluation at each stage gate assesses the formulation development investment against projected commercial returns. The cost-of-goods (COGS) model integrates raw material costs,

manufacturing yield, packaging, waste management, and overheads to establish the minimum viable commercial margin (Cooper, 2011). Market adoption modelling—incorporating farmer willingness-to-pay premium data from VoC surveys, competitive pricing analysis, and penetration rate assumptions by market segment—translates technical product differentiation into projected revenue and return on investment (ROI) (Mordor Intelligence, 2024). Products failing to demonstrate a commercially defensible margin or positive NPV at the Stage 3 gate are typically discontinued, regardless of technical merit, unless strategic market entry or portfolio completion rationale supports continued investment.

VIII. EMERGING TECHNOLOGIES AND FUTURE PERSPECTIVES

The agrochemical formulation sector is experiencing technological transformation driven by sustainability imperatives, precision agriculture requirements, and unprecedented scientific advances at the interface of materials science, nanotechnology, synthetic biology, and data science. Table 5 summarizes key emerging formulation technologies, their mechanisms, current regulatory status, and representative literature.

Table 5. *Emerging agrochemical formulation technologies: mechanisms of action, regulatory status as of 2024, and representative peer-reviewed references. ACS = American Chemical Society; Biol. = Biological; Chem. = Chemistry; Nanotech. = Nanotechnology.*

| Technology | Mechanism of Action | Regulatory Status (2024) | Key References |
|--|---|---|--|
| Nanoformulations (NF) (1–500 nm particles) | Sub-stomatal AI delivery via transcuticular nano-channels; enhanced dissolution via high surface area; phloem mobility of surface-functionalized nanocarriers | No dedicated nano-pesticide framework; EFSA and US-EPA reviewing nano-specific data requirements; ECHA nanomaterials definition applies in EU | Kah et al. (2018, Nature Nanotech.); Grillo et al. (2021, J Hazard Mater.); Guan et al. (2022, ACS Nano) |
| Controlled-Release Systems (CRS) | Diffusion through semi-permeable polymer membrane (CS); matrix erosion (PLA, starch granules); stimuli-triggered release (pH, moisture, enzyme) | CS code accepted by FAO/WHO JMPs; CIPAC MT 184 for encapsulation efficiency; EU requires release profile data in dossier | Peng et al. (2022, ACS Nano); Campos et al. (2020, Sci. Rep.); Grzegorzewski et al. (2020, J Agric Food Chem) |
| Biodegradable Encapsulants | PLA, chitosan, starch, or lignin matrices replace petrochemical polymer shells; soil-degradable under field conditions; | OECD TG 301 biodegradability mandated in EU; no specific regulatory incentive yet; anticipated preferential | Campos et al. (2020, Sci Total Environ); Yu et al. (2023, Green Chem); Avellan et al. (2021, ACS Sustain Chem Eng) |

| | reduced micro-plastic burden | status under Farm-to-Fork policy | |
|----------------------------------|--|--|--|
| AI-Assisted Formulation Design | QSPR and ML models predict optimal HLB, surfactant blends, and stability outcomes; neural networks trained on historical batch data flag stability risk early in development | Not directly regulated; data generated supports 3Rs (reduced animal testing); ML predictions used to guide but not replace experimental validation | Wink et al. (2022, Pest Manag Sci); Lieber et al. (2023, Digital Discovery); Walters & Murcko (2020, Nat Biotechnol) |
| Biological & Hybrid Formulations | Microbial AIs (Bacillus spp., Trichoderma spp., Beauveria bassiana) co-formulated with synthetic AIs in SC or WG; synergistic or complementary modes of action | EPA biopesticide tiered data scheme reduces data burden; EU classification by primary AI; CFU viability tested in parallel with AI stability across shelf-life | Jaber & Ownley (2018, Biol Control); Singh et al. (2023, Crop Prot); Mishra et al. (2022, Front Microbiol) |

8.1 Nanoformulations

Nanoformulations—defined by the EU Nanomaterials Regulation as containing engineered particles with at least one dimension in the 1–100 nm range—offer transformative potential through mechanisms inaccessible to conventional formulation technologies, including sub-stomatal AI delivery via transcuticular nano-channel penetration, phloem mobility enabling systemic distribution of otherwise poorly systemic molecules, and targeted delivery to specific cell organelles via surface-functionalized nanocarriers (Kah et al., 2018). Polymeric nanoparticles (PLGA, PLA), solid lipid nanoparticles, nanoemulsions (50–200 nm), and nanocapsules have been demonstrated to improve biological efficacy at 50–80% reduced AI loading compared with conventional formulations in laboratory studies (Grillo et al., 2021). However, commercialization faces substantial regulatory barriers: EFSA and US-EPA have not yet established dedicated nano-pesticide assessment frameworks, and novel nano-specific data requirements substantially increase development costs and timelines (EFSA, 2021).

8.2 Controlled-Release Systems

Controlled-release formulations extend the biological efficacy window of the AI, reduce application frequency, mitigate environmental exposure through temporal and spatial confinement of the active substance, and reduce mammalian toxicity risk through reduced peak AI concentration in the spray deposit (Peng et al., 2022). Mechanisms include diffusion through a semi-permeable polymer membrane (CS technology), erosion-controlled release from a degradable matrix (PLA, starch, or chitosan granules), and stimuli-triggered release in response to soil moisture, pH shifts, or enzymatic activity (Campos et al., 2020). pH-triggered release systems—in which the polymer shell dissolves selectively under the acidic conditions (pH 4.5–

5.5) of insect midgut—represent a particularly promising avenue for insecticide resistance management (Peng et al., 2022).

8.3 Biodegradable Encapsulants and Green Chemistry

The development of biodegradable encapsulant systems—employing PLA, chitosan, starch, or lignin matrices in place of petrochemical polymers—addresses growing concerns about the contribution of conventional CS formulations to micro-plastic contamination in agricultural soils (Campos et al., 2020). Biodegradability testing per OECD TG 301 is mandated in the EU registration context, and preferential regulatory status for biodegradable-encapsulant products is anticipated under Farm-to-Fork policy implementation (European Commission, 2020). The integration of green chemistry principles—atom economy, renewable feedstocks, biodegradable solvents, and reduced process energy—into formulation manufacturing represents an emerging dimension of corporate sustainability commitments and increasingly a competitive differentiator in public procurement and ESG-focused investment frameworks (Avellan et al., 2021).

8.4 AI-Assisted Formulation Design and Digital Agriculture Integration

The application of ML and artificial intelligence to agrochemical formulation represents the most transformative methodological innovation of the current decade (Wink et al., 2022). QSPR models trained on large databases of surfactant HLB values, critical micelle concentrations, and formulation performance outcomes can predict optimal excipient combinations for new AIs with substantially reduced experimental effort (Lieber et al., 2023). Neural network models trained on historical batch stability data can identify early warning signatures of stability risk from raw material analytical certificates, enabling proactive intervention before scale-up or batch failure (Walters & Murcko, 2020).

Digital integration with precision agriculture platforms—including variable-rate application systems, drone-mounted sprayers, and IoT-connected field monitoring networks—is creating new formulation requirements (Mordor Intelligence, 2024). Ultra-concentrated microformulations compatible with sub-litre-per-hectare drone application volumes, compatibility with adjuvant-free tank preparation protocols for automated precision sprayers, and RFID-tagged containers enabling track-and-trace from manufacturing to field application are among the innovation targets driven by digital agriculture adoption. These requirements will fundamentally reshape formulation design criteria and manufacturing processes over the coming decade (Fig 4).

Figure 4 — Innovation Roadmap for Agrochemical Formulation Technology (2024–2035)

NEAR-TERM (2024–2026): Optimization of Established Platforms

- Low-VOC EC reformulations (aliphatic/ester solvents replacing aromatics under REACH)
- CS scale-up for pyrethroid and neonicotinoid alternatives with reduced mammalian toxicity
- AI-assisted DoE for excipient optimization; ML-guided stability prediction tools
- WG with biodegradable binder systems; waterless processing for energy reduction

MID-TERM (2026–2030): Emerging Platform Commercialization

- Nano-SC and nano-OD commercial launches in lead markets with established regulatory pathways
- Biodegradable PLA/chitosan CRS products reaching commercial scale
- Hybrid biopesticide + synthetic AI co-formulations mainstream in key crops
- Dedicated nano-pesticide regulatory frameworks established (EPA/EFSA expected 2027–2029)
- Drone-optimized ultra-concentrate microformulations for precision aerial application

LONG-TERM (2030–2035): Next-Generation Precision Delivery

- Stimuli-responsive targeted delivery (pest-triggered, pH-triggered, enzyme-activated release)
- dsRNA-based formulations for gene-silencing biopesticides at commercial scale
- AI-driven real-time formulation adaptation for site-specific precision application systems
- Carbon-neutral manufacturing processes across all major formulation type platforms

Figure 4. *Innovation roadmap for agrochemical formulation technology from 2024 to 2035. Near-term innovations are at advanced development or commercial readiness stage; mid-term innovations have established proof-of-concept with emerging regulatory pathways; long-term innovations are primarily at research stage. dsRNA = double-stranded RNA; CRS = controlled-release system; VOC = volatile organic compound.*

IX. CONCLUSIONS

Agrochemical formulation development has evolved from a primarily empirical discipline into a sophisticated, data-intensive, and highly regulated science occupying a central role in determining the commercial success, regulatory approval, environmental acceptability, and user safety of crop protection products. This review demonstrates that modern formulation scientists must command multidisciplinary expertise spanning physical chemistry, polymer science, regulatory affairs, quality management, intellectual property strategy, and market intelligence—a breadth of competence reflecting the centrality of formulation science to the entire product development and commercialization value chain (van Emden & Peakall, 2024).

The major formulation types—EC, SC, WP, WG, CS, and OD—each occupy specific niches defined by the physicochemical characteristics of the AI, the requirements of the target application, and the prevailing regulatory and market environment. The ongoing transition away from high-solvent formulations toward aqueous, low-VOC, and encapsulated technologies is being accelerated by regulatory restriction of aromatic solvents and operator safety requirements in all major markets (European Commission, 2009). SC and WG formulations now represent dominant innovation platforms, while CS technology experiences rapid growth driven by controlled-release and reduced mammalian toxicity profiles (CropLife International, 2023).

The NPD stage-gate framework provides the structural scaffold within which scientific and commercial resources are efficiently allocated from concept to commercialization. Regulatory compliance—spanning product chemistry, CIPAC method validation, stability documentation, and toxicological and ecotoxicological data generation—is a continuous discipline integrated throughout development rather than a terminal activity. Post-market quality management through systematic complaint investigation, SPC monitoring, and CAPA implementation is equally critical to maintaining product integrity and regulatory standing throughout the commercial lifecycle (ICH Q10, 2008).

Looking forward, nanoformulations, stimuli-responsive controlled-release systems, biodegradable encapsulation technologies, biological hybrid products, and AI-assisted design platforms collectively define the technological frontier. Realizing their commercial potential requires parallel progress in regulatory framework development—particularly for nano-pesticides and RNA-based formulations—and in sustainable manufacturing processes delivering reduced carbon footprint alongside superior agronomic performance (Kah et al., 2018). The formulation scientist of the next decade will operate as much as a data scientist and regulatory strategist as a laboratory chemist, working at the convergence of digital agriculture, materials innovation, and the global imperative for sustainable food systems (Wink et al., 2022).

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