CSAR Update: Presentation for PCPC

John Balzano

COVINGTON

BEIJING BOSTON BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON
LOS ANGELES NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

www.cov.com

Agenda

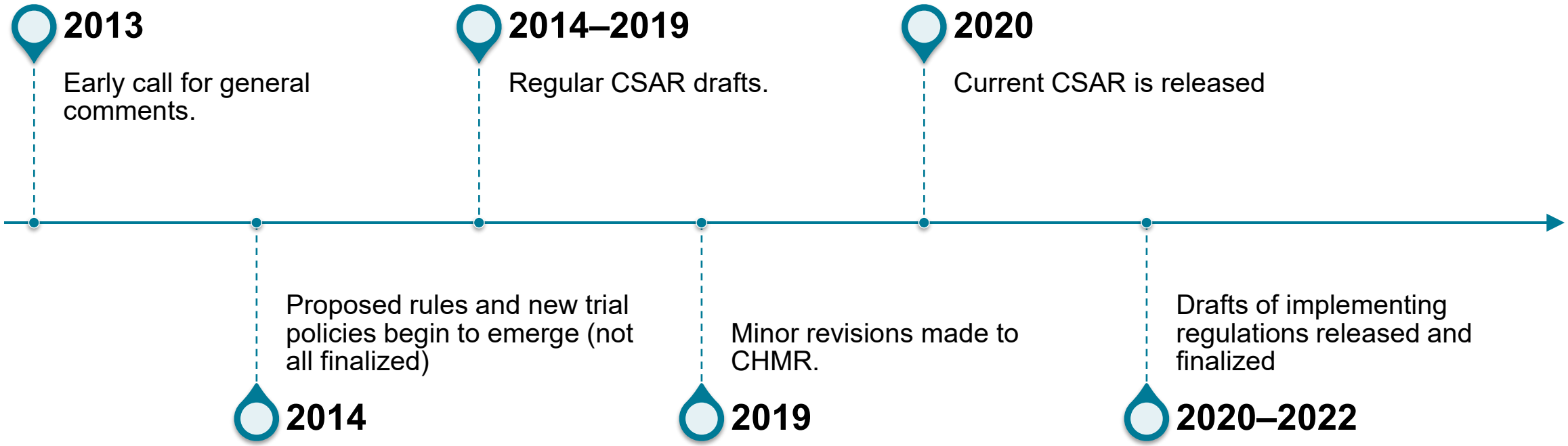
Development of the Cosmetics Supervision and Administration Regulation ("CSAR")

Development of implementing rules

October 2025 Opinion on CSAR Reform

Prospects for reform of CSAR

Prior CSAR Amendment Process



Key Changes Brought About by CSAR

- Universal implementation of the record-filing system for ordinary cosmetics.
- Implementation of safety assessments for products.
- Product categorization code requirements.
- New labeling requirements.

Key Changes Brought About by CSAR (Cont'd)

Substantially more information required about ingredient safety and quality even for existing ingredients.

An exemption from toxicology testing on animals for ordinary cosmetics (with exceptions, e.g., cosmetics for children and infants, new ingredients).

A new regime for new ingredient approval, record-filings for lower risk ingredients and registrations for higher risk ingredients (e.g., preservatives and new efficacy claims).

A more structured regime for conducting literature reviews and tests for supporting each claim made and a requirement to publish the support for claims.

Key Changes Brought About by CSAR (Cont'd)

New good manufacturing practice rules and guidelines for inspection, including a division of obligations between registrants and filers v. actual manufacturers.

A cosmetovigilance regime, including a recall standard and rules governing the reporting of serious and non-serious adverse reactions to an online platform.

New procedural rules on product testing, supplemental test methods, good manufacturing practice ("GMP") compliance, and soon inspections procedures.

Self-testing for domestically produced products (not directly connected).

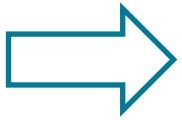
Key Changes: Responsible Parties

CSAR also restructured the framework of entities and individuals responsible for product safety and quality.

For example, potentially three entities are responsible for a product in different ways: registrant/filer ("R/F"), domestic responsible person (i.e., agent entity) of an overseas R/F, and actual manufacturer.

CSAR requires an individual in the R/F and actual manufacturer responsible for quality and safety.

A new rule in 2022 adds detail to the system of internal responsibility for cosmetic R/Fs.



CSAR adopts two relevant trends also applicable in the food, drug, and device spaces:

- Enhanced liability for entities, including fines and debarment.
- Liability at the individual level.

Overall Report Card

CSAR itself was a flexible system that accomplished important progress, including product and ingredient approvals.

The implementing rules set significant restrictions that in some respects added burdens, tracking drug and medical device regulatory measures.

Certain positive changes were implemented and have provided needed flexibility.

Progress Since CSAR

- NIFDC has regularly issued new ingredient approvals since CSAR's implementation.
- Increased reliance on safety assessments; in-house testing for ordinary domestic products.
- Generally applicable exemption from animal testing.
- Clearer (albeit burdensome) structure for claims regulation.

Core Issues for the Next CSAR

Continued registration/filing delays, including requirements for the amendment of dossiers for minor formulation changes under Article 42 of the Product Dossier Provisions.

Continued review of ordinary cosmetic applications creates uncertainty for marketed products.

Continued reliance on testing in accredited Chinese laboratories for required test reports for imported products and special cosmetics.

Core Issues (Cont'd)

Requirement for a manufacturing certificate to rely on animal testing exemption.

Continued animal testing for special cosmetics, and it is not clear how effective the new ingredient rules will be in practice.

Claims regulation is too rigid in certain respects, including requirements for data generated in China and lack of flexibility for support of certain claims.

Certificate of free sale requirement is too rigid.

Labeling requirement for consistency with foreign language labeling is inflexible and creates press to create China-specific labeling.

Core Issues (Cont'd)

System for filing ingredient safety information is burdensome and difficult to coordinate with product filings and registrations.

China is not adhering to INCI names, creating confusion and a lack of harmonization for ingredient safety profiles across major jurisdictions.

China does not adopt international standards, and is enforcing Chinese standards, including cosmetic GMP overseas including through overseas manufacturing inspections.

Additional Issues

Timelines for review of registration applications.

Communications with authorities on filings and registrations.

Implementation of new Environmental and Ecological Code, including proposed measures to require new chemical registration for cosmetic products.

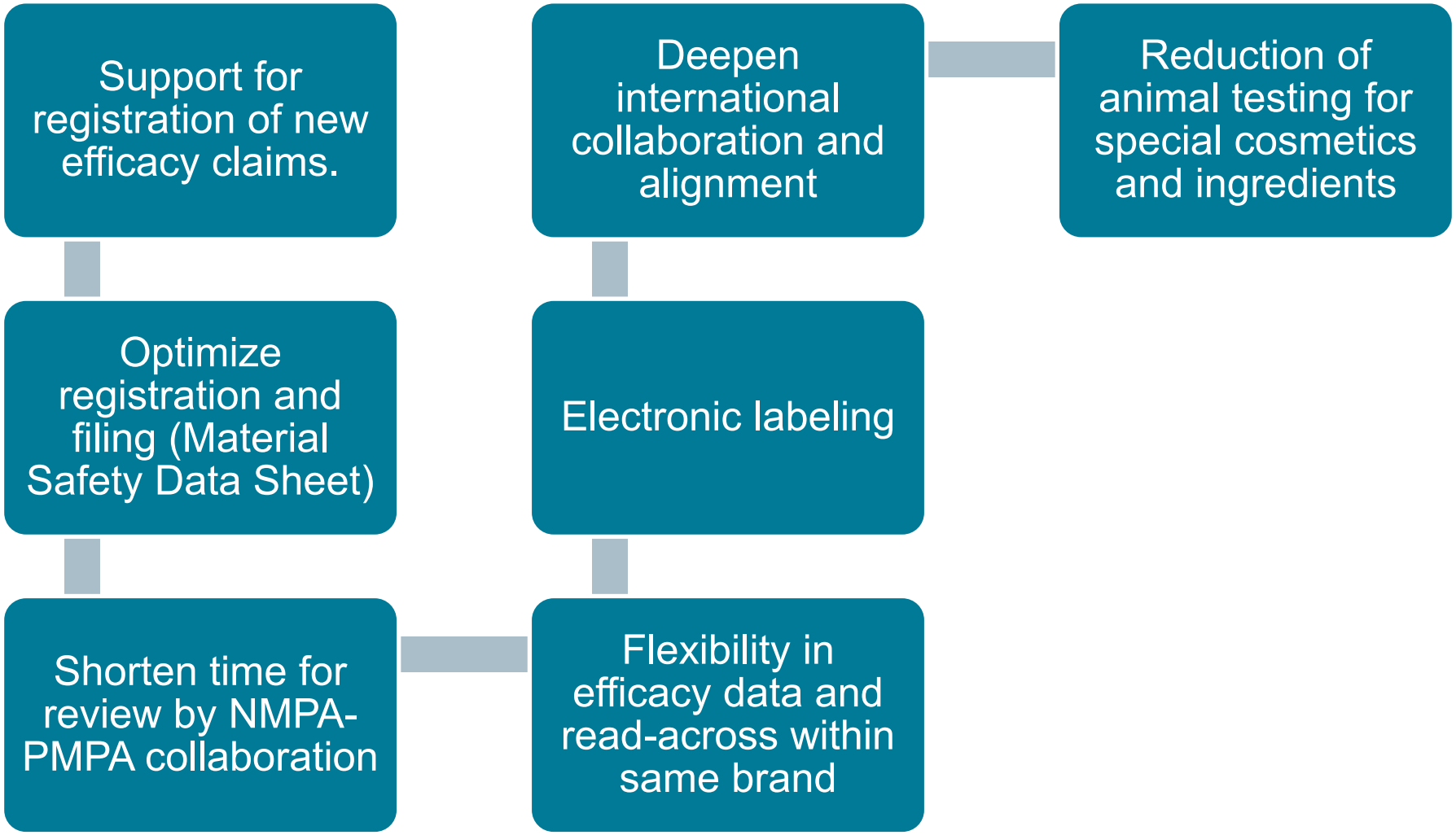
New Proposals

Opinions on Deepening the Reform of Cosmetics Supervision and Promoting High-Quality Industrial Development (2025).

Five pillars of reform:

Innovation	R/F efficiency	Supervision of production and distribution	Technical support	Alignment with international practices

Key Points in Opinions



Key Proposals to Date

Matters Concerning Cosmetic Registration and Filing (Draft for Comment)

Exempt first in world products from certificates of free sale.	Exempt ingredient toxicology testing for hair perm/dye, whitening and new ingredients during monitoring period.	Archive safety documentation independently, no filing requirement.
Read-across for similarly formulated products.	Flexibility to select claims methods.	Changes to domestic responsible entity without consent of original entity.

Key Proposals to Date

General Safety Requirements for Cosmetics

- Unified updates to Cosmetics Safety and Technical Standard
- Addition of packaging, storage and transportation
- Expanded prohibited list
- Adjustments to limits on specific substances, including tightening of microbial limits for certain products (e.g., children's cosmetics, sensitive skin)

Instructions for Use of Consumer Goods – Part 3: General Labelling for Cosmetics

- Electronic labeling

Key Proposals to Date

Measures for the Environmental Management Registration of New Chemical Substances （Revised Draft for Comment)

Remove the exemption for new chemical substance registration for finished cosmetic products.

Replace the current notification-based system for substances below one ton per year with a simplified registration process requiring pre-activity review and approval.

Expand the data requirements for substances with a volume of one to ten tons per year by requiring submission of health toxicological data.

Apply cumulative national tonnage thresholds when determining the requisite registration requirements.

Require applicants to be domestic entities.

Effective on August 15, 2026.

Recent Reform

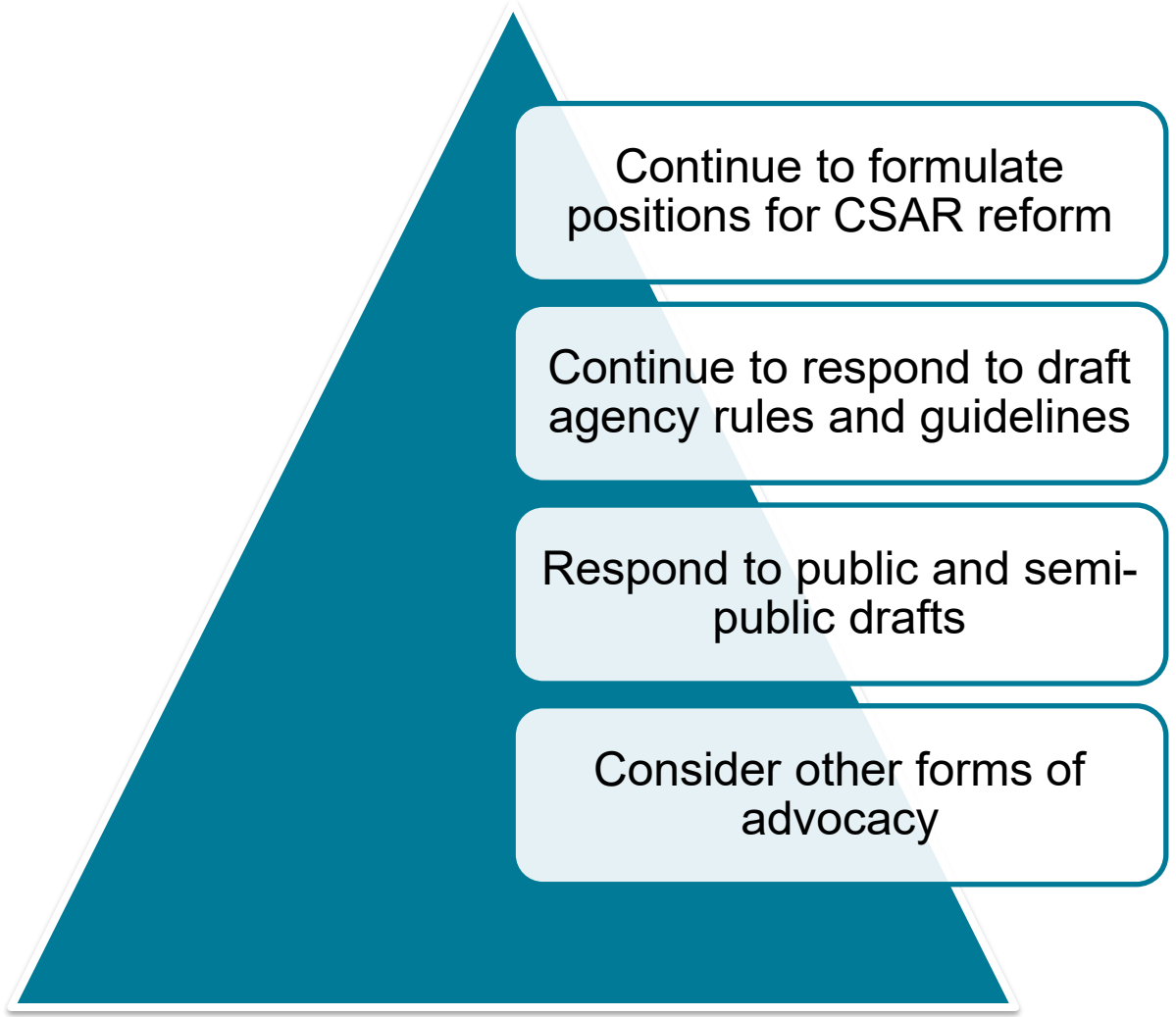
Regulations on the Management of Registration and Filing Documents for New Cosmetic Ingredients (Finalized on June 26, 2026).

Permits use of internationally accepted animal testing alternatives where other such methods have not been incorporated into Chinese standards.

Certain ingredients, such as acne, anti-wrinkle, and dandruff removal are no longer considered higher risk.

Existing data can be used to support safety assessments in applications according to Chinese or internationally accepted methods.

Next Steps


Continue to formulate positions for CSAR reform
Continue to respond to draft agency rules and guidelines
Respond to public and semi-public drafts
Consider other forms of advocacy

End

jbalzano@cov.com