

Membrane Materials, Manufacturing, and Regulatory Challenges

Synder[®]
Filtration

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Agenda

1. Introduction

2. Membrane Manufacturing Process Overview

3. Certification Process (Kosher, Halal)

4. Current Regulatory Challenges

Synder[®] *Filtration*

- **Founded in 1989 in Vacaville, California by the former Director of Bayer Pharmaceutical R&D, Ed Yeh.**
- **Pioneered use of Spiral Wound UF in Industrial Enzyme manufacturing.**
- **In 1994, Synder began manufacturing Spiral Wound UF membranes in Vacaville, California.**
- **In 2006, Synder expanded to China with the Introduction of Synder Jiangsu Membrane Technology (SJMT)**
- **In 2025, Synder expanded to RO with the addition of our new facility in Conroe, Texas.**

Vacaville, CA

HQ facility - Vacaville manufactures MF, UF, and NF membranes as well as small membrane systems and a variety of other filtration products.



SJMT

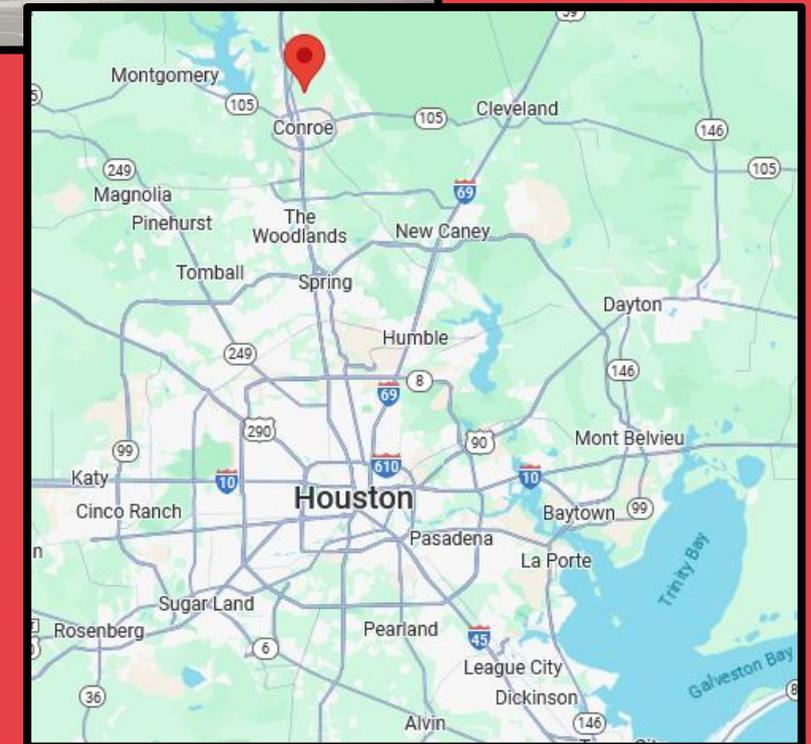
**Synder Jiangsu
Membrane Technology
mirrors the HQ facility
with a focus on the
eastern market.
Production capabilities,
materials, and
certifications are
identical between sites.**



Conroe, TX

New state-of-the-art 44,000 sq. ft. facility in Conroe, Texas integrated automated mixing, degassing, casting, and coating to produce high-quality RO membrane.

Complete spiral rolling operations are now operating as of February 2026



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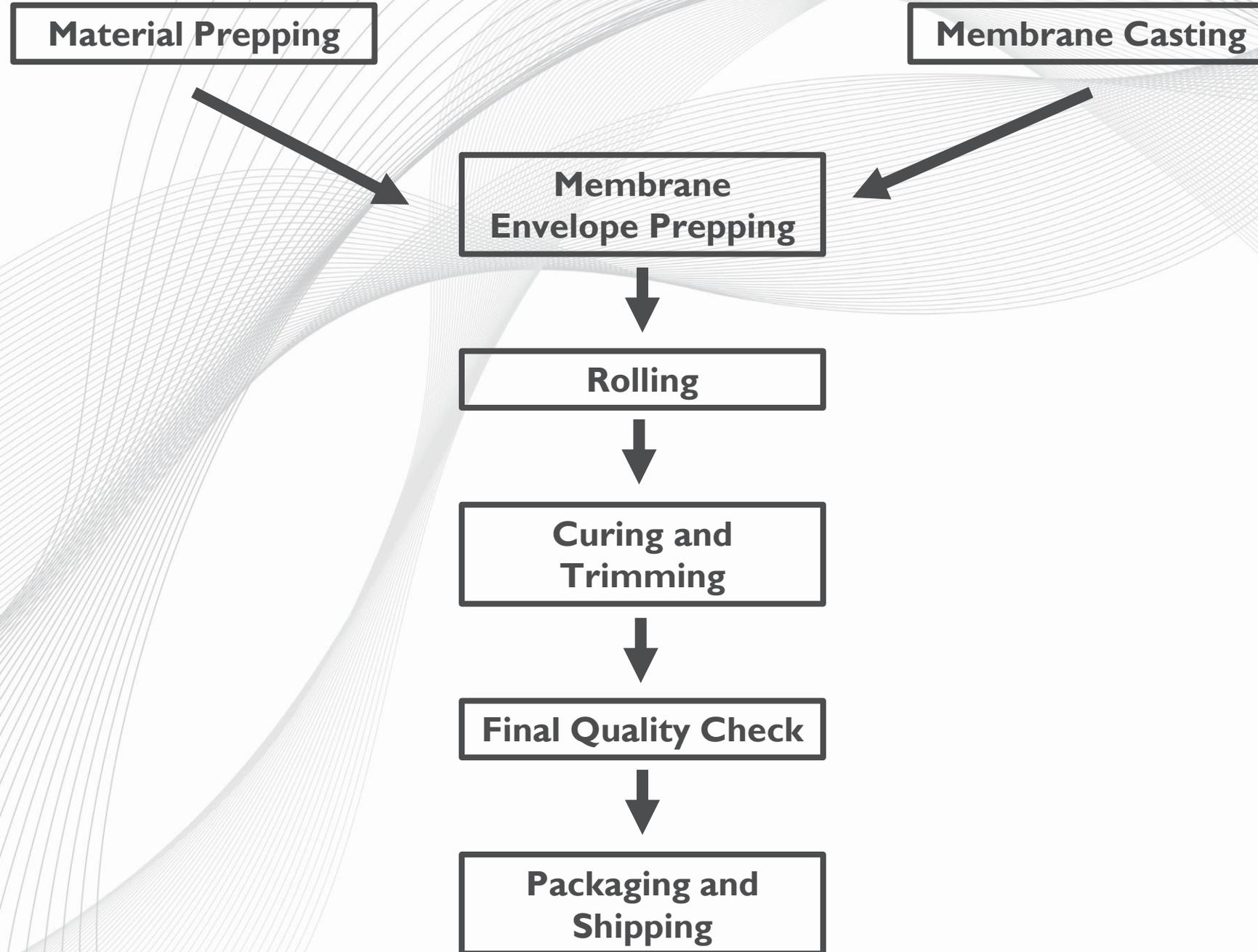
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Element Manufacturing



Membrane Casting

The desired polymer is mixed with proprietary solvents and other pore forming agents, degassed, and then cast onto the required backing material.



Phase inversion process for casting polymeric membrane onto a backing material.

Membrane Polymers

MF: Polyvinylidene Fluoride (PVDF)

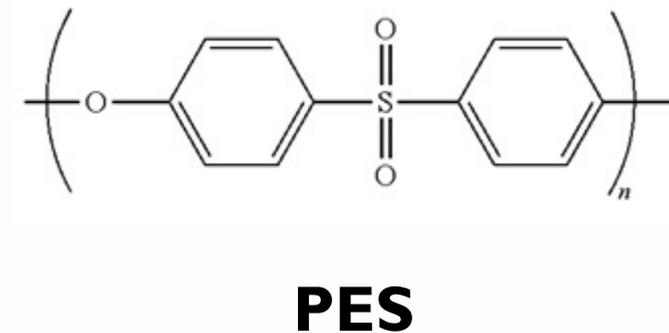
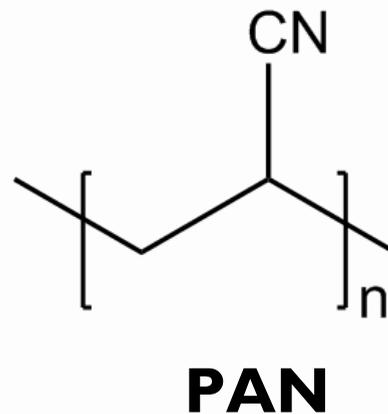
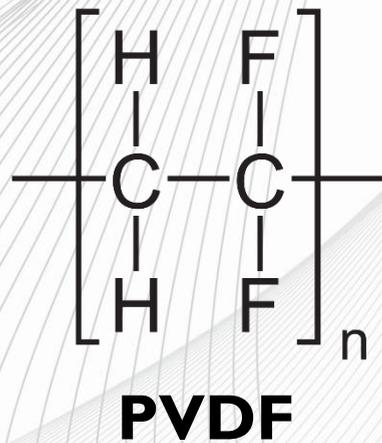
UF: PVDF, PES, PAN

NF/RO: Polyamide Thin-Film Composite (PA-TFC) on PS

Non-Woven Support Layer (Backing):

- Polyester (PE, Standard)
- Polypropylene (PP, MAX Series)

	PVDF (MF/UF)	PES (UF)	PAN (UF)	TFC (NF/RO)
Hydrophilic	+	++	+++	+
Physical Strength	+	+++	++	++
Chemical Resistance	+++	++	-	-



Material Prepping



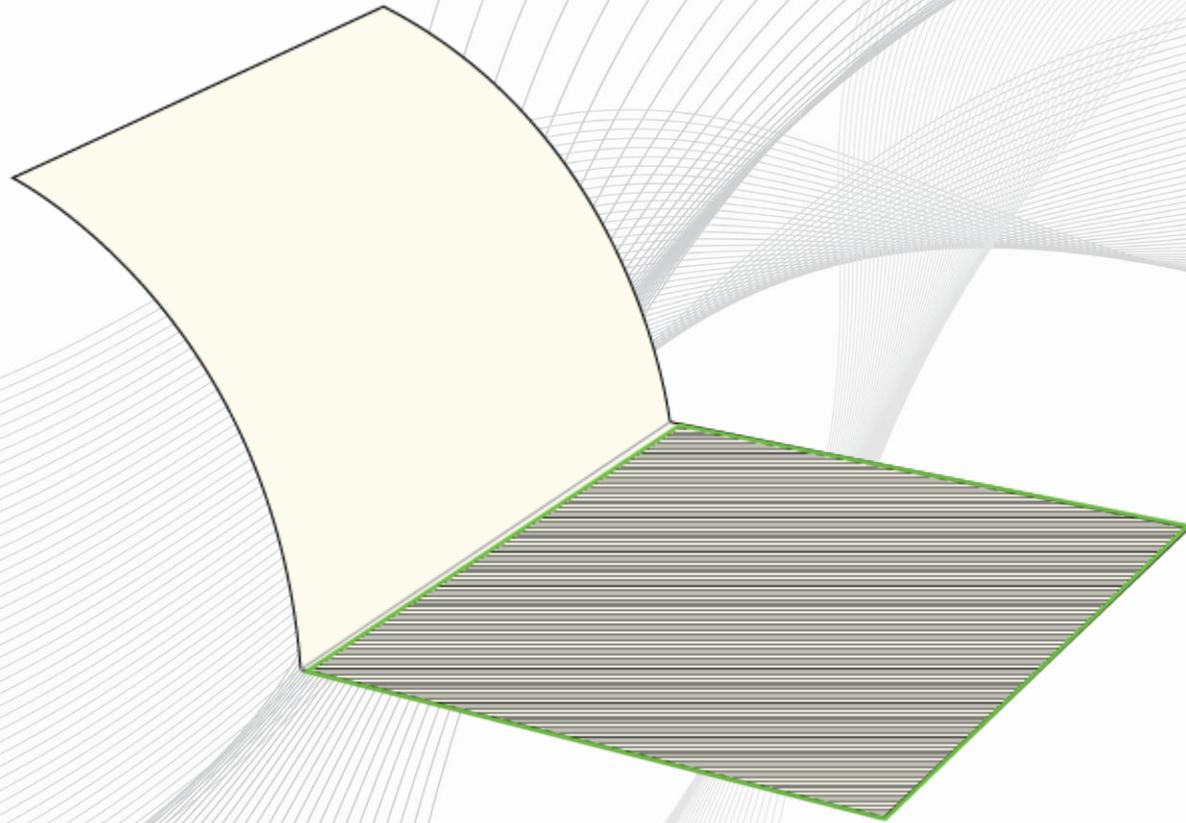
Woven, epoxy coated PE sheets are welded into a leaflet.

Permeate Tubes are Knurled and Taped

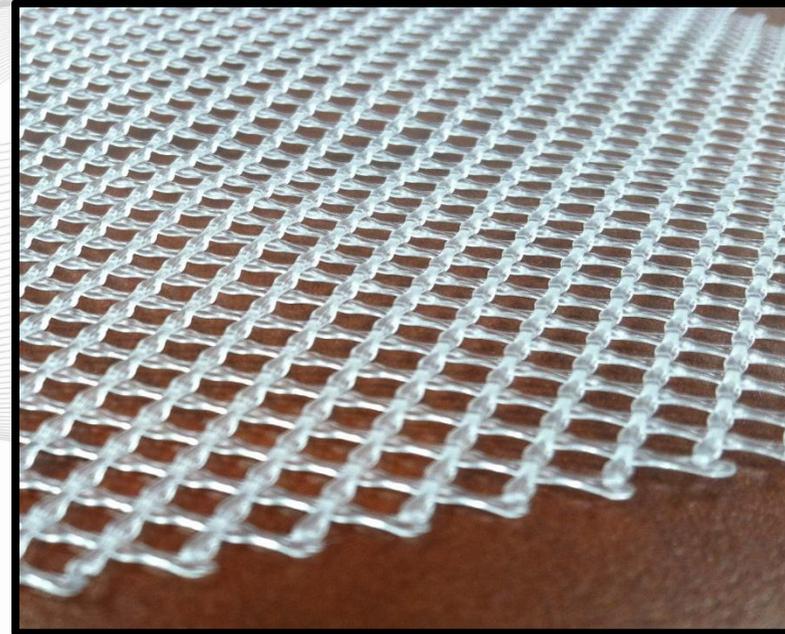


Commonly PS – alternatives include PES, 316SS, FRP, ABS

Membrane Envelope Prepping



**PP feed spacer is folded
between a cut sheet of
membrane.**

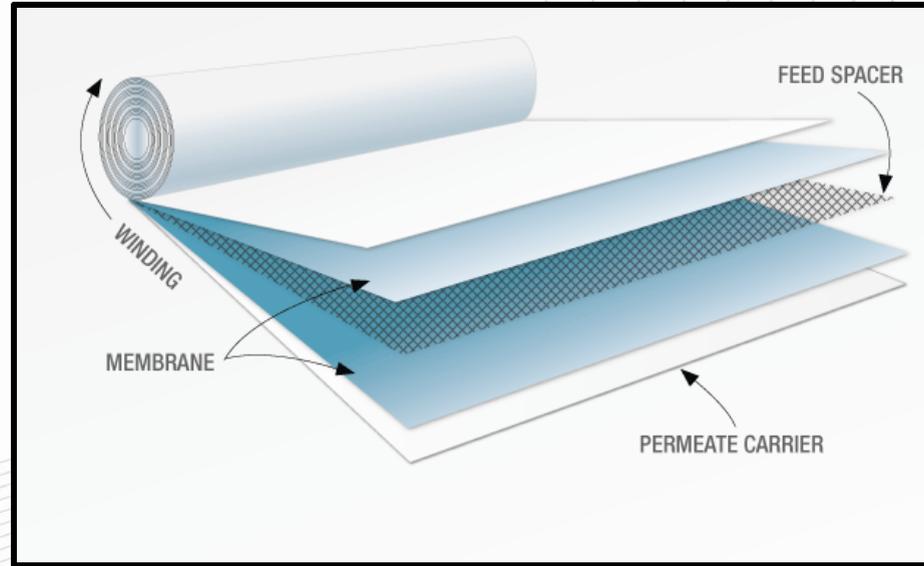


Diamond-Net Feed Spacer



Automated Prepping Machine

Rolling



Glue is applied between alternating sheets of membrane envelopes and permeate carrier. Typically, PU or a sanitary epoxy is used.



Semi-Automated Rolling Table

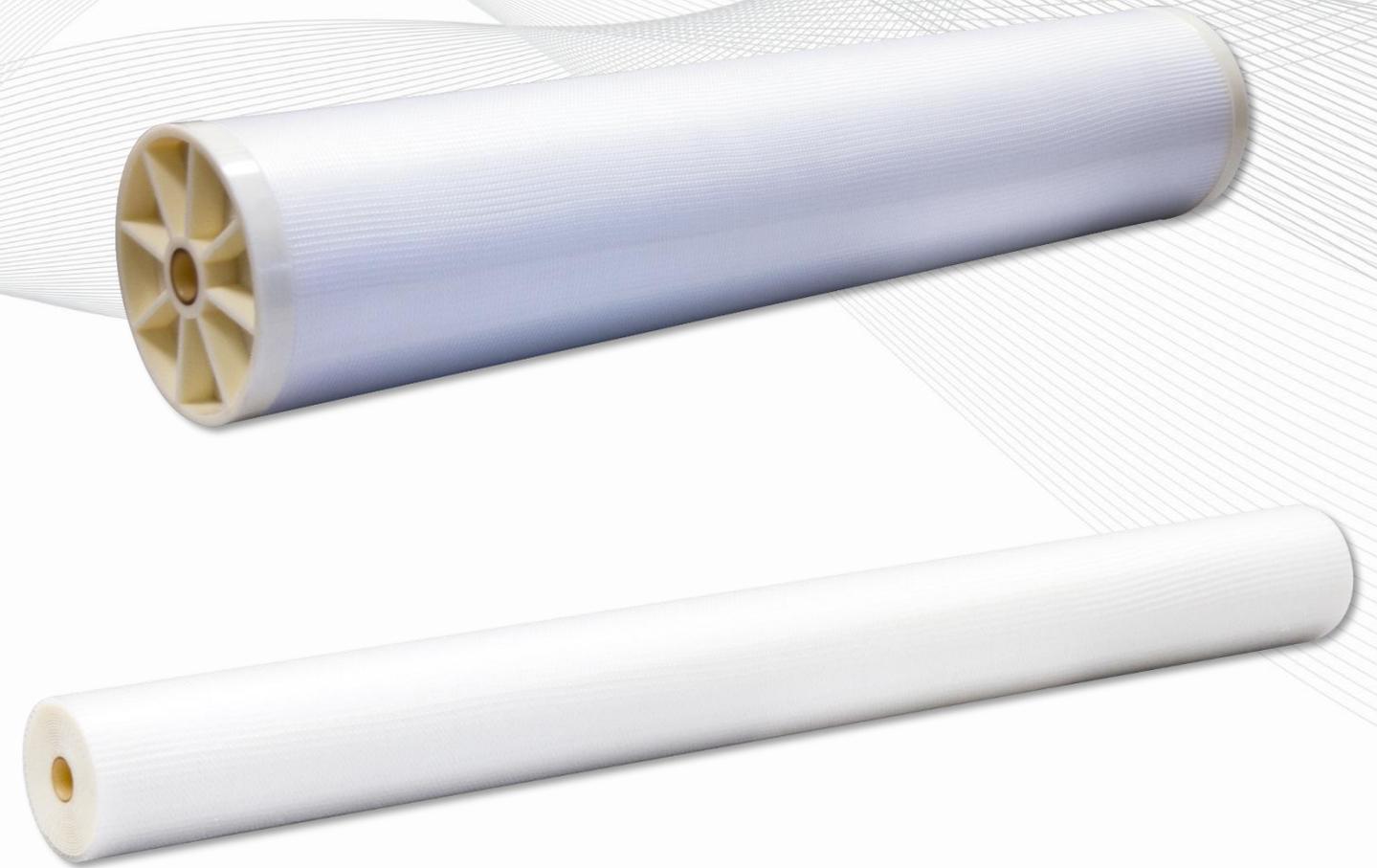
Curing, Trimming, Netting, and QC

After rolling, glue is cured for roughly 24 hours.

Then, excess material is trimmed off and a Polypropylene outer net is wrapped around the element.

PS ATD's or Shells may be applied here.

Several final quality checks are performed to test element integrity.



Packaging and Shipping

After final quality checks, membranes are preserved in Sodium Metabisulfite. Some NF/RO membranes will also use Glycerin as a preservative.

After wetting in preservative, elements are vacuum sealed in plastic bags and boxed for transport.



What goes into a Membrane?

Take, for example, a common **Microfiltration element**. **Synder's Standard FR membrane for protein processes** contains the following:

- PVDF (Membrane)
- Polyester (Backing)
- Epoxy Coated Woven Polyester (Permeate Carrier)
- Polyurethane (Adhesive)
- Polypropylene (Outer Net, Feed Spacer, Bag for Shipping)
- Polysulfone (Permeate Tube, ATD Interconnectors, End Plugs)
- EPDM (Lip Seals)
- Water (Part of Preservative Bath)
- Sodium Metabisulfite (Preservative Agent)
- Glycerin (Preservative Agent)

Also Used in Shipping, Installation, Etc

- Stainless Steel (Interconnectors, Housings, Permeate Tubes)
- Viton (Alternative to EPDM)
- Cardboard
- Styrofoam

**Recently Discussed by
Regulatory Agencies**

How are these materials regulated?

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Halal

Being Halal, simply put, means that something is permissible to consume for an Islamic person.

According to the American Halal Foundation, the most universally accepted basis for halal certification requirements is that everything is Halal, except ABCD IS Haram (non-halal).

- **A** – Alcohol (Specifically Ethanol) and other intoxicants
- **B** - Blood
- **C** – Carnivorous Animals (non fish)
- **D** – Dead Meat (not slaughtered per Islamic rites)
- **I** – Immolated Foods
- **S** – Swine (and porcine derivatives)



Kosher

A Kosher Certification is granted if foods or products made follow the Jewish dietary laws from the books of Deuteronomy and Leviticus.

Kashrut, the laws defining the Kosher status of a food, are numerous.

Relevant modern examples include:

- 1. Cannot contain blood.**
- 2. Animal products must be derived from animals slaughtered according to the Shechita process.**
- 3. Products derived from Pigs, Shellfish, or Carrion are not Kosher.**
- 4. Foods are categorized as Meat, Dairy, and Pareve (neutral). Meat and Dairy cannot be mixed. Any food processed on equipment previously used to process Dairy is considered a Dairy food.**



Certification

Generally, Kosher and Halal requirements go hand-in-hand. For food and equipment production, most rules overlap.

The Steps for Certification are as follows:

- 1. Confirm all materials of construction to the regulatory body. Animal Free or Kosher/Halal statements for each component are necessary.**
- 2. Usually, an auditor will come to the facility each year to inspect potentially non-compliant materials and to recertify.**
- 3. Whenever a new component is introduced, the regulatory body must be made aware to reissue a compliance certificate.**

3A 45-03

USDA outlines strict guidelines for sanitary design of spiral wound crossflow membrane filters.

Among other specifics, this regulates blisters, bypass flow, permeate tube bore depth.

End users bear the cost of non-compliance when USDA auditors autopsy membranes.

FDA/EU/China/Japan Compliance

Materials of Construction in Membrane Filtration are numerous, as are the legal standards these materials must follow.

The main regulatory challenge with membrane manufacturing is keeping up to date on these ever-changing rules.

United States of America

- U.S. FDA 21 CFR 177.2910 Ultrafiltration membranes
- U.S. FDA 21 CFR 177.1630 Polyethylene phthalate polymer, sections (a) through (3)
- U.S. FDA 21 CFR 177.2260 Filters, resin bonded
- U.S. FDA 21 CFR 177.1655 Polysulfone resins
- U.S. FDA 21 CFR 177.1520 Olefin polymers
- U.S. FDA 21 CFR 175.300 Resinous and polymeric coatings
- U.S. FDA 21 CFR 175.105 Adhesives

China

- General safety requirements for food contact materials and articles (GB 4806.1-2016)
- Food contact plastics materials and articles (GB 48067-2016)
- Standard for use of additives in food contact materials and articles (GB 9685-2016)

Japan

- Base polymer and additives listed in the Positive Lists for "Base polymers" and "Additives" (Appendix I in notification No. 196 of 2020)

Europe

- Plastics Regulation (Commission Regulation (EU) No. 10/2011, as amended)
- Framework Regulation (Regulation (EC) No. 1935-2004)
- Restriction of Use of Certain Epoxy Derivates (Commission Regulation (EC) No. 1895/2005)
- Good Manufacturing Practice Regulation (Commission Regulation (EC) No. 2023/2006, as amended)
- Registration, Evaluation, Authorization, and Restriction of Chemicals, Article 3 (Regulation (EC) 1907/2006, as amended)

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Packaging and Shipping

Constant efforts from **Governments** and **Companies** alike to find ways to reduce carbon footprint from packaging waste.

Larger boxes, cardboard end caps, and reduced PU foam help with this initiative, but the requirement of PP bags poses a challenge.

Airtight packaging is required to preserve membrane integrity in transit and in storage.



Recycling

Recycling remains a large challenge for membrane manufacturers and end-users.

A single packaged membrane may have as many as five separate recycling codes, as well as non-recyclable materials.

Recycling standards may vary by region considerably, adding to this challenge.



Producer Responsibility Organizations (PROs) are becoming more common to hold companies accountable for waste generation and recycling.

Oregon's Plastic Pollution and Recycling Modernization Act

Recycling

Both Mechanical and Chemical methods exist for recycling mixed plastics

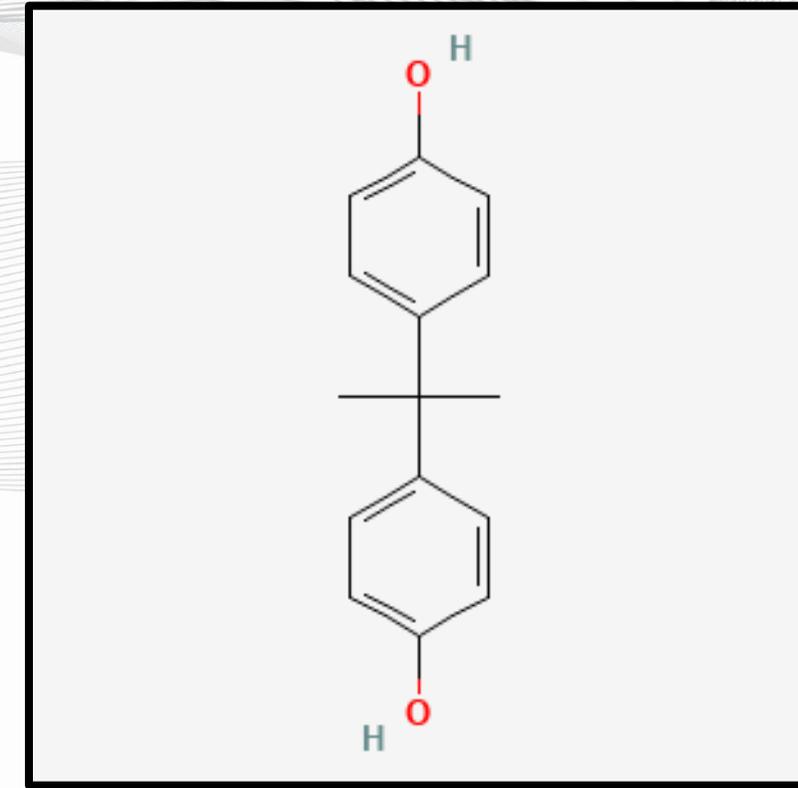
Mechanical recycling is more straightforward, but the resulting plastic has limited uses

Chemical recycling has more lucrative results but higher corresponding costs



BPA

Bisphenol A is a precursor chemical that can be used in the production of polycarbonates, relevantly Polysulfone, which can be in any number of membrane components including permeate tubes, ATDs, outer shells, and even the base polymer for NF/RO.



<https://pubchem.ncbi.nlm.nih.gov/compound/Bisphenol-A>

Certificates from plastics producers may use vague language, which makes it difficult to truly deem the membranes BPA free.

BPA

BPA may leech into foods, which, if consumed, can lead to damage to the reproductive system, endocrine system, and cause respiratory issues.

In the US, BPA is only banned for use in infant bottles and infant food packaging.



EU Food Safety Commission adopted a ban on BPA for all food contact materials in December 2024.

Notably, membranes are exempted. This exemption may not be permanent and is currently 'under review'.

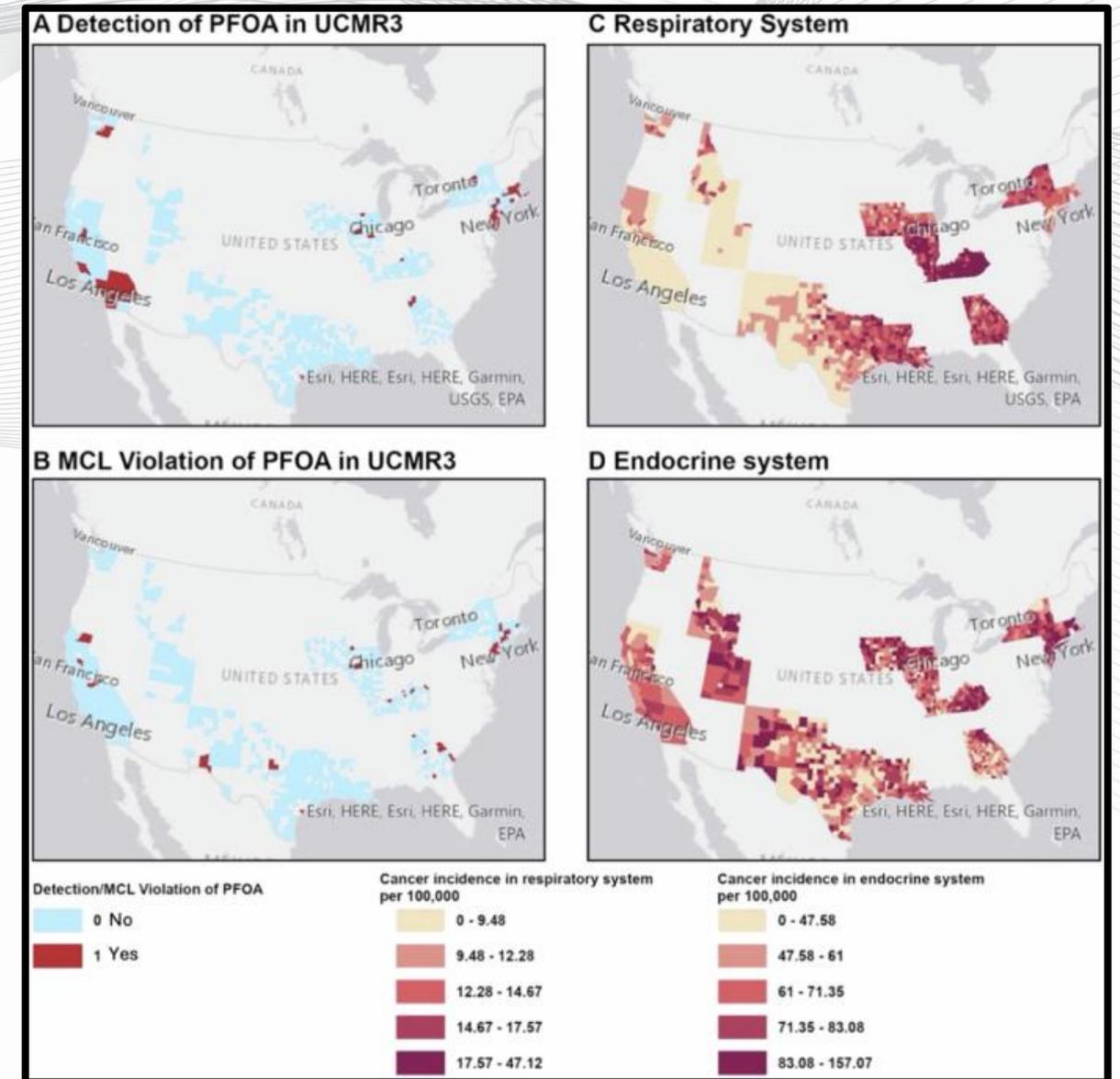


PFAS

PFAS (Per and Polyfluoroalkyl Substances) or “Forever Chemicals” have come under regulatory scrutiny.

Their presence of C-F bonds give them desirable properties, but also makes them resistant to degradation and easily dispersible in the environment.

Accumulation of PFAS in the body can lead to many negative health outcomes.



Li, S., Oliva, P., Zhang, L., Goodrich, J. A., McConnell, R., Conti, D. V., Chatzi, L., & Aung, M. (2025). Associations between per-and polyfluoroalkyl substances (PFAS) and county-level cancer incidence between 2016 and 2021 and incident cancer burden attributable to PFAS in drinking water in the United States. *Journal of Exposure Science & Environmental Epidemiology*. <https://doi.org/10.1038/s41370-024-00742-2>

PFAS

PVDF, an extremely common MF membrane polymer, is a PFAS chemical by some definitions.

There is currently no proposed legislation to ban PFAS in the US, however there have been several legal battles surrounding groundwater contamination.

The EU is implementing a PFAS ban, however exemptions are taking longer than predicted.

As of September 2025, it appears more likely than not that PVDF used in membranes will be banned in the EU.

The European Chemical's Agency (ECHA) will meet again soon to decide on the future legality of more than 10,000 substances and thousands of proposed exemptions.

The next meeting is set for Spring, 2026.

Micro/Nanoplastics

UC Irvine study published in 2024 found that bottled water contained large quantities of micro and nano plastics. PA and PS, which are not found in packaging materials, were found in final products. A probable source for these was RO treatment.

Qian, N.; Gao, X.; Lang, X.; Deng, H.; Bratu, T. M.; Chen, Q.; Stapleton, P.; Yan, B.; Min, W. Rapid single-particle chemical imaging of nanoplastics by SRS microscopy. *Proceedings of the National Academy of Sciences* **2024**, *121* (3). <https://doi.org/10.1073/pnas.2300582121>.

EU has already banned sales of ‘intentionally added’ microplastics.

There is no current legislation against ‘unintentional’ microplastics, but this may change in the future.



End of Life Testing

The risk of membrane materials leeching into an end product increases considerably as the membrane ages. This presents several challenges.

- 1. Many testing standards do not exist yet, and will likely vary region-to-region.**
- 2. Membranes can last 1-10 years depending on the application, as well as cleaning and operating conditions making defining 'End of Life' very difficult.**
- 3. Many potential foulants membrane release would require membranes to be removed.**
- 4. Who bears the cost on testing, removal, etc.?**

Where are Manufacturers Looking?

While some materials can be changed without impacting product performance, membrane manufacturers must look inward and to regulators for answers to current and future questions.

- 1. Manufacturers must reduce waste, replace materials, and continue R&D to replace any potentially harmful materials as fast as possible.**
- 2. Regulators must provide guidance on certification, allowable limits of certain contaminants, and accepted testing methods.**

Changes happens very slowly with membranes. It is important that manufacturers are proactive and that end users demand advancement, compliance, and excellence.



Thank you.

Any questions?

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