Legal Pitfalls in the PMN Process

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BEVERIDGE & DIAMOND PC

PMN Requirements Have Legal Consequences

Potential restrictions on use

Potential regulatory liability for mistakes

Potential liability to third parties

Don’t assume – check with your in-house counsel

BEFORE making that decision

NOT just to clean up the mess

TSCA Inventory

Basic concept – "new" vs. "existing" chemical substances

Congress wanted EPA to review all chemical substances and regulate as needed

- Much harder to regulate chemical substances already in commerce, which may be part of products throughout the economy on which many people rely
- Much easier to regulate chemicals before they enter commerce, for which there is no reliance or incorporation into products

Created a need to separate new chemical substances from existing chemical substances

- Different regulatory tools for new vs. existing chemicals

Solution: TSCA Inventory

TSCA Inventory

Late 1970s	• Inventory reporting
1979	• Initial Inventory with about 60,000 chemical substances
PMN process + NOC →	• Additional entries
Now:	• About 84,000 chemical substances
Any chemical substance not on the Inventory is a new chemical substance	• Subject to different requirements than those on the Inventory

Inventory: Getting It Wrong

Getting it wrong can mean:

Penalties of up to $37,500 per day

- For each day of illegal manufacture for up to 5 years
- For each incorrect import certification for up to 5 years

Business interruption

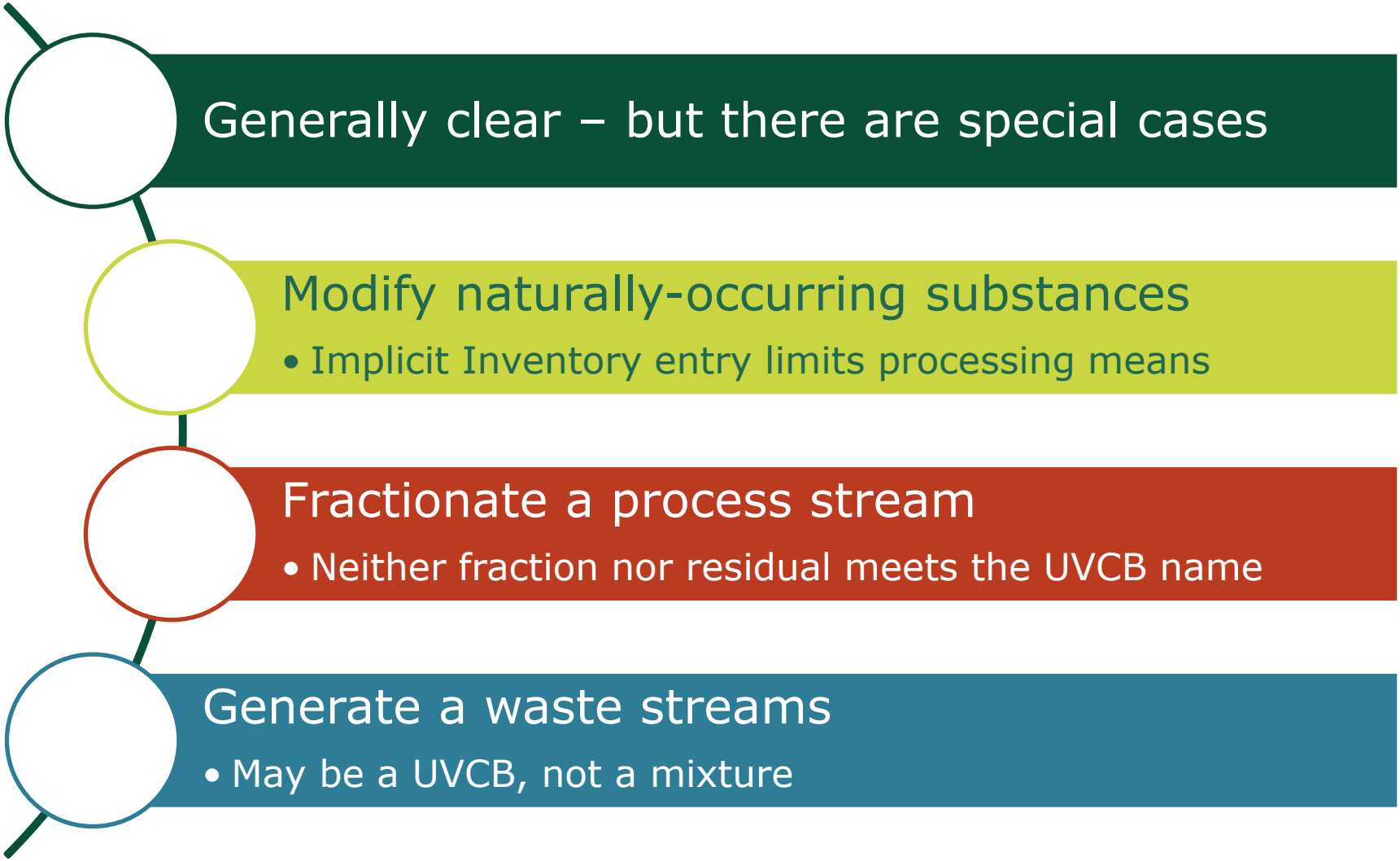
- Stop manufacture of chemical or products containing it for minimum 4 months (or risk criminal liability)
- Quarantine existing stocks – and possibly destroy them

Potential liability

- Contractual liability to customers reliant on chemical or products containing it
- Tort liability for manufacturing a harmful chemical illegally

Damage to the brand

When Is a Chemical "New"?



When Is a Chemical "New"?

Make a narrower or broader range of carbon chain lengths	• Inventory entries may specify chain lengths
Biobased alternatives to petroleum products	• UVCB names are petroleum-specific
Dual-use materials	• For volumes not regulated under FIFRA or FFDCA
Nanomaterials	• Even when the same name is on the Inventory • Unless same structure as macroscale material

When Is a Chemical "New"?

When a PMN exemption no longer applies

Waste stream is used under byproduct exemption

- Until another (non-covered) use is found
- Extract component chemical by reaction

In-process chemical is stored

- Previously non-isolated intermediate is isolated

Isomer is found to be fully functional

- No longer "unintentionally present"?

Export-only chemical has domestic use

When Is a Chemical "New"?

When EPA changes its interpretation

Statutory mixtures

- § 8(b)(2) categories
- Chlorinated paraffins

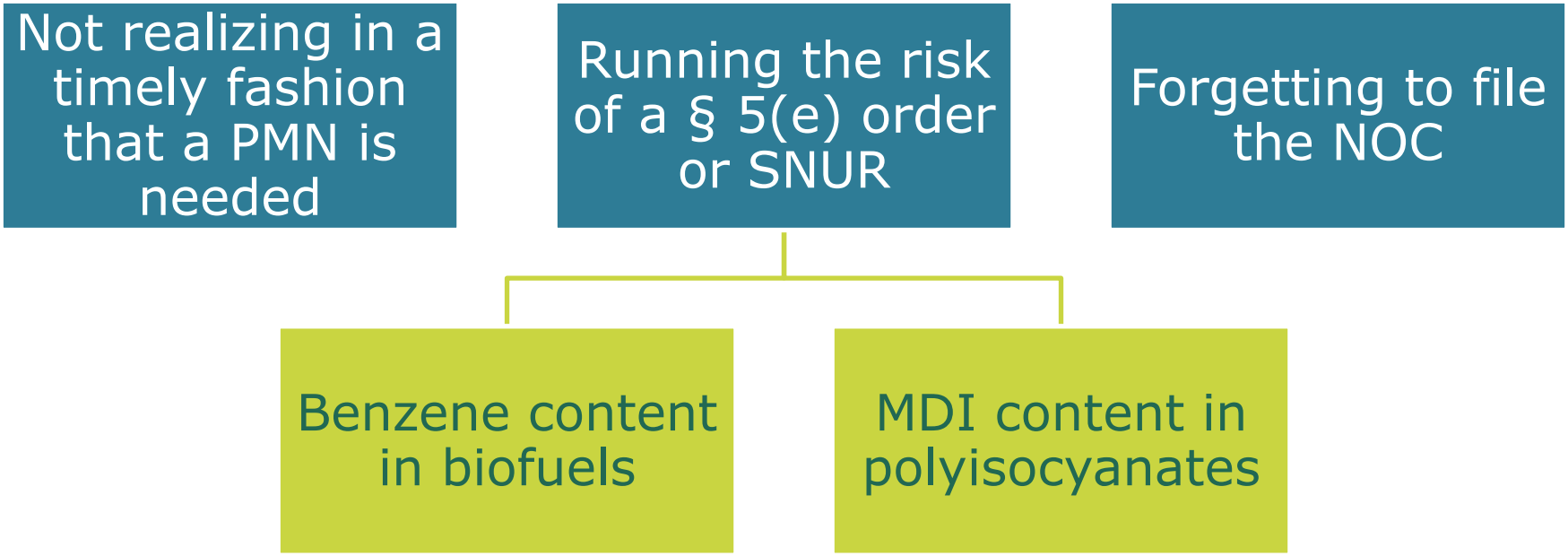
Activated phosphors – not mixtures

"Functions as intended"

Nomenclature changes

- Normal unless name says "branched"
- Specificity of carbon number ranges
- Enzymes and proteins
- Nanomaterials

Biggest PMN Traps



Future PMN Developments

Nanomaterials

- Questions about particle size
- Nomenclature

Senate version of TSCA legislation

- Likely to meet the safety standard
- Not likely to meet the safety standard
- EPA cannot tell – testing

Bottom Line

It’s a jungle out there

Be careful

Check with Legal before making decisions that implicate Inventory compliance

Questions?

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