



Regulatory Impacts of the PC Rule on Massachusetts Food Facilities





What is the PC Rule?

GMPs are updated and revised:

- ✓ Modernization of language (e.g. “shall” to “must”)
- ✓ Deleted provisions with recommendations
- ✓ Other provisions now binding: **Education and training**
- ✓ Explicitly address allergen cross-contact



What is the PC Rule?

Hazard and Risk-Based Preventive Controls (HARPC):

- ✓ Written food safety plan
- ✓ Hazard analysis
- ✓ Implementation of preventive controls
- ✓ Monitoring of preventive controls
- ✓ Corrective action
- ✓ Verification and validation of preventive controls
- ✓ Recall plan
- ✓ Supply chain program



Who is covered?

**All establishments required to register with FDA
as a “food facility”, including:**

Food manufacturers

Food wholesalers and distributors

Food warehouses

Farms that are “mixed-type” facilities



What are mixed-type facilities?

Farms that do processing and manufacturing that fall outside the PC Rule definition of a “farm”¹

¹The definition of a farm has been clarified and now covers two types of operations: a primary production farm and a secondary activities farm. The primary farm is located in one general location under one management and grows and harvest crops or raises animals or both. The secondary activities farm is an operation that is majority-owned by, but not located on, the primary production farm that harvests, packs and holds raw agricultural commodities grown and supplied by the primary production farm. Additional detail about what activities are considered part of the farm definition are provided in the PC Rule.



Who is **NOT** covered?

Do **NOT** have to register with FDA, so **NOT** subject to PC Rule:

- ✓ **Farms** as defined in the PC Rule
- ✓ **Retail** Establishments (including restaurants)
- ✓ **Non-profit** food facilities
- ✓ Private **residences**
- ✓ **Transport vehicles**
- ✓ **Fishing vessels**
- ✓ Facilities regulated by **USDA**



Exemptions from GMP Requirements

- GMP requirements in PC Rule apply to most covered facilities
- **GMP exemptions** are provided in PC rule for:
 - ✓ Facilities that **solely store or transport raw agricultural commodities (RAC)** - these are also exempt from HARPC if they solely store RAC **other than** fruits and vegetables
 - ✓ Most activities of mixed-type facilities that fall within the definition of farm



Exemptions from HARPC Requirements

- Activities of facility subject to **Parts 113 (microbiological hazards only), 120, 111, and 123**
- Certain low risk manufacturing, packing or holding activities of a **small/very small mixed-type facility**
- Manufacturing, packing or holding **alcoholic beverages**
- Activities of a facility subject to the **FSMA Produce Rule**
- Facilities that store **only unexposed packaged food**
- **Qualified facilities** (less than \$1 million in revenue/firm)
- Facilities that store **only RAC (other than fruits and vegetables)***

8 *These facilities are exempt from GMPs too. Facilities that store fruits and vegetables are subject to HARPC but exempt from GMPs





Modified Requirements

Exempt from HARPC but subject to modified requirements (simpler requirements discussed in Subpart D) apply to:

Qualified Facilities
(firms with less than \$1 million in annual revenue)

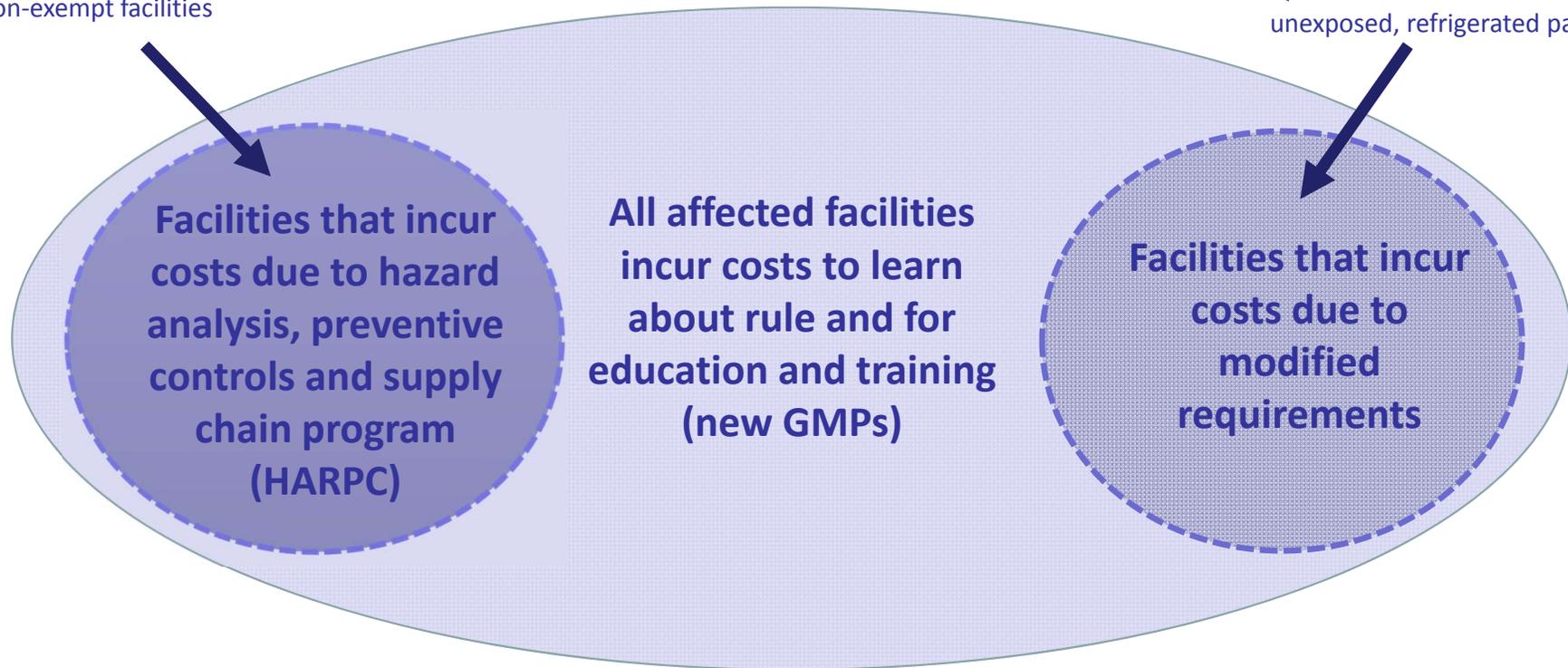
Facilities that solely store **unexposed, packaged food** requiring time and temperature controls



Compliance Costs of Federal PC Rule on Food Industry

Non-exempt facilities

Qualified facilities and those that store unexposed, refrigerated packaged food





Estimated Number of MA Facilities Affected*

1,916 establishments

1,716 manufacturers,
wholesalers, and distributors

200 mixed-type
facilities

1,067
exempt from
HARPC

287
qualified
facilities

361 subject
to full rule

198
qualified
facilities

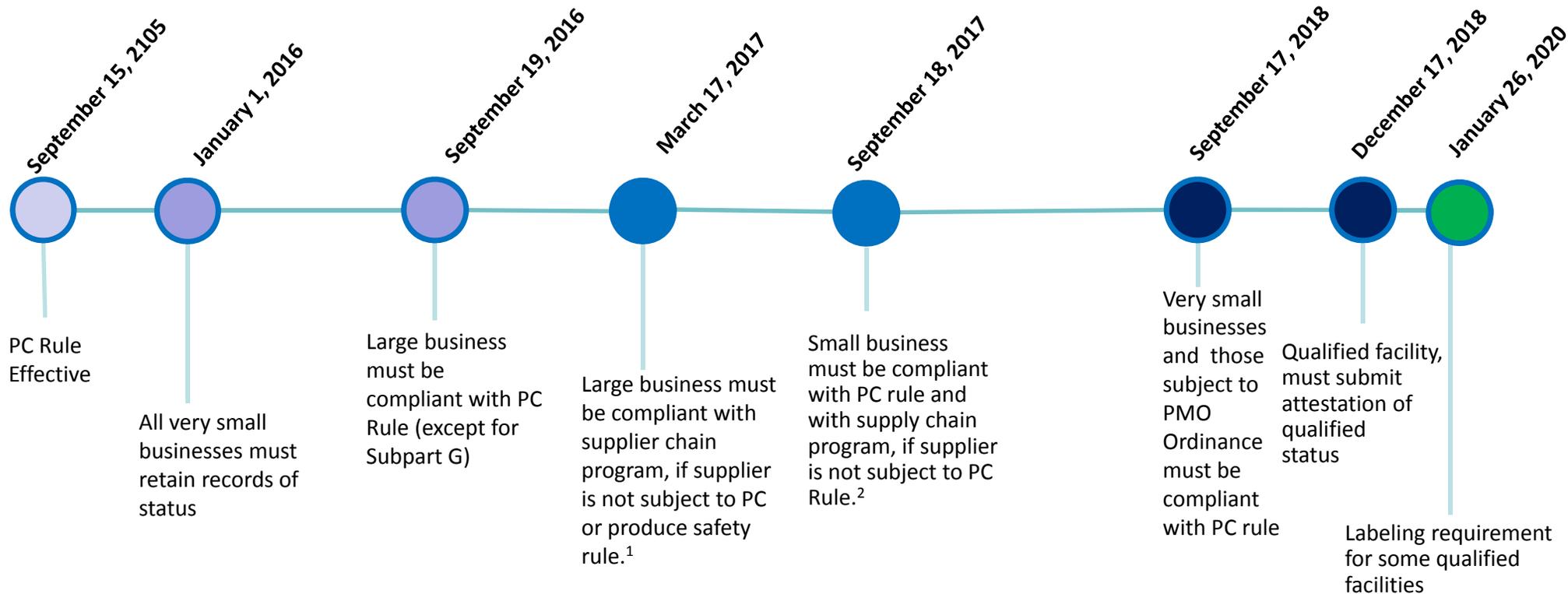
2 subject to
full rule**

11 *Estimated based on 2012 U.S. Census data, USDA and MDAR data.

**These may be exempt too if they are only conducting low-risk activities as defined in the rule.



Federal PC Rule Timeline



¹If supplier is subject to the PC rule, compliance is required six months after the supplier is required to comply with applicable rule.

²If supplier is subject to the PC rule, compliance is required six months after the supplier is required to comply with applicable rule or this date, whichever is later.





Compliance Time for MA Firms

September 19, 2016
156 large firms

September 18, 2017
845 small firms*
2 small mixed-type firms

September 17, 2018
577 very small firms
198 mixed-type firms

13 *Of the 1,422 small firms estimated in the ERG report, some are also very small (less than \$1 million in revenues). The 577 very small firms have been subtracted from the 1,422 small firms to estimate the number of small firms that must be in compliance by September 18, 2017





Entities Affected by the PC Rule

All in-scope MA facilities will need to comply with the Federal PC rule by the compliance dates set forth by FDA **regardless of MA adoption of the rule.**



Compliance costs with PC rule are attributable to Federal requirements



Cost Impact on Massachusetts Facilities



Rule is in force already, so MDPH adoption **will not** impose additional costs **to comply** with rule. MDPH adoption may impose other minor costs.



Minor Impacts of PC Rule Adoption by MDPH on MA Facilities

Longer inspections:

- Inspection of facilities subject to full rule will likely be similar to HACCP inspection (two-day inspection)
- Cost to industry of an additional day by a senior manager to accompany inspector
- Costs estimated at **\$860 per inspected facility**



Minor Impacts of PC Rule Adoption by MDPH on MA Facilities

Delay in adoption of PC Rule by MDPH:

- May require **FDA export certificate** instead of MDPH export certificate for a short time.
- Costs estimated at **\$205 per affected facility**
- State inspections may not acceptable in lieu of supplier audit



Conclusion

- Most costs attributable to FDA compliance with PC Rule
- Minor cost impact on MDPH inspected facilities
- Timing of adoption by MDPH will matter
- Minor cost impact on firms that export if adoption delayed



Questions

Any Questions?