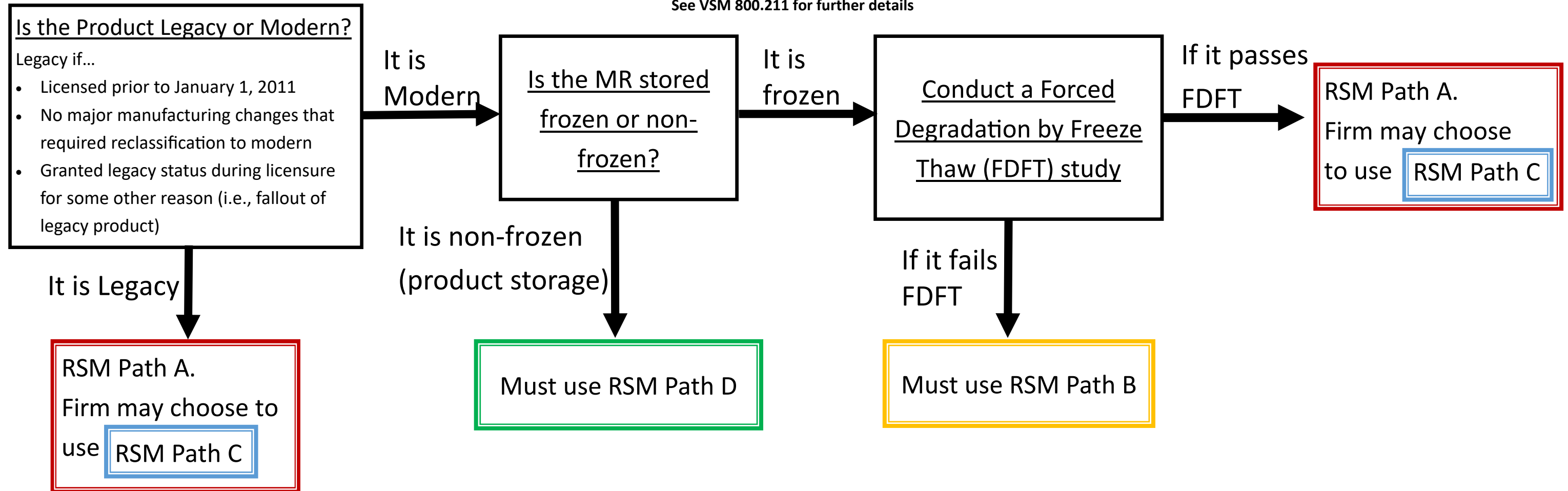


Companion Overview for 800.211 Guidance for Master Reference Qualification, Requalification, Dating and Monitoring

Start Here!

(RSM = Reference Stability Monitoring)
See VSM 800.211 for further details



RSM Path A

- Monitor using only serial release data every 30 months
- 15 year dating maximum
- Qualify or requalify in host animals

RSM Path B

- Monitor with RSM assays and serial release data every 30 months
- Prior to RSM plan approval and while validating RSM assays:
 - Dating in 5 year increments based on progress toward approval of RSM plan and RSM assay validation
 - Required to qualify/requalify in host animals once to have monitoring using validated RSM assays from time 0
- After RSM plan approved, RSM assays validated and time 0 testing concurrent with host animal qualification:
 - Future qualification *in vitro*
 - Indefinite dating

RSM Path C

- Same as RSM Path B except initially receives 15 year dating during which RSM plan must be approved and RSM assays validated

RSM Path D

- Same as RSM Path B except receives product dating until RSM plan is approved and RSM assays are validated during which host animal qualification/requalification expected