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Animal Cloning Update: Science, Safety and Supply Chain Management

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Joint AMI/FMI Committee Meeting
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Goal

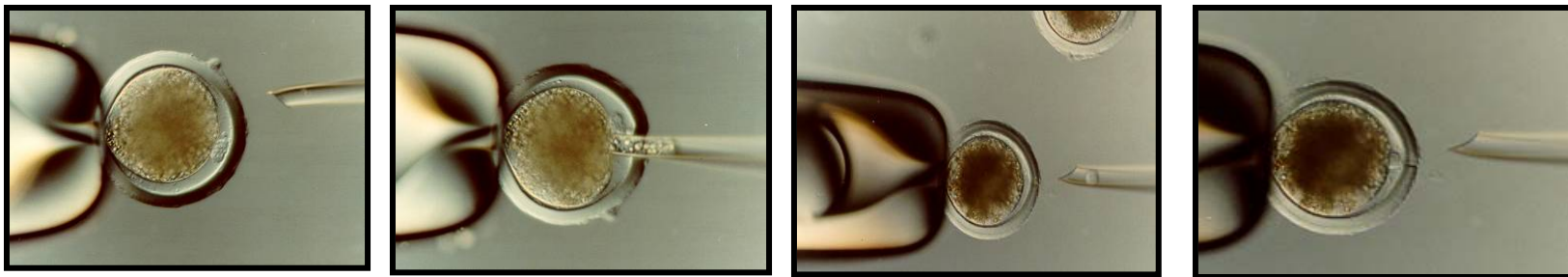
- Assisted reproductive technologies- What is cloning?
- Scientific consensus
 - FDA draft Risk Assessment
- Cloning in today's livestock production
- Steps toward successful adoption
 - Supply chain management
 - Consumer education
- We want your feedback!

Overview

- Assisted Reproductive Technologies (ART):
 - 1) Artificial Insemination (AI) - 1322
 - 2) Embryo Transfer – 1891
 - 3) In vitro fertilization – 1959
 - 4) Cloning
 - a. Embryo Splitting – 1980s
 - b. Somatic Cell Nuclear Transfer (SCNT) - 1996
- Livestock Industry uses AI:
 - 1) Beef – 50% of seedstock production
 - 2) Dairy – 75% of all dairy production
 - 3) Swine – 80% of all feeder pig production

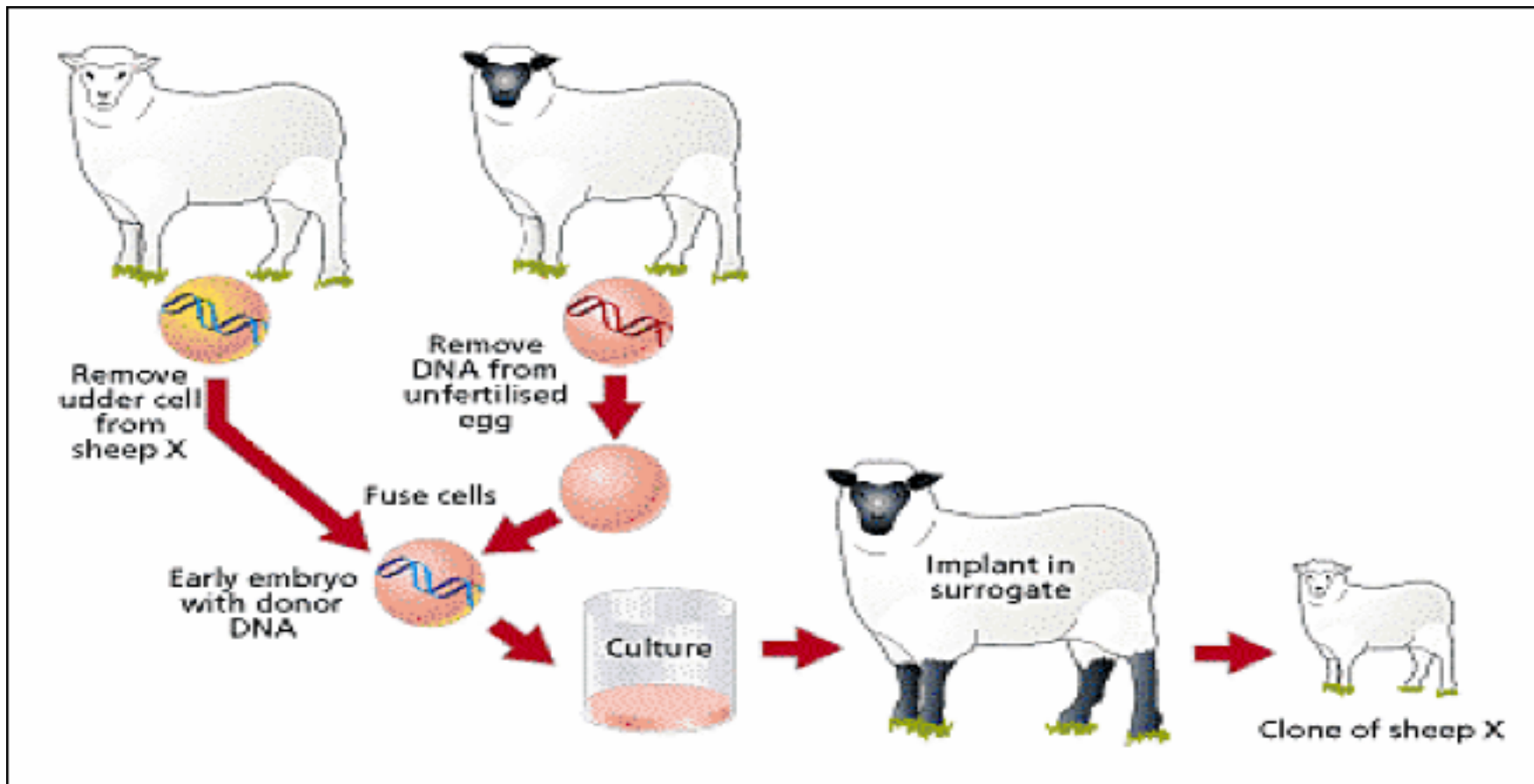
What is Cloning?

Cloning is simply an assisted reproductive technology which allows us to produce offspring that are genetically identical to the single donor animal (identical twins separated in time). **Progeny, which are not animal clones**, will provide most of the food from the cloning process.



Cloning Process

- How Dolly was produced:



FDA Draft Risk Assessment

- Among the most exhaustive food safety studies ever conducted.
- Public comment period closes May 3, 2007. All available at <http://www.fda.gov/cvm/cloning.htm>. *Final RA released by end of 2007?*
- The FDA asks that industry continue to refrain from selling these foods pending conclusion of this process.

Conclusions- Food Consumption

- Edible products from healthy clones of cattle, swine and goats, and their progeny, pose no increased food consumption risk relative to products from conventionally -derived animals.
- ***Meat and milk from clones and their progeny are as safe to eat as corresponding products derived from animals produced using contemporary agricultural practices.***

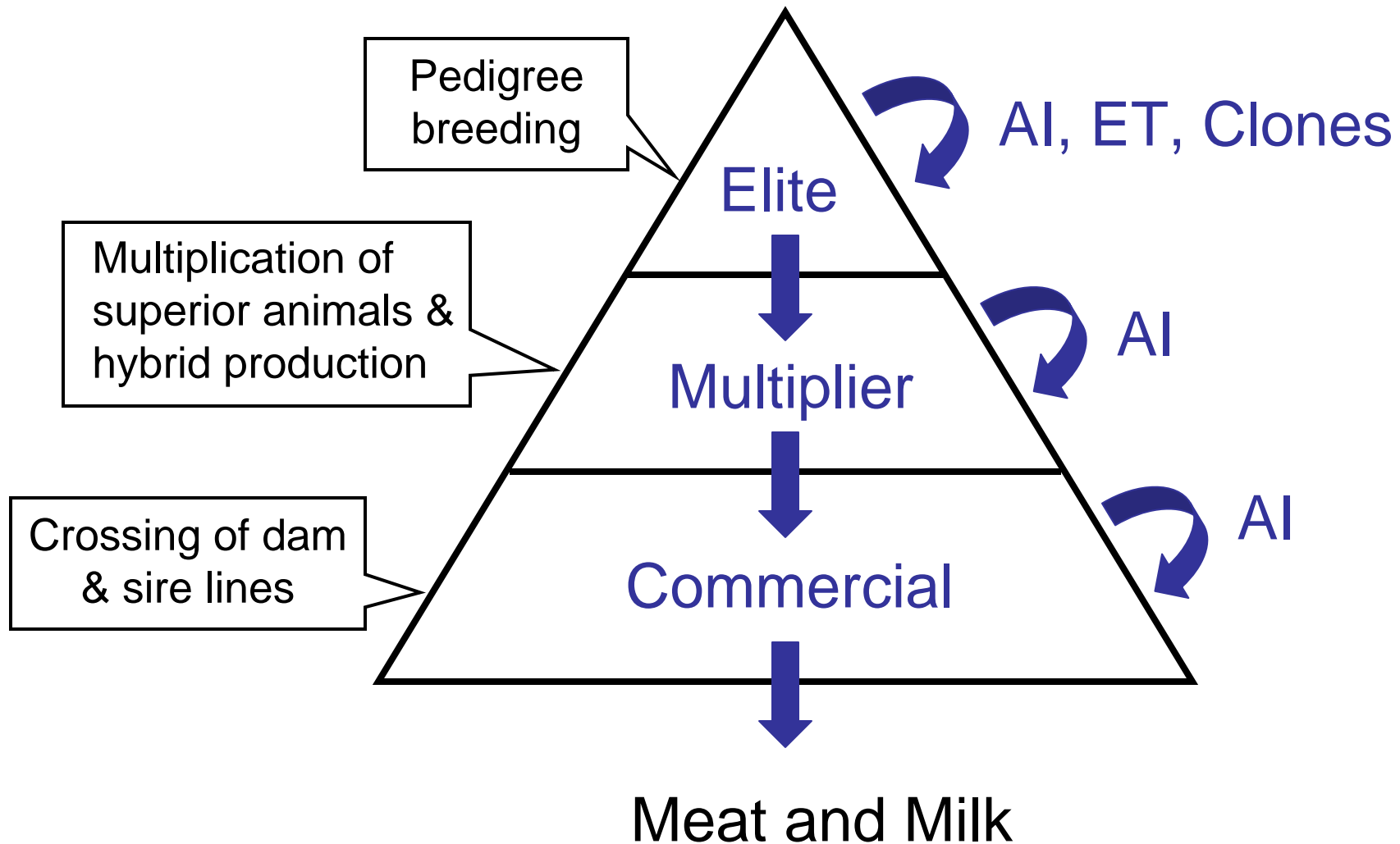
Proposed Risk Management Plan and Guidance for Industry

- FDA to continue to monitor the science
 - Open and informal channels of communications
 - Liaisons with professional, scientific, and veterinary organizations, including
 - development of a public database of health and production data
 - care standards for surrogate dams and clones

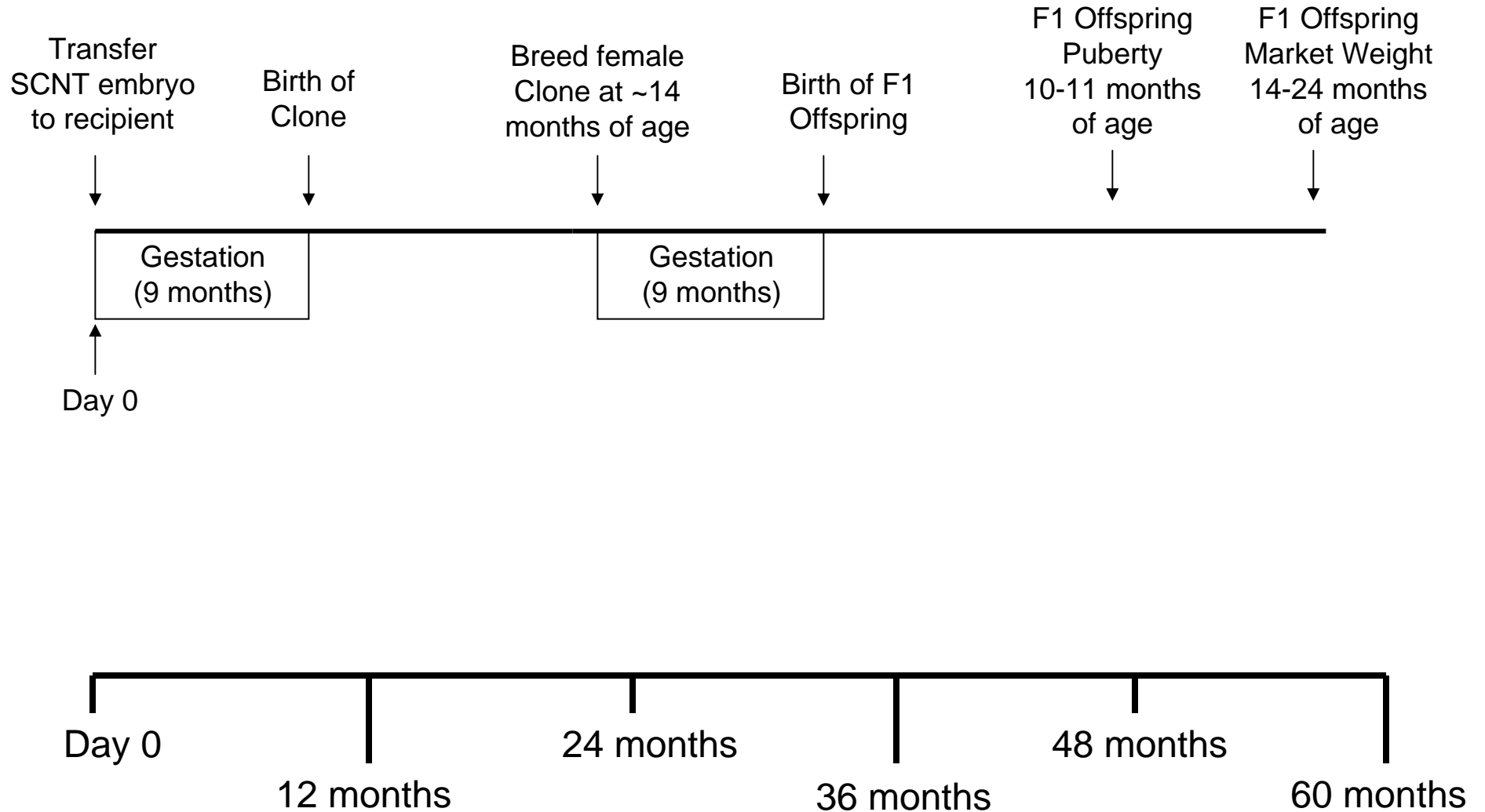
Points to Consider

- Scientific review and conclusions
- Thorough, comprehensive inclusion of world's data
 - Agrees two National Academy of Sciences reports
 - France, Japan, New Zealand have completed risk assessments
 - Canada and Australia have white papers
- Independent analysis of all of the data on cloning
- Transparency
- Reliable information
- Peer-reviewed

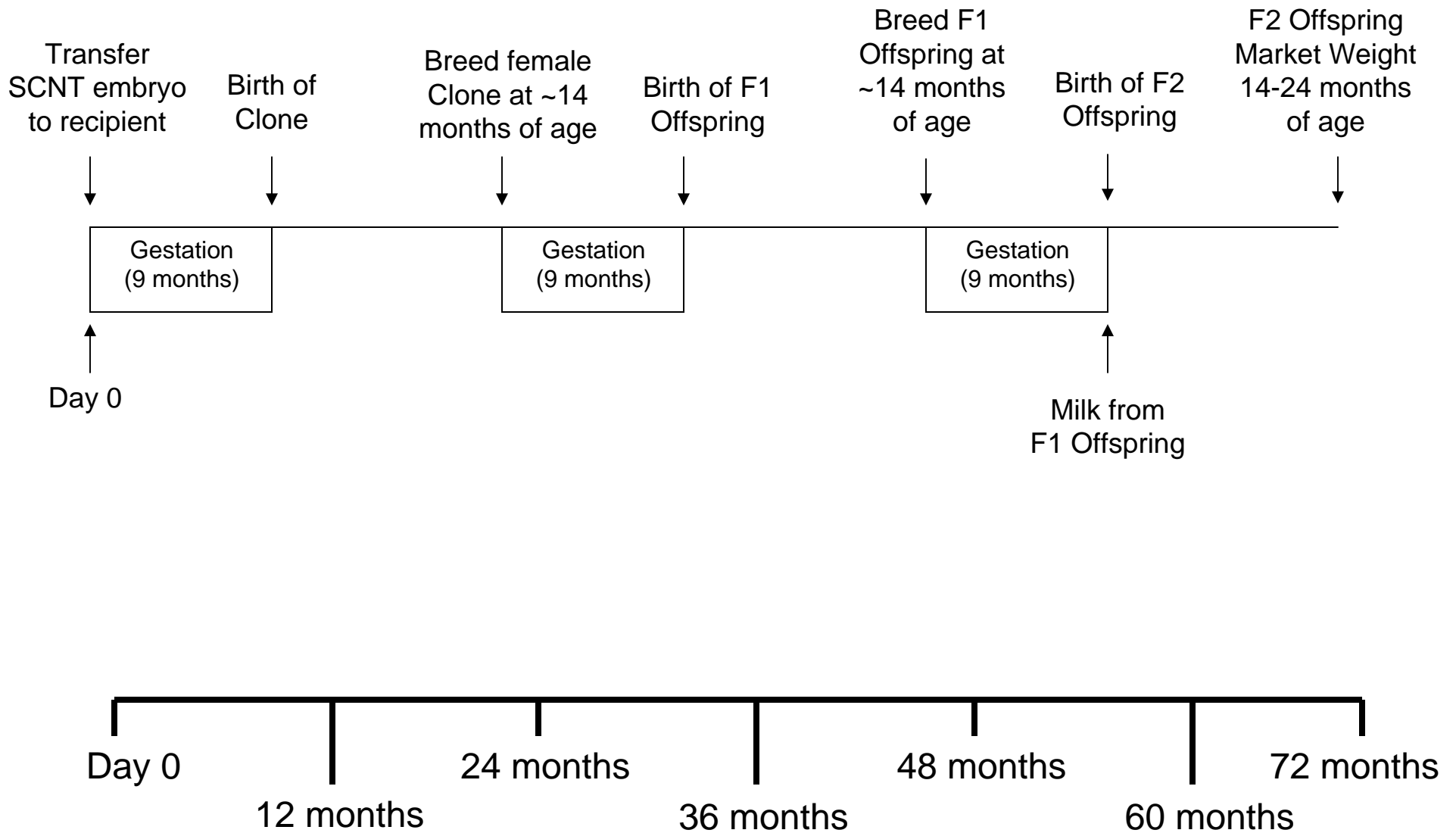
Beef and Dairy Breeding Pyramid



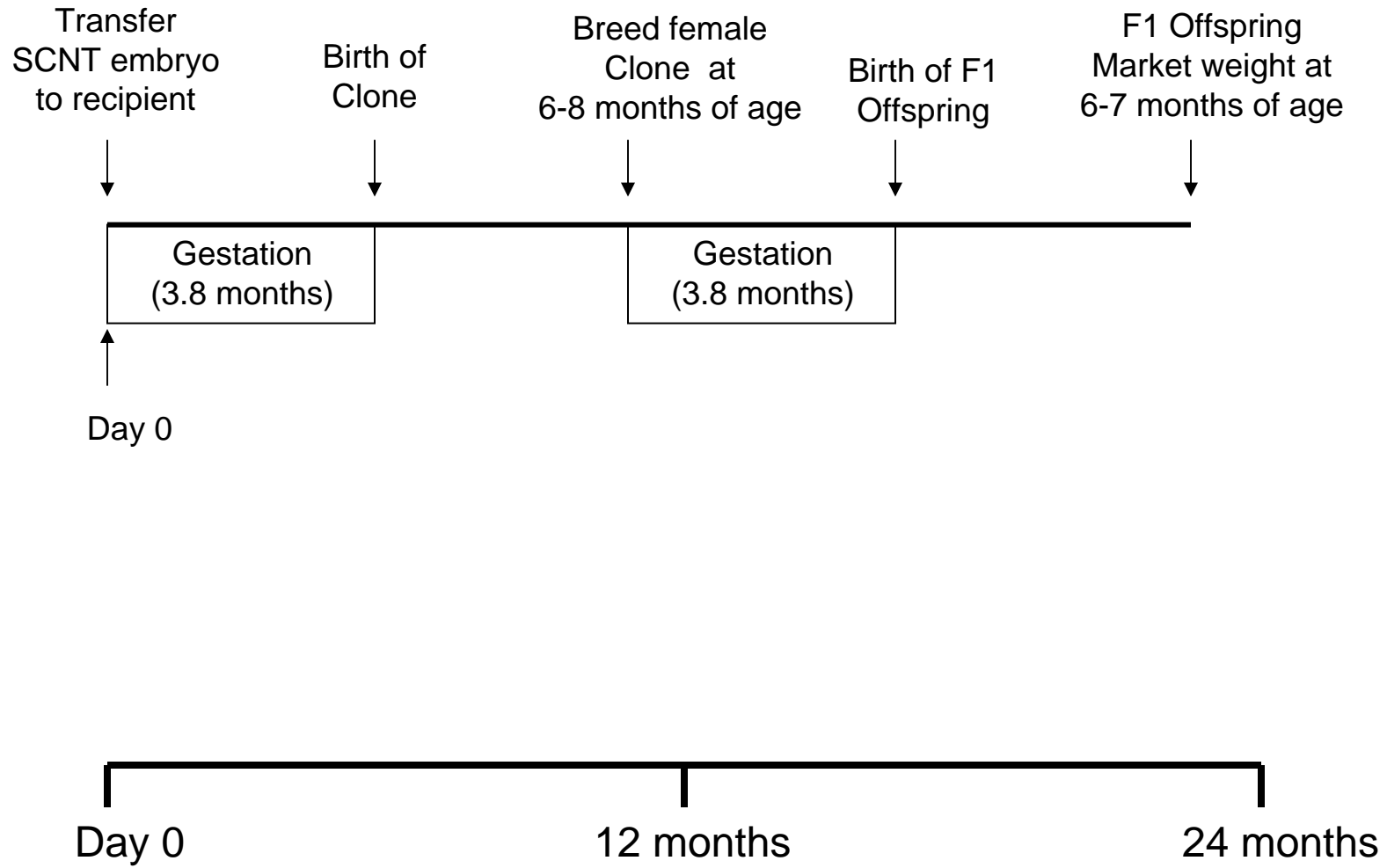
Timeline for Beef Clones & Offspring



Timeline for Dairy Clones & Offspring



Timeline for Swine Clones & Offspring

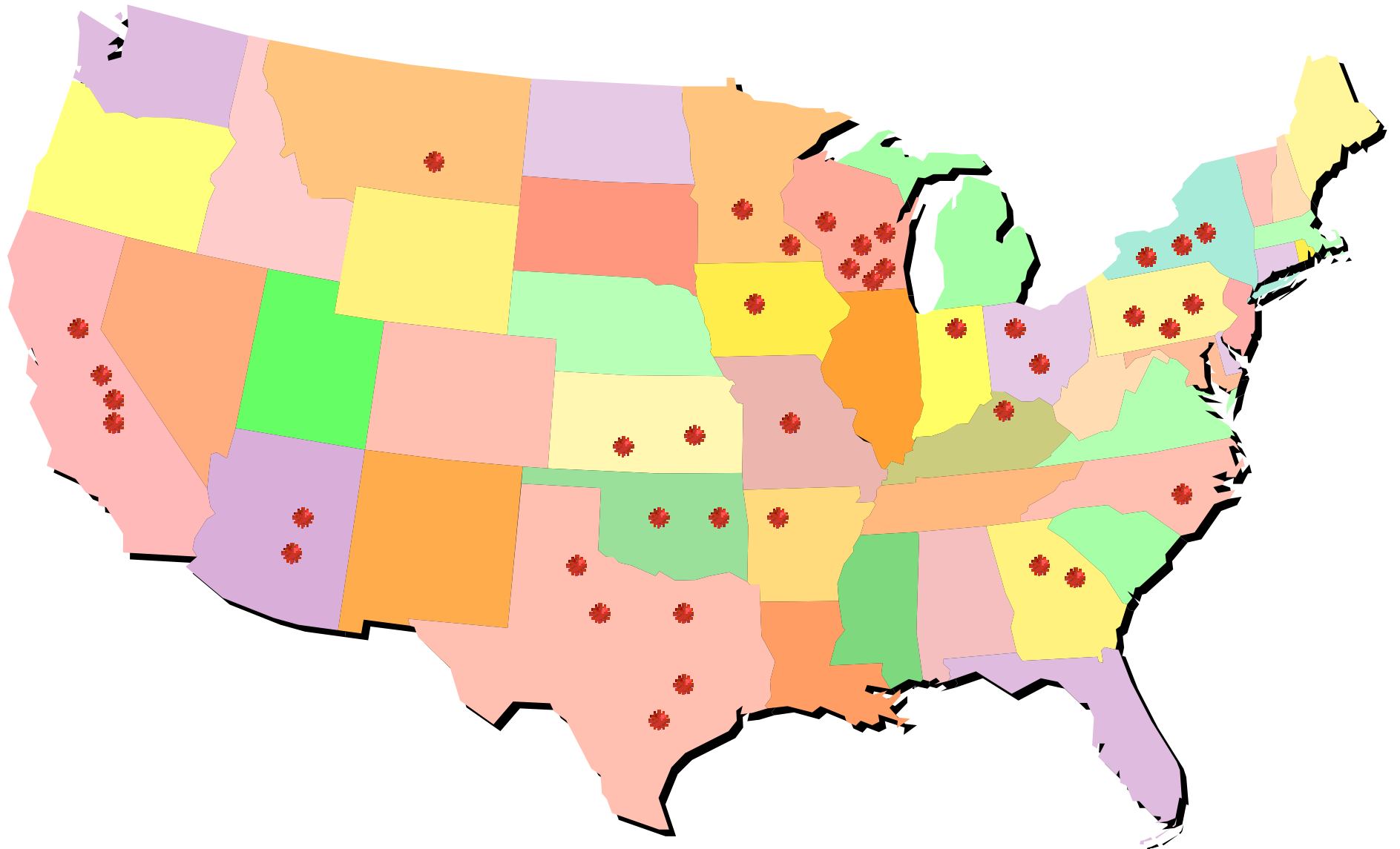


Supply Chain Management

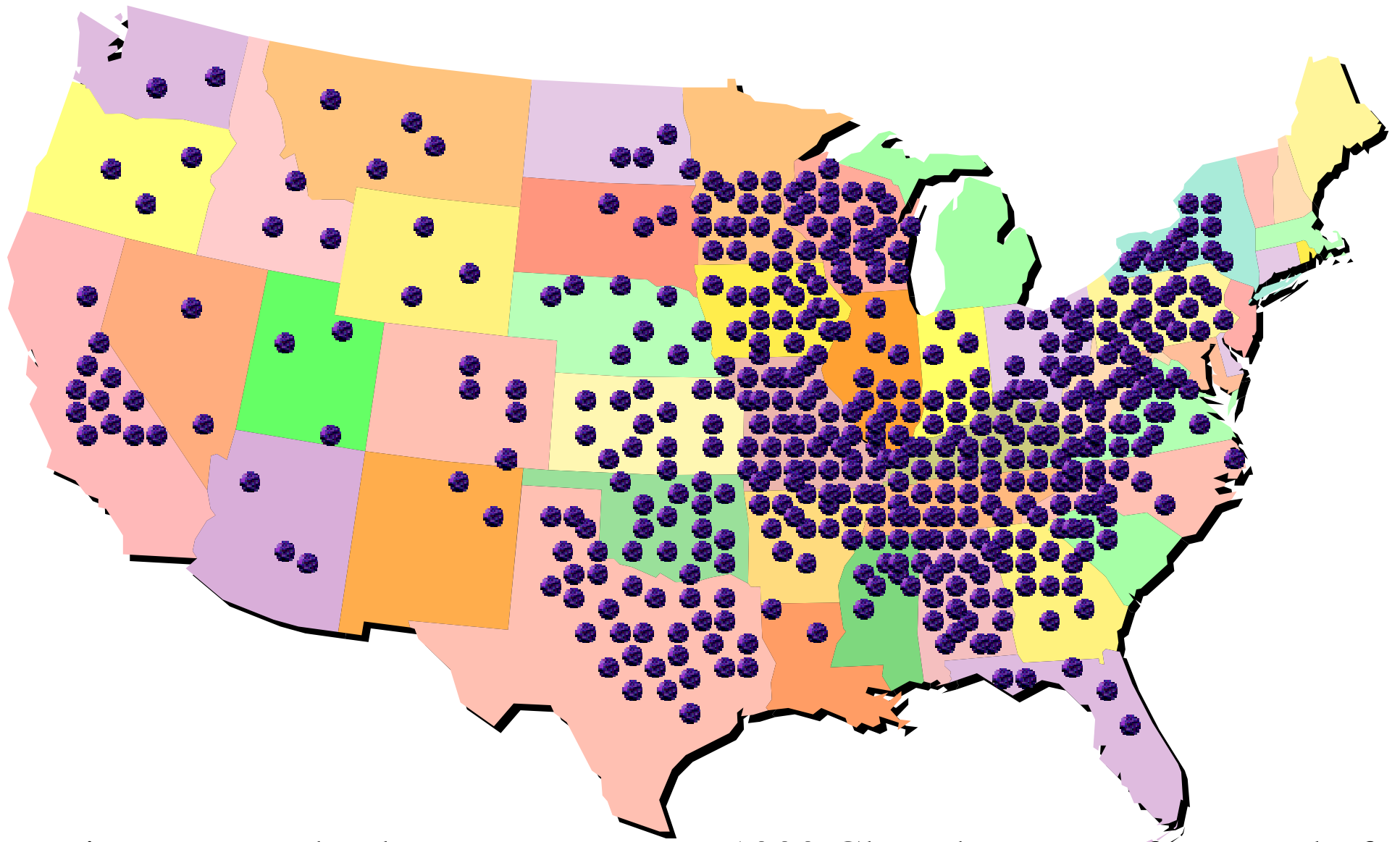
- On-going industry discussions
- Enable meat and milk companies to meet marketing requirements of their customers
 - NOT a safety or health issue
 - Enable labeling by exclusion
 - Compatible with NAIS
 - Cloned animals only
 - Not progeny

For Cloned Animals Only, Not Progeny

- Works for cloned animals
 - No “test” to detect cloned animals
 - Requires industry cooperation
 - Small numbers
- Won't work for progeny of cloned animals
 - No unique physical or genetic characteristics
 - Potential for many progeny
 - Requires NAIS-like program



Estimates - Each Red Dot represents 10 Cloned animals for a total of 400 Cloned adult animals within 3 years



Estimates - Each Blue Dot represents 1000 Cloned Progeny for a total of 390,000 F1 progeny from Cloned parents in the first 4 years.

Processed Based System

- Animal clones are uniquely identified
 - Tags
 - Tattoos
- Registry is a clearing house of information
 - Confidential
 - Focal point of communication for all groups
- Ensure tracking by all stakeholders
 - Technology companies
 - Registry (3rd Party)
 - Producers
 - Processors

Communication and Education

- Extensive media outreach
 - What cloning is
 - What it is not
 - Provide information for consumers, industry
- www.clonesafety.org
 - BIO, ViaGen, other cloning companies
- Processor and retailer meeting
- Appropriate consumer outreach

Why Clone?

- Disseminate best genotypes
 - Reduce genetic lag
 - Utilize broadly and directly
 - Amplify impact of superior animals
- Increase breeding progress
 - Females
 - Overcome death, infertility
 - Increase impact of outliers



Product Opportunities

- Proven Attributes
- Pro-environment
- Consistency



Top: cloned animal 1. Middle: cloned animal 2. Bottom: conventional control animal, matched for age, genetics, breed.

New Possibilities



**“It’s like duplicating Michael Jordan until you have five Michael Jordans on a team” – Donald Brown, Throckmorton, TX
(Fort Worth Star Telegram)**

Photo Credit: Carol Guzy, The Washington Post



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Questions?

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