

Cloning: Moving Forward Together

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(23 minutes)

Buenos dias (tardes).

Good morning (afternoon).

I am honored to join you today
as you explore options
for policies for Argentina
on cloning.

In the U.S., over the past year,
we have been working through
some of the same issues
you're facing here in Argentina.

We certainly don't have all the answers.

Our own policies are still unfolding and being refined.

So I am here both to share some of our experiences
as well as learn from you
about other approaches, other possibilities.

I appreciate the opportunity to be part of this forum to do that.

First, let me say
that we have experienced excellent cooperation
between the U.S. and Argentina
on biotechnology issues.

We would like to work equally well on cloning.

One of our goals in the U.S. is to increase dialogue
among our trading partners on cloning.

We have had formal and informal discussions with trading partners around the world at both the scientific and trade level.

And we would truly welcome broader, multilateral discussions on this issue.

Agricultural producers and consumers from all nations could benefit from a coordinated approach as we move ahead.

Cloning is a new technology that is not fully commercialized due to the uncertainty of acceptance in the marketplace.

Successfully moving from the laboratory to the marketplace requires positive contributions to the dialogue about the best way to go forward from all countries and companies involved in this advanced approach.

Safety of Products from Clones

Let me first tell you a little bit about who I am, and how I got involved in cloning earlier this year.

First and foremost, I'm a third generation rancher and farmer from north-central South Dakota, in the United States.

I own a diversified grain and cattle operation there.

At the U.S. Department of Agriculture,
I serve as the Under Secretary
for Marketing and Regulatory Affairs.

So questions about regulations and marketing agricultural products—
both in the U.S. and for export—
cross my desk.

And that's precisely what happened last January
when the U.S. Food and Drug Administration
completed its risk assessment
and declared that animal clones of cattle, swine, and goats and their products
are safe to eat.

The issue for us in the agricultural community in the U.S.
is no longer safety.

Our Food and Drug Administration completed
a peer-reviewed assessment of more than 600 studies
before releasing its finding
that food from clones is safe.

Our USDA scientists also looked at the studies,
and they agreed.

In addition, as you know, the European Food Safety Authority has come to similar conclusions.

We are confident—and I am personally confident—that food from these animals is safe to eat.

In fact, it is no different than food from conventionally bred animals.

However, around the globe there are questions of consumer acceptance.

And our commitment is to transparency.

We want to retain the trust of our customers.

We want them to know that the food they purchase is wholesome and nutritious.

And we want them to be clear about exactly what they are eating.

So, our challenge is to find ways to share information about cloning to facilitate wise, informed policies regarding the technology.

We must help our customers understand what cloning is; why it is safe; and what benefits it offers them as well as agricultural producers.

We want them to recognize that food from clones are not just okay to eat,

they may even be better products
because they came from superior animals
and their offspring, or because the animals may be more
healthy because of their inherent traits.

What is Cloning?

First, I think, we need to explain cloning carefully.

It sounds like biotechnology, but it's not.

This has been a key differentiation for our policy approach in the U.S.

As you know, biotechnology involves genetic modification—
fundamentally altering organisms.

Cloning is simply advanced reproductive technology.

It produces twins of superior animals,
not new and different animals.

However, the average citizen may not make this distinction.

So we need to be very clear:
cloning does not mean genetic engineering.

Therefore the regulatory approach, if any, by governments needs to be
different than that for biotechnology.

Cloning is simply the next step
in assisted reproductive technology—
beyond artificial insemination, embryo transfer
and *in vitro* fertilization.

The truth is, we've been cloning plants for hundreds of years,
except that the process is referred to

as “vegetative propagation.”

Researchers have been cloning livestock since 1996.

Recent developments in cloning
and the move toward commercialization
have occurred largely in the private sector
with three companies—

- Cyagra,
- ViaGen and
- Trans Ova Genetics.

As I said, we became involved in cloning at USDA since
last January 15 when the Food and Drug Administration
announced its finding
that meat and milk from cloned animals
is safe and no different
from traditionally bred animals.

Once the safety issues were settled by the scientists and regulators, the
marketing issue came to us.

Voluntary Moratorium

Today, USDA is playing a much larger role
as we seek to facilitate a smooth, seamless transition
as animal clones—or more likely their offspring—
move into the market.

Initially, we requested that producers
continue the voluntary moratorium
we’ve had in the U.S. for several years

on sending clones into the food supply.
At the time we made that request earlier this year,
we estimated this involved about 600 animals,
mostly beef cattle.

So in the U.S., these animals are few in number.

They are used primarily for reproduction purposes,
to disseminate the best genetics, not for food.

However, the moratorium covering offspring
has been lifted in the U.S.

Not everyone in the U.S. is thrilled with this possibility.

This is an important differentiation, from both a scientific and a practical
perspective. It does not make sense to lump offspring and
clones together.

Some folks need to be reassured
that there is no reason for concern.

Others will still want to be sure they have other options.

And we strive to meet the needs of a full range of customers and their
preferences.

In our country, the FDA finding,
which we agree with and support,
is key.

Meat and milk from animal clones and their offspring
are no different from products
from conventionally bred animals.

Scientists can't tell the difference.

And consumers can't tell the difference.

But, as we all know, scientific determinations of safety
don't necessarily ensure customer acceptance.
Consumer uncertainty in some parts of the world remains—
and the market is hesitant in the face of it.

Transition

At USDA, we have developed a transition plan
to help producers move forward
in marketing products from animal clones—
or more likely their progeny.

We have met multiple times with

- technology providers,
- producers,
- processors,
- distributors,
- retailers,
- consumer groups,
- the organic community,
- and trading partners, producers and suppliers.

We're continuing to emphasize the FDA's finding on safety and to explain how cloning works and the potential benefits of this technology.

We've also been working with technology providers—the cloning companies—as they implement a supply chain management system—more about that in a minute.

National Organic Program

At the same time, we remain committed to giving customers options for the food they purchase.

One of the ways we do that is through market-claim programs administered by USDA.

These programs verify

farmers' and ranchers' production practices,
in line with consumer requests.

One such program is our National Organic Program.

And the National Organic Program excludes cloning
for products from livestock represented as "organic."

This provides consumers a market alternative if they have personal concerns
regarding cloning technology.

This provides our preferred means of addressing personal consumer choices
without having to walk down a path of exclusionary labeling on
the vast majority of foods.

Industry's Role

As I mentioned, as we move forward
in the market transition for animal clones,
we're finding the role of the technology companies
to be crucial.

And the critical tool these companies are using in the U.S.
is the supply chain management system.

Eventually, over time
and with a strong education and outreach effort,
we believe most consumers
will come to understand both the safety
and the value
of products from animal clones.

However, during this time of transition,
this voluntary approach
 established by the technology providers
 is another way to provide options
 for those who want to be assured
 that they can purchase food
 that comes only from conventionally bred animals.

The supply chain management system,
developed and operated
 by two of the three cloning technology providers,
 tracks cattle and hog clones
 produced by these companies for their clients
 from birth to harvest or death.

It is an effort to enable producers and purchasers
to substantiate market claims that meat or milk
 does NOT come from clones,
 by keeping close tabs on the clones
 the companies have produced.

Again, I want to emphasize,
the supply chain management system,
 which is run by the cloning companies,
 tracks only clones.

Offspring of clones in the U.S.
are not covered by the marketing moratorium,
 and they're not tracked.

Their meat and milk can directly enter the U.S. food system just like the milk and meat of traditionally bred animals - because they are traditionally bred animals.

Let me explain briefly how the supply chain management system developed by these two companies works.

Client Education

It begins with client education. Agricultural producers who request cloning services learn that they will need to identify and track their clones as well as properly dispose of them.

This is part of the agreement they sign when they arrange for cloning.

The agreement also includes a monetary deposit and refund mechanism for reporting the final disposition of the animal to the cloning company.

Technology providers supply a certificate for each animal clone that passes with animal should it be sold or transferred to someone other than the original owner.

The cloning companies are also contacting past clients regarding the supply chain management system

to encourage them to participate in the clone registry—
at no cost.

In the case of dairy animals,
the owners are encouraged to communicate
with their milk marketer or processor
to determine whether the processor will accept milk
from a lactating clone.

(We have a system of dairy cooperatives in the U.S.
where much of our milk is combined and marketed.)

Dairy owners are expected to work with their coop
or directly with processors.

If processors do not accept milk from clones,
dairy owners should withhold the milk
from the market supply
and consume it themselves,
feed it on-farm to calves and other animals
or use other methods of on-farm disposal.

Animal Identification and Registry

As each clone is produced,
the cloning company will individually identify the animal
with a Radio Frequency Identification ear tag
and enter that information into a registry.

(This is consistent with the U.S.
National Animal Identification System.)

Then livestock auction markets, packers and processors,
dairy cooperatives and milk processors
can access that clone registry
to determine if an animal is a clone.

So, if the processor is marketing its products
as NOT from clones,
this registry is a checkpoint to verify that claim.

Marketing Incentive

To encourage producers to keep the clone registry up-to-date,
the supply chain management system
offers a rebate to livestock owners
for properly marketing or disposing of animals.

It gives three options:

1. If the animal dies or is euthanized, the farmer or rancher obtains a signed statement from the veterinarian stating that the animal has died, preferably stating the cause of death. This statement goes to the technology provider along with information on the disposition of the animal—burial, composting, incineration or rendering.
2. If the animal is used for personal consumption, producers must supply the cloning company with a signed statement from a processor that the animal was received and processed for the consumption of the owner.
3. If agricultural producers identify a marketing channel that will accept clones, they can use this option. They just need to submit to the cloning company a signed statement from the packer or processor that the plant has received the animal.

Under this system, once the farmer or rancher
verifies the disposition of the clones,
the technology provider
returns the incentive deposit.

We believe this supply chain management system provides transparency that will help increase ultimate acceptance of clones in the food system of the U.S.

It offers useful options for producers and maintains choice for customers.

Conclusion

In summary, cloning offers many exciting possibilities for improving quality
and increasing production of livestock,
benefiting both agricultural producers and consumers.

However, we recognize that it will take time for our customers to fully acknowledge
the value and safety
of this new assisted reproductive technology and for acceptance
to become widespread.

During this time of transition,
it is important for us to work together,
across international borders,
to educate consumers
and to be open about other options
for those who want to purchase meat and milk
only from conventionally bred animals.
The technology companies themselves have a vital role to play,
and we need to work closely with them
as we move forward.

I appreciate the opportunity to join you this morning,
and I look forward to learning more
about approaches to cloning technology
in Argentina.