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really look at question one, on just it's own merits that a risk assessment has identified the hazards. And characterized the risks.

And compared to some of the other ART's, that were mentioned today and even were developed prior to that, we have already gone off a lot further with this issue and this technology than what we did with those. And so I think it is a good first step. And I realize there are tons of data to come yet. So I think the answer to number one is yes.

Okay. We will move on to question two.

"Based on what we have presented, has the risk assessment adequately identified the hazards and characterized the risks relating to food consumption?"

And we will start again with Dr. Craigmill.

DR. CRAIGMILL: Just briefly. I think the answer is yes. And then I will fill in why. Again, it's very difficult to do an actual risk assessment on this other than a qualitative look at the possible hazards that might exist. And when I talk about a hazard, again, it's a possibility, it's not a probability.

I think if you looked at this scientifically, there is really little reason to expect that there could be a problem from this. Seeing as how you are taking a nucleus from one cow cell, or sheep cell, and putting it into the

cell body of another cow or sheep cell and you are just transferring genetic information, it's all epigenetic.

There is nothing new added there which would add any new toxins or potential proteins which would add new allergenicity problems.

In terms of the expression of proteins, that is a difficult question to answer. That is certainly something that could likely occur in the clone. It seems very unlikely in their offspring.

So in brief, I would just say that I think they have done an excellent job on this and support the recommendations that have come out.

DR. WADDELL: Mr. Wood.

MR. WOOD: In response to this question, in one of the first pieces that came out anticipating this event, somebody from the industry said, I think it was Mayor Times, quote "Is there a strong and impressive body of scientific evidence that will convince consumers that this food is safe?"

And that is a general question. Not a specific question that is before VMAC, but to that, I think the answer is still no. And looking more specifically at the second question and looking at what has been provided, there still is insufficient data in our view, my view, that regarding the composition of cloned bovine meat or milk, although a great

stride has been taken in the direction regarding bovine meat with the Cyagra data.

And it would be great to validate that with other data. I said in a break to somebody, I said, how many studies does it take to say that we now have something this scientifically valid? And I am sure that is a question that is open for debate.

But there is still insufficient data as far as I am concerned. Because not enough of the data on milk from clones, as was identified in the risk analysis in its executive summary. There is not enough data on the safety of pork, swine meat. There is no data on sheep clones.

So, that to me says that there still is not sufficient data upon which to take this step. And to respond to one of my colleagues here, it's not as if there never will be enough data on this question. I think that we are moving in the right direction.

And you have been encouraged by others to look at pathogen load. I think that is an important focus as well. And you asked whether or not the composition of food should be further examined. Then I think you ought to continue that focus as was called for by the National Academy of Science report.

So I don't believe that meat or milk should be approved from clones at this time as a result of this risk

assessment. Nor should the meat or milk of progeny until there is further review.

Also, the issue of labeling has been raised by one of the comments. And that certainly is a risk management step that, if there was approval, would allow consumer choice.

DR. WADDELL: Dr. Pappaioanou.

DR. PAPPATIOANOU: As before, I really do commend the group in terms of the risk assessment that was done and very much appreciate the constraints that they faced on the limited data. You can only do so much with what you have. And it was a very fair look.

However, again, some of the issues in terms of lack of information on several of the species. The desire to lurch into the expression of proteins and potential outcomes from that, or possible impacts on the intestinal flora in terms of overall as animals would go into the food supply, which is really where the rubber would meet the road, that is definitely deserving of more investigation.

Many of the assumptions and the biological hypotheses put forward are very believable. They make all kinds of sense. But, as I kept asking myself as I was actually looking at the data that was being presented, I didn't see where the data began to lead me to a confident answer.

And I am not one, I work in public health. We are used to making lots of decisions based on incomplete data. But it's easy to say well we will never have enough data to basically, with 100 percent confidence, be able to say that this is safe.

And that is true. There is nothing that is 100 percent. But one can generate data, studies that give more confidence and that does relate to the design of the study, the quality of the study, how the studies were conducted. How many animals were in the study.

And one can then come to a conclusion that if you come up with a quote, unquote "negative finding" of there is no difference, that you are at least 80/85/90 percent confident that you can believe the negative results.

So, again, my overall conclusion is that, no. Based on the posture of data, clearly not the model that was set forth or the process. But a good beginning as others have said, with hopefully the research agenda that comes out of this that can begin to be addressed to fill those gaps and to answer the question affirmatively. Thanks.

DR. WADDELL: Dr. Wages.

DR. WAGES: I am a little more comfortable with this question than I was with the first. Even though there may be some data lacking in both of these questions.

When I look at potential for food safety, there was

a variety of blood chemistries and blood values that were given in comparing the cloned versus uncloned animals. Or the comparators, if you will. Up into the 99 percent comparable to the comparative counterparts.

And I think if you look at, especially in the cattle data, if you will, I think if you look at, again, trends, I think with the numbers that we at least observed in cattle, I think if there was something that would come up from a nitrogen retention, some type of physiological problem that has the potential of affecting quality of meat or milk. I think it would have come out.

One think I would have like to have seen in the milk studies at least is butter fat content, even though that varies. Depending on diet it does give us a sense of the electrolyte or at least the acid based balance of the dairy cow. And if there are any changes there.

I am reasonably comfortable that the food consumption portion of the cloning issue, I think we have identified the potential hazards and the answer to that question would be yes.

I think one thing that would solidify even things more for me would be I think there is a lot of universities that would just be tickled to death to get these cloned progeny, food science departments, and pick these guys apart. And actually provide some of that final data in carcass

quality and even analysis of meat or milk.

And that might be something that could be very, very useful to put more of an end to some of the questions or speculations on the quality of meat. So, yes.

DR. WADDELL: Dr. Parkhurst.

DR. PARKHURST: Thank you. Again, I would have to say I don't know. I don't see that there really is enough data. But I do think that in your presentation you have presented a well constructed design as to how you could get more data.

And, in fact, I thought that that was some of the things that you were asking for. You said in general there is just so much variation in the whole population that we consider normal. How can we go about and get something on cloning animals that would be any different.

And one thing I would suggest is to look at the analysis of variants components. That is a study in which you would be able to see if they came from the same population or if there was something different along those lines. That is the biggest thing I have to say right now.

DR. WADDELL: Dr. Jack.

DR. JACK: Thank you. Again, I think I am going to fall in line with most of my colleagues. I believe that a lot of the -- I tend to fill that the evidence or my sense of what is going on with the risk assessment for food, I feel a

little bit better about that than the risk to the animal health.

So that is if these animals are living to maturity or getting to a point where they enter the food chain that a cow is a cow is a cow. That you are taking the nucleus of a normal healthy animal and sticking in another cell.

I guess my concern though is that we don't have much data on the progeny. And if those are the animals that are really going to enter the food chain, we really need to take a look at those.

And, again, my intellectually, it would seem a fair assumption that the progeny shouldn't be changed at all. But we don't have any evidence to show that one way or the other. We just don't know.

So, you know, based on the assumption that the offspring are like the parent, we are in good shape. But it's still an assumption.

DR. WADDELL: Dr. Nolan.

DR. NOLAN: Thank you. Well, based on the data presented and on the rationale assumptions on which their interpretation were based, I don't think there is any reason to assume that the milk or the meat from these clones or their progeny will be unsafe.

But I do feel uncomfortable, often and unqualified, yes. Again, like many of my colleagues here, I think it

would be good to see more data. And I would especially like to see data on the progeny since they are the ones likely to enter the food supply.

I think it's an interest, something we may want to see addressed is the microbial flora of the clones and their progeny. Thanks.

DR. WADDELL: Dr. McGlone.

DR. McGLONE: On this question, I think based on composition data, that the answer to the question is yes. That the cloned animal is functionally similar in composition. But I think, qualifying my yes, that in this case the consumer wants more.

The public wants more. And in fact in this case science at the moment cannot deliver that. The consumer has the fear of the unknown of things that might be in the meat that are not yet described, perhaps.

And the only way to confront that from a science point of view and move on is to actually do the studies where when products are fed. And not only where they are fed to normal animals, but also to animals at risk and to young animals, neonatal animals, because people have a fear of what goes in the mouth of their children. And any other member of the population that might be at risk, perhaps people that are sick or elderly.

So to go an extra step in this case, I believe, is

required. More so than if it were normal food stuff that doesn't have any consumer hot button attached to it. So in this case I think we need some data that go one step beyond what would normally be required under these circumstances in order to develop the confidence. So that we don't lose the confidence that the consumer has in our food supply. And we can in fact culture it and nurture it and help the animal industry satisfy this consumer desire for animal products.

DR. WADDELL: Dr. Kochevar.

DR. KOCHEVAR: I think that one of the slides that was shown pointed out that until this fall no, zero peer review publications relevant to SCNT on --- were available. And then the Walsh study was then looked in some detail.

I think those studies are the direct evidence that you need to be able to answer yes to number two. I think you have abundant indirect evidence. And that evidence is, again, back to the bovine data set.

You had such high percentages of sort of concordance between the clones and the normal animals. 90 percent, 99 percent in that. That the reasonable expectation is that these animals have those parameters that similar and obviously function normally in terms of being able to emulate and reproduce and various things. Then it is a reasonable assumption to say that they are not going to be a danger in terms of the food supply. That is all indirect

evidence, though.

And so truly if you had to have direct evidence, you really would have to do some of the studies that you mentioned on your wish list. I don't think those should. I mean those kind of studies seems to me would not take an overwhelmingly long period of time to do. Those are basically meat composition and milk.

They are confounded by the variability in normal milk and the meat. But, except for that caveat than those studies seemingly should be fairly direct. And I do think that data would be very useful to support the argument.

DR. WADDELL: Again, taking the question in its face value, and what we were presented earlier today, I would have to answer yes to question number two also. And echo many of the comments from the rest of the Committee as far as the data. But, I think that it is coming. The thing is coming. But we, you know, have to make the first step somewhere along the line.

Are there any other comments from the Committee?

(No response.)

DR. WADDELL: Hearing none, that concludes our deliberations.

MS. SINDELAR: Dr. Matheson will take over for the concluding remarks and next steps.