Modernizing the Regulatory System for Biotechnology Products

Third Public Meeting Transcript – Part Two

University of California, Davis

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How to Read this Transcript

The text below each respective time stamp corresponds directly to the time of the recording file, which can be accessed at this URL: https://youtu.be/3dcDy4wsBaQ.

Public Comment Period Introduction: Dr. Mike Firko, USDA APHIS Deputy Administrator, Biotechnology Regulatory Services

1
00:00:34,852 --> 00:00:36,313
>> Dr. Firko >> Hello.

2
00:00:36,313 --> 00:00:37,440
It's 12:50.

3
00:00:37,440 --> 00:00:40,469
It's time to start with the public comments.

4
00:00:41,830 --> 00:00:43,401
So, the way that we're gonna do this.

5
00:00:47,468 --> 00:00:49,279
The way that we're gonna do this,

6
00:00:49,279 --> 00:00:53,100
we have the list of folks who have registered to speak so far.

7
00:00:53,100 --> 00:00:59,550
I think the length of that list is about 36, 37, something like that.

8
00:00:59,550 --> 00:01:01,830
They are all listed alphabetically.

9
00:01:01,830 --> 00:01:02,486
Colleen, where are you?

10
00:01:10,388 --> 00:01:14,431
So Colleen will be standing right over here by this tripod and

11
00:01:14,431 --> 00:01:19,519
she will have the alphabetized list of people who have registered to speak.

12
00:01:20,600 --> 00:01:24,850
And if you're wondering when it will be your turn, check with,

13
00:01:24,850 --> 00:01:27,050
there's Coleen, she just came in.

14
00:01:27,050 --> 00:01:29,154
Come on up here and let me read the first [INAUDIBLE]

15
00:01:35,958 --> 00:01:40,275
So the first speaker is Amir Bibi, and then Austin Che.

16
00:01:41,440 --> 00:01:44,280
And then third, Cecilia Chi-Ham,

17
00:01:44,280 --> 00:01:48,760
and Coleen will be standing right here, or right over there.

18
00:01:48,760 --> 00:01:53,790
And what I would ask you to do is if you're next,

19
00:01:53,790 --> 00:01:58,520
or maybe two people later, kinda be ready come up cuz we're gonna try to

20
00:01:58,520 --> 00:02:03,630
do this expeditiously so everyone has a chance to make their statement.

21
00:02:03,630 --> 00:02:05,070
There were about four or

22
00:02:05,070 --> 00:02:10,220
five people who registered this morning on site to make a public comment.

23
00:02:10,220 --> 00:02:15,160
We'll deal with that group after we've gone through all the pre-registered folks.

24
00:02:15,160 --> 00:02:15,910
And it was four?

25
00:02:17,290 --> 00:02:19,370
One, two, three, yeah, four people.

26
00:02:19,370 --> 00:02:27,829
And we'll do those four after we finish the 41 who are registered.

27
00:02:27,829 --> 00:02:28,329
So, Amir Bibi.

28
00:02:45,178 --> 00:02:49,558
So, Amir Bibi, are you here?

29
00:02:49,558 --> 00:02:50,170
Okay.

30
00:02:50,170 --> 00:02:51,065
Maybe he'll come back.

Public Comment #1: Austin Che

31
00:02:51,065 --> 00:02:53,403
Austin Che.

32
00:02:53,403 --> 00:02:57,118
Thank you.

33
00:02:57,118 --> 00:03:00,576
>> Hi my name is Austin Che, I'm a cofounder of Ginkgo Bioworks,

34
00:03:00,576 --> 00:03:03,930
an organism engineering company located in Boston.

35
00:03:03,930 --> 00:03:08,420
I and three of my colleagues from MIT Department of Biological Engineering

36
00:03:08,420 --> 00:03:11,750
founded a company in 2008 along with Tom Knight,

37
00:03:11,750 --> 00:03:14,070
who is considered the father of synthetic biology.

38
00:03:14,070 --> 00:03:19,430
Today, we're about 65 people, constructing our second generation automated foundry,

39
00:03:19,430 --> 00:03:20,630
which we will launch this summer.

40
00:03:22,120 --> 00:03:26,330
One of the common misconceptions about our industry is that biotech is mostly about

41
00:03:26,330 --> 00:03:27,430
health and medicine.

42
00:03:27,430 --> 00:03:31,130
However, biotech, while, and it's already having major impacts and

43
00:03:31,130 --> 00:03:35,000
manufacturing agriculture, energy and other fields.

44
00:03:35,000 --> 00:03:38,710
At Ginkgo we're using biotechnology to develop solutions to challenges in

45
00:03:38,710 --> 00:03:42,050
many different industries from flavors and fragrances to food and

46
00:03:42,050 --> 00:03:44,400
nutrition, cosmetics and consumer products.

47
00:03:45,630 --> 00:03:48,084
Because biotech will impact a great number of products,

48
00:03:48,084 --> 00:03:52,000
There is rightfully national recognition of its importance and

49
00:03:52,000 --> 00:03:56,090
of the importance of effective regulation that can scale with the industry.

50
00:03:56,090 --> 00:03:59,850
We are committed to creating a better, more sustainable products and

51
00:03:59,850 --> 00:04:02,970
to transparency about our products and processes.

52
00:04:02,970 --> 00:04:05,940
So we therefore, we support strongly the efforts today to

53
00:04:05,940 --> 00:04:08,410
improve the regulatory clarity and transparency.

54
00:04:11,200 --> 00:04:14,715
We want the market to have confidence in our products, but to be clear,

55
00:04:14,715 --> 00:04:19,880
biotechnology is a process that makes products and not the product itself.

56
00:04:19,880 --> 00:04:24,411
The United States has well established regulatory processes that categorizes

57
00:04:24,411 --> 00:04:27,868
products by their use and not by the manufacturing process.

58
00:04:27,868 --> 00:04:31,453
This is not to say that there shouldn't be regulation on environmental worker

59
00:04:31,453 --> 00:04:33,200
safety associated with the process.

60
00:04:33,200 --> 00:04:36,280
But that we must ensure that any new regulatory requirements for

61
00:04:36,280 --> 00:04:40,630
products are data-driven and are focused on ensuring the safety of the product.

62
00:04:40,630 --> 00:04:45,290
Thank you.
>> [APPLAUSE]

63
00:04:45,290 --> 00:04:46,144
>> Dr. Firko >> Thank you, Mr.

64
00:04:46,144 --> 00:04:48,100
Che, he earned an extra minute here.

65
00:04:49,460 --> 00:04:52,548
Next is, unless Amir Bibi is here?

66
00:04:54,941 --> 00:04:58,830
No, okay, so the next commenter is Cecilia Chi-Ham,

67
00:04:58,830 --> 00:05:02,576
after that will be Noelle Crockett, Cockett, sorry.

Public Comment #2: Cecilia Chi-Ham

68
00:05:08,328 --> 00:05:12,235
>> Good afternoon, my name is Cecilia Chi-Ham, I'm representing HM Clause,

69
00:05:12,235 --> 00:05:16,218
a business unit of Limagrain International Cooperative Agricultural Group.

70
00:05:16,218 --> 00:05:20,270
HM Clause specializes in breeding, production, and sales of vegetable seed.

71
00:05:20,270 --> 00:05:23,930
I am here to share an abbreviation commentary of the opportunities and values

72
00:05:23,930 --> 00:05:28,040
we see in the ability to use new plant breeding techniques in vegetable breeding.

73
00:05:28,040 --> 00:05:31,910
Please refer to the complete commentary which I will submit following this meeting

74
00:05:31,910 --> 00:05:33,240
for the records.

75
00:05:33,240 --> 00:05:36,470
Plant breeding has been safely practiced for thousands of years.

76
00:05:36,470 --> 00:05:40,640
Recent technical advances can greatly accelerate the process of plant breeding.

77
00:05:40,640 --> 00:05:43,170
The opportunities provided by these techniques can be

78
00:05:43,170 --> 00:05:47,132
best understood when contrasted with the existing practices of plant breeding.

79
00:05:47,132 --> 00:05:51,540
Plant breeding is a conceptually simple process composed of two main steps.

80
00:05:51,540 --> 00:05:55,670
First step is to generate a population of plants with genetic variation.

81
00:05:55,670 --> 00:05:58,290
The second step is to screen through this population and

82
00:05:58,290 --> 00:06:02,960
select individual plants with a valuable useful combination of traits.

83
00:06:02,960 --> 00:06:07,460
The genetic variation that we need for step one can vary in source and degree.

84
00:06:07,460 --> 00:06:11,440
For example, we can have many millions of genetic sequence changes,

85
00:06:11,440 --> 00:06:16,230
which we could achieve by crossing the plant with this wild type plant species.

86
00:06:16,230 --> 00:06:17,230
We could have hundreds or

87
00:06:17,230 --> 00:06:21,510
thousands of genetic changes by treating the plant with chemical radiation.

88
00:06:21,510 --> 00:06:24,070
In fact, this is how genetic variation is produced in nature,

89
00:06:24,070 --> 00:06:29,450
through solar radiation, and crosses with its relative wild type species.

90
00:06:29,450 --> 00:06:32,070
Regardless of the source or degree of genetic variation,

91
00:06:32,070 --> 00:06:35,110
the critical step in successful plant breeding is the screening and

92
00:06:35,110 --> 00:06:37,520
selection that occurs in the second step.

93
00:06:37,520 --> 00:06:41,650
Before any new variety is released to the market for consumer consumption, it

94
00:06:41,650 --> 00:06:46,370
undergoes multiple years of field testing and trialing in multiple locations.

95
00:06:46,370 --> 00:06:49,150
In which we select for plant with the combination of genetic

96
00:06:49,150 --> 00:06:52,960
variation that result in a novel plant species that is safe for

97
00:06:52,960 --> 00:06:56,330
the farmers to grow and the consumers to eat.

98
00:06:56,330 --> 00:06:59,790
The new plant breeding techniques recently developed can be used to create

99
00:06:59,790 --> 00:07:03,830
even as little as a single genetic sequence change in the plant gnome.

100
00:07:03,830 --> 00:07:05,722
These new techniques are also targeted,

101
00:07:05,722 --> 00:07:10,550
making it possible to recreate in one plant a genetic change known to already

102
00:07:10,550 --> 00:07:15,270
exist in another plant from a crossable or a highly related species.

103
00:07:15,270 --> 00:07:19,560
In this way, plant breeder may improve a plant by bringing only the genetic sequent

104
00:07:19,560 --> 00:07:24,440
changes necessary to introduce a new genetic trait, for example, like disease

105
00:07:24,440 --> 00:07:29,668
resistance, while maintaining the rest of the genetic information intact.

106
00:07:29,668 --> 00:07:33,419
We propose that plant varieties of products developed using these new green

107
00:07:33,419 --> 00:07:36,349
techniques should not be subject to GMO level regulation,

108
00:07:36,349 --> 00:07:38,236
if they meet the following criteria.

109
00:07:38,236 --> 00:07:42,736
When plant varieties could be obtained by cross-breeding, when plant varieties have

110
00:07:42,736 --> 00:07:46,869
been or could be obtained by mutagenesis of crossable or highly related plants,

111
00:07:46,869 --> 00:07:50,537
when no exogenous heritable material is introduced into the progeny.

112
00:07:50,537 --> 00:07:54,965
The continued ability of plant breeders to contribute to the agricultural challenges

113
00:07:54,965 --> 00:07:59,028
will rely on the development of scientific tools necessary to generate genetic

114
00:07:59,028 --> 00:07:59,710
diversity.

115
00:07:59,710 --> 00:08:03,690
As well as the applicable US and international regulatory policies.

116
00:08:03,690 --> 00:08:04,874
Thank you.

Public Comment #3: Noelle Cockett

117
00:08:11,735 --> 00:08:14,159
>> I'm Noelle Cockett, Provost and

118
00:08:14,159 --> 00:08:18,610
Executive Vice President at Utah State University.

119
00:08:18,610 --> 00:08:24,175
At Utah State, we have a large group focused on the identification of genetic

120
00:08:24,175 --> 00:08:31,390
causes and controls of both desirable and undesirable traits in plants and animals.

121
00:08:31,390 --> 00:08:35,980
These traits are the results of somatic mutation in

122
00:08:35,980 --> 00:08:39,080
the DNA of a single animal or plant.

123
00:08:39,080 --> 00:08:44,080
The likelihood of that exact mutation occurring again is close

124
00:08:44,080 --> 00:08:49,370
to zero because of the randomness of that mutation.

125
00:08:49,370 --> 00:08:52,780
The study of these traits includes significant and

126
00:08:52,780 --> 00:08:55,880
long term analysis of the effects and

127
00:08:55,880 --> 00:09:02,360
outcomes in the animals and plants in which the mutation has arisen.

128
00:09:02,360 --> 00:09:07,590
For example, there's a trait in sheep call callipyge that

129
00:09:07,590 --> 00:09:14,630
increases the production of lean meat by 30% without any additional input.

130
00:09:14,630 --> 00:09:22,830
The mutation arose in a male sheep born in 1980 in a commercial flock in
Oklahoma and

131
00:09:22,830 --> 00:09:28,230
has been extensively studied by several groups over the last 30 years.

132
00:09:28,230 --> 00:09:33,120
It has not been widely used in the US because of a tenderness issue,

133
00:09:33,120 --> 00:09:38,920
despite the dramatic improvement in lean meat production per animal.

134
00:09:38,920 --> 00:09:45,359
At USU, we would like to use the genetic editing technique to alter or

135
00:09:45,359 --> 00:09:50,023
edit the DNA to include the callipyge mutation and

136
00:09:50,023 --> 00:09:54,908
will result in an animal that has no other residual or

137
00:09:54,908 --> 00:09:57,925
associated changes in its DNA.

138
00:09:57,925 --> 00:10:03,001
USU is interested in transferring the callipyge into sheeps and

139
00:10:03,001 --> 00:10:08,171
goats in third world countries where tenderness is not an issue,

140
00:10:08,171 --> 00:10:11,370
but the production of protein is.

141
00:10:11,370 --> 00:10:16,490
As one of the chief administrators at USU, I'm deeply concerned with pursuing

142
00:10:16,490 --> 00:10:21,670
this genetic edited project, given the high cost, long timeline,

143
00:10:21,670 --> 00:10:28,480
and uncertainty of approval of genetically edited products that go in the food chain.

144
00:10:28,480 --> 00:10:32,670
We would be using a technology that replicates a naturally

145
00:10:32,670 --> 00:10:36,770
occurring mutation that has been extensively studied.

146
00:10:36,770 --> 00:10:42,280
Therefore, I respectfully encourage the agencies to develop a framework for

147
00:10:42,280 --> 00:10:47,290
establishing risk of these products that incorporate the previous

148
00:10:47,290 --> 00:10:51,990
work on these naturally occurring mutations.

149
00:10:51,990 --> 00:10:56,232
Also, I believe, as the previous presenter spoke on,

150
00:10:56,232 --> 00:11:01,290
that there should not be increased regulation of these animals and

151
00:11:01,290 --> 00:11:05,985
plants simply because of its production by genetic editing,

152
00:11:05,985 --> 00:11:09,710
which results in no other alteration of the DNA.

153
00:11:09,710 --> 00:11:12,137
>> Thank you.

Public Comment #4: Jessica Denning

154
00:11:17,094 --> 00:11:17,930
Jessica?

155
00:11:20,914 --> 00:11:23,259
Is Jessica Denning here?

156
00:11:26,313 --> 00:11:27,160
You are, this is you?

157
00:11:27,160 --> 00:11:28,252
Good.

158
00:11:39,157 --> 00:11:41,026
>> My gosh, that light goes right into my eyes.

159
00:11:41,026 --> 00:11:46,520
So [COUGH] I'd just like to say on behalf of Moms Across America

160
00:11:46,520 --> 00:11:51,210
that we are seeing our children's health issues, allergies, and immune

161
00:11:52,820 --> 00:11:58,020
problems and autism improve when we avoid GMOs and related pesticides.

162
00:11:58,020 --> 00:12:03,520
Most of the commercial jam foods are pesticide delivery systems,

163
00:12:03,520 --> 00:12:09,570
either containing a BT toxin or designed to be doused with an herbicide.

164
00:12:09,570 --> 00:12:12,400
And we have 500,000 more pounds of glyphosate

165
00:12:12,400 --> 00:12:14,230
since 2000 when we started this.

166
00:12:14,230 --> 00:12:18,670
So there has been an increase although industry figures would say otherwise.

167
00:12:18,670 --> 00:12:23,335
We're seeing it, I measured it in my water in Carmichael and Elk Grove, glyphosate,

168
00:12:23,335 --> 00:12:26,540
[COUGH] finding it in our rain in the midwest.

169
00:12:27,560 --> 00:12:30,640
We need GMO labels to be able to care for our children.

170
00:12:30,640 --> 00:12:34,060
We expect safe, healthy food and honest labelling.

171
00:12:34,060 --> 00:12:37,070
I'm so thrilled to see the corporations that are coming forward

172
00:12:37,070 --> 00:12:38,230
to voluntarily label.

173
00:12:38,230 --> 00:12:42,423
In the last couple weeks, ConAgra, Kelloggs,

174
00:12:42,423 --> 00:12:48,340
General Mills, and I'm really pleased to see Neil, in our break out session,

175
00:12:48,340 --> 00:12:53,450
talking about how to make this understandable for consumers.

176
00:12:53,450 --> 00:12:55,030
We just want a clear honest label.

177
00:12:55,030 --> 00:12:56,610
We wanna know what we're buying.

178
00:12:56,610 --> 00:12:59,040
I personally get a rotten headache, and my joints ache for

179
00:12:59,040 --> 00:13:03,480
days from eating conventional corn, but not from organic.

180
00:13:03,480 --> 00:13:07,532
I only know that myself, but myself is all I have.

181
00:13:07,532 --> 00:13:12,658
And so as a science teacher, I'm really concerned because

182
00:13:12,658 --> 00:13:18,450
we see such an increase in allergies, both acute and in chronic.

183
00:13:18,450 --> 00:13:23,590
In California because I'm legislative director for label GMOs in California and

184
00:13:23,590 --> 00:13:27,680
I am west coast director of Moms Across America, I'm in the legislature a lot.

185
00:13:27,680 --> 00:13:32,550
And I watched our senators and our assemblymen in California pass a bill that

186
00:13:32,550 --> 00:13:37,870
would give millions of dollars to put many Epi-pens in every school

187
00:13:37,870 --> 00:13:43,300
because our children are dropping dead on the classroom floor from a bite of food.

188
00:13:43,300 --> 00:13:45,260
We have a right to know what's in our food.

189
00:13:45,260 --> 00:13:47,910
We have more food allergies than we've ever had.

190
00:13:47,910 --> 00:13:52,010
Half of our children, if you include diabetes, are chronically ill.

191
00:13:52,010 --> 00:13:56,370
I'm asking the USDA and the FDA to look at the child.

192
00:13:56,370 --> 00:13:59,980
So when Baba used to cook, she would always at 10 AM, she'd say,

193
00:13:59,980 --> 00:14:01,800
well how's Joe and how's Andy?

194
00:14:01,800 --> 00:14:04,820
And before she started to put the bones for the soup,

195
00:14:04,820 --> 00:14:10,150
she would think about what to put in that food because every food was a medicine.

196
00:14:10,150 --> 00:14:15,806
And she could cook anything, but every food has its own phytochemicals.

197
00:14:15,806 --> 00:14:17,906
So, I,

198
00:14:26,950 --> 00:14:32,258
See if I covered everything, I would like to say there's no gold standard for

199
00:14:32,258 --> 00:14:37,850
testing and double blind as a science teacher of these foods on human beings.

200
00:14:37,850 --> 00:14:41,595
And so we are the experiment, and in that light, in order for

201
00:14:41,595 --> 00:14:44,681
doctors to diagnose their patients, in order for

202
00:14:44,681 --> 00:14:49,257
moms to know what to feed our families, then we need to have clear labels.

203
00:14:49,257 --> 00:14:54,030
And that's happening and it's good news and it needs to be mandatory.

204
00:14:54,030 --> 00:14:57,900
And I thought the bar code was a great idea, but that needs to be in addition to

205
00:14:57,900 --> 00:15:01,400
a simple clear label that says there's something altered in that corn.

206
00:15:01,400 --> 00:15:08,625
There's something altered in that soy, so I think that's what I had to say.

207
00:15:08,625 --> 00:15:10,447
Thank you.

208
00:15:10,447 --> 00:15:11,887
>> Thank you, Jessica.

Public Comment #5: Antony Evans

209
00:15:11,887 --> 00:15:15,684
Next will be Anthony Evans and Sally Fox after Anthony.

210
00:15:26,174 --> 00:15:32,460
>> Hi, I'm Anthony Evans, CEO and cofounder of Tex Biotechnologies.

211
00:15:32,460 --> 00:15:37,351
We are a San Francisco startup that genetically engineers organisms,

212
00:15:37,351 --> 00:15:40,950
mostly plants, intended for cultivation at home.

213
00:15:40,950 --> 00:15:43,394
An example of the kind of products we develop,

214
00:15:43,394 --> 00:15:46,920
I have with me an engineered moss that you can sample if you like.

215
00:15:46,920 --> 00:15:50,628
This moss has been engineered with fragrance genes from other plants,

216
00:15:50,628 --> 00:15:52,244
so no plant pest parts in here.

217
00:15:52,244 --> 00:15:55,649
So that consumers can grow it at home as a replacement for

218
00:15:55,649 --> 00:15:59,134
scented air candles or petroleum based air fresheners.

219
00:15:59,134 --> 00:16:03,871
And I just wanna show that to show the enormous breadth of diversity of products

220
00:16:03,871 --> 00:16:07,532
that we could in the future, develop with biotechnology and

221
00:16:07,532 --> 00:16:11,049
to encourage USDA and OSTP and the other agencies to ensure

222
00:16:11,049 --> 00:16:16,030
that we have a valid regulatory process that works for these products.

223
00:16:16,030 --> 00:16:19,190
I applaud the work that you're doing to review the coordinative framework,

224
00:16:19,190 --> 00:16:23,360
the existing regulatory process has significantly restricted innovation with

225
00:16:23,360 --> 00:16:28,020
bad technology, as you're hearing again and again from practitioners of this.

226
00:16:28,020 --> 00:16:30,490
The case studies discussed today are a good start, but

227
00:16:30,490 --> 00:16:34,810
they reflect the products of the last decades not the next decades.

228
00:16:34,810 --> 00:16:38,680
So other case studies on this future products are vital to

229
00:16:38,680 --> 00:16:43,650
the success of this effort, these case studies should also include an assessment

230
00:16:43,650 --> 00:16:48,060
of the reasonableness of any imposed regulatory burden.

231
00:16:48,060 --> 00:16:52,170
We're forced to use a number of techniques so that the products we develop are not

232
00:16:52,170 --> 00:16:56,290
regulated under the current schemes, because the current regulatory system

233
00:16:56,290 --> 00:17:00,800
imposes an unreasonable burden on regulated articles.

234
00:17:00,800 --> 00:17:02,580
This makes it almost impossible for

235
00:17:02,580 --> 00:17:06,478
small companies to develop regulated GE plants or animals.

236
00:17:06,478 --> 00:17:11,450
There are three primary challenges that the current system imposes.

237
00:17:11,450 --> 00:17:15,260
First is the cost of complying with the cost of deregulation,

238
00:17:15,260 --> 00:17:19,020
these costs are out of line with the potential risks, and this explains why

239
00:17:19,020 --> 00:17:23,040
there are only GE plants on the market for the largest commodity cash crops,

240
00:17:23,040 --> 00:17:27,790
although there exists many potential benefits in the long tail of crops.

241
00:17:27,790 --> 00:17:31,400
Second is the time of the regulatory review process,

242
00:17:31,400 --> 00:17:35,480
which discourages many scientists from ever starting a company,

243
00:17:35,480 --> 00:17:38,810
few scientists have the stamina and patience and persistence

244
00:17:38,810 --> 00:17:42,240
to devote 20 years of their lives to bringing their creations to market.

245
00:17:42,240 --> 00:17:45,355
Yet this is precisely how long the Arctic Apple and

246
00:17:45,355 --> 00:17:50,030
Aquabounty Salmon Products have taken to receive regulatory approval.

247
00:17:50,030 --> 00:17:54,940
Even today, we're suffering from long waits on am I regulated letters which is

248
00:17:54,940 --> 00:17:58,730
supposed to be fast and under 90 days, we submitted several in August and

249
00:17:58,730 --> 00:18:01,450
September that we've yet to hear back from from the USDA.

250
00:18:02,518 --> 00:18:06,090
Third, pre market approval inhibits product development

251
00:18:06,090 --> 00:18:09,670
by preventing the use of agile only product development processes which have

252
00:18:09,670 --> 00:18:12,089
shown to be key in innovation in other industries.

253
00:18:13,090 --> 00:18:16,800
In conclusion reducing the regulatory burden seems out of scope for

254
00:18:16,800 --> 00:18:19,330
this review but this is the real issue.

255
00:18:19,330 --> 00:18:23,570
So I issue OSTP to follow up this review process with another working group

256
00:18:23,570 --> 00:18:27,330
to develop additional policy steps that can reduce the regulatory burden

257
00:18:27,330 --> 00:18:29,910
in order to enhance and promote innovation with this technology.

258
00:18:29,910 --> 00:18:30,410
Thank you.

259
00:18:43,074 --> 00:18:48,250
>> So next will be Sally Fox and Maria Frasier was registered,

260
00:18:48,250 --> 00:18:52,295
not sure if she's here, and then Don Gibson.

261
00:18:56,177 --> 00:18:57,660
So Sally Fox first.

262
00:18:58,690 --> 00:19:00,190
>> Sally left. >> Sally left, okay.

263
00:19:01,620 --> 00:19:04,060
Next would be Marie Frazier, if she's prepared.

264
00:19:05,450 --> 00:19:07,280
Gone too.

Public Comment #6: Don Gibson

265
00:19:07,280 --> 00:19:08,440
Don Gibson.

266
00:19:08,440 --> 00:19:10,080
You started up, I should've let you just keep coming.

267
00:19:16,816 --> 00:19:20,070
>> First of all I wanna thank the Office of Science and Technology Policy for

268
00:19:20,070 --> 00:19:22,790
hosting this and opening it up to public comment.

269
00:19:22,790 --> 00:19:27,295
My name is Don Don Gibson, I'm a doctoral candidate in the plant biology department,

270
00:19:27,295 --> 00:19:31,685
and I've also had the opportunity to found a biotech company startup.

271
00:19:31,685 --> 00:19:33,070
Many of us graduate students and

272
00:19:33,070 --> 00:19:36,485
postdocs wanna spin off our research that we're doing in our labs.

273
00:19:36,485 --> 00:19:41,205
We get into life science to benefit the world, to improve our economy, to

274
00:19:41,205 --> 00:19:45,290
grow healthier and more nutritious food, that have less impact on the environment.

275
00:19:45,290 --> 00:19:48,665
However, our research is currently limited by what

276
00:19:48,665 --> 00:19:51,274
the high regulatory level burdens are,

277
00:19:51,274 --> 00:19:57,010
many of us cannot even imagine to try to turn some of our products into market.

278
00:19:57,010 --> 00:20:02,610
For example, I study a transcription factor in tomatoes that,

279
00:20:02,610 --> 00:20:06,650
hopefully, can overcome nutrient stress, however, the market for tomatoes and

280
00:20:06,650 --> 00:20:09,930
the potential benefit to growers and consumers, is not large enough for

281
00:20:09,930 --> 00:20:13,120
hopefully to allow us to actually take this product to market.

282

00:20:13,120 --> 00:20:18,230
This is a problem, because if those of us in the research and

283
00:20:18,230 --> 00:20:22,830
academic community cannot afford the regulatory burdens to overcome and

284
00:20:22,830 --> 00:20:25,110
actually produce a product for the market,

285
00:20:26,720 --> 00:20:32,130
we're losing a lot of potential especially since we're receiving tax payer funding.

286
00:20:32,130 --> 00:20:36,825
If we can actually show that our tax payer funding to produce great research can

287
00:20:36,825 --> 00:20:40,090
actually turn the beneficial products I think that's a real waste.

288
00:20:40,090 --> 00:20:42,880
In addition for acceptance of technology,

289
00:20:42,880 --> 00:20:45,800
we all know that this technology is not accepted by all Americans and

290
00:20:45,800 --> 00:20:49,600
one there is a barrier of millions and millions of dollars,

291
00:20:49,600 --> 00:20:53,600
you prevent small companies and startups from entering this market and this space.

292
00:20:53,600 --> 00:20:59,420
I just wish to call upon the regulatory bodies to simplify and

293
00:20:59,420 --> 00:21:02,790
streamline and lower the barriers for entry, especially for

294
00:21:02,790 --> 00:21:05,710
startups, new companies, and small businesses.

295
00:21:05,710 --> 00:21:08,870
In addition with the new technology coming on line, such as

296
00:21:09,952 --> 00:21:14,085
I asked upon the regulatory branches to not impose the same level high regulations

297
00:21:14,085 --> 00:21:18,120
that prevents researchers like myself from entering markets and starting companies.

298
00:21:18,120 --> 00:21:18,620
Thank you.

299
00:21:23,330 --> 00:21:24,350
>> Thank you.

Public Comment #7: William Haun

300
00:21:24,350 --> 00:21:30,725
The next registered person is William Hahn And after William Hahn, Andrew Hessel.

301
00:21:44,882 --> 00:21:48,722
>> Hello, my name is BJ Hahn, I'm director of product development for

302
00:21:48,722 --> 00:21:54,470
a company called Calyx, a small ag biotech company based in New Brighton, Minnesota.

303
00:21:54,470 --> 00:21:59,810
I appreciate everyone's listening to my comments and

304
00:21:59,810 --> 00:22:04,370
for the USDA, FDA, and EPA for organizing this interesting discussion.

305
00:22:04,370 --> 00:22:06,900
The time is right to modernize the regulatory system for

306
00:22:06,900 --> 00:22:09,850
biotechnology products under the coordinated framework.

307
00:22:09,850 --> 00:22:14,330
The federal agency has had 30 years of experience with conducting environmental

308
00:22:14,330 --> 00:22:18,920
and food safety risk assessments involving genetically engineered organisms.

309
00:22:18,920 --> 00:22:22,620
Those 30 years of experience continues to affirm the most significant conclusions

310
00:22:22,620 --> 00:22:27,170
of a National Academy of Science's 1987 white paper which stated in part, there's

311
00:22:27,170 --> 00:22:31,970
no evidence of unique hazards either in the use of recombinant DNA techniques or

312
00:22:31,970 --> 00:22:36,190
in the moving of genes between unrelated organisms.

313
00:22:36,190 --> 00:22:41,000
30 years of growing and producing food from these bio technology products

314
00:22:41,000 --> 00:22:42,759
provides additional support to those conclusions.

315
00:22:43,880 --> 00:22:47,870
Nevertheless the past 30 years, the US regulatory system has disproportionately

316
00:22:47,870 --> 00:22:51,730
tilted the playing field against researchers and small companies

317
00:22:51,730 --> 00:22:55,390
that use genetic engineering to improve food production and agriculture.

318
00:22:57,290 --> 00:23:01,690
The result has been a concentration of agriculture technology in six large

319
00:23:01,690 --> 00:23:06,610
multinational companies that dominate the market for crops and new genetic traits.

320
00:23:06,610 --> 00:23:09,680
There are a number of consequences to this concentration,

321
00:23:09,680 --> 00:23:13,850
there are substantial barriers to entry to small and medium sized enterprises.

322
00:23:13,850 --> 00:23:16,470
Their opportunity cost of agriculture and food production,

323
00:23:16,470 --> 00:23:19,706
from lengthening the time to market for new trades of crops for products.

324
00:23:19,706 --> 00:23:23,470
Their increasing pressures on declining natural resources, and

325
00:23:23,470 --> 00:23:28,130
trends of higher standards of living and preference for animal proteins.

326
00:23:28,130 --> 00:23:30,160
And finally, there are fewer and fewer funding sources for

327
00:23:30,160 --> 00:23:33,138
innovation in agriculture, which again stifles innovation.

328
00:23:33,138 --> 00:23:36,624
That's why Calyx has chosen to focus on developing new food crops with genome

329
00:23:36,624 --> 00:23:40,005
editing techniques, and these new breeding techniques deliver targeted

330
00:23:40,005 --> 00:23:43,777
gene edits without introducing foreign genetic material into the final product.

331
00:23:43,777 --> 00:23:49,225
Our products can address consumer demand for better nutrition, they are non GMO and

332
00:23:49,225 --> 00:23:54,612
indistinguishable from products made with chemical or high energy mutagenesis.

333
00:23:54,612 --> 00:23:56,580
Calyx products meet the same standard of food and

334
00:23:56,580 --> 00:23:59,844
environmental safety as traditionally bred and genetically engineered crop.

335
00:23:59,844 --> 00:24:03,598
But the costs of development and pre-market approvals are today a fraction

336
00:24:03,598 --> 00:24:06,540
of the costs comparable to genetically engineered crops.

337
00:24:07,680 --> 00:24:11,000
Today the United States is at an important intersection of social science and

338
00:24:11,000 --> 00:24:12,400
technology innovation.

339
00:24:12,400 --> 00:24:17,700
The GMO story is about perceived not actual risks to safety.

340
00:24:17,700 --> 00:24:21,130
US consumers are demanding that genetically engineered foods be labeled.

341
00:24:21,130 --> 00:24:25,940
Yet food science supports the fact that most genetically engineered crops are not

342
00:24:25,940 --> 00:24:29,080
materially different than traditionally bred crops and do not warrant labeling.

343
00:24:30,220 --> 00:24:33,154
Believes that current efforts to modernize regulatory systems for biotechnology

344
00:24:33,154 --> 00:24:37,910
products must supply that experience gained from the past 30 years to tailor

345
00:24:37,910 --> 00:24:41,654
federal oversight of all new crops, both genetically engineered [COUGH] and

346
00:24:41,654 --> 00:24:48,020
those produced with new breeding techniques to actual risk,

347
00:24:48,020 --> 00:24:49,925
actual as opposed to hypothetical risks.

348
00:24:52,370 --> 00:24:55,400
A new long term strategy for regulation must be predictable and equitable for

349
00:24:55,400 --> 00:24:57,920
small and large developers both public and private and

350
00:24:57,920 --> 00:25:02,180
must encourage innovation by minimizing unnecessary regulation.

351
00:25:02,180 --> 00:25:04,740
Is committed to delivering healthier food for a better life and

352
00:25:04,740 --> 00:25:07,210
looks forward to commenting on future rule making opportunities.

353
00:25:07,210 --> 00:25:07,710
Thank you.

Public Comment #8: Andrew Hessel

354
00:25:10,923 --> 00:25:15,271
>> Andrew Hessel, next will be Marcia Ishii-Eiteman.

355
00:25:18,466 --> 00:25:19,923
>> My name is Andrew Hessel,

356
00:25:19,923 --> 00:25:25,250
I'm a distinguished researcher with the Autodesk bio-nano research group.

357
00:25:25,250 --> 00:25:29,910
Autodesk is a global leader in design, engineering and entertainment software.

358
00:25:29,910 --> 00:25:34,500
It's headquartered in San Rafael, California and has offices globally.

359
00:25:34,500 --> 00:25:39,383
The company is over 8,000 employees, 2.5 billion in annual revenue and

360
00:25:39,383 --> 00:25:43,410
a market capitalization of about $13 billion.

361
00:25:43,410 --> 00:25:47,200
Our software products are used by designers, manufacturers,

362
00:25:47,200 --> 00:25:49,140
engineers, artists, and

363
00:25:49,140 --> 00:25:53,970
students throughout the world every day to help make the world around us.

364
00:25:55,120 --> 00:25:59,620
Biotechnology has been changing the way many things are made including foods,

365
00:25:59,620 --> 00:26:01,908
fuels, fabrics, and more.

366
00:26:01,908 --> 00:26:04,870
And we're working to provide researchers and

367
00:26:04,870 --> 00:26:08,360
developers with software tools that can support this work.

368
00:26:09,410 --> 00:26:14,910
Digitization significantly reduces barriers and costs, and accordingly

369
00:26:14,910 --> 00:26:20,850
biotechnology is becoming accessible to smaller companies and even individuals.

370
00:26:20,850 --> 00:26:24,800
The diversity of the biotech community is increasing, research and

371
00:26:24,800 --> 00:26:26,510
development is accelerating.

372
00:26:27,720 --> 00:26:32,600
This is an incredible scientific and economic opportunity, it's not unlike

373
00:26:32,600 --> 00:26:37,170
the rapid advancement we've seen in the computer industry over the last 40 or so

374
00:26:37,170 --> 00:26:38,560
years.

375
00:26:38,560 --> 00:26:42,540
But rapid change is a challenge for regulators, educators and

376
00:26:42,540 --> 00:26:43,619
enforcement agencies.

377
00:26:44,700 --> 00:26:47,780
Accordingly, modernization is imperative.

378
00:26:47,780 --> 00:26:49,820
Without modernization regulatory and

379
00:26:49,820 --> 00:26:54,230
oversight mechanisms will simply not be able to keep pace with the technological

380
00:26:54,230 --> 00:26:59,580
progress and the increase in the number of participants in this industry.

381
00:26:59,580 --> 00:27:03,820
We recognize and applaud your efforts to understand the needs of this community.

382
00:27:03,820 --> 00:27:06,760
We look forward to a clear, transparent and

383
00:27:06,760 --> 00:27:11,620
effective regulatory framework for the modern biotechnology industry.

384
00:27:11,620 --> 00:27:12,120
Thank you.

Public Comment #9: Marcia Ishii-Eiteman

385
00:27:19,905 --> 00:27:21,390
>> Thank you, Marcia?

386
00:27:22,810 --> 00:27:26,810
I'm gonna let you say your last name, because I probably mangled it.

387
00:27:26,810 --> 00:27:30,750
>> Sure, actually my name is Dana Pearlson, Marcia had a family emergency so

388
00:27:30,750 --> 00:27:33,910
I will be speaking on behalf of Marcia Ishii-Eiteman

389
00:27:33,910 --> 00:27:35,655
from Pesticide Action Network.

390
00:27:35,655 --> 00:27:38,170
Marcia is the senior scientist.

391
00:27:39,190 --> 00:27:40,690
This statement is from Marcia Ishii-Eiteman,

392
00:27:40,690 --> 00:27:43,940
Senior Scientist at Pesticide Action Network.

393
00:27:43,940 --> 00:27:47,730
She says, thank you for the opportunity to comment on the coordinated framework.

394
00:27:47,730 --> 00:27:50,030
Since its introduction, the coordinated framework and

395
00:27:50,030 --> 00:27:53,823
the three agencies responsible for the regulation of biotechnology,

396
00:27:53,823 --> 00:27:58,480
the USDA, EPA and FDA, have failed in their collective responsibility to protect

397
00:27:58,480 --> 00:28:02,610
the farmers' livelihoods, the health and well-being of rural communities,

398
00:28:02,610 --> 00:28:08,120
consumers, ecosystems, and the natural environment from a wide range of

399
00:28:08,120 --> 00:28:11,980
socioeconomic, health, and environmental harms that have been associated with

400
00:28:11,980 --> 00:28:16,290
the introduction of biotechnology products over the past 20 years.

401
00:28:16,290 --> 00:28:19,530
Examples of harms arising due to the framework's inadequate and

402
00:28:19,530 --> 00:28:24,380
minimalist approach to biotech regulations include a dangerous increase in hazardous

403
00:28:24,380 --> 00:28:28,785
herbicide use in GE crop production with resulting threats to public health,

404
00:28:28,785 --> 00:28:32,370
non-target organisms, and ecosystem services.

405
00:28:32,370 --> 00:28:37,180
The rapid spread of herbicide resistant weeds now infesting over 60 million acres

406
00:28:37,180 --> 00:28:42,650
of American farmland as well as transgenic contamination of non-GMO crops.

407
00:28:42,650 --> 00:28:48,940
Extensive crop damage from herbicide drift of GMO fields as well as loss of non-GMO

408
00:28:48,940 --> 00:28:53,920
organic and other price premiums due to actual or perceived genetic contamination.

409
00:28:53,920 --> 00:28:58,490
And reduced access to national or international markets and farmers loss of

410
00:28:58,490 --> 00:29:02,280
income, farm businesses and livelihoods, weakened local economies,

411
00:29:02,280 --> 00:29:05,740
and the unraveling of the very fabric of rural community life.

412
00:29:05,740 --> 00:29:08,930
Pesticide Action Network urges USDA, EPA,

413
00:29:08,930 --> 00:29:13,830
and FDA to develop new framework with mandatory federal regulations of

414
00:29:13,830 --> 00:29:17,950
all products developed through genetic engineering processes.

415
00:29:17,950 --> 00:29:22,070
Specifically, the USDA should implement its noxious weed authority,

416
00:29:22,070 --> 00:29:26,020
which includes consideration of a broad socioeconomic impacts.

417
00:29:26,020 --> 00:29:30,120
Two, monitor impacts of GE crop production at all stages

418
00:29:30,120 --> 00:29:33,080
from field trials through post commercialization.

419
00:29:33,080 --> 00:29:38,068
And revise regulatory decisions as necessary based on emerging evidence.

420
00:29:38,068 --> 00:29:41,890
Three, include a mechanism to compensate farmers fairly for loss or

421
00:29:41,890 --> 00:29:46,750
damage caused by genetic contamination, or herbicide drift from GE fields.

422
00:29:46,750 --> 00:29:50,500
And four, conduct impact assessment not only of the product, but

423
00:29:50,500 --> 00:29:53,360
the production systems for which they have been designed.

424
00:29:53,360 --> 00:29:54,480
The EPA, for its part,

425
00:29:54,480 --> 00:29:59,040
should require independent safety testing regarding potential cumulative or

426
00:29:59,040 --> 00:30:04,150
synergistic effects of herbicides slated for use within GE crop production systems.

427
00:30:04,150 --> 00:30:06,055
And FDA should require independent and

428
00:30:06,055 --> 00:30:10,530
long-term safety testing of all GMO foods, and GMO containing products.

429
00:30:10,530 --> 00:30:14,550
In sum, all agencies should use their full authority to develop robust and

430
00:30:14,550 --> 00:30:17,210
binding federal regulations in a framework

431
00:30:17,210 --> 00:30:20,200
that eliminates existing gaps in agency oversight.

432
00:30:20,200 --> 00:30:23,626
And that ensures that a majeure of highest priority the protection of farmers

433
00:30:23,626 --> 00:30:25,959
livelihoods, public health and the environment.

Public Comment #10: Jill Kauffman Johnson

434
00:30:30,766 --> 00:30:35,255
>> Next is Jill Kauffman Johnson and then Pam Larry

435
00:30:45,873 --> 00:30:47,050
>> Hi, thank you.

436
00:30:47,050 --> 00:30:48,560
I'm Jill Kauffman Johnson.

437
00:30:48,560 --> 00:30:51,960
I'm with the company TerraVia, formerly Solazyme and

438
00:30:51,960 --> 00:30:54,450
I'm the global sustainability director.

439
00:30:54,450 --> 00:30:57,540
Thank you for hosting this public meeting and your sincere effort

440
00:30:57,540 --> 00:31:01,690
in making the regulatory process more transparent and accessible.

441
00:31:01,690 --> 00:31:05,690
TerraVia offers a new source of food, nutrition and specialty ingredients.

442
00:31:05,690 --> 00:31:09,916
We were founded with the mission to create products that are better for people and

443
00:31:09,916 --> 00:31:11,290
the planet.

444
00:31:11,290 --> 00:31:14,690
We are harnessing the power of algae, the mother of all plants and

445
00:31:14,690 --> 00:31:19,610
Earth's original super food to make a portfolio of breakthrough ingredients.

446
00:31:19,610 --> 00:31:24,020
Our company also manufactures a range of specialty personal care ingredients like

447
00:31:24,020 --> 00:31:28,599
our breakthrough sustainable alternative to palm oil, for key, strategic partners.

448
00:31:30,130 --> 00:31:35,540
Our algae platform uses contained fermentation to convert sugars into oils,

449
00:31:35,540 --> 00:31:38,480
proteins and other ingredients, in a matter of days.

450
00:31:38,480 --> 00:31:41,482
And we believe, it is an important technology,

451
00:31:41,482 --> 00:31:46,480
to not only mitigate climate change, But provide resilient solutions as well.

452
00:31:46,480 --> 00:31:51,210
As we face a changing climate and the needs of a growing population estimated to

453
00:31:51,210 --> 00:31:55,941
reach 9 billion people in the next few decades, we will need increasingly new

454
00:31:55,941 --> 00:32:00,407
sources of food and materials that require fewer resources to make them.

455
00:32:00,407 --> 00:32:05,392
And as a society, we need to encourage a new generation of solutions to meet those

456
00:32:05,392 --> 00:32:10,290
pressing needs we will fundamentally need to do more with less.

457
00:32:10,290 --> 00:32:14,500
So the fact is, that is what the bio-economy is all about.

458
00:32:14,500 --> 00:32:16,920
It is about doing more with less.

459
00:32:16,920 --> 00:32:21,520
Much of the bio-economy is based on microorganisms, converting plant sugars

460
00:32:21,520 --> 00:32:26,910
to new materials for enzymes, proteins, bioplastics, and bio-based ingredients.

461
00:32:26,910 --> 00:32:31,430
It is imperative that we accelerate the transition to a low-carbon economy.

462
00:32:31,430 --> 00:32:34,070
It is a social and environmental imperative.

463
00:32:35,420 --> 00:32:38,980
The coordinated framework update effort is at the center of facilitating this

464
00:32:38,980 --> 00:32:39,690
transition.

465
00:32:39,690 --> 00:32:43,499
And ensuring that it's done safely, with integrity and with public confidence.

466
00:32:44,640 --> 00:32:48,810
Tera Via has been working with the FDA and the EPA for more than five years, and

467
00:32:48,810 --> 00:32:52,080
has completed numerous PMNs and NCAMs.

468
00:32:52,080 --> 00:32:57,259
We have received four FDA GRAS, no questions letters for our food products.

469
00:32:57,259 --> 00:33:01,715
Tera Via believes in and is inspired by innovation.

470
00:33:01,715 --> 00:33:05,225
Biotechnology has the potential to provide breakthrough solutions when applied

471
00:33:05,225 --> 00:33:08,822
responsibly with transparency and public engagement.

472
00:33:08,822 --> 00:33:13,825
Tera Via is committed to these principles and has been acting upon these principles.

473
00:33:14,890 --> 00:33:17,840
For newer companies that are getting started on approaching regulatory

474
00:33:17,840 --> 00:33:20,860
agencies, providing a single point of contact for regulatory

475
00:33:20,860 --> 00:33:26,100
oversight in R&D and commercial activity, each agency would be a terrific start.

476
00:33:26,100 --> 00:33:30,080
One person to contact who can route questions and provide guidance.

477
00:33:30,080 --> 00:33:34,060
It would also be helpful if the agencies identify key forms to participate and

478
00:33:34,060 --> 00:33:37,910
be accessible directly with the community of the innovators.

479
00:33:37,910 --> 00:33:41,590
Finally, providing accessible and understandable information for

480
00:33:41,590 --> 00:33:44,855
the public is critical in promoting better understanding about the stringent

481
00:33:44,855 --> 00:33:49,030
regulations already in place to ensure the protection in environmental and

482
00:33:49,030 --> 00:33:50,190
public health.

483
00:33:50,190 --> 00:33:54,520
We appreciate your effort to engage the public in this journey of innovation and

484
00:33:54,520 --> 00:33:56,984
transition to a low carbon healthy society.

485
00:33:56,984 --> 00:34:00,468
We all need to get this right.

486
00:34:00,468 --> 00:34:05,043
>> [APPLAUSE]

Public Comment #11: Pamm Larry

>> Next is Pamm Larry and

487
00:34:05,043 --> 00:34:06,588
then Andrew Levine.

488
00:34:12,148 --> 00:34:15,651
>> Hi, my name's Pam Larry, and I'm a consumer advocate for

489
00:34:15,651 --> 00:34:18,325
labeling of genetically engineered foods.

490
00:34:18,325 --> 00:34:22,505
I started by being the grandmother that started Proposition

491
00:34:22,505 --> 00:34:25,315
37 to label genetically engineered food in California.

492
00:34:25,315 --> 00:34:28,785
I started that in 2011 and continue to work on this issue.

493
00:34:30,170 --> 00:34:35,850
I come here to respectfully tell the government agencies and the corporations

494
00:34:35,850 --> 00:34:41,740
that there is no trust with the consumer and the people that buy your products.

495
00:34:41,740 --> 00:34:45,810
There is no trust because we are, I'm sorry,

496
00:34:45,810 --> 00:34:47,680
getting a little nervous up here for some reason.

497
00:34:48,840 --> 00:34:52,290
Because all we see is it there is a clear and

498
00:34:52,290 --> 00:34:55,380
present protection of the rights of corporate personhood and

499
00:34:55,380 --> 00:35:00,859
profit over real persons, the environment and all other living systems.

500
00:35:02,100 --> 00:35:07,400
Some, I know I sense a sincere desire to engender trust among consumers,

501
00:35:07,400 --> 00:35:09,570
so I have some suggestions.

502
00:35:09,570 --> 00:35:13,750
The first one is to have true openness in science to encourage and

503
00:35:13,750 --> 00:35:20,756
support dissent and whistleblowing at the university, corporate, and agency level.

504
00:35:20,756 --> 00:35:26,737
Not to to demean, vilify and cause people to lose their funding or

505
00:35:26,737 --> 00:35:30,107
for people to lose their jobs, at for

506
00:35:30,107 --> 00:35:35,111
instance the EPA when they notice there is a connection

507
00:35:35,111 --> 00:35:39,383
between neonicotinoids and bee population.

508
00:35:39,383 --> 00:35:42,453
If you truly want us to trust your science,

509
00:35:42,453 --> 00:35:48,168
then share your raw data with scientists that we have identified that we trust,

510
00:35:48,168 --> 00:35:51,523
so that we can get their interpretation also.

511
00:35:51,523 --> 00:35:57,577
Put as many resources into non-GE technologies that are available

512
00:35:57,577 --> 00:36:02,790
to solve the problems of climate change and agriculture.

513
00:36:04,470 --> 00:36:08,890
We would like to see more funding in that direction.

514
00:36:08,890 --> 00:36:14,364
Create regions where GE crops are grown to protect non-GE crops from
contamination.

515
00:36:14,364 --> 00:36:21,253
Follow the IARC's findings on glyphosate as a probable carcinogen and

516
00:36:21,253 --> 00:36:25,860
we're asking EPA to not renew that herbicide.

517
00:36:27,810 --> 00:36:32,780
The FDA has no mechanism for people to report problems with GE food.

518
00:36:32,780 --> 00:36:34,420
We've tried.

519
00:36:34,420 --> 00:36:37,180
So if there's no process to report problems,

520
00:36:37,180 --> 00:36:42,346
how can you have any data to tell us that these products are safe?

521
00:36:42,346 --> 00:36:45,747
Gosh, there's so much.

522
00:36:45,747 --> 00:36:51,027
[LAUGH] Finally, I guess since I've run out of time, is that to hold patent

523
00:36:51,027 --> 00:36:56,923
holders responsible for the outcome now, and in the future for their creations.

524
00:36:56,923 --> 00:37:03,813
We have too many instances in our history with chemical problems and other things.

525
00:37:03,813 --> 00:37:07,211
Companies create these things and then they leave and

526
00:37:07,211 --> 00:37:12,010
taxpayers are left to pick up the pieces with unintended consequences.

527
00:37:12,010 --> 00:37:17,420
There is no consensus on the safety of genetically engineered products.

528
00:37:17,420 --> 00:37:20,495
Taxpayers and consumers will continue watching, thank you.

529
00:37:20,495 --> 00:37:24,920
>> [APPLAUSE]
>> Next,

Public Comment #12: Andrew LaVigne

530
00:37:24,920 --> 00:37:29,770
Andrew LaVigne and then Al Lynn.
>> Thank you,

531
00:37:29,770 --> 00:37:32,720
I'm Andy LaVigne with the American Seed Trade Association.

532
00:37:32,720 --> 00:37:34,500
We were founded in 1883 and

533
00:37:34,500 --> 00:37:38,133
are one of the oldest trade associations in the US at this time.

534
00:37:38,133 --> 00:37:41,850
Our members consist of over 700 companies involved in seed production,

535
00:37:41,850 --> 00:37:45,255
distribution, plant breeding and related industries.

536
00:37:45,255 --> 00:37:48,410
We'd like to say we produce everything from alfalfa to zucchini,

537
00:37:48,410 --> 00:37:49,790
everything in between.

538
00:37:49,790 --> 00:37:53,702
We produce organic seed, conventional seed and biotech seeds.

539
00:37:53,702 --> 00:37:55,850
With respect to this review process,

540
00:37:55,850 --> 00:37:59,480
it's imperative that we follow the foundation that has been established for

541
00:37:59,480 --> 00:38:02,530
the regulatory process and oversight for the past 30 decades.

542
00:38:02,530 --> 00:38:05,663
Robbie, you hit on that, and thank you for that, so it will save time.

543
00:38:05,663 --> 00:38:10,340
We support that process of continuing to look at regulation in that manner.

544
00:38:10,340 --> 00:38:12,450
The challenge, I think as we talked about in our group is,

545
00:38:13,810 --> 00:38:16,450
science is evolving faster than regulation can get there,

546
00:38:16,450 --> 00:38:17,928
but we have to figure out how we deal with that.

547
00:38:17,928 --> 00:38:22,972
The goal of plant breeders has always been to improve existing plant varieties and

548
00:38:22,972 --> 00:38:28,120
breeders have historically integrated the latest discoveries in plant biology and

549
00:38:28,120 --> 00:38:30,370
genetics into their methodologies.

550
00:38:30,370 --> 00:38:34,720
In addition to using spontaneous induced genetic variation or

551
00:38:34,720 --> 00:38:39,560
mutation, breeders can now make very targeted and specific changes in

552
00:38:39,560 --> 00:38:44,130
existing plant genes in a way that mimics the changes that occur in nature.

553
00:38:44,130 --> 00:38:47,070
By applying these newer methods, plant breeders are more efficient and

554
00:38:47,070 --> 00:38:50,860
precise in making the same desired changes that could be made

555
00:38:50,860 --> 00:38:53,418
through earlier plant breeding methods.

556
00:38:53,418 --> 00:38:57,710
Plant varieties improved with the latest breeding methods are subjected to the same

557
00:38:57,710 --> 00:39:02,690
critical performance evaluations and processes that breeders have always used

558
00:39:02,690 --> 00:39:05,680
to create new plant varieties that are safe to grow and to eat.

559
00:39:05,680 --> 00:39:10,740
Any guidance proposed by this review of the coordinated framework should not

560
00:39:10,740 --> 00:39:15,090
only be based in the principles initially articulated in the coordinated framework,

561
00:39:15,090 --> 00:39:19,020
In the executive orders, but more importantly on over 100 years of

562
00:39:19,020 --> 00:39:23,890
experience in incorporating scientific advances to develop improved,

563
00:39:23,890 --> 00:39:27,840
safe, nutritious, and environmentally adapted plant varieties.

564
00:39:28,970 --> 00:39:32,520
A fundamental principle for determining whether a pre-market review and

565
00:39:32,520 --> 00:39:36,878
clearance process is justified for plant varieties is.

566
00:39:36,878 --> 00:39:40,975
Plant varieties developed through the latest breeding methods should not be

567
00:39:40,975 --> 00:39:44,633
differentially regulated if they are similar or indistinguishable

568
00:39:44,633 --> 00:39:48,997
from varieties that could have been produced through earlier breeding methods.

569
00:39:48,997 --> 00:39:50,367
More specifically,

570
00:39:50,367 --> 00:39:55,544
new breeding varieties should not be subject to a pre market regulatory review,

571
00:39:55,544 --> 00:40:00,418
if there is no insertion and stable transmission to a subsequent generation

572
00:40:00,418 --> 00:40:04,091
of genetic material that encodes an expressed protein.

573
00:40:04,091 --> 00:40:08,281
Additionally, based on over 30 years of regulatory experience,

574
00:40:08,281 --> 00:40:12,472
if there is insertion and stable transmission of genetic material,

575
00:40:12,472 --> 00:40:17,314
new plant varieties should not be subject to a pre-market regulatory review if

576
00:40:17,314 --> 00:40:21,504
the inserted genetic material is from a sexually compatible plant,

577
00:40:21,504 --> 00:40:25,693
if there is familiarity or experience with the introduced trait, or

578
00:40:25,693 --> 00:40:30,140
if the genetic material encodes a protein that has a history of safe use.

579
00:40:31,320 --> 00:40:34,270
This regulatory scope would allow plant breeders to quickly and

580
00:40:34,270 --> 00:40:38,740
efficiently deliver targeted genetic improvements that would be possible, but

581
00:40:38,740 --> 00:40:43,188
with much greater difficulty using more efficient breeding methods.

582
00:40:43,188 --> 00:40:46,400
Additionally, we urge the US government to actively engage with other

583
00:40:46,400 --> 00:40:48,550
countries on this important topic.

584
00:40:48,550 --> 00:40:50,940
Consistent policies across countries for

585
00:40:50,940 --> 00:40:55,240
products developed through newer breeding methods, such as gene editing,

586
00:40:55,240 --> 00:40:59,180
will facilitate innovation in all countries and minimize trade impacts.

587
00:40:59,180 --> 00:41:03,370
Inconsistent and disproportionate regulatory hurdles will limit the access

588
00:41:03,370 --> 00:41:05,460
to the latest plant breeding tools for

589
00:41:05,460 --> 00:41:09,510
small to medium size companies and public breeding institutions.

590
00:41:09,510 --> 00:41:12,520
Thank you.
>> Thank you.

Public Comment #13: Al Lin

591
00:41:12,520 --> 00:41:15,713
Next Al Lin, and after Mr. Lin, John Lindbo.

592
00:41:18,148 --> 00:41:19,954
Good afternoon, my name is Al Lin,

593
00:41:19,954 --> 00:41:24,770
I'm a Professor of Law at the University of California Davis School of Law.

594
00:41:24,770 --> 00:41:29,030
There is no doubt that our approach to biotechnology regulation requires

595
00:41:29,030 --> 00:41:30,420
updating, and I commend you for

596
00:41:30,420 --> 00:41:34,512
taking on this difficult task of updating the coordinated framework and

597
00:41:34,512 --> 00:41:38,890
developing a long-term strategy for biotechnology regulation.

598
00:41:38,890 --> 00:41:41,345
But as some of the discussion this morning suggested,

599
00:41:41,345 --> 00:41:44,360
the case studies that we've looked at today are very limited.

600
00:41:44,360 --> 00:41:46,680
And they do not adequately account for

601
00:41:46,680 --> 00:41:51,010
new technological developments, such as gene drives and gene editing.

602
00:41:51,010 --> 00:41:55,570
I heard two basic responses to those discussion points.

603
00:41:55,570 --> 00:41:57,210
First, that's not this case study.

604
00:41:57,210 --> 00:42:01,950
But that's not an adequate answer, we all know that these cases are on the way.

605
00:42:01,950 --> 00:42:05,490
Second response was come see us.

606
00:42:05,490 --> 00:42:07,150
I don't think that's an adequate answer, either.

607
00:42:07,150 --> 00:42:09,870
We need transparency, and we need certainty.

608
00:42:11,300 --> 00:42:14,700
How exactly would the coordinated framework apply to these new but

609
00:42:14,700 --> 00:42:18,320
increasingly popular techniques is not clear.

610
00:42:18,320 --> 00:42:20,490
Many of them don't involve a plant pest component,

611
00:42:20,490 --> 00:42:22,490
so there would be no APHIS review.

612
00:42:22,490 --> 00:42:25,370
Many of them don't involve some sort of pesticidal mechanism or

613
00:42:25,370 --> 00:42:28,010
microbes so there would be no EPA review.

614
00:42:28,010 --> 00:42:33,560
If there's no food or drug aspect to it, there's probably no FDA review, either.

615
00:42:33,560 --> 00:42:34,990
Consider a couple of examples.

616
00:42:34,990 --> 00:42:36,530
The glowing plant.

617
00:42:36,530 --> 00:42:40,220
APHIS, apparently, concluded that this was not a plant pest, and

618
00:42:40,220 --> 00:42:43,450
as a result there has been no government oversight.

619
00:42:43,450 --> 00:42:46,800
Similarly, genetically engineered mosquitoes.

620
00:42:46,800 --> 00:42:48,919
Not a plant pest, so here would be no APHIS review.

621
00:42:48,919 --> 00:42:52,760
Maybe you would say this is an animal drug because it affects the structure or

622
00:42:52,760 --> 00:42:54,320
function of an animal.

623
00:42:54,320 --> 00:42:58,250
But one of the key aspects of evaluating an animal drug is determining whether it's

624
00:42:58,250 --> 00:42:59,700
safe for an animal.

625
00:42:59,700 --> 00:43:03,320
But that doesn't make sense in the context of genetically engineered mosquitoes.

626
00:43:04,510 --> 00:43:05,040
So what do we do?

627
00:43:05,040 --> 00:43:08,020
I mean, ideally we should move beyond the coordinated framework.

628
00:43:08,020 --> 00:43:10,170
It involves too siloed an approach,

629
00:43:10,170 --> 00:43:15,190
and its applicability, as these examples suggest, depends on happenstance.

630
00:43:15,190 --> 00:43:19,130
And as other commentators have noted the techniques chosen are sometimes

631
00:43:19,130 --> 00:43:21,850
chosen in order to circumvent the framework.

632
00:43:23,160 --> 00:43:28,180
And, of course, EPA, the leading environmental agency in this country,

633
00:43:28,180 --> 00:43:30,510
its oversight is very limited on the framework,

634
00:43:30,510 --> 00:43:34,050
basically the cases involving pesticides or microbes.

635
00:43:34,050 --> 00:43:36,690
More radical change may require new legislation, or

636
00:43:36,690 --> 00:43:39,130
new interpretations of existing statutory authority.

637
00:43:40,590 --> 00:43:43,530
Assuming we have to work within the limits of what we have,

638
00:43:43,530 --> 00:43:47,730
the coordinated framework, I would suggest we should, to the extents possible,

639
00:43:47,730 --> 00:43:48,930
try to do three things.

640
00:43:48,930 --> 00:43:53,386
Number one, maximize transparency, whether through public disclosure of

641
00:43:53,386 --> 00:43:57,087
applications regarding products that are in the pipelines, or

642
00:43:57,087 --> 00:44:01,078
labeling of products involving genetically modified components.

643
00:44:01,078 --> 00:44:05,894
Second, we should provide meaningful oversight, whether that's in the form of

644
00:44:05,894 --> 00:44:10,786
performing environmental assessments rather than categorical exclusions under

645
00:44:10,786 --> 00:44:15,741
NIFA, whether in the case of inclining away from relying on tolerance exemptions,

646
00:44:15,741 --> 00:44:20,627
or whether in the form of having FDA make initial determinations regarding GRAS,

647
00:44:20,627 --> 00:44:22,688
rather than relying on industry.

648
00:44:22,688 --> 00:44:25,210
And third, we should try to break down siloes.

649
00:44:25,210 --> 00:44:29,050
Perhaps an executive order along the lines of mandating participation by

650
00:44:29,050 --> 00:44:33,240
all potentially relevant agencies would help to advance this goal.

651
00:44:33,240 --> 00:44:39,506
Ultimately, we need to build public trust to advance the goals that we all seek in

652
00:44:39,506 --> 00:44:45,329
terms of getting these products that are safe and effective on the market.

653
00:44:45,329 --> 00:44:45,928
Thank you.

Public Comment #14: John Lindbo

654
00:44:48,968 --> 00:44:52,093
>> John Lindbo is next, and then Belinda Martineau.

655
00:44:55,208 --> 00:44:58,357
>> My name is John Lindbo, I'm a research scientist at HM Clause, and

656
00:44:58,357 --> 00:45:02,770
I'm making these comments on behalf of the California Seed Association.

657
00:45:02,770 --> 00:45:08,240
The CSA was founded in 1940 and it has over 125 companies as members.

658
00:45:08,240 --> 00:45:12,110
Member companies are involved in diverse aspects of the seed industry, including

659
00:45:12,110 --> 00:45:17,520
breeding and plant variety development, seed production, sales, and distribution.

660
00:45:17,520 --> 00:45:21,250
CSA members produce, distribute, and sell seeds for feed, fiber, and

661
00:45:21,250 --> 00:45:25,020
food crops, including vegetables all over the world.

662
00:45:25,020 --> 00:45:28,870
And CSA members produce seeds for growers that use either conventional or

663
00:45:28,870 --> 00:45:31,440
organic food production methods.

664
00:45:31,440 --> 00:45:34,410
Today's plant growers face many challenges.

665
00:45:34,410 --> 00:45:38,080
The climate is changing, pathogens are evolving, and

666
00:45:38,080 --> 00:45:40,340
new disease problems are emerging.

667
00:45:40,340 --> 00:45:44,840
These changes make it more difficult for growers to reliably produce food.

668
00:45:44,840 --> 00:45:48,940
CSA member companies work hard to develop and sell plant varieties that have

669
00:45:48,940 --> 00:45:54,220
the combination of good field performance, yield and acceptable product quality.

670
00:45:54,220 --> 00:45:55,660
And we do this through plant breeding.

671
00:45:57,110 --> 00:46:01,090
Plant breeders develop new varieties by introducing genetic variation into plants

672
00:46:01,090 --> 00:46:05,740
and then selecting the genetic variance with the desirable combination of traits.

673
00:46:05,740 --> 00:46:10,350
This variation can come from other crossable plants, such as wild relatives,

674
00:46:10,350 --> 00:46:14,520
or from mutations that occur spontaneously or are induced.

675
00:46:14,520 --> 00:46:18,350
But regardless of where the genetic variation comes from,

676
00:46:18,350 --> 00:46:20,810
new varieties are extensively trialed and

677
00:46:20,810 --> 00:46:24,496
tested for multiple years under various growing conditions.

678
00:46:24,496 --> 00:46:29,230
This rigorous, multi-year testing process is how we know we have generated the new

679
00:46:29,230 --> 00:46:32,830
variety that is competitive with commercial varieties.

680
00:46:32,830 --> 00:46:34,310
This strategy has been used for

681
00:46:34,310 --> 00:46:39,930
decades to produce hundreds of thousands of new, safe, useful plant varieties.

682
00:46:39,930 --> 00:46:44,330
New technologies are now available that will let breeders move, reproduce or

683
00:46:44,330 --> 00:46:50,160
mimic the genetic variations found in plants in a way that is more precise,

684
00:46:50,160 --> 00:46:56,970
more accurate, and more intentional than currently accepted breeding practices.

685
00:46:56,970 --> 00:47:00,410
Because of the pace of climate and environmental change, and the emergence

686
00:47:00,410 --> 00:47:05,210
and evolution of diseases, plant breeders and consumers need these new tools.

687
00:47:05,210 --> 00:47:09,470
These new tools will help ensure reliable production of safe, nutritious,

688
00:47:09,470 --> 00:47:13,572
affordable food that can be grown in a more sustainable manner.

689
00:47:13,572 --> 00:47:17,813
Because of the proven safety of the breeding selection process, and

690
00:47:17,813 --> 00:47:23,005
the ability of new breeding techniques to generate far less uncontrolled
variation

691
00:47:23,005 --> 00:47:27,686
than currently accepted breeding practices, we propose that varieties or

692
00:47:27,686 --> 00:47:31,928
products developed with these new breeding techniques should not be

693
00:47:31,928 --> 00:47:35,660
subject to regulatory review prior to commercialization,

694
00:47:35,660 --> 00:47:40,632
if the variety could have been obtained by crossbreeding, the variety mimics or

695
00:47:40,632 --> 00:47:43,191
duplicates varieties that have been, or

696
00:47:43,191 --> 00:47:48,091
could be, obtained by mutagenesis, either natural or induced mutagenesis,

697
00:47:48,091 --> 00:47:52,827
and the variety contains no exogenous, non-native heritable material.

698
00:47:52,827 --> 00:47:56,712
We know that undue regulation of these accelerated breeding techniques

699
00:47:56,712 --> 00:47:59,495
will stifle innovation, increase food cost, and

700
00:47:59,495 --> 00:48:02,807
harm the competitiveness of the California seed industry.

701
00:48:02,807 --> 00:48:03,397
Thank you.

Public Comment #15: Belinda Martinaeu

702
00:48:17,900 --> 00:48:21,837
My PhD is in plant molecular genetics, and 25 years ago-

703
00:48:21,837 --> 00:48:23,578
>> Start with your name for the record.

704
00:48:23,578 --> 00:48:28,338
>> My name is Belinda Martinaeu, and my PhD is in plant molecular genetics.

705
00:48:28,338 --> 00:48:32,837
And 25 years ago, I spent 4 years interacting with FDA scientists as

706
00:48:32,837 --> 00:48:37,188
the agency was first learning how crop genetic engineering worked,

707
00:48:37,188 --> 00:48:42,810
what risks it might pose and how best to regulate these new food and feed products.

708
00:48:42,810 --> 00:48:45,630
These interactions were part of gaining regulatory approval for

709
00:48:45,630 --> 00:48:48,050
the first whole GE food to be commercialized,

710
00:48:48,050 --> 00:48:52,050
the Flavr Savr tomato, developed at Calgene, where I was working at the time.

711
00:48:53,280 --> 00:48:54,520
We went to FDA early.

712
00:48:56,000 --> 00:48:58,340
This tomato still serves as a good example for

713
00:48:58,340 --> 00:49:02,400
how to modernize the regulatory system for biotechnology products.

714
00:49:02,400 --> 00:49:06,310
We knew from the get-go that the GE process could result in unintended,

715
00:49:06,310 --> 00:49:11,020
unexpected changes in GE plants via insertional mutations or

716
00:49:11,020 --> 00:49:15,020
somaclonal variation and informed FDA accordingly.

717
00:49:15,020 --> 00:49:19,440
That's why animal feeding studies are conducted with GE foods and why FDA should

718
00:49:19,440 --> 00:49:22,940
require follow up of the feeding studies carried out with NK603 corn.

719
00:49:24,840 --> 00:49:27,880
We were still dialoguing with FDA

720
00:49:27,880 --> 00:49:32,300
after the 1992 policy was published when FDA scientists asked us to make sure

721
00:49:32,300 --> 00:49:36,260
only the DNA we intended to insert in our tomatoes had been inserted.

722
00:49:36,260 --> 00:49:38,690
To our surprise, we found that 20% of the time,

723
00:49:38,690 --> 00:49:43,950
the entire minimally characterized vector backbone sequences had been inserted too.

724
00:49:43,950 --> 00:49:47,360
This is still a problem when using the agro based method.

725
00:49:47,360 --> 00:49:51,510
Although I learned recently of a GE developer who is not initially aware of

726
00:49:51,510 --> 00:49:52,990
this problem, and

727
00:49:52,990 --> 00:49:57,070
it's a reason why regulation of GE foods should be required by FDA.

728
00:49:58,180 --> 00:50:01,590
We also didn't understand exactly how the gene inserted into Flavr Savr

729
00:50:01,590 --> 00:50:04,960
tomatoes worked in 1994 when it was commercialized.

730
00:50:04,960 --> 00:50:08,620
Turned out to be RNA silencing, discovered years later.

731
00:50:08,620 --> 00:50:09,860
The science had evolved.

732
00:50:10,880 --> 00:50:13,930
We now know that alterations and indigenous versions of these

733
00:50:13,930 --> 00:50:19,570
small regulatory RNAs can be another source of unintended changes in GE crops.

734
00:50:19,570 --> 00:50:24,620
And even the new CRISPR-Cas9 process can have off target effects.

735
00:50:24,620 --> 00:50:30,380
Genetic engineers currently cannot prevent these unattended processes from occurring,

736
00:50:30,380 --> 00:50:32,010
but they can look afterward for

737
00:50:32,010 --> 00:50:35,040
unintended, unexpected changes in a GE crop.

738
00:50:36,090 --> 00:50:40,610
But FDA should not just strongly encourage developers to voluntarily

739
00:50:40,610 --> 00:50:43,840
consult the agency about these and other issues.

740
00:50:43,840 --> 00:50:46,800
Because of the possibility of these unintended changes,

741
00:50:46,800 --> 00:50:51,130
the fact that a food or feed crop has undergone genetic engineering should

742
00:50:51,130 --> 00:50:56,780
trigger mandatory pre-market federal regulation.

743
00:50:56,780 --> 00:50:59,507
As mentioned earlier, FDA regulated

744
00:50:59,507 --> 00:51:05,290
the antibiotic resistance protein produced in Flavr Savr tomatoes as a food additive.

745
00:51:05,290 --> 00:51:10,180
Why hasn't the FDA considered other foreign proteins expressed in other GE

746
00:51:10,180 --> 00:51:13,380
crops, insecticidal proteins or

747
00:51:13,380 --> 00:51:17,870
other antibiotic resistance proteins, for example, as food additives as well?

748
00:51:19,170 --> 00:51:22,480
Calgene voluntarily labelled the Flavr Savr tomato in 1994,

749
00:51:22,480 --> 00:51:24,520
and it sold like hot cakes.

750
00:51:24,520 --> 00:51:29,660
I am happy to see that more and more food companies are now finally doing the same.

751
00:51:29,660 --> 00:51:33,490
But for the administration to obtain its goal of ensuring public confidence in

752
00:51:33,490 --> 00:51:36,870
the regulatory system and improving its transparency,

753
00:51:36,870 --> 00:51:40,608
it should require mandatory labelling of all GE foods.

754
00:51:40,608 --> 00:51:42,012
Thank you.

Public Comment #16: Josh Wilson

755
00:51:46,168 --> 00:51:51,838
>> The next speaker has withdrawn, and because of our arbitrary alphabetic, we're

756
00:51:51,838 --> 00:51:57,350
going to move someone who registered at the meeting today to move into that slot.

757
00:51:58,480 --> 00:52:01,530
This is Josh Wilson who registered on site this morning.

758
00:52:01,530 --> 00:52:02,165
Thank you.

759
00:52:02,165 --> 00:52:09,248
>> [INAUDIBLE] Thanks for letting me speak to you people.

760
00:52:09,248 --> 00:52:15,790
All right, it is important to understand that I stay involved out of the love and

761
00:52:15,790 --> 00:52:19,890
concern for my family, my community, and my country.

762
00:52:21,490 --> 00:52:24,198
I've read tens of thousands of federal documents, RMPs,

763
00:52:24,198 --> 00:52:29,000
regional management plans, scientific studies,

764
00:52:29,000 --> 00:52:33,115
I follow RSS feeds, stakeholders, sign ups, notifications, I read it all.

765
00:52:33,115 --> 00:52:39,072
This subject, biotechnology, has changed my life in many ways.

766
00:52:39,072 --> 00:52:42,356
One of them is the way I eat, I'm figuring it out now, and

767
00:52:42,356 --> 00:52:46,737
I'm starting to eat organic because that is not food that has been driven off

768
00:52:46,737 --> 00:52:48,809
technology in the last 15 years.

769
00:52:50,280 --> 00:52:52,720
And its been here for 4.5 billion years.

770
00:52:52,720 --> 00:52:54,540
I trust that, my body knows it.

771
00:52:54,540 --> 00:52:58,970
All right, I have responded with 22 public comments on my record.

772
00:52:58,970 --> 00:53:03,638
I also host a blog on Facebook called We the People, and

773
00:53:03,638 --> 00:53:08,612
it follows the unfolding agenda in the last eight months,

774
00:53:08,612 --> 00:53:11,778
the APHIS, FDA has been presenting.

775
00:53:11,778 --> 00:53:17,100
It really does show the agenda of where they're trying to go, which is very risky.

776
00:53:17,100 --> 00:53:20,690
I'm also a writer, and

777
00:53:20,690 --> 00:53:25,670
the subject has made it into the plot of my movie, American Nobody.

778
00:53:25,670 --> 00:53:27,720
I wanna touch on two things.

779
00:53:27,720 --> 00:53:32,060
Most important, craziest aspect is deregulation.

780
00:53:32,060 --> 00:53:35,640
This is the craziest way we could ever possibly think of going.

781
00:53:35,640 --> 00:53:37,480
There is no record keeping.

782
00:53:37,480 --> 00:53:42,100
There is no follow up to anything that a company may have made, and

783
00:53:42,100 --> 00:53:46,880
there are unreversible consequences, and there is no quick antidote.

784
00:53:48,930 --> 00:53:54,375
Our federal government is advertising to many multinational

785
00:53:54,375 --> 00:53:59,608
companies around the globe, letting them know about their

786
00:53:59,608 --> 00:54:05,379
three traits that can be stacked out of 111 traits that exist.

787
00:54:05,379 --> 00:54:09,509
We can now take three of them, or soon, you can take three of them, and

788
00:54:09,509 --> 00:54:13,510
you can get deregulated status, and that is completely reckless.

789
00:54:15,290 --> 00:54:20,430
It'll open up the floodgates, we'll watch patents flood the federal registry.

790
00:54:23,520 --> 00:54:28,900
The next one is deregulation will be a staple for all these internal

791
00:54:28,900 --> 00:54:33,460
federal government programs, like the BLM, the National Seed Program,

792
00:54:34,470 --> 00:54:37,710
plenty of other ones cuz once it's deregulated, it's not followed.

793
00:54:37,710 --> 00:54:45,433
They can now freely move into lease agreements and other sort of things.

794
00:54:45,433 --> 00:54:49,942
If the conservatives really knew what the agenda was,

795
00:54:49,942 --> 00:54:54,844
that our federal government's gonna run into the woods and

796
00:54:54,844 --> 00:54:59,941
start changing the DNA, I doubt [LAUGH] they would stand behind

797
00:54:59,941 --> 00:55:05,357
what they're not talking about in these presidential debates.

798
00:55:05,357 --> 00:55:07,550
Notice this topic hasn't come up?

799
00:55:07,550 --> 00:55:08,160
I wonder why.

800
00:55:09,720 --> 00:55:12,120
There's so much more.

801
00:55:12,120 --> 00:55:15,950
Obama did behavioral science, everyone should read into that, it's iffy.

802
00:55:16,990 --> 00:55:19,790
APHIS, I'm not gonna get into that one right now.

803
00:55:19,790 --> 00:55:23,935
Tom Vilsack, you should come to my movie, and

804
00:55:23,935 --> 00:55:29,783
maybe put QR codes on the boxes of genetically engineered stuff,

805
00:55:29,783 --> 00:55:35,544
so we can follow what type of long term problems this could have.

806
00:55:35,544 --> 00:55:39,330
So, QR codes on GE foods, not the other way around.

807
00:55:39,330 --> 00:55:40,860
We were here first, organic.

808
00:55:43,220 --> 00:55:45,860
Why have voters not heard about this debate?

809
00:55:45,860 --> 00:55:47,201
I already said that.

810
00:55:47,201 --> 00:55:51,905
And we need grocery chains, distributors,

811
00:55:51,905 --> 00:55:57,475
bakers, food chains to start supporting our local,

812
00:55:57,475 --> 00:56:00,586
do I still have 15 minutes?

813
00:56:00,586 --> 00:56:01,803
>> No, you're over.

814
00:56:01,803 --> 00:56:03,103
>> I'm over.

815
00:56:03,103 --> 00:56:04,566
I'll leave it at that.

816
00:56:04,566 --> 00:56:06,131
Love should conquer.

817
00:56:06,131 --> 00:56:11,435
Scientists, please start holding your bosses liable so

818
00:56:11,435 --> 00:56:17,196
when we do learn biotechnology, we can do it in a safe manner.

819
00:56:17,196 --> 00:56:18,449
Please.

820
00:56:18,449 --> 00:56:18,976
Thank you.

821
00:56:18,976 --> 00:56:20,864
>> Is this your microphone here?

822
00:56:20,864 --> 00:56:22,124
>> It is, [INAUDIBLE].

823
00:56:22,124 --> 00:56:22,624
>> Yeah.

Public Comment #17: Andy May

824
00:56:24,920 --> 00:56:29,206
>> Next speaker, Andy May and after that, Margo McMillan.

825
00:56:44,798 --> 00:56:47,420
Hello. My name is Andy May.

826
00:56:47,420 --> 00:56:49,450
Thank you very much for

827
00:56:49,450 --> 00:56:53,080
hosting the meeting allowing us to participate in the discussion here.

828
00:56:53,080 --> 00:56:57,080
I'm the chief scientific officer of a company called Biosciences,

829
00:56:57,080 --> 00:57:00,880
who are a small bio technology company based in Berkeley.

830
00:57:00,880 --> 00:57:04,840
We develop genome engineering and analysis technologies based on proteins derived

831
00:57:04,840 --> 00:57:09,037
from systems, and we focus on the developments of new bio-based product.

832
00:57:10,550 --> 00:57:14,820
These systems allow us to make precise changes in genomes that can be used to

833
00:57:14,820 --> 00:57:18,060
accelerate and improve the breeding of plants and animals,

834
00:57:18,060 --> 00:57:24,754
the developments of new therapeutics and industrial microorganisms.

835
00:57:24,754 --> 00:57:30,840
Using these technologies we have the potential to improve animal welfare,

836
00:57:30,840 --> 00:57:34,640
to reduce pesticide and fungicide use, treat genetic diseases, and

837
00:57:34,640 --> 00:57:36,429
produce chemicals without reliance on oil.

838
00:57:38,090 --> 00:57:41,700
The current regulatory framework was written many years ago and

839
00:57:41,700 --> 00:57:44,869
has been effective, but is complicated, lengthy and expensive.

840
00:57:44,869 --> 00:57:50,290
We believe it's key to develop a new modern framework that allows

841
00:57:50,290 --> 00:57:54,510
us to adopt and use new technologies as they emerge for developing new products,

842
00:57:54,510 --> 00:57:57,740
while retaining the appropriate oversight, and protecting public safety.

843
00:57:59,790 --> 00:58:02,850
We believe that products should be regulated and not the processes.

844
00:58:04,940 --> 00:58:07,890
This discussion towards the development of a new coordinated framework

845
00:58:07,890 --> 00:58:10,160
cannot be a one and done conversation.

846
00:58:10,160 --> 00:58:13,080
The framework has to contain some flexibility and

847
00:58:13,080 --> 00:58:15,800
needs to build in a mechanism for continued reassessment and

848
00:58:15,800 --> 00:58:18,039
adaptation as new and exciting approaches emerge.

849
00:58:19,150 --> 00:58:23,620
That said, we need that framework, as small companies and innovators to provide

850
00:58:23,620 --> 00:58:27,540
certainty and clarity to enable continued investment in developing new products.

851
00:58:29,330 --> 00:58:32,212
Many of the new technologies we have available to us are applicable in many

852
00:58:32,212 --> 00:58:33,008
different fields.

853
00:58:33,008 --> 00:58:36,534
And decisions that we make around regulations in one area,

854
00:58:36,534 --> 00:58:41,262
such as therapeutics, agriculture or industrial biosciences will echo, and

855
00:58:41,262 --> 00:58:44,170
have implications in each of those other areas.

856
00:58:45,640 --> 00:58:47,564
We have the tools available to us, now,

857
00:58:47,564 --> 00:58:50,688
to make new products that will be of enormous benefit to society.

858
00:58:50,688 --> 00:58:55,312
And it's paramount that the new framework encourages innovation, and
development,

859
00:58:55,312 --> 00:58:58,073
while combining that with appropriate oversight.

860
00:58:58,073 --> 00:59:03,450
Thank you.

861
00:59:03,450 --> 00:59:06,700
>> Thank you. Next will be Margot McMillen and

862
00:59:06,700 --> 00:59:07,520
Jim Murray.

Public Comment #18: Margot McMillen

863
00:59:11,750 --> 00:59:14,900
>> Hi, I'm another proxy for Margo McMillen,

864
00:59:14,900 --> 00:59:18,840
who's the owner of Terra Bella Farms near Hatton, Missouri.

865
00:59:18,840 --> 00:59:20,181
She was unable to fly out.

866
00:59:20,181 --> 00:59:26,130
Terra Bella farm is a organic farm surrounded by GMO row crop farms.

867
00:59:26,130 --> 00:59:28,720
Our farm has been hit with herbicide drift

868
00:59:28,720 --> 00:59:32,300
from sprays on GMOs twice in the last three years.

869
00:59:32,300 --> 00:59:35,796
This has resulted in a substantial financial cost to the farm

870
00:59:35,796 --> 00:59:37,226
in loss of vegetable crops.

871
00:59:37,226 --> 00:59:40,885
In 2014, our entire tomato crop was killed by drift,

872
00:59:40,885 --> 00:59:45,950
resulting in a $25,000 loss, our entire year's profit.

873
00:59:45,950 --> 00:59:50,920
Because of the widespread planting of USDA-approved Roundup ready crops,

874
00:59:50,920 --> 00:59:55,124
the midwest is now also overrun with weeds resistant to Roundup,

875
00:59:55,124 --> 00:59:57,738
such as the highly allergenic ragweed.

876
00:59:57,738 --> 01:00:00,704
The financial cost in days of lost work for

877
01:00:00,704 --> 01:00:06,500
allergy sufferers must be taken into consideration when regulating GMOs.

878
01:00:06,500 --> 01:00:09,895
Yet the EPA continues to approve the use of hazardous,

879
01:00:09,895 --> 01:00:13,450
drift-prone herbicides to be used with these GMOs.

880
01:00:13,450 --> 01:00:15,700
Coordinated framework has been an utter failure.

881
01:00:15,700 --> 01:00:19,660
The three agencies involved have together failed to protect the health and

882
01:00:19,660 --> 01:00:22,950
livelihoods of farmers in rural communities like ours.

883
01:00:22,950 --> 01:00:27,680
Regarding USDA's role in particular, we at Terra Bella Farm,

884
01:00:27,680 --> 01:00:32,080
strongly disagree with the agencies narrow definitions of its responsibility as only

885
01:00:32,080 --> 01:00:38,250
having to do- with regulating GMOs if they include plant pest components.

886
01:00:38,250 --> 01:00:41,990
Based on the experience and losses of many farmers, foresters, vintners,

887
01:00:41,990 --> 01:00:45,930
and others, GMO crops fit the definition of a noxious weed.

888
01:00:45,930 --> 01:00:48,380
As well, the spread of these crops is having

889
01:00:48,380 --> 01:00:51,990
harmful socioeconomic impacts across the Midwest.

890
01:00:51,990 --> 01:00:55,850
We insist that you regulate GMOs with the most diligence possible.

891
01:00:55,850 --> 01:01:00,140
For example, instead of trying to further weaken its already flawed rules, USDA

892
01:01:00,140 --> 01:01:04,830
should be proposing stronger rules to more strictly regulate GMOs by anticipating and

893
01:01:04,830 --> 01:01:08,810
preventing the disastrous consequences that we, and other farmers,

894
01:01:08,810 --> 01:01:10,500
are experiencing now.

895
01:01:10,500 --> 01:01:14,350
The whole system of genetic engineering threatens plant and animal health.

896
01:01:14,350 --> 01:01:20,100
Transgenic contamination of non-GMO crops and wild relatives is a growing problem.

897
01:01:20,100 --> 01:01:23,260
The GMO solution to resistant weeds is turning to older and

898
01:01:23,260 --> 01:01:25,080
more potent chemicals.

899
01:01:25,080 --> 01:01:30,034
USDA has already approved new crops modified to resist 2,4-D and

900
01:01:30,034 --> 01:01:34,940
dicamba with new threats to human health or plant health.

901
01:01:34,940 --> 01:01:39,260
These unintended consequences are predictable and could have been avoided,

902
01:01:39,260 --> 01:01:42,670
but the sound science and organic agriculture which offers this safe and

903
01:01:42,670 --> 01:01:45,350
healthy alternative path has been ignored.

904
01:01:45,350 --> 01:01:50,125
We at Terra Bella Farm urge the OSTP, USDA, EPA and FDA to establish a new

905
01:01:50,125 --> 01:01:54,758
framework that not only regulates biotech products more strictly.

906
01:01:54,758 --> 01:01:59,810
But puts US agriculture on a path towards ecologically, sustainable organic farming.

907
01:01:59,810 --> 01:02:01,960
Thank you.
>> Thank you.

908
01:02:04,801 --> 01:02:07,661
After Mr Murray, we will have Kenneth Oye.

Public Comment #19: James Murray

909
01:02:12,098 --> 01:02:13,580
>> Hello, my name is James Murray.

910
01:02:13,580 --> 01:02:15,000
I am a professor here at Davis.

911
01:02:16,150 --> 01:02:19,770
I'm a professor in the College of Agriculture, Department of Animal Science,

912
01:02:19,770 --> 01:02:22,030
and also in the School of Veterinary Medicine.

913
01:02:22,030 --> 01:02:27,180
I have been involved in the field genetic engineering animals for over 30 years.

914
01:02:27,180 --> 01:02:32,140
And I think we really need to be clear that regulatory dysfunction has stifled

915
01:02:32,140 --> 01:02:36,670
development of GE animals in the public sector.

916
01:02:36,670 --> 01:02:41,288
And the public sector is where all GE animal development has taken place.

917
01:02:41,288 --> 01:02:43,625
We simply can't afford the regulatory costs and

918
01:02:43,625 --> 01:02:46,340
burdens to move forward with our products.

919
01:02:46,340 --> 01:02:48,920
But I wanted to comment specifically in two areas.

920
01:02:48,920 --> 01:02:52,828
First, I think it's very telling that two important players are missing here.

921
01:02:52,828 --> 01:02:56,343
The USDA's Food Safety Inspection Service,

922
01:02:56,343 --> 01:03:01,850
which should be the primary contact point for GE animals going for food.

923
01:03:01,850 --> 01:03:05,335
And the FDA CVM, which is the primary contact point,

924
01:03:05,335 --> 01:03:07,980
are both missing from this discussion.

925
01:03:09,170 --> 01:03:13,720
I think the fact that they're missing actually limits

926
01:03:13,720 --> 01:03:16,530
the communication that can take place.

927
01:03:16,530 --> 01:03:23,140
Second, at least in the GE animal field, which has largely not been talked about.

928
01:03:23,140 --> 01:03:25,310
We need science based assessment of products.

929
01:03:25,310 --> 01:03:28,450
As present, we have a process based on regulation.

930
01:03:28,450 --> 01:03:34,113
We have regulation based on process, it's the of

931
01:03:34,113 --> 01:03:38,978
DNA construct that triggers regulatory review.

932
01:03:38,978 --> 01:03:40,049
It's the process,

933
01:03:40,049 --> 01:03:43,830
not the end point of the product which we really want to be regulated.

934
01:03:43,830 --> 01:03:46,926
Which in the case of food or medical model or

935
01:03:46,926 --> 01:03:51,486
in the case of production of a biologic, all of these go to CVM.

936
01:03:51,486 --> 01:03:56,412
So all animals go to the same entry point regardless of the type of

937
01:03:56,412 --> 01:03:59,894
product that they're designed to produce.

938
01:03:59,894 --> 01:04:03,429
This leads to the second part, which is science based regulation.

939
01:04:03,429 --> 01:04:07,790
The FDA considers DNA to be safe to eat, that is, it's GRAS.

940
01:04:07,790 --> 01:04:13,475
Whether you eat organic or GE, you're eating DNA in everything you eat.

941
01:04:13,475 --> 01:04:16,893
Yet the injected transgene is considered to be a drug, and

942
01:04:16,893 --> 01:04:20,608
the trans gene DNA that has passed through one or more meiosis.

943
01:04:20,608 --> 01:04:25,242
In the case of the Aqua Bounty salmon, we're talking 20 or 25 generations now,

944
01:04:25,242 --> 01:04:26,950
is considered a drug residue.

945
01:04:29,260 --> 01:04:32,000
So, DNA is safe to eat on the one hand,

946
01:04:32,000 --> 01:04:35,449
when it's consumed in a non GE animal or plant.

947
01:04:35,449 --> 01:04:38,824
But the same sequence, when transferred, is considered a drug, or

948
01:04:38,824 --> 01:04:41,690
a drug residue which implies potentially being harmful.

949
01:04:41,690 --> 01:04:45,338
This is a contradiction which is scientifically indefensible.

950
01:04:45,338 --> 01:04:49,758
And I would just end with, in conclusion that the public sector developers would

951
01:04:49,758 --> 01:04:53,919
hope that this review would result in substantive changes in the regulatory

952
01:04:53,919 --> 01:04:57,690
process, as well as improved coordination, which, personally,

953
01:04:57,690 --> 01:05:01,286
I think's probably been lacking for most of the last 30 years.

954
01:05:04,908 --> 01:05:11,786
After Kenneth we have Bill Peck.

Public Comment #20: Kenneth Oye

955
01:05:11,786 --> 01:05:13,226
>> Thank you very much.

956
01:05:13,226 --> 01:05:18,621
I'm Ken Oye from MIT, director on the Program of Emerging Technologies, and I'm

957
01:05:18,621 --> 01:05:24,261
also the Director of Policy and Practices at NSF SynBERC, the synthetic biology ERC.

958
01:05:24,261 --> 01:05:28,378
I'm gonna be presenting a couple highlights from a report.

959
01:05:28,378 --> 01:05:33,948
We actually prepared a 20 page document on the specifics of revision or

960
01:05:33,948 --> 01:05:37,055
reform of the coordinated framework and

961
01:05:37,055 --> 01:05:40,818
also on what to do in terms of long term strategy.

962
01:05:40,818 --> 01:05:43,668
So let me kinda go into a couple of the points.

963
01:05:43,668 --> 01:05:48,574
First, this document was prepared with colleagues from Stanford and Harvard and

964
01:05:48,574 --> 01:05:53,138
the Woodrow Wilson Center, and our method was to be drawing on experience.

965
01:05:53,138 --> 01:05:55,644
What we did was a series of case studies,

966
01:05:55,644 --> 01:05:59,927
six workshops taking examples of applications of synthetic biology

967
01:05:59,927 --> 01:06:02,978
including stuff that we've talked about here.

968
01:06:02,978 --> 01:06:08,212
Altro biofields for example, but also the weird stuff that's coming soon,

969
01:06:08,212 --> 01:06:13,284
gene drives and other applications of bio technology that are not quite yet

970
01:06:13,284 --> 01:06:18,035
here, but actually raised regulatory issues that really do need to be

971
01:06:18,035 --> 01:06:20,318
discussed much more carefully.

972
01:06:20,318 --> 01:06:26,371
The method that we use took us into some down-in-the-weeds analysis of some gaps or

973
01:06:26,371 --> 01:06:30,168
mismatches as well as long-term recommendations.

974
01:06:30,168 --> 01:06:34,329
In terms of down in the weeds, Mark was talking, for example,

975
01:06:34,329 --> 01:06:38,963
about how regulatory focus is on transgenic insertions, and, yet,

976
01:06:38,963 --> 01:06:43,990
if we look at the technology's underdevelopment now, deletions are often

977
01:06:43,990 --> 01:06:48,808
being used in ways that produce quite novel applications in organisms.

978
01:06:48,808 --> 01:06:52,688
Or, there was a long discussion of bio-containment, early today.

979
01:06:52,688 --> 01:06:55,963
And the containment was in terms of physical containment, and

980
01:06:55,963 --> 01:06:58,388
that's the focus of regulation at this time.

981
01:06:58,388 --> 01:07:02,695
Yet our good engineers are developing methods of biological containment,

982
01:07:02,695 --> 01:07:06,193
including codon knockouts to reduce lateral gene transfer,

983
01:07:06,193 --> 01:07:08,883
or multiple nutrient dependency strategies,

984
01:07:08,883 --> 01:07:13,810
where the dependencies are on amino acids that don't exist in nature.

985
01:07:13,810 --> 01:07:17,940
These, again, don't fit neatly within the existing regulatory framework,

986
01:07:17,940 --> 01:07:22,498
they are not well understood at this time, and again, the regulations have to adjust,

987
01:07:22,498 --> 01:07:24,179
or move to take account of them.

988
01:07:24,179 --> 01:07:28,470
We had a lot of discussion of FDA regulation 187, not the regulation but

989
01:07:28,470 --> 01:07:32,149
the guidance, and its application to demonstrate safety and

990
01:07:32,149 --> 01:07:36,372
efficacy from the perspective of an animal is entirely appropriate, but

991
01:07:36,372 --> 01:07:39,798
it doesn't work well if we're talking invasive species.

992
01:07:39,798 --> 01:07:45,608
Let me note in conclusion that the latter part of this document focuses on providing

993
01:07:45,608 --> 01:07:51,598
for planned adaptation in the presence of substantial uncertainty and complexity.

994
01:07:51,598 --> 01:07:56,201
In fact, we began the day, Robbie, with your reference to the need for

995
01:07:56,201 --> 01:08:00,198
regulations that were based on the best available science.

996
01:08:00,198 --> 01:08:02,538
And we have to do a little better than that.

997
01:08:02,538 --> 01:08:04,913
We have to actually be ginning up, and

998
01:08:04,913 --> 01:08:09,074
focusing on the development of the science to inform regulation,

999
01:08:09,074 --> 01:08:13,457
building on and expanding from things like the BRAG Program in USDA but

1000
01:08:13,457 --> 01:08:17,840
also even on IP issues building on the example of the ARS agreements for

1001
01:08:17,840 --> 01:08:20,098
broader licensing arrangements.

1002
01:08:20,098 --> 01:08:23,315
So for more on these points please go to MIT POET and

1003
01:08:23,315 --> 01:08:28,142
there aren't many poets at MIT, programming on emerging technologies,

1004
01:08:28,142 --> 01:08:31,989
and the white paper sitting right at the top of the website.

1005
01:08:31,989 --> 01:08:32,529
Thank you.

1006
01:08:35,728 --> 01:08:40,166
>> After Bill Peck, Dana Pearls.

Public Comment #21: Bill Peck

1007
01:08:40,166 --> 01:08:41,266
>> Good afternoon, everyone.

1008
01:08:41,266 --> 01:08:45,206
Thank you for giving me opportunity to present a few thoughts.

1009
01:08:45,206 --> 01:08:46,086
>> State your name.

1010
01:08:46,086 --> 01:08:46,606
>> I will.

1011
01:08:46,606 --> 01:08:47,186
>> Okay.

1012
01:08:47,186 --> 01:08:52,028
[LAUGH] This is an important meeting >> My name is Bill Peck.

1013
01:08:52,028 --> 01:08:53,499
I'm the co-founder and

1014
01:08:53,499 --> 01:08:57,776
Chief Technical Officer at Twist Bio-Science located in the Bay area.

1015
01:08:57,776 --> 01:09:01,358
For the past 16 years, I've been involved in the DNA breeding revolution.

1016
01:09:01,358 --> 01:09:06,152
It's been an exciting time to see such a progress in breeding and

1017
01:09:06,152 --> 01:09:08,418
all the fruits that is bared.

1018
01:09:08,418 --> 01:09:12,350
Now, usually I don't have a problem with my voice.

1019
01:09:12,350 --> 01:09:15,795
Now, insights gleaned from the vast amount of bred DNA is enabling

1020
01:09:15,795 --> 01:09:17,098
its logical extension.

1021
01:09:17,098 --> 01:09:20,578
That is, using the information intelligently to write DNA.

1022
01:09:20,578 --> 01:09:25,309
Our ability to write DNA ultimately enables great possibilities,

1023
01:09:25,309 --> 01:09:29,127
one where we maintain our current quality of life while

1024
01:09:29,127 --> 01:09:33,868
establishing a symbiotic method to coexist with our environment.

1025
01:09:33,868 --> 01:09:39,850
Twist was founded three years ago to answer a DNA write capacity bottleneck and

1026
01:09:39,850 --> 01:09:42,488
accelerate this important work.

1027
01:09:42,488 --> 01:09:46,138
We now employ over 100 people engaged in this effort.

1028
01:09:46,138 --> 01:09:51,483
Twist primary mission is to provide synthetically manufactured genes

1029
01:09:51,483 --> 01:09:56,568
at scale to accelerate the biotechnology design build test cycle.

1030
01:09:56,568 --> 01:10:00,020
In the context in today's discussion,

1031
01:10:00,020 --> 01:10:04,792
we're a tools provider where we provide tools to people

1032
01:10:04,792 --> 01:10:09,778
you heard from earlier, Ganko, Zymer Jin in the future.

1033
01:10:09,778 --> 01:10:14,470
It is these companies that will be providing products across a wide

1034
01:10:14,470 --> 01:10:18,258
range of industries from fuels to pharmaceuticals.

1035
01:10:18,258 --> 01:10:20,524
As is typical of a tools provider,

1036
01:10:20,524 --> 01:10:26,075
we concentrate particularly difficult technology, in our case semiconductor and

1037
01:10:26,075 --> 01:10:29,841
automation technology, and turning on the thing here.

1038
01:10:36,818 --> 01:10:41,018
To manufacturer enabling products, in our case, genes.

1039
01:10:41,018 --> 01:10:44,655
As you bring our scale online, we'll have ready access to tools that will greatly

1040
01:10:44,655 --> 01:10:46,458
accelerate the field to new engineers.

1041
01:10:46,458 --> 01:10:50,744
We are committed to provide these tools to the new engineers in a safe and

1042
01:10:50,744 --> 01:10:51,878
responsible way.

1043
01:10:51,878 --> 01:10:56,830
And just as structural, or in my case aeronautical engineers,

1044
01:10:56,830 --> 01:11:01,782
have their efforts regulated in the interest of public safety,

1045
01:11:01,782 --> 01:11:03,983
so shall our efforts here and

1046
01:11:03,983 --> 01:11:09,230
in the future provide these framework to ensure the public safety.

1047
01:11:10,510 --> 01:11:14,428
We're seeing surprising interest in a wide variety of areas.

1048
01:11:14,428 --> 01:11:18,947
You may have seen the New York Times article we're providing DNA to store

1049
01:11:18,947 --> 01:11:20,340
data storage.

1050
01:11:20,340 --> 01:11:23,538
So a photograph or picture, very much like you do in a hard drive.

1051
01:11:26,318 --> 01:11:29,288
In this case though, we're using the information of life.

1052
01:11:29,288 --> 01:11:33,640
And as our mission at Twist, to use this information of life,

1053
01:11:33,640 --> 01:11:38,258
to again foster the symbiotic relationship with our ecosystem.

1054
01:11:38,258 --> 01:11:41,854
We especially support the construction of an open communication path between

1055
01:11:41,854 --> 01:11:45,403
the practitioners such as ourselves, regulators, and all stakeholders.

1056
01:11:45,403 --> 01:11:51,277
We take an active role to ensure we go out into the community like I am here and

1057
01:11:51,277 --> 01:11:56,130
understand existing regulatory and security restraints and

1058
01:11:56,130 --> 01:12:01,840
learn how we can participate in the future for regulatory environment.

1059
01:12:01,840 --> 01:12:04,270
While policies and procedures require both time and

1060
01:12:04,270 --> 01:12:08,136
monetary investment from small companies like Twist, where company is committed

1061
01:12:08,136 --> 01:12:11,688
to accelerating scientific research to improve lives world wide.

1062
01:12:11,688 --> 01:12:14,550
These advances in precision biology hold great promise for

1063
01:12:14,550 --> 01:12:17,850
improving human health in a global environment.

1064
01:12:17,850 --> 01:12:21,400
Twist Biosciences is proud to be part of this promise and

1065
01:12:21,400 --> 01:12:24,050
also support the principle use of the technology.

1066
01:12:24,050 --> 01:12:27,700
Finally, we applaud the efforts of all the agencies represented here today and

1067
01:12:27,700 --> 01:12:30,460
support the efforts to refresh the coordinated framework to

1068
01:12:30,460 --> 01:12:33,130
reflect the current biotechnology context.

1069
01:12:33,130 --> 01:12:34,314
Thank you.

1070
01:12:34,314 --> 01:12:39,302
>> [APPLAUSE]
>> Dana Perls is next and

1071
01:12:39,302 --> 01:12:40,638
then Allison Pieja.

Public Comment #22: Dana Perls

1072
01:12:43,128 --> 01:12:46,410
>> Hi, this is actually my comment now.

1073
01:12:46,410 --> 01:12:50,363
My name is Dana Perls, Food and Technology campaigner with Friends of the Earth.

1074
01:12:50,363 --> 01:12:53,830
I'm pleased to provide comment on the coordinated framework.

1075
01:12:53,830 --> 01:12:59,370
Friends of the Earth urges the EPA, FDA, and USDA to develop a new framework

1076
01:12:59,370 --> 01:13:04,190
with mandatory federal regulations for all products, including plants, insects,

1077
01:13:04,190 --> 01:13:08,860
and animals developed through any gene editing processes.

1078
01:13:08,860 --> 01:13:12,180
This framework should prioritize the protection of farmer's livelihoods,

1079
01:13:12,180 --> 01:13:17,300
public health, and the environment ahead of chemical and agribusiness interests.

1080
01:13:17,300 --> 01:13:21,490
As we have learned from first generation GE organisms ranging from herbicide

1081
01:13:21,490 --> 01:13:26,410
tolerant crops to GE salmon, despite existing risk assessment frameworks,

1082
01:13:26,410 --> 01:13:30,380
significant gaps exist between the regulatory agencies responsible for

1083
01:13:30,380 --> 01:13:32,750
the oversight of GE products.

1084
01:13:32,750 --> 01:13:35,670
For example, herbicide tolerant crops have led to the increased

1085
01:13:35,670 --> 01:13:38,850
use of hundreds of millions of pounds of new pesticides.

1086
01:13:38,850 --> 01:13:41,510
For new genetic engineering techniques like synthetic biology,

1087
01:13:41,510 --> 01:13:44,070
there are currently no national regulations,

1088
01:13:44,070 --> 01:13:49,110
which fully assess potential risks of commercialized and environmental
releases.

1089
01:13:50,200 --> 01:13:54,000
To make the coordinated framework into an appropriate system that protects
public

1090
01:13:54,000 --> 01:13:57,880
farmers and the environment, we need at least three basic protections.

1091
01:13:57,880 --> 01:13:59,720
First, safety testing.

1092
01:13:59,720 --> 01:14:04,590
EPA, USDA, and FDA need mandatory regulations and independent assessments

1093
01:14:04,590 --> 01:14:12,240
for any organism, developed using genetic engineering and gene editing
processes.

1094
01:14:12,240 --> 01:14:16,090
These regulations should address long term safety risks and direct and

1095
01:14:16,090 --> 01:14:18,160
indirect environmental harm.

1096
01:14:18,160 --> 01:14:21,590
Until demonstrated to be safe, GE crops, insects, and

1097
01:14:21,590 --> 01:14:23,850
animals should not be commercialized.

1098
01:14:23,850 --> 01:14:26,458
Two, manufacture liability.

1099
01:14:26,458 --> 01:14:31,427
Biotech companies that produce and sell GE crops, insects, and animals must be held

1100
01:14:31,427 --> 01:14:35,017
liable for the significant costs that their products cause,

1101
01:14:35,017 --> 01:14:39,805
resulting from contamination of organic and non-GE farms and products.

1102
01:14:39,805 --> 01:14:42,725
The burden for preventing contamination should be carried by

1103
01:14:42,725 --> 01:14:48,015
the company's profiting from the sales of GE products, not by those who are harmed.

1104
01:14:48,015 --> 01:14:52,035
And third, guarantee the public's right to know in the name of transparency.

1105
01:14:52,035 --> 01:14:56,238
Mandatory labelling should be required for all genetically engineered foods and

1106
01:14:56,238 --> 01:15:00,950
gene editing produced organisms as well.

1107
01:15:00,950 --> 01:15:05,310
Given the clear gaps in the coordinated framework and without strong national

1108
01:15:05,310 --> 01:15:09,950
regulatory oversight with technology, specific risk assessments including

1109
01:15:09,950 --> 01:15:14,859
environmental health and socioeconomic impacts, Friends of the Earth urges

1110
01:15:17,080 --> 01:15:21,040
a firm moratorium on the environmental release and commercial use

1111
01:15:21,040 --> 01:15:26,300
of new organisms derived from genetic engineering and gene editing technologies.

1112
01:15:26,300 --> 01:15:28,918
Thank you for the opportunity to comment on this very important issue.

1113
01:15:28,918 --> 01:15:29,698
>> Thank you.

1114
01:15:33,410 --> 01:15:36,760
Allison Pieja and then Pamela Ronald.

Public Comment #23: Allison Pieja

1115
01:15:36,760 --> 01:15:40,426
Say your name because I might have not said it correctly.

1116
01:15:40,426 --> 01:15:42,490
>> Good afternoon, and thank you all for your time.

1117
01:15:42,490 --> 01:15:43,844
My name is Allison Pieja,

1118
01:15:43,844 --> 01:15:46,928
and I'm the chief technology officer of Mango Materials.

1119
01:15:46,928 --> 01:15:50,605
Mango Materials is a small startup company in the Bay Area that produces a natural,

1120
01:15:50,605 --> 01:15:53,770
bio-degradable alternative to conventional oil-based plastics.

1121
01:15:54,770 --> 01:15:57,720
To do this, we feed methane to a community of bacteria and

1122
01:15:57,720 --> 01:16:01,130
then induce them to produce the biodegradable material.

1123
01:16:01,130 --> 01:16:03,930
If we didn't use methane, this potent greenhouse gas would typically be

1124
01:16:03,930 --> 01:16:07,690
flared or vented to the atmosphere at waste treatment plants or landfills or

1125
01:16:07,690 --> 01:16:11,070
agricultural sites and could contribute significantly to climate change.

1126
01:16:11,070 --> 01:16:14,990
Our technology will simultaneously mitigate climate change and

1127
01:16:14,990 --> 01:16:17,090
eliminate plastic pollution.

1128
01:16:17,090 --> 01:16:17,880
My cofounders and

1129
01:16:17,880 --> 01:16:22,400
I founded Mango Materials based on our PhD research at Stanford University.

1130
01:16:22,400 --> 01:16:25,410
We're excited to turn our graduate lab scale research into reality and

1131
01:16:25,410 --> 01:16:28,160
develop a product that will benefit society and the environment.

1132
01:16:29,620 --> 01:16:32,990
Our mission is to transform waste into eco-friendly affordable materials while

1133
01:16:32,990 --> 01:16:35,170
creating a positive environmental impact.

1134
01:16:35,170 --> 01:16:38,230
Our main goal is to sort of replace this product, plastic, that we see causing

1135
01:16:38,230 --> 01:16:42,660
significant environmental damage, both through its production and its disposal,

1136
01:16:42,660 --> 01:16:46,040
and also to mitigate climate change by the use of methane.

1137
01:16:46,040 --> 01:16:48,810
We envision a more sustainably, environmentally conscious future where

1138
01:16:48,810 --> 01:16:51,165
companies are more accountable for the products they produce.

1139
01:16:51,165 --> 01:16:53,850
As a startup at the forefront of the industry,

1140
01:16:53,850 --> 01:16:56,160
we face an exciting journey to commercialization.

1141
01:16:56,160 --> 01:16:58,880
We'd also face necessarily several challenges.

1142
01:16:58,880 --> 01:17:01,510
We've already overcome many of these challenges and have grown our business

1143
01:17:01,510 --> 01:17:05,590
from three founders with just an idea funded by a single government grant to

1144
01:17:05,590 --> 01:17:10,280
a team, a rapidly growing team of 18 people, scientists and business people,

1145
01:17:10,280 --> 01:17:13,040
operating a pilot production system at a wastewater treatment plant and

1146
01:17:13,040 --> 01:17:16,209
navigating a complex network of potential customers, funders, and partners.

1147
01:17:17,380 --> 01:17:21,361
One challenge we face is to produce an environmentally conscious product, while

1148
01:17:21,361 --> 01:17:25,238
also achieving a price point that will allow us to compete based on costs alone.

1149
01:17:25,238 --> 01:17:29,480
A second challenge we face is scaling a biotechnology manufacturing process.

1150
01:17:29,480 --> 01:17:33,470
A third challenge we face is education and teaching the general public, as well as

1151
01:17:33,470 --> 01:17:36,605
regulators and larger companies, about different biomaterials and

1152
01:17:36,605 --> 01:17:39,920
their relative abilities to be completely broken down in various environments,

1153
01:17:39,920 --> 01:17:41,860
as well as their various properties.

1154
01:17:41,860 --> 01:17:44,973
It's important that the public is assured that this new technology is safe and

1155
01:17:44,973 --> 01:17:47,385
positive for society, which it certainly is.

1156
01:17:47,385 --> 01:17:48,530
Safety is our number one priority,

1157
01:17:48,530 --> 01:17:51,540
and we value transparent communication with the public.

1158
01:17:51,540 --> 01:17:54,352
We are confident we can surmount all these challenges, and we ask for

1159
01:17:54,352 --> 01:17:56,330
regulatory support in doing so.

1160
01:17:56,330 --> 01:17:59,200
We firmly believe that companies such as Mango Materials represent

1161
01:17:59,200 --> 01:18:00,850
the future of the industry.

1162
01:18:00,850 --> 01:18:03,710
We're supportive of government efforts to reform the regulatory system to

1163
01:18:03,710 --> 01:18:06,990
streamline development of innovative, sustainable solutions.

1164
01:18:06,990 --> 01:18:10,130
These new technologies can create more prosperity with a much smaller

1165
01:18:10,130 --> 01:18:12,900
environmental impact than others before.

1166
01:18:12,900 --> 01:18:15,750
We understand our impact on the planet now better,

1167
01:18:15,750 --> 01:18:20,070
and we are striving to make changes, to change business as usual,

1168
01:18:20,070 --> 01:18:22,720
to conserve resources and sustain future generations.

1169
01:18:22,720 --> 01:18:25,960
We need a streamlined regulatory system to get us there as quickly as possible.

1170
01:18:25,960 --> 01:18:28,666
Thank you.

1171
01:18:28,666 --> 01:18:31,106
>> Thank you.

1172
01:18:31,106 --> 01:18:32,386
Next is Pamela Ronald.

1173
01:18:36,586 --> 01:18:38,326
Doesn't look like Pamela is here.

Public Comment #24: Pablo Ross

1174
01:18:38,326 --> 01:18:38,966
Pablo Ross?

1175
01:18:43,398 --> 01:18:46,378
After Pablo will be Brenda Ruiz.

1176
01:18:59,188 --> 01:19:03,814
>> Okay, good afternoon, and thank you for the opportunity to address the panel and

1177
01:19:03,814 --> 01:19:04,830
the people here.

1178
01:19:04,830 --> 01:19:07,010
And my name is Pablo Ross.

1179
01:19:07,010 --> 01:19:11,310
I'm an associate professor in animal science here at UC Davis.

1180
01:19:11,310 --> 01:19:16,098
And I work developing some of these technologies and applying them to generate

1181
01:19:16,098 --> 01:19:21,973
animals with improved characteristics that will provide better food, better fiber.

1182
01:19:21,973 --> 01:19:26,547
Maybe work for people, and, really, I was very disappointed for

1183
01:19:26,547 --> 01:19:29,244
the case studies that were presented,

1184
01:19:29,244 --> 01:19:33,998
because they really don't address the future of biotechnologies.

1185
01:19:33,998 --> 01:19:39,072
And we're not at a time where we can really modify,

1186
01:19:39,072 --> 01:19:45,454
or change, any single one of the letters of the DNA in an animal.

1187
01:19:45,454 --> 01:19:51,108
I mean, from all of the 300 million letters that are there,

1188
01:19:51,108 --> 01:19:56,230
we can very precisely modify the ones that will produce,

1189
01:19:56,230 --> 01:20:01,906
like I said, better products, better health for the animal.

1190
01:20:01,906 --> 01:20:08,590
And so the potential is only limited to our imagination.

1191
01:20:08,590 --> 01:20:13,680
However, when we think about our best ideas, and we confront them

1192
01:20:13,680 --> 01:20:18,930
with the regulatory process, and with the prospective of having any of these

1193
01:20:18,930 --> 01:20:24,410
better animals make it into the market and benefit the public.

1194
01:20:24,410 --> 01:20:28,675
They really tumble and disappear, and so,

1195
01:20:28,675 --> 01:20:33,631
what we need, I think, from this new initiative,

1196
01:20:33,631 --> 01:20:38,473
is a really streamlined, transparent, quick,

1197
01:20:38,473 --> 01:20:44,816
affordable system that will allow us to assess the possibilities

1198
01:20:44,816 --> 01:20:50,613
of developing these ideas so they can make it to the market.

1199
01:20:50,613 --> 01:20:56,023
And then, yeah basically so, thank you.

1200
01:20:59,181 --> 01:21:01,549
Thank you.

1201
01:21:01,549 --> 01:21:06,445
So the next two folks who registered to make a statement did not

1202
01:21:06,445 --> 01:21:08,716
sign in today as being here.

1203
01:21:08,716 --> 01:21:13,684
Brenda Louise, Nicholas Short, if you're here, this is your turn.

1204
01:21:13,684 --> 01:21:15,800
It looks, okay.

1205
01:21:18,305 --> 01:21:21,068
Which one was that?

1206
01:21:21,068 --> 01:21:25,800
Okay Nick is not here, so the next registered speaker is Zia Sonabend.

1207
01:21:31,585 --> 01:21:33,010
After Zia, Joe Tarrantino.

1208
01:21:41,439 --> 01:21:43,756
>> Thank you.

1209
01:21:54,629 --> 01:21:58,181
>> Thank you.

Public Comment #25: Zea Sonnabend

1210
01:21:58,181 --> 01:21:59,650
My name is Zea Sonnabend.

1211
01:21:59,650 --> 01:22:03,366
I'm a certified organic farmer from Watsonville, California.

1212
01:22:03,366 --> 01:22:08,989
I'm here today representing California Certified Organic Farmers,

1213
01:22:08,989 --> 01:22:14,611
the largest accredited certification agency in the US with 3,069

1214
01:22:14,611 --> 01:22:20,715
clients nationwide representing two point four million acres of farmland.

1215
01:22:20,715 --> 01:22:25,566
We feel that the coordinated framework from 1986 did not have the weight of law

1216
01:22:25,566 --> 01:22:30,009
behind it, and thus, has had no requirements for adequate regulations.

1217
01:22:31,380 --> 01:22:35,040
Therefore, it does not seem to be protecting the environment or

1218
01:22:35,040 --> 01:22:39,263
the public interest, at least from the organic farmer's point of view.

1219
01:22:39,263 --> 01:22:42,425
The individual agencies of USDA, EPA, and FDA,

1220
01:22:42,425 --> 01:22:47,772
have chosen a very cramped interpretation of the regulation of genetic engineering

1221
01:22:47,772 --> 01:22:52,741
that only looks at plant noxious weeds, animal, drugs, etc without

1222
01:22:52,741 --> 01:22:58,340
looking at all the unique risks of engineered crops, insects and foods.

1223
01:22:58,340 --> 01:23:01,313
Indirect risks such as the harm from using

1224
01:23:01,313 --> 01:23:04,579
on engineered crops thus leading to resistant weeds.

1225
01:23:04,579 --> 01:23:09,980
The lack of genetic diversity caused by all these herbicides in the wild plants.

1226
01:23:09,980 --> 01:23:14,504
The effect on pollinators from the decline in genetic diversity and

1227
01:23:14,504 --> 01:23:18,550
the harm to humans from the increased risk of toxic chemicals

1228
01:23:18,550 --> 01:23:22,455
are serious concern to organic producers and consumers.

1229
01:23:22,455 --> 01:23:28,888
Under the USDA organic regulations, GMOs are considered an excluded method [COUGH].

1230
01:23:28,888 --> 01:23:34,424
Organic farms are being contaminated with genetically modified pollen and wind blown

1231
01:23:34,424 --> 01:23:39,578
seed and are suffering economic harm from this trespass by having to bear expense

1232
01:23:39,578 --> 01:23:45,369
of extra prevention measures, testing, and having crops rejected in the marketplace.

1233
01:23:46,650 --> 01:23:51,700
We believe a true coordinated framework needs a few points if

1234
01:23:51,700 --> 01:23:56,660
it is to be an overall approach to regulating these things.

1235
01:23:56,660 --> 01:23:59,583
There needs to be mandatory regulations for

1236
01:23:59,583 --> 01:24:03,932
all organisms developed using genetic engineering processes.

1237
01:24:03,932 --> 01:24:08,661
This includes properly defining all the new gene editing and

1238
01:24:08,661 --> 01:24:11,824
RNAi and all these other technologies.

1239
01:24:11,824 --> 01:24:17,781
And considering stacked traits and their possible synergistic

1240
01:24:17,781 --> 01:24:22,640
effects as well as the individual components of it.

1241
01:24:22,640 --> 01:24:25,065
Integrated risk assessment should be robust and

1242
01:24:25,065 --> 01:24:29,156
should include impacts like what happens to pollen that travels long distances?

1243
01:24:29,156 --> 01:24:34,190
What happens to Monarch butterflies when their habitats are destroyed by chemicals?

1244
01:24:34,190 --> 01:24:37,656
And what happens to bees when more toxic materials are used to sustain

1245
01:24:37,656 --> 01:24:39,450
the genetically modified crops?

1246
01:24:39,450 --> 01:24:43,517
Long-term and indirect risks should be looked at because

1247
01:24:43,517 --> 01:24:46,756
all things in the environment are connected.

1248
01:24:46,756 --> 01:24:51,471
And GMOs have risks that are proving to be quite different from traditional crops.

1249
01:24:51,471 --> 01:24:55,463
There needs to be regulation, a firm regulation and

1250
01:24:55,463 --> 01:25:00,880
better outreach on how to use the GMO products responsibly.

1251
01:25:00,880 --> 01:25:05,740
Why should organic producers have to have the large buffers,

1252
01:25:05,740 --> 01:25:08,084
but the GMO polluters do not.

1253
01:25:08,084 --> 01:25:13,373
If genetic engineering is able to make such large advantages with new techniques,

1254
01:25:13,373 --> 01:25:17,826
why not require GMO plants who produce pollen to have the pollen fall to

1255
01:25:17,826 --> 01:25:19,736
the ground at the fence line?

1256
01:25:19,736 --> 01:25:21,981
That should be able to be genetically engineered so

1257
01:25:21,981 --> 01:25:24,496
we're not experiencing pollution from these sources.

1258
01:25:24,496 --> 01:25:29,003
Organic farmers should have the right to practice their trade

1259
01:25:29,003 --> 01:25:32,550
without being infringed by the trespass.

1260
01:25:32,550 --> 01:25:37,498
Organic consumers have the right to expect organic content products

1261
01:25:37,498 --> 01:25:39,212
to not contain GMO’s.

1262
01:25:39,212 --> 01:25:40,247
The government so

1263
01:25:40,247 --> 01:25:44,594
far seems to be more interested in advancing commercialization of GMOs and

1264
01:25:44,594 --> 01:25:48,888
not in protecting everyone's right to choose how to farm and what to eat.

1265
01:25:48,888 --> 01:25:50,851
Thank you.

Public Comment #26: Joe Tarantino

1266
01:25:55,527 --> 01:25:59,010
>> Joe Tarantino is coming up, and Scott Thunell is next.

1267
01:25:59,010 --> 01:25:59,957
See how tall you are.

1268
01:25:59,957 --> 01:26:03,885
[LAUGH] >> Hello,

1269
01:26:03,885 --> 01:26:06,791
my name is Joe Tarantino, and I am with Ecovative Design.

1270
01:26:06,791 --> 01:26:11,246
Ecovative Design is a biomaterials company, using fungi to grow

1271
01:26:11,246 --> 01:26:16,520
alternatives to synthetic materials such as styrofoam and particle board.

1272
01:26:16,520 --> 01:26:19,167
Now, there are a number of problems with synthetic materials.

1273
01:26:19,167 --> 01:26:24,331
Through biology, we are able to mitigate these problems, and grow materials

1274
01:26:24,331 --> 01:26:29,967
that use rapidly renewable resources that do not require the use of toxic chemicals,

1275
01:26:29,967 --> 01:26:35,620
that pose no human or environmental health hazards, and that are home compostable.

1276
01:26:39,365 --> 01:26:43,151
We can do this today using wild type organisms.

1277
01:26:43,151 --> 01:26:47,911
And we create products that are cost and performance competitive.

1278
01:26:47,911 --> 01:26:53,197
However, this is not enough to shift massive industries

1279
01:26:53,197 --> 01:26:57,500
from a chemical paradigm to a biological one.

1280
01:26:59,000 --> 01:27:03,689
Through biotechnology, we can alter the organisms that we

1281
01:27:03,689 --> 01:27:08,752
work with to create a more efficient process, to reduce costs,

1282
01:27:08,752 --> 01:27:14,307
to increase performance, and to add whole new modes of performance.

1283
01:27:14,307 --> 01:27:16,548
Ultimately cheaper, better,

1284
01:27:16,548 --> 01:27:22,196
sustainable materials will ensure widespread option, and healthier living.

1285
01:27:22,196 --> 01:27:27,513
As such, Ecovative is in support of biotechnology and the regulation thereof.

1286
01:27:27,513 --> 01:27:30,394
We look to regulation to provide a well-defined,

1287
01:27:30,394 --> 01:27:34,620
reasonable framework from within which we can realize these potentials.

1288
01:27:34,620 --> 01:27:36,559
Thank you.

1289
01:27:40,000 --> 01:27:42,068
>> Thank you.

1290
01:27:42,068 --> 01:27:46,108
>> After Scott Finnell, Paul Towers is listed but he didn't register.

1291
01:27:46,108 --> 01:27:48,500
So if he's not here, Alan Van Dane will be Next.

Public Comment #27: Scott Thenell

1292
01:27:52,959 --> 01:27:56,423
>> Good afternoon, and thank you for the opportunity to present my perspectives.

1293
01:27:56,423 --> 01:27:57,507
I'm Scott Thenell.

1294
01:27:57,507 --> 01:28:01,905
I’m a food scientist and managing partner of Thenell and Associates.

1295
01:28:01,905 --> 01:28:07,193
We're a regulatory consulting firm that provides advice to companies that make and

1296
01:28:07,193 --> 01:28:11,000
market genetically engineered plants and plant products.

1297
01:28:14,050 --> 01:28:15,450
From my perspective,

1298
01:28:15,450 --> 01:28:18,079
I think the coordinated framework has worked pretty well.

1299
01:28:19,450 --> 01:28:24,250
That said, we've heard of a number of gaps identified today and

1300
01:28:24,250 --> 01:28:29,250
I think it's appropriate in light of the development of technologies

1301
01:28:29,250 --> 01:28:31,570
to re-examine, and modernize it.

1302
01:28:33,560 --> 01:28:37,700
Federal agencies have 30 years of experience of doing environmental, and

1303
01:28:37,700 --> 01:28:40,030
food safety assessments.

1304
01:28:40,030 --> 01:28:44,140
And I think that involving genetically engineered organisms, and

1305
01:28:44,140 --> 01:28:47,270
I think that we need to build on that.

1306
01:28:49,310 --> 01:28:54,180
My perspective is informed by working with a lot of small companies and

1307
01:28:54,180 --> 01:28:55,819
public universities.

1308
01:28:57,430 --> 01:29:00,520
And what I'm seeing is that current regulations pose

1309
01:29:02,330 --> 01:29:09,060
a very substantial opportunity cost on both human and animal health,

1310
01:29:09,060 --> 01:29:15,290
on natural resources, and on US trade and agricultural production.

1311
01:29:15,290 --> 01:29:19,060
I'd like to illustrate my point with a brief example.

1312
01:29:19,060 --> 01:29:24,480
1990 I started with a small bio-tech company, DNA Plant Technology, and we

1313
01:29:24,480 --> 01:29:30,170
were involved in genetically engineering fruits and vegetables for quality traits.

1314
01:29:30,170 --> 01:29:34,260
About two years after starting the regulatory process we had achieved

1315
01:29:35,470 --> 01:29:40,340
approvals in the US, Canada, and Mexico for a delayed ripening tomato.

1316
01:29:41,990 --> 01:29:44,120
Fast forward to 20 years, and

1317
01:29:44,120 --> 01:29:49,580
today I'm helping Texas A&M University

1318
01:29:49,580 --> 01:29:53,150
prepare some submissions for genetically engineered cottonseed.

1319
01:29:55,570 --> 01:29:59,780
Which has the potential to transform cottonseed from a relatively

1320
01:29:59,780 --> 01:30:02,080
underutilized byproduct,

1321
01:30:03,170 --> 01:30:09,240
with the potential now to be new protein source to feed 500 million people.

1322
01:30:09,240 --> 01:30:13,570
We do that by basically knocking out an important seed toxin.

1323
01:30:14,900 --> 01:30:19,910
It took Texas A&M seven years from discovery to proof of concept, and

1324
01:30:19,910 --> 01:30:24,390
now four years later, once we started the regulatory process,

1325
01:30:24,390 --> 01:30:28,443
four years later and about $2.3 million,

1326
01:30:28,443 --> 01:30:34,761
we're going to submit to the US agencies for approval.

1327
01:30:36,820 --> 01:30:41,315
Unfortunately those approvals don't permit us to move that product outside

1328
01:30:41,315 --> 01:30:45,840
the United States cultivated outside the United States or

1329
01:30:45,840 --> 01:30:47,650
exported for feed and food.

1330
01:30:47,650 --> 01:30:52,560
The cost of global regulation is completely outside the scope of

1331
01:30:53,580 --> 01:30:55,660
a university public breeding program.

1332
01:30:57,860 --> 01:31:02,570
So I have a series of questions, but I think the most important one is to how

1333
01:31:02,570 --> 01:31:10,930
boldly are the US agencies willing to modernize this scope of regulation.

1334
01:31:10,930 --> 01:31:16,150
I would leave you with the idea that the new long term strategy has to return

1335
01:31:16,150 --> 01:31:21,710
to the regulatory principles that we've seen published in executive orders and

1336
01:31:21,710 --> 01:31:22,880
White House memoranda.

1337
01:31:22,880 --> 01:31:27,920
It needs to be predictable and equitable for small and

1338
01:31:27,920 --> 01:31:32,350
large companies, both public and private, and

1339
01:31:32,350 --> 01:31:37,150
it has to encourage innovation by minimizing unnecessary regulations.

1340
01:31:37,150 --> 01:31:43,030
Thank you. >> Thank you.

1341
01:31:43,030 --> 01:31:45,220
>> Is Paul Towers here?

1342
01:31:45,220 --> 01:31:46,742
>> He's not.

1343
01:31:46,742 --> 01:31:47,440
>> Not.

1344
01:31:47,440 --> 01:31:48,130
Okay.

1345
01:31:48,130 --> 01:31:53,589
Alan, after Alan Van Dane,
Alison Van Eenennaam.

Public Comment #28: Alan Van Deynze

1346
01:31:53,589 --> 01:31:57,070
>> Thanks for getting my name almost right.

1347
01:31:57,070 --> 01:31:57,970
No, you did really well.

1348
01:31:57,970 --> 01:32:00,270
My name is Alan Van Deynze.

1349
01:32:00,270 --> 01:32:04,170
I'm Associate Director of plant breeding at UC Davis.

1350
01:32:04,170 --> 01:32:08,302
And I'm also past chair of the US Plant Breeding Coordinating Committee.

1351
01:32:08,302 --> 01:32:10,660
I have been involved in agriculture all my life.

1352
01:32:11,860 --> 01:32:14,980
I would like to thank the office of Science and Technology for

1353
01:32:14,980 --> 01:32:19,890
providing this opportunity to comment, and I welcome you to California

1354
01:32:19,890 --> 01:32:24,269
where you get most of your nutrition all year round from fruits and vegetables.

1355
01:32:25,340 --> 01:32:27,850
So plant breeding is really the basis of this.

1356
01:32:27,850 --> 01:32:30,525
And plant breeding has been extremely successful at meeting

1357
01:32:30,525 --> 01:32:34,160
the challenges of growing population and changing environment for

1358
01:32:34,160 --> 01:32:39,230
over 100 years now, leveraging really impactful innovations along the way.

1359
01:32:39,230 --> 01:32:44,420
These include understanding just the basic genetic principles, hybridization and

1360
01:32:44,420 --> 01:32:45,750
hybrid vigor.

1361
01:32:45,750 --> 01:32:51,550
Mutation breeding, genomics, bioinformatics, and yes, biotechnologies.

1362
01:32:51,550 --> 01:32:54,180
But biotechnologies is a very broad term.

1363
01:32:54,180 --> 01:32:59,142
These include haploid production, grafting, protoplast fusion,

1364
01:32:59,142 --> 01:33:03,630
meristem tip culture, embryo rescue, and y crosses.

1365
01:33:05,010 --> 01:33:09,550
These have all been applied across all crops to maintain yield and quantity, and

1366
01:33:09,550 --> 01:33:12,700
work to the key to the success of the green revolution,

1367
01:33:12,700 --> 01:33:18,050
which is a basis of self-sustenance for several countries.

1368
01:33:18,050 --> 01:33:21,970
So, plant breeding has delivered safe food to our tables,

1369
01:33:21,970 --> 01:33:25,700
requiring an increase in numbering of tools to ensure our food security,

1370
01:33:25,700 --> 01:33:27,460
and most importantly our nutritional security.

1371
01:33:28,870 --> 01:33:33,500
This has been achieved with a practical set of regulations in the seed and

1372
01:33:33,500 --> 01:33:36,780
the food industries to maintain product quality,

1373
01:33:36,780 --> 01:33:38,725
trade in exchange of genetic materials.

1374
01:33:38,725 --> 01:33:44,320
Transgenic technologies, insertion of genes from plants,

1375
01:33:44,320 --> 01:33:48,010
within and across species have a special regulation though.

1376
01:33:48,010 --> 01:33:52,850
They're regulated on the DNA manipulation process rather than the crop product.

1377
01:33:52,850 --> 01:33:54,160
This is very unique.

1378
01:33:55,340 --> 01:33:58,670
Public plant breeding programs and education of the key to innovation

1379
01:33:58,670 --> 01:34:02,861
required to feed a growing population in developed and in developing countries.

1380
01:34:02,861 --> 01:34:07,350
Public scientists horticulture crops, critical to nutritional security

1381
01:34:07,350 --> 01:34:11,950
in California, have not been able to use the full plant breeder's toolbox,

1382
01:34:11,950 --> 01:34:14,450
due to increasing regulatory costs and requirements.

1383
01:34:16,240 --> 01:34:18,850
We're already making significant advances in horticultural and

1384
01:34:18,850 --> 01:34:22,750
field crops, with new plant breeding tools, including gene editing,

1385
01:34:22,750 --> 01:34:25,629
that allow us to use hypothesis driven plant breeding techniques.

1386
01:34:26,840 --> 01:34:30,530
Using the information, increasing information, that we learn about genes and

1387
01:34:30,530 --> 01:34:31,980
genomes.

1388
01:34:31,980 --> 01:34:36,760
By using natural DNA processes, we can now efficiently imitate mother nature

1389
01:34:36,760 --> 01:34:41,160
to create small mutations and alleles, for crop improvement.

1390
01:34:42,860 --> 01:34:47,660
These new tools are especially useful in our crops, and many of them are perennial,

1391
01:34:47,660 --> 01:34:52,010
have complex genetics, and they're found in vegetables, and nuts,

1392
01:34:52,010 --> 01:34:53,440
and fruit crops here in California.

1393
01:34:54,600 --> 01:35:00,820
So we urge the Office of Science and Technology to lead the world to recognize

1394
01:35:00,820 --> 01:35:06,510
that science has overwhelmingly shown that plant breeding and its products are safe.

1395
01:35:06,510 --> 01:35:09,320
That DNA technology per se is safe.

1396
01:35:09,320 --> 01:35:12,060
That crops by definition are inherently safe,

1397
01:35:12,060 --> 01:35:14,430
domesticated animals are inherently safe.

1398
01:35:14,430 --> 01:35:16,610
Traits are inherently safe.

1399
01:35:16,610 --> 01:35:21,740
And we urge the office to allow plant breeders in all crops to use all

1400
01:35:21,740 --> 01:35:27,780
the plant breeding tools by developing a transparent, practical, coordinated and

1401
01:35:27,780 --> 01:35:32,640
predictable regulation system, that is based on products and not on process.

1402
01:35:32,640 --> 01:35:37,070
The product based food system, the regulatory has served us well.

1403
01:35:37,070 --> 01:35:37,570
Thank you.

1404
01:35:41,670 --> 01:35:44,809
>> Allison Van Eenennaam is next, And then Joanna Voight.

Public Comment #29: Allison Van Eenennaam

1405
01:35:47,586 --> 01:35:52,326
Thank you and I guess, I'm Allison Van Eenennaam, and I work in Animal Science

1406
01:35:52,326 --> 01:35:56,620
department here in Animal Biotechnology and I got my PhD in genetics.

1407
01:35:56,620 --> 01:35:58,429
I'm also a mother and a consumer.

1408
01:35:58,429 --> 01:36:02,383
And I guess I'd like to say everything Alan said except replace plant with

1409
01:36:02,383 --> 01:36:02,903
animal.

1410
01:36:02,903 --> 01:36:07,777
And I think you'll see and I think it's been clear that there's a number of people

1411
01:36:07,777 --> 01:36:11,948
that have come up before this group from the public sector breeders who

1412
01:36:11,948 --> 01:36:17,110
have been basically precluded from using the tool of genetic engineering.

1413
01:36:17,110 --> 01:36:21,070
And I think I join Pablo Ross in my department in being

1414
01:36:21,070 --> 01:36:25,040
a little frustrated that none of the examples considered today address gene

1415
01:36:25,040 --> 01:36:29,680
editing applications that didn't result in a transgene being put in the end product.

1416
01:36:29,680 --> 01:36:32,660
In 30 years science has moved on and

1417
01:36:32,660 --> 01:36:37,630
we have evolved and global breeders are super interested in using these precise

1418
01:36:37,630 --> 01:36:41,830
techniques to introduce useful genetic variation into their breeding programs.

1419
01:36:41,830 --> 01:36:46,326
And as an animal breeder, I still don't know if I make a single base pair change

1420
01:36:46,326 --> 01:36:49,920
in an animal, is that, or is that not a regulated article.

1421
01:36:49,920 --> 01:36:53,850
And I think these problems, or these questions need to be addressed fairly

1422
01:36:53,850 --> 01:36:59,445
urgently, because we are actually, bringing these animals into existence.

1423
01:36:59,445 --> 01:37:02,345
Under the coordinated framework we've been discussing this morning,

1424
01:37:02,345 --> 01:37:06,965
were meant to be regulating based on risk, and further, that oversight will be

1425
01:37:06,965 --> 01:37:11,135
exercised only when the risk posed by the introduction is unreasonable.

1426
01:37:11,135 --> 01:37:15,945
That is, when the value in the reduction in risk obtained by additional oversight

1427
01:37:15,945 --> 01:37:20,200
is greater than the cost thereby imposed by that regulation.

1428
01:37:20,200 --> 01:37:23,290
And I would argue that in the case of animal biotechnology,

1429
01:37:23,290 --> 01:37:26,550
that is actually not what is happening in practice.

1430
01:37:26,550 --> 01:37:27,210
The trigger for

1431
01:37:27,210 --> 01:37:32,110
regulation of animal biotechnology is the use of our DNA technologies.

1432
01:37:32,110 --> 01:37:34,130
That's a process based trigger.

1433
01:37:34,130 --> 01:37:39,170
And basically, as was alluded to by Dr. Murray, all of the animals that inherit

1434
01:37:39,170 --> 01:37:44,720
that DNA, that drug residue, are regulated by the FDA.

1435
01:37:44,720 --> 01:37:47,130
The fast growing salmon for example,

1436
01:37:47,130 --> 01:37:51,890
which was first created a quarter of a century ago, went through over

1437
01:37:51,890 --> 01:37:55,955
an $80 million regulatory evaluation process to get to market.

1438
01:37:55,955 --> 01:38:04,280
The regulation was much more expensive than the risk there.

1439
01:38:04,280 --> 01:38:07,620
We breed fast growing animals all the time using conventional methods,

1440
01:38:07,620 --> 01:38:12,030
including fast-growing salmon, which are subject to no regulatory oversight.

1441
01:38:12,030 --> 01:38:17,210
And the most profound implication of these high costs is it's basically precluded

1442
01:38:17,210 --> 01:38:20,710
the public sector from developing useful genetic plants and

1443
01:38:20,710 --> 01:38:22,030
animals to bring to market.

1444
01:38:22,030 --> 01:38:25,810
And that's basically who's responsible for doing public good breeding.

1445
01:38:25,810 --> 01:38:29,690
And I think there's a lot of angst amongst the breeders particularly at

1446
01:38:29,690 --> 01:38:33,430
this land grant university, and land grant universities throughout the nation

1447
01:38:33,430 --> 01:38:36,770
are being, basically prohibited from using the technology.

1448
01:38:36,770 --> 01:38:40,610
Because there's no way our universities can come up with a multi-million dollar

1449
01:38:40,610 --> 01:38:44,570
regulatory package to bring these products to market.

1450
01:38:44,570 --> 01:38:47,840
And I think that the gene edited products really mimic

1451
01:38:47,840 --> 01:38:51,010
the process of naturally occurring mutations.

1452
01:38:51,010 --> 01:38:56,010
Especially those that feature allele integration, or analogous to mutagenesis,

1453
01:38:56,010 --> 01:38:59,990
pose the same risks and benefits as traditional breeding methods.

1454
01:38:59,990 --> 01:39:05,300
And if regulations on gene editing are not clearly based on product risk

1455
01:39:05,300 --> 01:39:08,210
along with the consideration of the potential benefits rather than

1456
01:39:08,210 --> 01:39:09,980
the use of the product of gene editing.

1457
01:39:09,980 --> 01:39:13,550
Then there's a real risk of precluding the public sector and

1458
01:39:13,550 --> 01:39:18,020
small companies from using these valuable technologies in their breeding programs,

1459
01:39:18,020 --> 01:39:22,090
resulting in tremendous opportunity costs in foregone innovation,

1460
01:39:22,090 --> 01:39:25,380
which will have detrimental effects on global food security.

1461
01:39:25,380 --> 01:39:26,413
Thank you.

Public Comment #30: Joanna Voigt

1462
01:39:30,714 --> 01:39:33,104
>> Next is Joanna Voigt.

1463
01:39:33,104 --> 01:39:37,541
And after Joanna, Sriema Walawage.

1464
01:39:37,541 --> 01:39:39,610
>> Hi, this is my last proxy.

1465
01:39:41,130 --> 01:39:42,430
My name is Joanna Voight.

1466
01:39:42,430 --> 01:39:46,350
My family has been farming in Kansas for five generations.

1467
01:39:46,350 --> 01:39:48,800
As a teenager, I helped my dad

1468
01:39:48,800 --> 01:39:53,200
plant 700 pecan seedlings on his farm on the banks of the Kansas River.

1469
01:39:53,200 --> 01:39:56,470
We grafted 13 pecan cultivars, chosen for flavor and

1470
01:39:56,470 --> 01:40:00,050
diversity, onto the hearty root stock of the seedlings.

1471
01:40:00,050 --> 01:40:04,310
After a number of years, they were bearing heavily enough to harvest in quantity and

1472
01:40:04,310 --> 01:40:07,300
we established a you-pick operation at the farm and

1473
01:40:07,300 --> 01:40:10,750
sold harvested pecans at the local farmer's market.

1474
01:40:11,860 --> 01:40:15,390
Now, I have moved on to work for the Kansas Rural Center,

1475
01:40:15,390 --> 01:40:20,050
a nonprofit organization established in 1979 to promote a food and

1476
01:40:20,050 --> 01:40:25,000
farm system That is ecologically sound, economically viable, and socially just.

1477
01:40:25,000 --> 01:40:29,520
I appreciate the opportunity to provide comment on the coordinated framework.

1478
01:40:29,520 --> 01:40:33,535
Because of the potentially profound impacts of the products of biotechnology

1479
01:40:33,535 --> 01:40:37,910
on agriculture, farmers, food, and the environment, I feel that it is critically

1480
01:40:37,910 --> 01:40:41,588
important to have input from a wide and diverse range of participants.

1481
01:40:41,588 --> 01:40:45,457
And particularly those people directly involved in farming and

1482
01:40:45,457 --> 01:40:50,042
food production in the midwest, as midwestern farmers stand to be directly

1483
01:40:50,042 --> 01:40:55,350
and imminently impacted by the release of new bioproducts and biotechnology.

1484
01:40:55,350 --> 01:40:56,840
With only two opportunities for

1485
01:40:56,840 --> 01:41:01,700
public comment in locations far from the commodity crop epicenter of the US,

1486
01:41:01,700 --> 01:41:05,530
it seems that those who stand to be impacted the most by the release of new

1487
01:41:05,530 --> 01:41:10,570
products of biotechnology are the most under-represented in the discussion.

1488
01:41:10,570 --> 01:41:14,640
The unintended consequences of previous products of biotechnology are things we

1489
01:41:14,640 --> 01:41:17,530
in the midwest deal with on a persistent basis.

1490
01:41:17,530 --> 01:41:21,360
From the emergence of super weeds, and the resulting increase in the amounts
and

1491
01:41:21,360 --> 01:41:24,810
strength of chemicals being used to combat resistant weeds.

1492
01:41:24,810 --> 01:41:28,730
To decline and pollinate our population, stemming from the use of GMO seeds,

1493
01:41:28,730 --> 01:41:32,720
treated with systemic pesticides, to losses in genetic diversity,

1494
01:41:32,720 --> 01:41:35,400
resulting from GMO corn pollen drift.

1495
01:41:35,400 --> 01:41:38,910
To the release of products such as StarLink corn that have not been approved

1496
01:41:38,910 --> 01:41:43,710
for export, and have resulted in huge economic losses for Midwestern farmers.

1497
01:41:43,710 --> 01:41:46,560
The consequences of new products of biotechnology have

1498
01:41:46,560 --> 01:41:49,230
been at times profoundly significant.

1499
01:41:49,230 --> 01:41:53,260
The results and consequences demonstrate the need for regulatory process for

1500
01:41:53,260 --> 01:41:56,080
the release of new products of biotechnology

1501
01:41:56,080 --> 01:41:58,120
that includes extremely thorough studying and

1502
01:41:58,120 --> 01:42:02,870
careful consideration of all potential consequences and adequate input from

1503
01:42:02,870 --> 01:42:07,000
people who are impacted most directly by products of biotechnology.

1504
01:42:07,000 --> 01:42:07,769
Thank you.

1505
01:42:12,828 --> 01:42:15,038
>> Sriema Walawage?

1506
01:42:18,122 --> 01:42:20,790
Patrick Westfall.

1507
01:42:20,790 --> 01:42:23,480
After Patrick, Randy Berka.

Public Comment #31: Patrick Westfall

1508
01:42:31,230 --> 01:42:34,657
>> Good afternoon everyone, my name is Patrick Westfall, and I've had

1509
01:42:34,657 --> 01:42:39,148
the privilege of serving as a scientist in the synthetic biology industry since 2006.

1510
01:42:39,148 --> 01:42:42,450
In the last ten years, I've been fortunate enough to work for both the large,

1511
01:42:42,450 --> 01:42:46,209
established biotechnology leader, as well as a couple of rapidly growing start-ups,

1512
01:42:46,209 --> 01:42:49,216
including my current position as Director of Business Development and

1513
01:42:49,216 --> 01:42:53,205
Fundamental Science at Zymergen Incorporated in Emeryville, California.

1514
01:42:53,205 --> 01:42:54,130
Zymergen discovers and

1515
01:42:54,130 --> 01:42:58,870
produces useful organic chemicals using innovations in microbial production.

1516
01:42:58,870 --> 01:43:02,970
The speed at which science of biological engineering has been moving is astounding.

1517
01:43:02,970 --> 01:43:05,360
Biotech product ideas that used to take decades to develop,

1518
01:43:05,360 --> 01:43:07,500
from the proof of concepts stage to commercial relevance,

1519
01:43:07,500 --> 01:43:10,290
can now be done in a matter of years if not months.

1520
01:43:10,290 --> 01:43:14,090
These are real products that have impact on our everyday lives, from providing life

1521
01:43:14,090 --> 01:43:17,670
saving medical treatments, enhancing the safety of our food supply, and

1522
01:43:17,670 --> 01:43:23,645
reducing our environmental impact and dependence on imported production inputs.

1523
01:43:23,645 --> 01:43:26,020
However, the cost and time to bring these materials to market,

1524
01:43:26,020 --> 01:43:28,220
even when showing an equivalency to current products,

1525
01:43:28,220 --> 01:43:32,550
is not compatible with the speed of which the technology is capable of moving.

1526
01:43:32,550 --> 01:43:36,380
I have seen first hand how progress and innovation can be stifled by a regulatory

1527
01:43:36,380 --> 01:43:40,790
system whose rules are difficult to parse, pose great compliance expense, and

1528
01:43:40,790 --> 01:43:43,280
is not reflective of the current scientific understanding and

1529
01:43:43,280 --> 01:43:45,220
product development realities.

1530
01:43:45,220 --> 01:43:48,909
The current system poses an unreasonable barrier to new market entrants who may not

1531
01:43:48,909 --> 01:43:52,546
have the staffing and tens of millions of dollars over decades to bring products to

1532
01:43:52,546 --> 01:43:54,041
market under its requirements.

1533
01:43:54,041 --> 01:43:57,542
The ability to streamline the regulatory process while maintaining exceptional

1534
01:43:57,542 --> 01:44:00,942
standard of safety would give more opportunities to innovative organizations

1535
01:44:00,942 --> 01:44:03,897
such as Zymergen to have a positive impact on the global bioeconomy.

1536
01:44:03,897 --> 01:44:08,400
We must modernize the system by making it more transparent and easier to navigate.

1537
01:44:08,400 --> 01:44:11,371
We need a system that is flexible, can grow and adapt to change and

1538
01:44:11,371 --> 01:44:15,070
more closely, matches the pace, at which innovation is moving.

1539
01:44:15,070 --> 01:44:18,020
Finally, we need a system that enhances education and communication between

1540
01:44:18,020 --> 01:44:21,070
private industry, government regulators and a consuming public.

1541
01:44:22,410 --> 01:44:25,360
To close, I'd like to recognize that the topic of regulation of biotechnology

1542
01:44:25,360 --> 01:44:28,580
affects us all, at a personal and sometimes professional level.

1543
01:44:28,580 --> 01:44:30,210
As we proceed with updating how the government and

1544
01:44:30,210 --> 01:44:32,370
private industry approaches modernizing this process,

1545
01:44:32,370 --> 01:44:36,700
let me emphasize that everyone involved has a vested interest in maintaining

1546
01:44:36,700 --> 01:44:39,790
a high standard of safety for all products that are evaluated.

1547
01:44:39,790 --> 01:44:41,550
Let us proceed with an assumption of goodwill and

1548
01:44:41,550 --> 01:44:45,310
recognize that no one individual scientist, government employees, or

1549
01:44:45,310 --> 01:44:49,010
industrial institutions would benefit from intentionally developing products that did

1550
01:44:49,010 --> 01:44:52,250
not meet both an ethical and scientific safety standard for the public.

1551
01:44:52,250 --> 01:44:55,910
We simply ask the system be timely, decisions be data driven,

1552
01:44:55,910 --> 01:44:59,130
and applications of the rule be fair, proportionate, and

1553
01:44:59,130 --> 01:45:01,898
transparent for all parties who engage in the process.

1554
01:45:01,898 --> 01:45:02,932
Thank you.

1555
01:45:07,517 --> 01:45:11,912
>> After Randy Burka, Lisa Griffith.

Public Comment #32: Randy Burka

1556
01:45:11,912 --> 01:45:14,040
Thank you.

1557
01:45:14,040 --> 01:45:16,790
>> Thank you for the opportunity to comment on the environmental impact

1558
01:45:16,790 --> 01:45:20,890
statement on the introduction of products of biotechnology.

1559
01:45:20,890 --> 01:45:22,840
My name is Randy Burka, and I work for

1560
01:45:22,840 --> 01:45:27,840
Novazymes, the leading producer of industrial enzymes and microbials.

1561
01:45:27,840 --> 01:45:32,810
We produce biotechnology for a wide variety of industries, including food,

1562
01:45:32,810 --> 01:45:36,920
house hold cleaning supplies, biofuels, and bio agriculture.

1563
01:45:38,230 --> 01:45:40,810
At Novazymes, we are particularly concerned about the need for

1564
01:45:40,810 --> 01:45:44,670
the federal government to take a consistent, efficient and

1565
01:45:44,670 --> 01:45:48,180
predictable regulatory approach to biotechnology.

1566
01:45:48,180 --> 01:45:50,760
A lack of coordination between APHIS and

1567
01:45:50,760 --> 01:45:55,030
other federal regulators could lead to challenges for businesses like ours.

1568
01:45:55,030 --> 01:45:58,741
Including the ability to deliver products to the market quickly and

1569
01:45:58,741 --> 01:46:01,606
the ability to strategically invest in research and

1570
01:46:01,606 --> 01:46:05,008
development to support the next generation of innovations.

1571
01:46:05,008 --> 01:46:10,890
The coordinated framework effort should focus on three main priorities.

1572
01:46:10,890 --> 01:46:14,674
One, maintain high standards based on the best science that

1573
01:46:14,674 --> 01:46:18,544
deliver appropriate health and environmental protection.

1574
01:46:18,544 --> 01:46:22,673
Two, establish transparent coordinated, predictable and

1575
01:46:22,673 --> 01:46:29,080
efficient regulatory practices across agencies with overlapping jurisdictions.

1576
01:46:29,080 --> 01:46:32,320
And third, promote public confidence in the oversight

1577
01:46:32,320 --> 01:46:37,430
of the products of biotechnology though clear and transparent public
engagement.

1578
01:46:37,430 --> 01:46:40,840
I'm submitting a more detailed and technical comment for your review.

1579
01:46:40,840 --> 01:46:41,518
Thank you.

Public Comment #33: Lisa Griffith

1580
01:46:47,810 --> 01:46:48,560
>> Lisa Griffith.

1581
01:46:49,900 --> 01:46:52,050
After Lisa, John Cumbers.

1582
01:46:56,530 --> 01:47:00,700
>> Hi, I'm here as a proxy to read the comment from Lisa Griffith,

1583
01:47:00,700 --> 01:47:04,080
from the National Family Farm Coalition.

1584
01:47:04,080 --> 01:47:05,740
The National Family Farm Coalition,

1585
01:47:05,740 --> 01:47:09,440
representing thousands of independent family farmers, ranchers, and fishermen

1586
01:47:09,440 --> 01:47:13,860
throughout the United States wishes to state our support for a fully revamped,

1587
01:47:13,860 --> 01:47:19,400
coordinated framework to regulate biotechnology products in the US.

1588
01:47:19,400 --> 01:47:25,240
The current coordinated framework seems designed to advance the release of GMOs,

1589
01:47:25,240 --> 01:47:27,070
not to ensure their safety.

1590
01:47:27,070 --> 01:47:32,160
We hope that the FDA, EPA, USDA, and other agencies take the opportunity to change

1591
01:47:32,160 --> 01:47:36,620
the course of their regulatory review by adopting an approach that seeks to ensure

1592
01:47:36,620 --> 01:47:40,840
first and foremost that GMO's and their accompanying pesticides are safe.

1593
01:47:40,840 --> 01:47:45,330
The new framework must be based on comprehensive pre-release analysis of

1594
01:47:45,330 --> 01:47:50,105
any new GMO's to address the concerns of in socioeconomic, environmental and

1595
01:47:50,105 --> 01:47:53,953
health impacts on the farmers or fisherman, their families and

1596
01:47:53,953 --> 01:47:56,681
communities largely rural naming GM crops.

1597
01:47:56,681 --> 01:48:00,650
We also believe that GM foods, including seafood, should undergo long term

1598
01:48:00,650 --> 01:48:05,180
testing to ensure that they are safe for live stalk and human consumption.

1599
01:48:05,180 --> 01:48:08,410
The U.S. government agencies responsible for testing, approving, and

1600
01:48:08,410 --> 01:48:12,140
monitoring GMOs, the department of agriculture, the EPA and

1601
01:48:12,140 --> 01:48:16,990
the FDA, should not rely on information provided by those who manufacture GMOs or

1602
01:48:16,990 --> 01:48:20,270
profit from their production to determine how to test them.

1603
01:48:20,270 --> 01:48:24,963
Each agency has the means, authority, and public responsibility to regulate GM

1604
01:48:24,963 --> 01:48:29,793
crops and the pesticides used with them to ensure safe planting and harvesting that

1605
01:48:29,793 --> 01:48:34,777
does not harm farmers and workers, their livelihoods, or regional biodiversity.

1606
01:48:34,777 --> 01:48:38,782
For the past 20 years we have watched government agencies approve dozens of GM

1607
01:48:38,782 --> 01:48:41,831
crops despite concerns raised by farmers, fisherman, and

1608
01:48:41,831 --> 01:48:43,890
other members of the public.

1609
01:48:43,890 --> 01:48:47,590
These concerns include, but are not limited to,

1610
01:48:47,590 --> 01:48:53,570
reduced farmer choices for non GMO crops due to consolidated seed industry,

1611
01:48:53,570 --> 01:48:56,920
loss of independent seed dealers in the rural businesses,

1612
01:48:56,920 --> 01:49:01,750
crop contamination from seeds and pesticides, particularly those that drift.

1613
01:49:01,750 --> 01:49:06,490
Fence row to fence row planting GMO's resulted in habitat loss for birds,

1614
01:49:06,490 --> 01:49:09,320
bees, butterflies and other wildlife.

1615
01:49:09,320 --> 01:49:13,930
The reduced use of crop rotations, cover crops and similar nutrient conservation

1616
01:49:13,930 --> 01:49:18,680
weed control methods, the emergence of scores of herbicide resistant weeds.

1617
01:49:18,680 --> 01:49:22,040
The loss of organic and non-GMO certification for farmers,

1618
01:49:22,040 --> 01:49:25,810
followed by lower price points.

1619
01:49:25,810 --> 01:49:29,800
Diminished research and development of non-GM seeds at public universities,

1620
01:49:29,800 --> 01:49:31,520
including land-grant colleges.

1621
01:49:31,520 --> 01:49:35,480
And the unproven but noted correlation between cancers and other diseases

1622
01:49:35,480 --> 01:49:39,210
in rural areas where herbicide resistant GMOs are regularly planted.

1623
01:49:39,210 --> 01:49:42,930
We reiterate our stance that in a nation built on opportunity, U.S.

1624
01:49:42,930 --> 01:49:45,920
government agencies should ensure that our farmers and ranchers

1625
01:49:45,920 --> 01:49:50,530
have the opportunity to raise non-GM crops without worry of contamination and

1626
01:49:50,530 --> 01:49:55,000
destruction through seeds or herbicides in the genetically modified crops approved by

1627
01:49:55,000 --> 01:49:58,200
these agencies are absolutely safe for consumption.

1628
01:49:58,200 --> 01:50:00,858
Thank you for the opportunity to submit the comments.

1629
01:50:04,075 --> 01:50:07,495
>> So John Cumbers is our last registered speaker, so

1630
01:50:07,495 --> 01:50:09,840
this is a three minute warning.

1631
01:50:09,840 --> 01:50:11,810
If you would like to make a comment and

1632
01:50:11,810 --> 01:50:15,280
you haven't made a comment, you'll have your chance after Mr. Cumbers, thank you.

Public Comment #34: John Cumbers

1633
01:50:18,720 --> 01:50:19,900
>> Good afternoon everybody.

1634
01:50:19,900 --> 01:50:23,290
My name is John Cumbers and I have a PhD in cell molecular biology.

1635
01:50:23,290 --> 01:50:27,130
In addition to working at NASA in the synthetic biology program for

1636
01:50:27,130 --> 01:50:30,360
the last seven years, I'm the founder of SynBioBeta.

1637
01:50:30,360 --> 01:50:34,440
SynBioBeta is a global activity help for the synthetic biology industry and

1638
01:50:34,440 --> 01:50:37,380
we bring together the industry three times a year for

1639
01:50:37,380 --> 01:50:41,920
events in America, the United Kingdom and China.

1640
01:50:41,920 --> 01:50:45,280
We also maintain a company database with over 280 companies,

1641
01:50:45,280 --> 01:50:49,110
track investment in the field, job creation, and economic growth and

1642
01:50:49,110 --> 01:50:52,440
support entrepreneurs, investors, and policy makers.

1643
01:50:52,440 --> 01:50:56,810
I'm uniquely qualified to serve as the voice of the synthetic biology industry

1644
01:50:56,810 --> 01:51:00,590
and the rapid progress that it's making.

1645
01:51:00,590 --> 01:51:04,680
I'd like to thank OSTP for this opportunity to speak and for

1646
01:51:04,680 --> 01:51:08,020
recognizing the need for the government to take an active role in the regulation of

1647
01:51:08,020 --> 01:51:10,100
the future products of biotechnology.

1648
01:51:10,100 --> 01:51:14,060
There are a number of challenges in innovation posed by the regulatory system

1649
01:51:14,060 --> 01:51:15,510
as it exists today.

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01:51:15,510 --> 01:51:20,140
Given their experience in traversing the regulatory pathways to commercialization,

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01:51:20,140 --> 01:51:24,210
small companies developing new products, that you've heard of many of them speaking

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01:51:24,210 --> 01:51:29,110
today, believe that the current regulatory framework imposes significant burdens

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01:51:29,110 --> 01:51:33,780
on innovation, and in so reduces the economic potential of this industry.

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01:51:33,780 --> 01:51:37,520
It's time to try a less burdensome regulatory approach aligned with

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01:51:37,520 --> 01:51:40,800
the actual scientific consensus on the risks.

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01:51:40,800 --> 01:51:43,220
I want to applaud the government for protecting his issue and

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01:51:43,220 --> 01:51:44,860
thank you all for being here.

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01:51:44,860 --> 01:51:49,410
I think it's important that we all try to develop a long term strategy for

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01:51:49,410 --> 01:51:52,910
the regulation of biotechnology products in a safe and

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01:51:52,910 --> 01:51:55,400
transparent manner that the public has confidence in.

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01:51:55,400 --> 01:52:00,010
And that we develop this framework to ensure the biotechnology used is best

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01:52:00,010 --> 01:52:00,920
in the public interest.

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01:52:01,940 --> 01:52:06,093
Here are five general points that I'd like to highlight that I urge you to consider

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01:52:06,093 --> 01:52:10,257
as you review the current framework and make recommendations for improvements.

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01:52:10,257 --> 01:52:13,618
Number one, a basic need is to promote transparency and

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01:52:13,618 --> 01:52:16,620
access to both the process and the evidence base in

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01:52:16,620 --> 01:52:21,560
which we assess the efficacy and safety of new biotechnology products.

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01:52:21,560 --> 01:52:24,640
Number two, we need to build more easily accessible and

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01:52:24,640 --> 01:52:29,050
scalable communication interfaces between practitioners and regulators.

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01:52:29,050 --> 01:52:32,960
This is especially important for small businesses and new investors who

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01:52:32,960 --> 01:52:37,060
have little experience or resources to explore the regulatory landscape.

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01:52:37,060 --> 01:52:41,310
Number three, it's critical to treat the regulation of emerging biotechnology

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01:52:41,310 --> 01:52:45,740
as a sustaining challenge that requires ongoing research and engagement.

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01:52:45,740 --> 01:52:49,410
Number four we need to create new programs and train new people willing and

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01:52:49,410 --> 01:52:55,090
able to identify, articulate and work on immediate and long term challenges.

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01:52:55,090 --> 01:52:59,070
We must experiment with mechanisms that incentivize and empower the best minds

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01:52:59,070 --> 01:53:02,690
developing these new technologies to also care about regulating them.

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01:53:03,700 --> 01:53:06,660
And number five, it is necessary to ensure that the people and

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01:53:06,660 --> 01:53:10,060
the organizations facing these challenges are resourced to meet

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01:53:10,060 --> 01:53:14,630
an increasing number, diversity and sophistication of products.

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01:53:14,630 --> 01:53:15,294
Thank you.

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01:53:20,239 --> 01:53:22,213
>> We have a few minutes left in the session.

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01:53:22,213 --> 01:53:26,277
Is there anyone else who would like to make a comment for the record?

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01:53:28,401 --> 01:53:32,820
If not, I thank all of the speakers very much.

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01:53:32,820 --> 01:53:37,540
We finished on time and I'd like to thank everyone who attended.

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01:53:37,540 --> 01:53:43,520
Clearly there is a great diversity of beliefs, of understanding,

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01:53:43,520 --> 01:53:47,950
of opinion and this was a very respectful and professional meeting.

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01:53:47,950 --> 01:53:49,460
Thank you.

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01:53:49,460 --> 01:53:54,522
>> [APPLAUSE]