SC#93346.9

No. 32935-6

COURT OF APPEALS, DIVISION III
OF THE STATE OF WASHINGTON

ZURIEL, INC., a Washington corporation;
EDWARD D. OCHOA, Jr.,

Respondents,

v.

DAN GALBREATH and JANE DOE GALBREATH, husband and wife; DOUBLE UP RANCH, INC., a Washington corporation; GREG GALBREATH and JANE DOE GALBREATH, husband and wife; 82 FARMS, INC., a Washington corporation,

Petitioners.

PETITION FOR REVIEW

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes/Court Rules

Other Authorities

I. IDENTITY OF PETITIONERS

The petitioners for review are Dan Galbreath and Jane Doe Galbreath, husband and wife; Double Up Ranch, Inc., a Washington corporation; Greg Galbreath and Jane Doe Galbreath, husband and wife; 82 Farms, Inc., a Washington corporation (All hereinafter referred to as "Double Up").

II. COURT OF APPEALS DECISION

The Court of Appeals final decision on this case is *Zuriel, Inc. v. Galbreath*, 32935-6-III, 2016 WL 3251883 (June 7, 2016)(Copy in Appendix, pp. A-2). The Court of Appeals denied a motion for reconsideration on June 7, 2016 (Copy in Appendix, pp. 4).

III. ISSUES FOR REVIEW

1. Was Double Up prejudiced by the refusal to give accurate instructions on Federal Law that supported its argument that a majority of the potatoes were unmarketable due to the presence of pesticides never applied by Double Up?

2. Was the directed verdict on liability improperly granted when Plaintiff Zuriel *et al* never asked for a full chemical history for the property and there was no fiduciary relationship?

IV. STATEMENT OF THE CASE

Double Up subleased agricultural ground to Zuriel for potatoes. Zuriel claims that its potatoes were unmarketable due to carryover of the pesticide[1] Clopyralid that was applied by Double Up the previous year. The potatoes also contained residues of Picloram and Triclopyr, pesticides that were never applied by Double Up. The same federal law that prohibits the sale of potatoes with Clopyralid also prohibits the sale of potatoes with Triclopyr or Picloram.

Double Up's primary theory of the case on causation was that to the extent the potatoes could not be marketed due to the presence of chemicals never applied by Double Up, Double Up did not proximately cause the loss suffered due to the unmarketability of the potatoes.

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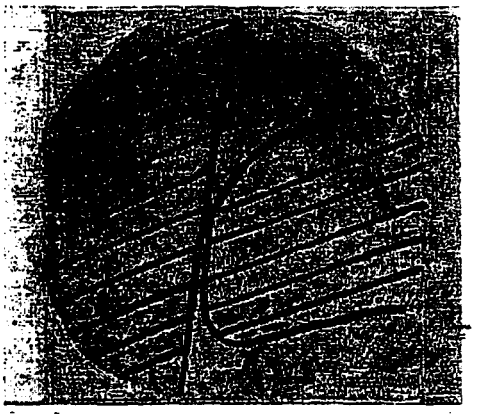
[1] "Pesticide" is used herein as defined in FIFRA (the Federal Insecticide, Fungicide and Rodenticide Act), 7 U.S.C.A. § 136(u)(Copy in Appendix, p. A-83).

The lease and lease negotiations between the parties were completely oral. (RP 523) During the lease negotiations, Zuriel did not ask for a complete history of the chemicals or pesticides applied to the property even though he knew Double Up was farming 4,000 – 5,000 acres. (RP 529) At the time of the lease negotiations, Double Up did not remember the application of Widematch, an herbicide containing Clopyralid. (RP 340) Double Up, because it did not remember the application, told Zuriel that the circle "should be good" for potatoes. (RP 527) If Ochoa had asked for a chemical history, Galbreath provided the application records to Zuriel that would have revealed the May 11, 2011 Widematch application. (RP 340; 530) Zuriel admitted that there was no partnership between Double Up and Zuriel, and the he never told Double Up he considered them in sort of a partnership. (RP 525). There was no other evidentiary basis for a fiduciary or quasi-fiduciary relationship.

Washington State Department of Agiculture (WSDA) food safety manager Gena Reich testified that growers commonly

segregate crops around contaminants and WSDA allows harvest to the next clean test. (RP 308-309) Applying the WSDA methodology to the Picloram and Triclopyr test results on a map of the field shows that the following lined out areas were unmarketable due to the presence of Picloram and Triclopyr:



(Exhibit 25 Resized to fit screen; Red lines added to show areas from positive results for Picloram and Triclopyr to next negative or "clean" sample results for those pesticides)

Double Up proposed three instructions regarding federal law as follows:

Instruction No. 21

Federal law prohibits anyone from putting potatoes into the stream of commerce if any trace of the herbicide Clopyralid is found in the potatoes.

(CP 53)

Instruction No. 22

Federal law prohibits anyone from putting potatoes into the stream of commerce if any trace of the herbicide Picloram is found in the potatoes.

(CP 54)

Instruction No. 23

Federal law prohibits anyone from putting potatoes into the stream of commerce if any trace of the herbicide Triclopyr is found in the potatoes.

(CP 55)

The Court refused to give the proposed instructions on federal law. Double Up took exception to that refusal. (RP 1684-1685). The Court gave no general instruction that federal law prohibited the sale of potatoes with pesticide residues. Zuriel has not argued that that the proposed instructions were inaccurate or misleading.

V. ARGUMENT

1. Standards of Review.

a. Refusal to Give Jury Instructions.

The standard of review for refusal to give jury instructions are stated in *Barrett v. Lucky Seven Saloon, Inc.*, 152 Wn. 2d 259, 266-67, 96 P.3d 386, 389 (2004) as follows:

> This court reviews de novo the alleged errors of law in a trial court's instructions to the jury. *Hue v. Farmboy Spray Co.*, 127 Wash.2d 67, 92, 896 P.2d 682 (1995). Instructions are inadequate if they prevent a party from arguing its theory of the case, mislead the jury, or misstate the applicable law. *Bell v. State*, 147 Wash.2d 166, 176, 52 P.3d 503 (2002). Failure to permit instructions on a party's theory of the case, where there is evidence supporting the theory, is reversible error. *State v. Williams*, 132 Wash.2d 248, 259–60, 937 P.2d 1052 (1997) (citing *State v. Griffin*, 100 Wash.2d 417, 420, 670 P.2d 265 (1983)). As with a trial court's instruction misstating the applicable law, a court's omission of a proposed statement of the governing law will be "reversible error where it prejudices a party." *Hue*, 127 Wash.2d at 92, 896 P.2d 682. If a party proposes an instruction setting forth the language of a statute, the instruction will be "appropriate only if the statute is applicable, reasonably clear, and not misleading." *Bell*, 147 Wash.2d at 177, 52 P.3d 503.

(Underlining added.)

b. Review of Directed Verdict.

The granting of a directed verdict is reviewed *de novo*. *Ramey v. Knorr*, 130 Wn. App. 672, 676, 124 P.3d 314, 317 (2005). *Chaney v. Providence Health Care*, 176 Wn. 2d 727, 732, 295 P.3d 728, 731 (2013) held:

> A directed verdict is appropriate if, as a matter of law, there is no substantial evidence or reasonable inference to sustain a verdict for the nonmoving party. *Harris v. Drake,* 152 Wash.2d 480, 493, 99 P.3d 872 (2004) (citing *Moe v. Wise,* 97 Wash.App. 950, 956, 989 P.2d 1148 (1999)).

2. The Federal Food Drug And Cosmetic Act (FDCA) Prohibits The Sale Of Potatoes That Have Detectable Residues Of Picloram Or Triclopyr.

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction or delivery into interstate commerce of "adulterated food". 21 U.S.C.A. § 331 (Copy in Appendix, pp. A - 28) Food is deemed to be "adulterated" if it contains an unsafe pesticide residue. 21 U.S.C.A. § 342(a). (Copy in Appendix, pp. A - 41) 21 U.S.C. § 346a states that food with pesticide residues

are deemed unsafe unless there is an exemption or tolerance. (Copy in Appendix, pp. A - 43) FIFRA registered herbicides including Clopyralid, Picloram, and Triclopyr are "pesticide chemicals" under the FDCA. See 21 U.S.C.A. § 321(q)(1). (Copy in Appendix, pp. A - 25)

There is no tolerance adopted by regulation for Clopyralid, Picloram, or Triclopyr in potatoes. See 40 C.F.R. § 180.431 (Copy in Appendix, pp. A - 19), 40 C.F.R. § 180.292 (Copy in Appendix, pp. A - 13) and 40 C.F.R. § 180.417 (Copy in Appendix, pp. A - 16) There are no regulatory exemptions for any of the three herbicides in potatoes. See 40 C.F.R. § 180.905 *et seq.* (Copy in Appendix, pp. A – 23)

Therefore, Zuriel's potatoes could not legally be sold into commerce if any Picloram or Triclopyr residues were detected, whether or not the Clopyralid found was from Double Up's 2011 Widematch application. Double Up also presented expert testimony that the quantity of Clopyralid found in the potatoes was far higher than what would have remained from the 2011

Widematch application, and the potatoes would have shown no significant symptoms from just the Widematch application. (RP 1124, 1176, 1243-44)

Accordingly, it was illegal under federal law for Ochoa to sell the potatoes regardless of WSDA's action once he knew that Picloram and Triclopyr were present in the potatoes. The fact that WSDA relied on the easier-to-find Chlopyralid does not excuse Ochoa from following the federal law on Picloram and Triclopyr.

This was a primary defense theory of the case: Federal Law made it illegal to sell the potatoes due to the presence of Picloram and Triclopyr whether or not some or all of the Clopyralid residues found in the Potatoes were from Double Up's Widematch application. Indeed, it is precisely the same law – the Federal Food, Drug, and Cosmetic Act (FDCA) – that precluded the marketing of the potatoes because of the residues of all three pesticides.

Without a jury instruction telling the jury that was the law, however, Double Up could not make that argument because the

jury did not know that federal law prohibited the sale due to the presence of all three pesticides.

3. Double Up Was Prejudiced by the Refusal to Instruct on Federal Law *Because The Jury Was Instructed To Disregard Any Arguments Not Supported By the Instructions*.

Judges tell juries what the law is, not witnesses or attorneys. Even expert witnesses are not allowed to state opinions of domestic law. In *Orion Corp. v. State*, 103 Wn. 2d 441, 461, 693 P.2d 1369, 1381 (1985), the Washington Supreme Court bluntly stated bluntly:

> . . . Experts are not to state opinions of law. Comment, ER 704.

The referenced comment stated in relevant part:

> Except for testimony concerning foreign law, experts are not to state opinions of law or mixed fact and law. . . .

5B Wash. Prac., Evidence Law and Practice § 704.1 (5th ed.)

The jury was specifically instructed to disregard any argument that was not supported by the law stated in the instructions. Instruction No. 1 given by the trial court states, in relevant part:

> . . . You must apply the law from my instructions to the facts that you decide have been proved, and in this way decide the case.
>
> * * *
>
> . . . You should disregard any remark, statement or argument that is not supported by the evidence or the law as I have explained it to you.

(CP 287 and 288; Underlining added)

Accordingly, Double Up could not make its causation argument based on admittedly applicable federal law without violating Instruction No. 1.

Zuriel relied below on *State v. Hathaway*, 161 Wash.App. 634, 251 P.3d 253 (2011). *Hathaway* is based on the existence of a general instruction covering the issue to be argued:

> . . . But it is not error for a trial court to refuse a specific instruction when a more general instruction adequately explains the law . . . Wash.App. 634.

Here, there was no general instruction on federal law or on the Federal Food, Drug, and Cosmetic Act (FDCA). The instructions made no reference to federal law at all. There was no instruction to which Double Up could refer to support an argument

that "These potatoes could not be sold with or without the Clopyralid from the 2011 Widematch application because of federal law." Accordingly, this is not a case where the trial court's refusal to instruct on the three pesticides can be excused by the existence of an applicable general instruction.

4. The Absence Of The Federal Law Instructions Prejudiced Double Up And Allowed the Jury to Be Confused and Misled.

How much more prejudice could exist than eliminating the federal law basis for Double Up's primary causation defense? Double Up was prevented from arguing that federal law made the potatoes unmarketable *with or without any carryover Clopyralid* from the 2011 Widematch application. Double Up could not make that "no causation" argument without violating Instruction No. 1. Instead, Double Up was limited to arguing that the other pesticides were the only proximate cause of the damage to the potatoes with no supporting instruction. The prejudice is obvious.

Indeed, the instructions were necessary to avoid jury confusion created by WSDA's failure to cite the Clopyralid in its

embargo order. Zuriel's entire argument on the point is based on the fact that the WSDA did not cite the presence of Picloram and Clopyralid in its embargo order. Without the federal law instructions, the jury was free to accept Zuriel's argument that the fact that the WSDA didn't cite the presence of Picloram and Triclopry in its embargo order somehow makes federal law irrelevant. Without instructions stating that federal law prohibited the sale of the potatoes due to the Picloram and Triclopyr residues, there was nothing to prevent the jury from being misled into concluding that all of the potatoes were unmarketable SOLELY due to the Clopyralid applied by Double Up the year before. There is no possible doubt that a portion of the potatoes were rendered unmarketable under federal law because of the Picloram and Triclopyr. Under the WSDA's testimony that it was a common methodology to segregate fields by contaminant, the majority of the field was could not be legally sold under federal law due to the presence of Picloram and Triclopyr.

However, the jury was kept ignorant of that federal law.

This is precisely the type of prejudice that requires a new trial.

5. The Trial Court and Court of Appeals Improperly Refused the Federal Law Instructions Because They Disregarded Double Up's Theory of the Case.

The Court of Appeals held that the federal law instructions were "irrelevant" and "not useful" because of the nature of Ochoa's claim:

> Here, the instructions were irrelevant to the issue of liability because Ochoa never claimed that the presence of any of the three herbicides was the basis for the negligent misrepresentation. Rather, it was the false statement concerning the condition of the field that was the basis for liability. Galbreath's application of the Clopyralid was evidence that he should have known that the land was unfit to use, but was not itself a basis for liability. The presence of other herbicides than the one that led WSDA to embargo the entire crop was a matter for the jury to consider when considering causation. The jury was properly instructed on superseding cause. Clerk's Papers at 302.
>
> The court had a very tenable basis for declining to give the instructions since they were not useful to the jury. The evidence of the other herbicides was relevant to Galbreath's causation defense and was properly argued to the jury in conjunction with the superseding cause instruction. There was no need for the additional instructions.

Zuriel, Inc. v. Galbreath, 32935-6-III, 2016 WL 3251883, (Wash. Ct. App. June 7, 2016)

The Court of Appeals could reach this conclusion only by accepting Zuriel's theory of the case and assuming that Double Up was a tortfeasor because of the failure to remember and disclose the Clopyralid application from the year before. However, Double Up was not a tortfeasor if the same harm would have been suffered with or without the 2011 Widematch application. To be a tortfeasor, one's breach of duty must be the proximate cause of damages to the plaintiff:

> The standard formulation for proving proximate causation in tort cases requires, "first, a showing that the breach of duty was a cause in fact of the injury, and, second, a showing that as a matter of law liability should attach." *Harbeson v. Parke–Davis, Inc.*, 98 Wash.2d 460, 475–76, 656 P.2d 483 (1983).

Mohr v. Grantham, 172 Wn. 2d 844, 850, 262 P.3d 490, 493 (2011) (footnote omitted).

The Court of Appeals' reliance on Zuriel's theory of the case to affirm the denial of instructions critical to Double Up's theory of the case shows that the Court of Appeals ignored established

precedent, quoted above, that a party is entitled to instructions to support its theory of the case if there is evidence to support that theory. The Court of Appeals accepted Zuriel's theory of the case as the ONLY theory of the case, disregarded the presence of other pesticides that made the potatoes unmarketable under federal law, and disregarded the evidence that the harm – unmarketability – was divisible according to the WSDA testimony, and deemed by fiat that federal law is "irrelevant" and "not useful" to the jury. Unless this Court reverses and orders a new trial, we will never know if the jury finds the accurate instructions on federal law "relevant" and "useful."

Zuriel argued below, and the Court of Appeals apparently agreed *sub silentio*, that all of this was irrelevant because of joint and several liability rules and was covered by the superseding cause instruction. However, joint and several liability applies only if the harm is indivisible or not "segregable." *Seattle-First Nat. Bank v. Shoreline Concrete Co.*, 91 Wn. 2d 230, 588 P.2d 1308 (1978); *Cox v. Spangler*, 141 Wn.2d 431, 5 P.3d 1265 (2000).

Under the WSDA testimony, the commonly applied methodology of clearing crops to the next test free of a contaminant, the harm here was divisible as to what portions of the field were unmarketable due to Clopyralid and what portions of the field were unmarketable due to Picloram and Triclopyr in addition to Clopyralid.

The meaning of "cause in fact" is that the "consequences for which recover is sought" would not have occurred "but for" the conduct of the defendant. *Guerin v. Thompson*, 53 Wn. 2d 515, 519, 335 P.2d 36, 38 (1959) quoting *Eckerson v. Ford's Prairie Sch.Dist. No. 11*, 3 Wash.2d 475, 482, 101 P.2d 345 (1940):

> 'An actual cause, or cause in fact, exists when the act of the defendant is a necessary antecedent of the consequences for which recovery is sought, that is, when the injury would not have resulted 'but for' the act in question. But a cause in fact, although it is a *sine qua non* of legal liability, . . .'

(Underlining added.)

In this case, the "consequences for which recover is sought" is that the potatoes were unmarketable. However, the only basis for unmarketability caused by Double Up is if the potatoes were unmarketable due to Clopyralid **from Double Up's 2011 Widematch application**. It is not disputed, and cannot be disputed, that it was also illegal to sell potatoes with residues of Picloram and Triclopyr, chemicals never applied by Double Up. There can be no "but for" causation flowing from the 2011 Widematch application to the extent the potatoes could not be sold due to Picloram and Triclopyr – the same damage would have been suffered "with or without" the 2011 Widematch application.

Double Up was prevented from arguing its main proximate cause argument by the trial court's refusal to instruct on federal law and was prejudiced by that refusal.

6. The Directed Verdict was Improper Because Caveat Emptor Applies to Leases of Open Farmland And Reasonable Inferences Existed in Double Up's Favor on Breach of Duty.

Caveat emptor continues to apply to leases of open farm land. *Teglo v. Porter*, 65 Wn.2d 772, 773-74, 399 P.2d 519, 520

(1965). Accordingly, actual, subjective knowledge of the alleged defect and that injury will result *at the time the lease was being negotiated* is required to establish liability. *Burbo v. Harley C. Douglass, Inc.*, 125 Wn. App. 684, 698, 106 P.3d 258, 266 (2005), citing *Nauroth v. Spokane County,* 121 Wash.App. 389, 393, 88 P.3d 996 (2004). A reasonable inference exists that a farmer who farms 4,000 to 5,000 acres would not remember each and every chemical application made to each circle or parcel he farms the previous year.

Even if *caveat emptor* did not apply (though it does), Zuriel's claim of negligent misrepresentation requires proof that Double Up knew or should have known of the defect. See WPI 165.04 and cases cited in comment thereto. The only evidence suggesting a fiduciary relationship was Zuriel's self-serving testimony that it subjectively believed that it was "almost in a partnership" with Double Up, but he admits that he never told Double Up of that belief. (RP 525) Zuriel further admits that there was no partnership. (RP 525) Zuriel further admitted that it just

assumed that Double Up would remember every application to every field (RP 524) even though it knew Double Up was "farming well over four or five thousand acres." (RP 529) A reasonable inference exists that Zuriel was making up his "almost partnership" testimony. A reasonable inference exists that Double Up, which Zuriel knew farmed 4,000 to 5,000 acres, did not know, and should not have known, at the time of the lease negotiations, of the Clopyralid application made the prior year, let alone that the application created a risk of carryover.

Further, the jury could have concluded that the field was in fact "good for spuds" based on the expert testimony that there would have been no significant symptoms or damages from whatever small amount of Clopyralid might have remained from the 2011 application. The directed verdict should be reversed.

VI. CONCLUSION

The Court of Appeals should be reversed and remanded for trial with appropriate jury instructions on federal law.

RESPECTFULLY SUBMITTED this 6nd day of July, 2016.

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APPENDIX

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WA State Court of Appeals, Division III

COURT OF APPEALS, DIVISION III, STATE OF WASHINGTON

ZURIEL, INC., a Washington corporation; EDWARD D. OCHOA, Jr., Respondents, v. DAN GALBREATH and JANE DOE GALBREATH, husband and wife; DOUBLE UP RANCH, INC., a Washington Corporation; GREG GALBREATH and JANE DOE GALBREATH, husband and wife; 82 FARMS, INC., an Washington Corporation, Appellants.	No. 32935-6-III ORDER DENYING MOTION FOR RECONSIDERATION AND AMENDING OPINION

THE COURT has considered appellant's motion for reconsideration and the answer thereto, and is of the opinion the motion should be denied. Therefore,

IT IS ORDERED, the motion for reconsideration of this court's decision of May 5, 2016 is hereby denied.

IT IS FURTHER ORDERED the opinion filed May 5, 2016 is amended as follows:

On page five, line fifteen the word "signing" is changed to "entering".

PANEL: Judges Korsmo, Siddoway, Lawrence-Berrey

FOR THE COURT:

Fearing, C.J.

GEORGE FEARING, Chief Judge

FILED
May 5, 2016
In the Office of the Clerk of Court
WA State Court of Appeals, Division III

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION THREE

ZURIEL, INC., a Washington corporation; EDWARD D. OCHOA, Jr., Respondents, v. DAN GALBREATH and JANE DOE GALBREATH, husband and wife; DOUBLE UP RANCH, INC., a Washington Corporation; GREG GALBREATH and JANE DOE GALBREATH, husband and wife; 82 FARMS, INC., a Washington Corporation, Appellants.	)	No. 32935-6-III UNPUBLISHED OPINION

KORSMO, J. — Respondents leased farmland to grow potatoes without being told that appellants had treated the field with an herbicide that rendered the land unsuitable for potato farming. We affirm the jury's verdict in favor of the lessees.

FACTS

Among their 6,000 acres of farm holdings, cousins Dan and Greg Galbreath and their respective corporations (collectively Galbreath) hold a 20 year lease on 480 acres belonging to the Ahern Family Revocable Trust. Since acquiring that lease in 2003, the

Galbreaths have subleased portions of the 480 acres to Edward Ochoa, his father, and their corporation (collectively Ochoa).

In 2012 the Galbreaths leased 130 acres of the Ahern property to Ochoa knowing that the Ochoas intended to raise potatoes. Dan Galbreath told Mr. Ochoa that the land would be good for potatoes. He apparently did not remember that his cousin had treated the 130 acre segment with Clopyralid when growing wheat on that field the previous year. The herbicide's producer had warned users against growing potatoes for 18 months in any field treated with Clopyralid.

The potatoes were planted but the crop soon developed visible deformities. The Washington State Department of Agriculture (WSDA) investigated and took soil samples. WSDA found significant Clopyralid contamination in all of the samples, as well as some Picloram and Triclopyr contamination in two samples. Because of the Clopyralid contamination, the entire crop was unmarketable and the WSDA embargoed it.

Ochoa filed suit against Galbreath on a theory of negligent misrepresentation based on Dan Galbreath's statement that the field was good for potatoes and his failure to disclose the herbicide application. The Galbreaths presented expert testimony that the concentration of Clopyralid was too high given the amount they had used, leading their expert to believe there must have been an additional source of contamination. At the close of the testimony, the trial court directed a verdict for the plaintiffs on the issue of liability, but instructed the jury on questions of causation and damages. The court denied

a defense request to give instructions concerning federal regulations governing Clopyralid, Picloram and Triclopyr contamination.

The jury entered a verdict in favor of the Ochoas for $584,558.94. The Galbreaths timely appealed to this court.

ANALYIS

The Galbreaths present two issues in this appeal. They first contend that the trial court erred in directing a verdict on liability. They also contend that the court erred in denying their requested instructions. We address the two issues in the order stated.

Directed Verdict on Liability

Galbreath claims that the doctrine of caveat emptor applies, requiring that Ochoa show he had actual knowledge of the contamination. We disagree.

This court reviews de novo a decision on a motion for a directed verdict. *Schmidt v. Coogan*, 162 Wn.2d 488, 491, 173 P.3d 273 (2007). A directed verdict must be granted where, viewing the evidence most favorably for the nonmoving party, the court can say that there is not substantial evidence or a reasonable inference to sustain a verdict for the nonmoving party. *Davis v. Microsoft Corp.*, 149 Wn.2d 521, 531, 70 P.3d 126 (2003). A party is liable in fraud where he knows his statements to be false and intends to deceive the other party, and liable in negligence where his statements are innocently made but without due care as to their truthfulness or accuracy. *See Brown v. Underwriters at*

Lloyd's, 53 Wn.2d 142, 145-153, 332 P.2d 228 (1958) (discussing the histories of and differences between fraud and negligent misrepresentation).

The elements of a claim of negligent misrepresentation that a plaintiff must establish are:

> (1) the defendant supplied information for the guidance of others in their business transactions that was false, (2) the defendant knew or should have known that the information was supplied to guide the plaintiff in his business transactions, (3) the defendant was negligent in obtaining or communicating the false information, (4) the plaintiff relied on the false information, (5) the plaintiff's reliance was reasonable, and (6) the false information proximately caused the plaintiff damages.

Ross v. Kirner, 162 Wn.2d 493, 499, 172 P.3d 701 (2007). This version of the tort requires that the defendant affirmatively made an actual misrepresentation.

A second version of the tort exists when the defendant fails to disclose material information. The failure to disclose establishes negligent misrepresentation when the party owes a duty to disclose. *Van Dinter v. Orr*, 157 Wn.2d 329, 333, 138 P.3d 608 (2006). This duty arises in several circumstances, including: (1) the existence of a fiduciary relationship, (2) disclosure is necessary to prevent an incomplete statement from being misleading, (3) the facts are within the knowledge of one party and not easily ascertained by the other, (4) one party relies on the superior specialized knowledge of the other, or (5) one party lacks business experience and the other would gain an unfair advantage by remaining silent. *Id.* at 334.

Ochoa pursued both theories of negligent misrepresentation at trial. The trial court did not identify which theory it relied on in granting the directed verdict. Since the record clearly establishes that Dan Galbreath made the false statement that the field was good for potatoes, and that statement suffices to support the directed verdict, we need only discuss the affirmative misrepresentation theory.

Initially, however, we note that the Galbreaths confuse the two theories by asserting that caveat emptor mandates that plaintiffs show actual knowledge in order to establish a claim. The authority they cite involved a claim of fraud rather than negligence. *See Burbo v. Harley C. Douglass, Inc.*, 125 Wn. App. 684, 697-698, 106 P.3d 258 (2005). They do not cite, and we have not found, any authority to support an argument that actual knowledge is necessary in a claim of affirmative misrepresentation.

The issue then was whether the Dan Galbreath statement supported the decision to direct a verdict on the question of liability. It did. Galbreath knew that Ochoa desired to lease the 130 acres in order to plant potatoes. He provided the information in order to help guide Ochoa into signing the lease. He negligently communicated the false information by not remembering or investigating his own previous use of the field the year before; if he had checked with his cousin he would have remembered that the field could not be used for potatoes that year. Ochoa relied on the information, and did so reasonably given that Galbreath himself was a veteran potato farmer who also worked that land.

The Galbreath statement satisfied the five elements that establish the liability prong of the negligent misrepresentation tort. They essentially were uncontested. The trial court understandably directed the verdict for the plaintiffs on liability and left the question of proximate cause (as well as damages, if necessary) for the jury to decide.

The trial court did not err in directing the verdict on liability in favor of Ochoa.

Jury Instructions

Galbreath also argues that the trial court erred in failing to give their requested instructions that federal law prohibited the sale of potatoes containing traces of the other two herbicides found in the Ochoas potato field.[1] The trial court correctly recognized that the information could only be used with respect to the defendant's intervening cause argument and was irrelevant to the liability issue. The trial court did not abuse its broad discretion in this area.

Well settled law governs our review of jury instruction issues. Jury instructions are sufficient if they correctly state the law, are not misleading, and allow the parties to argue their respective theories of the case. *State v. Dana*, 73 Wn.2d 533, 536-537, 439 P.2d 403 (1968). The trial court also is granted broad discretion in determining the wording and number of jury instructions. *Petersen v. State*, 100 Wn.2d 421, 440, 671 P.2d 230 (1983). Discretion is abused when it is exercised on untenable grounds or for

[1] They do not assign error to the failure to give the Clopyralid instruction.

untenable reasons. *State ex rel. Carroll v. Junker*, 79 Wn.2d 12, 26, 482 P.2d 775 (1971). A party is entitled to have its theory of the case presented to the jury by proper instructions if there is any evidence to support it. *DeKoning v. Williams*, 47 Wn.2d 139, 141, 286 P.2d 694 (1955). However, it is not entitled to instructions that are irrelevant to the issues upon which the case is tried. *Poston v. W. Dairy Prods. Co.*, 179 Wash. 73, 88, 36 P.2d 65 (1934).

Here, the instructions were irrelevant to the issue of liability because Ochoa never claimed that the presence of any of the three herbicides was the basis for the negligent misrepresentation. Rather, it was the false statement concerning the condition of the field that was the basis for liability. Galbreath's application of the Clopyralid was evidence that he should have known that the land was unfit to use, but was not itself a basis for liability. The presence of other herbicides than the one that led WSDA to embargo the entire crop was a matter for the jury to consider when considering causation. The jury was properly instructed on superseding cause. Clerk's Papers at 302.

The court had a very tenable basis for declining to give the instructions since they were not useful to the jury. The evidence of the other herbicides was relevant to Galbreath's causation defense and was properly argued to the jury in conjunction with the superseding cause instruction. There was no need for the additional instructions.

The judgment is affirmed.

A majority of the panel has determined this opinion will not be printed in the Washington Appellate Reports, but it will be filed for public record pursuant to RCW 2.06.040.

Korsmo, J.

WE CONCUR:

Siddoway, J.

Lawrence-Berrey, A.C.J.

40 CFR 180.292 - Picloram; tolerances for residues.

§ 180.292 Picloram; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide picloram, 4-amino-3,5,6-trichloropicolinic acid, including its metabolites and degradates, in or on the commodities in the following table from its application in the acid form or in the form of its salts. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only picloram, 4-amino-3,5,6-trichloropicolinic acid, in or on the commodity.

Commodity	Parts per million
Barley, grain	0.5
Barley, pearled barley	3.0
Barley, straw	1.0
Cattle, fat	0.4
Cattle, meat	0.4
Cattle, meat byproducts	15
Egg	0.05
Goat, fat	0.4
Goat, meat	0.4
Goat, meat byproducts	15
Grain, aspirated fractions	4.0
Grass, forage	400
Grass, hay	225
Hog, fat	0.05
Hog, meat	0.05
Hog, meat byproducts	0.05
Horse, fat	0.4
Horse, meat	0.4
Horse, meat byproducts	15
Milk	0.25
Oat, forage	1.0
Oat, grain	0.5

Oat, groats/rolled oats	3.0
Oat, straw	1.0
Poultry, fat	0.05
Poultry, meat	0.05
Poultry, meat byproducts	0.05
Sheep, fat	0.4
Sheep, meat	0.4
Sheep, meat byproducts	15
Wheat, bran	3.0
Wheat, forage	1.0
Wheat, germ	3.0
Wheat, grain	0.5
Wheat, middlings	3.0
Wheat, shorts	3.0
Wheat, straw	1.0

(b) ***Section 18 emergency exemptions.*** [Reserved]

(c) ***Tolerances with regional registrations.*** [Reserved]

(d) ***Indirect or inadvertent residues.*** [Reserved]

40 CFR 180.417 - Triclopyr; tolerances for residues.

§ 180.417 Triclopyr; tolerances for residues.

(a) ***General.***

(1) Tolerances for residues of the herbicide triclopyr per se, as a result of the application/use of butoxyethyl ester of triclopyr and triethyylamine salt of triclopyr, are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Egg	0.05
Fish	3.0
Grass, forage	700.0
Grass, hay	200.0
Milk	0.01
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, meat byproducts, except kidney	0.1
Rice, grain	0.3
Rice, straw	10.0
Shellfish	3.5

(2) Tolerances for the combined residues of the herbicide triclopyr ((3,5,6-trichloro-2-pyridinyl)oxy) acetic acid and its metabolite 3,5,6-trichloro-2-pyridinol (TCP), as a result of the application/use of butoxyethyl ester of triclopyr or the triethylamine salt of triclopyr, are established in or on the following raw agricultural commodities:

Commodity	Parts per million
Cattle, fat	0.05
Cattle, kidney	0.5
Cattle, liver	0.5
Cattle, meat	0.05
Cattle, meat byproducts, except kidney and liver	0.05
Goat, fat	0.05
Goat, kidney	0.5
Goat, liver	0.5
Goat, meat	0.05
Goat, meat byproducts, except kidney and liver	0.05
Hog, fat	0.05

Hog, kidney	0.5
Hog, liver	0.5
Hog, meat	0.05
Hog, meat byproducts, except kidney and liver	0.05
Horse, fat	0.05
Horse, kidney	0.5
Horse, liver	0.5
Horse, meat	0.05
Horse, meat byproducts, except kidney and liver	0.05
Sheep, fat	0.05
Sheep, kidney	0.5
Sheep, liver	0.5
Sheep, meat	0.05
Sheep, meat byproducts, except kidney and liver	0.05

(b) ***Section 18 emergency exemptions.*** [Reserved]

(c) ***Tolerances with regional registrations.*** [Reserved]

(d) ***Indirect or inadvertent residues.*** [Reserved]

[50 FR 18486, May 1, 1985, as amended at 55 FR 26440, June 28, 1990; 60 FR 4095, Jan. 20, 1995; 62 FR 46894, Sept. 5, 1997; 63 FR 45406, Aug. 26, 1998; 67 FR 35048, May 17, 2002; 67 FR 58725, Sept. 18, 2002; 72 FR 41931, Aug. 1, 2007]

40 CFR 180.431 - Clopyralid; tolerances for residues.

§ 180.431 Clopyralid; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide clopyralid, including its metabolites and degradates, in or on the commodities in the table below from its application in the acid form or in the form of its salts. Compliance with the tolerance levels specified below is to be determined by measuring only clopyralid, (3,6-dichloro-2-pyridinecarboxylic acid), in or on the following commodities:

Commodity	Parts per million
Asparagus	1.0
Barley, bran	12
Barley, grain	3.0
Barley, hay	9.0
Barley, pearled barley	12
Barley, straw	9.0
Beet, garden, tops	3.0
Beet, garden, roots	4.0
Beet, sugar, molasses	10
Beet, sugar, roots	2.0
Beet, sugar, tops	3.0
Brassica, head and stem, subgroup 5A	2.0
Bushberry subgroup 13-07B	0.50
Canola, meal	6.0
Canola, seed	3.0
Cattle, fat	1.0
Cattle, liver	3.0
Cattle, meat	1.0
Cattle, meat byproducts, except liver	36.0
Corn, field, forage	3.0
Corn, field, grain	1.0
Corn, field, milled byproducts	1.5
Corn, field, stover	10.0
Corn, pop, grain	1.0
Corn, pop, stover	10.0
Corn, sweet, forage	7.0
Corn, sweet, kernel plus cob with husks	

removed	1.0
Corn, sweet, stover	10.0
Crambe, seed	3.0
Cranberry	4.0
Egg	0.1
Flax, meal	6.0
Flax, seed	3.0
Fruit, stone, group 12	0.5
Goat, fat	1.0
Goat, liver	3.0
Goat, meat	1.0
Goat, meat byproducts, except liver	36.0
Grass, forage	500.0
Grass, hay	500.0
Hog, fat	0.2
Hog, meat	0.2
Hog, meat byproducts	0.2
Hop, dried cones	5.0
Horse, fat	1.0
Horse, liver	3.0
Horse, meat	1.0
Horse, meat byproducts, except liver	36.0
Milk	0.2
Mustard greens	5.0
Mustard, seed	3.0
Oat, forage	9.0
Oat, grain	3.0
Oat, groats/rolled oats	12
Oat, straw	9.0
Peppermint, tops	3.0
Plum, prune, dried	1.5
Poultry, fat	0.2
Poultry, meat	0.2
Poultry, meat byproducts	0.2
Rapeseed, seed	3.0
Rapeseed, forage	3.0
Sheep, fat	1.0
Sheep, liver	3.0
Sheep, meat	1.0
Sheep, meat byproducts, except liver	36.0
Spearmint, tops	3.0
Spinach	5.0
Strawberry	4.0
Swiss chard	3.0

Turnip, greens	4.0
Turnip, roots	1.0
Wheat, bran	12
Wheat, forage	9.0
Wheat, germ	12
Wheat, grain	3.0
Wheat, middling	12
Wheat, shorts	12
Wheat, straw	9.0

40 CFR 180.905 - Pesticide chemicals; exemptions from the requirement of a tolerance.

§ 180.905 Pesticide chemicals; exemptions from the requirement of a tolerance.

(a) When applied to growing crops, in accordance with good agricultural practice, the following pesticide chemicals are exempt from the requirement of a tolerance:

(1) Petroleum oils.

(2) Piperonyl butoxide.

(3) Pyrethrins.

(4) Rotenone or derris or cube roots.

(5) Sabadilla.

(b) These pesticides are not exempted from the requirement of a tolerance when applied to a crop at the time of or after harvest.

[75 FR 60245, Sept. 29, 2010]

U.S. Code at 321(q)(1)

(q)

(1)

(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such

commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 348(h)(6) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], this clause does not exclude any substance from

21 U.S. Code § 331 - Prohibited acts

Current through Pub. L. 114-38. (See Public Laws for the current Congress.)

US Code **Notes** **Authorities (CFR)**

prev | next

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb–3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb–3, 373, 374(a), 379aa, or 379aa–1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (
|
) or (m), 360ccc–1(i), 360e(f), 360i, 360bbb–3, 379aa, 379aa–1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section

2223111 of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section.. [2] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) Repealed. Pub. L. 105–115, title IV, §421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(o) In the case of a prescription drug distributed or offered for

sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387e of this title, the failure to provide any information required by section 360(i), 360(k),387e(i), or 387e(i) of this title, or the failure to provide a notice required by section 360(i)(2) or 387e(i)(3) of this title.

(q)

(1) The failure or refusal—

(A)to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g, 387h, or 387o of this title;

(B)to furnish any notification or other material or information required by or under section360i, 360j(g), 387d, 387i, or387t of this title; or

(C)to comply with a requirement under section 360l or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device or tobacco product in violation of

an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e)of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, the distribution of drugs in violation of section 353(e) of this title, failure to comply with the requirements under section 360eee–1 of this title, the failure to comply with the requirements under section 360eee–3 of this title, as applicable, or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A),360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a

certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1)the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2)the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3)the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted.

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order

under section 334(h) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(
o
) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary undersection 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa–1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa–1

of this title) submitted to the Secretary.

(jj)

(1) The failure to submit the certification required by section 282(j)(5)(B) of title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of title 42.

(3) The submission of clinical trial information under subsection (j) ofsection 282 of title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353c
1
of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed undersection 262 of title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1)such drug or such biological product was marketed in food before any approval of the drug undersection 355 of this title, before licensure of the biological product under such section 262 of title 42, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2)the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3)the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A)a regulation issued under section 348 of this title prescribing conditions of safe use in food;

(B)a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C)the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D)a food contact substance notification that is effective under section 348(h) of this title; or

(E)such drug or biological product had been marketed for smoking cessation prior toSeptember 27, 2007; or

(4)the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of this title.

(nn) The falsification of a report or notification required under section 350f(d) of this title.

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 387k of this title.

(qq)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1)the product is approved by the Food and Drug Administration;

(2)the Food and Drug Administration deems the product to be safe for use by consumers;

(3)the product is endorsed by the Food and Drug Administration for use by consumers; or

(4)the product is safe or less harmful by virtue of—

(A)its regulation or inspection by the Food and Drug Administration; or

(B)its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title.

(vv) The failure to comply with the requirements under section 350h of this title.

(ww) The failure to comply with section 350i of this title.

(xx) The refusal or failure to follow an order under section 350 l
of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in

place a foreign supplier verification program in compliance with such section 384a of this title.

(aaa) The failure to register in accordance with section 381(s) of this title.

(bbb) The failure to notify the Secretary in violation of section 360bbb–7 of this title.

(ccc)

(1) The resale of a compounded drug that is labeled "not for resale" in accordance with section 353b of this title.

(2) With respect to a drug to be compounded pursuant to section353a or 353b of this title, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 353b of this title.

21 U.S. Code § 342 - Adulterated food

Current through Pub. L. 114-38. (See Public Laws for the current Congress.)

US Code **Notes** **Authorities (CFR)**

prev | next

A food shall be deemed to be adulterated—

(a)POISONOUS, INSANITARY, ETC., INGREDIENTS

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.[1] (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning ofsection 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in

part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant tosection 348 of this title.

21 U.S. Code § 346a - Tolerances and exemptions for pesticide chemical residues

Current through Pub. L. 114-38. (See Public Laws for the current Congress.)

US Code **Notes** **Authorities (CFR)**

prev | next

(a)REQUIREMENT FOR TOLERANCE OR EXEMPTION

(1)GENERAL RULE Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 342(a)(2)(B) of this title unless—

(A)a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B)an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

(2)PROCESSED FOOD Notwithstanding paragraph (1)—

(A)if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance for the pesticide

chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title.

(3) RESIDUES OF DEGRADATION PRODUCTS If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation

product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) EFFECT OF TOLERANCE OR EXEMPTION

While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 342(a)(1) of this title.

(b) AUTHORITY AND STANDARD FOR TOLERANCE

(1) AUTHORITY The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's own initiative under subsection (e) of this section.

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2)STANDARD

(A)General rule

(i)Standard
The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii)Determination of safety
As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii)Rule of construction
With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B)Tolerances for eligible pesticide chemical residues

(i)Definition As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I)the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or

anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II)the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

(III)with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii)Determination of tolerance Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I)at least one of the conditions described in clause (iii) is met; and

(II)both of the conditions described in clause (iv) are met.

(iii)Conditions regarding use For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate,

wholesome, and economical food supply.

(iv)Conditions regarding risk For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v)Review

Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(vi)Infants and children
Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C)Exposure of infants and children In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i)shall assess the risk of the pesticide chemical residue based on—

(I)available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II)available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III)available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii)shall—

(I)ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II)publish a specific determination regarding the

safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D)Factors In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i)the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii)the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii)available information concerning the relationship of the results of such studies to human risk;

(iv)available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v)available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi)available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii)available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii)such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix)safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E)Data and information regarding anticipated and actual residue levels

(i)Authority

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by

the Food and Drug Administration.

(ii)Requirement
If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) of this section require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1) of this section, or an order under subsection (f)(2) of this section, as appropriate, to modify or revoke the tolerance.

(F)Percent of food actually treated In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i)finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii)finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii)finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv)provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3)DETECTION METHODS

(A)General rule

A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B)Detection limit

A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4)INTERNATIONAL STANDARDS

In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c)AUTHORITY AND STANDARD FOR EXEMPTIONS

(1)AUTHORITY The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A)in response to a petition filed under subsection (d) of this section; or

(B)on the Administrator's initiative under subsection (e) of this section.

(2)STANDARD

(A)General rule

(i)Standard
The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii)Determination of safety
The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B)Factors
In making a determination under this paragraph, the

Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2) of this section.

(3)LIMITATION An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A)that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B)that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d)PETITION FOR TOLERANCE OR EXEMPTION

(1)PETITIONS AND PETITIONERS Any person may file with the Administrator a petition proposing the issuance of a regulation —

(A)establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B)establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2)PETITION CONTENTS

(A)EstablishmentA petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)

(I)an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II)a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii)the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii)data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv)full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v)full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi)a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii)a proposed tolerance for the pesticide chemical

residue, if a tolerance is proposed;

(viii)if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix)such information as the Administrator may require to make the determination under subsection (b)(2)(C) of this section;

(x)such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi)information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii)practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii)such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B)Modification or revocation

The Administrator may by regulation establish the requirements for information and data to support a

petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3)NOTICE

A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4)ACTIONS BY THE ADMINISTRATOR

(A)In general The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i)issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii)issue a proposed regulation under subsection (e) of this section, and thereafter issue a final regulation under such subsection; or

(iii)issue an order denying the petition.

(B)Priorities

The Administrator shall give priority to petitions for the

establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C)Expedited review of certain petitions

(i)Date certain for review

If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B) of this section, the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii)Required determinations

If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) of this section continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B) of this section. If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(e)ACTION ON ADMINISTRATOR'S OWN INITIATIVE

(1)GENERAL RULE The Administrator may issue a regulation—

(A)establishing, modifying, suspending under subsection (|)(3) of this section, or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B)establishing, modifying, suspending under subsection (|)(3) of this section, or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C)establishing general procedures and requirements to implement this section.

(2)NOTICE
Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f)SPECIAL DATA REQUIREMENTS

(1)REQUIRING SUBMISSION OF ADDITIONAL DATA If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A)issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section

3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)];

(B)issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act [15 U.S.C. 2603]; or

(C)publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i)requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii)describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)] or section 4 of the Toxic Substances Control Act [15 U.S.C. 2603];

(iii)describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv)requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v)establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect

produced by a naturally occurring estrogen or other endocrine effects.

(2)NONCOMPLIANCE

If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2) of this section, the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g)EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW

(1)EFFECTIVE DATE

A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) of this section shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2)FURTHER PROCEEDINGS

(A)Objections

Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) of this section, any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1) of this section, a copy of each objection filed by a person other than the

petitioner shall be served by the Administrator on the petitioner.

(B)Hearing

An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C)Final decision

As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h)JUDICIAL REVIEW

(1)PETITION

In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C) of this section, or any order issued under subsection (f)(1)(C) or (g)(2)(C) of this section, or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2)RECORD AND JURISDICTION

A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3)ADDITIONAL EVIDENCE

If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the

proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4)FINAL JUDGMENT; SUPREME COURT REVIEW

The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided insection 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5)APPLICATION

Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i)CONFIDENTIALITY AND USE OF DATA

(1)GENERAL RULE

Data and information that are or have been submitted to the Administrator under this section orsection 348 of this title in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a, 136h].

(2)EXCEPTIONS

(A)In general Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i)employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this chapter or other Federal statutes intended to protect the public health; or

(ii)contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this chapter or such statutes.

(B)Congress

This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3)SUMMARIES

Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) of this section and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j)STATUS OF PREVIOUSLY ISSUED REGULATIONS

(1)REGULATIONS UNDER SECTION 346

Regulations affecting pesticide chemical residues in or on raw

agricultural commodities promulgated, in accordance withsection 371(e) of this title, under the authority of section 346(a)[1] of this title upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e) of this section, and shall be subject to review under subsection (q) of this section.

(2)REGULATIONS UNDER SECTION 348

Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 348 of this title on or before August 3, 1996, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

(3)REGULATIONS UNDER SECTION 346A

Regulations that established tolerances or exemptions under this section that were issued on or beforeAugust 3, 1996, shall remain in effect unless modified or revoked under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

(4)CERTAIN SUBSTANCES With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 321(q)(1) of this title but was so included on the day before October 30, 1998, the following applies as of October 30, 1998:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day beforeOctober 30, 1998, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 348

of this title.

(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before August 3, 1996) is deemed to have been issued under section 348 of this title.

(k)TRANSITIONAL PROVISION If, on the day before August 3, 1996, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1)regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) of this section orsection 321(s) of this title as then in effect; or

(2)regarded by the Secretary as a substance described by section 321(s)(4) of this title;

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of August 3, 1996. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c) of this section.

(l)HARMONIZATION WITH ACTION UNDER OTHER LAWS

(1)COORDINATION WITH FIFRA
To the extent practicable and consistent with the review deadlines in subsection (q) of this section, in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(2)REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A)the date by which each such cancellation of a registration has become effective; or

(B)the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3)SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS

(A)Suspension

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A suspension under

this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B)Effect of suspension

The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4)TOLERANCES FOR UNAVOIDABLE RESIDUES

In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to August 3, 1996, under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) of this section and the unavoidability of the residue. Subsection (e) of this section shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5)PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE Notwithstanding any other provision of this chapter, if

a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A)the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B)the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this chapter;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e) of this section, the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6)TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION
If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after August 3, 1996, governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2)

of this section and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m)FEES

(1)AMOUNT The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A)the acceptance for filing of a petition submitted under subsection (d) of this section;

(B)establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C)the acceptance for filing of objections under subsection (g) of this section; or

(D)the certification and filing in court of a transcript of the proceedings and the record under subsection (h) of this section;

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2)DEPOSIT

All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and

Rodenticide Act [7 U.S.C. 136a-1(k)]. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3)PROHIBITION

During the period beginning onOctober 1, 2007, and ending onSeptember 30, 2017, the Administrator shall not collect any tolerance fees under paragraph (1).

(n)NATIONAL UNIFORMITY OF TOLERANCES

(1)"QUALIFYING PESTICIDE CHEMICAL RESIDUE" DEFINED For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A)was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(5)] on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act [7 U.S.C. 136 et seq.] on April 25, 1985; or

(B)was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act [7 U.S.C. 136a-1(g)] on or after August 3, 1996.

(2)"QUALIFYING FEDERAL DETERMINATION" DEFINED For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A)is issued under this section after August 3, 1996, and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or

(c)(2) (in the case of an exemption) of this section; or

(B)

(i)pursuant to subsection (j) of this section is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) of this section as exempt from the requirement for a tolerance; and

(ii)is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section.

(3)LIMITATION

The Administrator may make the determination described in paragraph (2)(B)(ii) only by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) of this section and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h) of this section.

(4)STATE AUTHORITY

Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5)Petition procedure

(A)In general
Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B)Petition requirements Any petition under subparagraph (A) shall—

(i)satisfy any requirements prescribed, by rule, by the Administrator; and

(ii)be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C)Authorization The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i)is justified by compelling local conditions; and

(ii)would not cause any food to be a violation of Federal law.

(D)Treatment
In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) of this section to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under

this paragraph as a petition under subsection (d) of this section, the Administrator shall thereafter act on the petition pursuant to subsection (d) of this section.

(E)Review

Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h) of this section.

(6)URGENT PETITION PROCEDURE

Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7)RESIDUES FROM LAWFUL APPLICATION

No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8)SAVINGS

Nothing in this chapter preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o)CONSUMER RIGHT TO KNOW Not later than 2 years after August 3, 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1)A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2)A listing of actions taken under subparagraph (B) of subsection (b)(2) of this section that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p)ESTROGENIC SUBSTANCES SCREENING PROGRAM

(1)DEVELOPMENT

Not later than 2 years after August 3, 1996, the Administrator

shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2)IMPLEMENTATION
Not later than 3 years after August 3, 1996, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136w(d)] or the science advisory board established by section 4365[2] of title 42, the Administrator shall implement the program.

(3)SUBSTANCES In carrying out the screening program described in paragraph (1), the Administrator—

(A)shall provide for the testing of all pesticide chemicals; and

(B)may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4)EXEMPTION
Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5)COLLECTION OF INFORMATION

(A)In general

The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

(B)Procedures

To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C)Failure of registrants to submit information

(i)Suspension

If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii)Hearing

If a person requests a hearing under clause (I), the hearing shall be conducted in accordance with section 554 of title 5. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii)Termination of suspensions
The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D)Noncompliance by other persons
Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act [15 U.S.C. 2615] in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6)AGENCY ACTION
In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this chapter, as is necessary to ensure the protection of public health.

(7)REPORT TO CONGRESS Not later than 4 years after August 3, 1996, the Administrator shall prepare and submit to Congress

a report containing—

(A)the findings of the Administrator resulting from the screening program described in paragraph (1);

(B)recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C)recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q)SCHEDULE FOR REVIEW

(1)IN GENERAL The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day beforeAugust 3, 1996, as expeditiously as practicable, assuring that—

(A)33 percent of such tolerances and exemptions are reviewed within 3 years ofAugust 3, 1996;

(B)66 percent of such tolerances and exemptions are reviewed within 6 years ofAugust 3, 1996; and

(C)100 percent of such tolerances and exemptions are reviewed within 10 years ofAugust 3, 1996.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections[31] (b)(2) or (c)(2) of this section and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) of this section to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2)PRIORITIES

In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3)PUBLICATION OF SCHEDULE

Not later than 12 months afterAugust 3, 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to August 3, 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r)TEMPORARY TOLERANCE OR EXEMPTION

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) of this section shall apply to actions taken under this subsection.

(s)SAVINGS CLAUSE

Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act [15 U.S.C. 2601 et seq.] or the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]

7 U.S Code at 136(u)

(u)PESTICIDE

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w)[1] of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x)[1] of title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body

No. 329356

COURT OF APPEALS, DIVISION III
OF THE STATE OF WASHINGTON

ZURIEL, INC., a Washington corporation; EDWARD D. OCHOA, Jr.,

Plaintiffs/Respondents,

v.

DAN GALBREATH and JANE DOE GALBREATH, husband and wife; DOUBLE UP RANCH, INC., a Washington corporation; GREG GALBREATH and JANE DOE GALBREATH, husband and wife; 82 FARMS, IN., a Washington corporation,

Defendants/Appellants.

AFFIDAVIT OF SERVICE

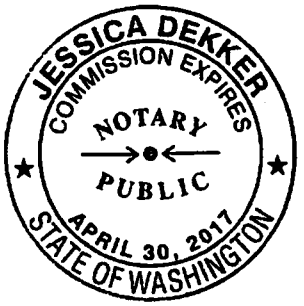
STATE OF WASHINGTON)
) ss.
COUNTY OF BENTON)

I, CAROLINE FERGEN, being first duly sworn upon oath, depose and state:

That I am over the age of 18 years; that on the 6th day of July, 2016, I caused to be served true and correct copies of Appellants' Petition for Review and this Affidavit of Service upon John G. Schultz, attorney for respondents, at LEAVY, SCHULTZ, DAVIS, P.S., 2415 West Falls Avenue, Kennewick, WA 99336, by hand delivery via office courier.

Caroline Fergen
CAROLINE FERGEN

SUBSCRIBED AND SWORN to before me this 6th day of July, 2016.



NOTARY PUBLIC, in and for the State of Washington, residing at: Kennewick
My Commission Expires: 4-30-17