



Department of Pesticide Regulation



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MEMORANDUM

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DATE: April 1, 2016

SUBJECT: GUIDANCE FOR EVALUATING CASES OF DDT DETECTS ON
COMMODITIES THAT ARE NOT COVERED BY FDA ACTION LEVELS

Summary: Human Health Assessment Branch (HHAB) recommends that Enforcement Branch (EB) should use FDA action levels for similar commodities (e.g., from the same crop group) to evaluate residues of DDT (1,1,1-trichloro-2,2-bis(p-chlorophenyl)ethane) and related isomers and metabolites (DDTr) detected in commodities without action levels. For cases submitted to HHAB for risk assessment, an acute reference dose of 0.0017 mg/kg/day will be used to evaluate risk.

HHAB Recommendations and Conclusions: EB requested guidance from HHAB for evaluating cases of DDT detects on commodities that are not covered by FDA action levels, specifically, maximum residues that would not be expected to result in an acute health concern. HHAB reviewed current FDA action levels, toxicity data for DDTr, and residue data from USDA's PDP program and DPR's residue monitoring program. We made the following conclusions regarding the evaluation of potentially illegal DDTr residues on fresh produce, that is, residues that exceed the FDA action level or residues detected on commodities that don't have action levels:

- California soils, and soils around the world where crops are grown for the California market, contain legacy residues of DDT due to previous use as an insecticide on food crops and the long half-life of the chemical in the environment.



- CDFA published a report in 1985 (updated in 1996) that investigated possible illegal use of DDT in California and concluded that DDT residue profiles in food were due to higher than expected persistence of the chemical in California soils and not to illegal applications.
- DDT use in California was restricted in 1963. The last year that significant amounts were used was 1970 when 1.2 million pounds were applied in the state.
- A 2002 risk assessment by ATSDR showed that diet was the primary route of exposure to DDT for the general public. Consumption of meat, fish, and poultry were the main contributors. Among other food categories, leafy vegetables and root vegetables contained higher residues than fruits, legumes, and garden vegetables. Chronic dietary exposure was over 10-fold lower than the cRfD of 0.5 ug/kg/day for every subpopulation evaluated, indicating that there was no health concern from DDT residues in the diet. Infants and children up to age 2 y were the highest exposed subpopulations with exposures of approximately 0.044 ug/kg/day.
- DDT has moderate acute toxicity based on its oral LD₅₀ values in laboratory animals. While available studies evaluated its neurotoxicity, liver and reproductive toxicity, there are significant gaps in the database, particularly for neurodevelopmental toxicity and for studies specifically on p,p-DDE, the most commonly detected DDT-related chemical in the California Pesticide Residue Monitoring Program (CPRMP).

- U.S. EPA established a chronic oral RfD of 0.5 ug/kg/day DDT_r based on liver lesions in rats in a feeding study, and an oral cancer slope factor of 0.34 (mg/kg/day)⁻¹ based on liver tumor data from six studies in mice and rats. ATSDR recommended an acute RfD of 0.5 ug/kg DDT_r based on neurotoxicity in neonatal mice after a single dose.
- Our analysis shows that the current levels of DDT_r being detected by CPRMP are unlikely to pose an acute health concern. For example, using the aRfD of 0.0017 mg/kg/day, the acute threshold residues for cilantro and spinach are:
 - Cilantro, 170 ppm (highest detect = 0.05 ppm);
 - Spinach, 0.34 ppm (highest detect = 0.051 ppm).
- For 2006-2015, the highest number of detections for the CPRMP were in spinach, kale, and cilantro. The single highest residue was 0.09 ppm (DDE) on Swiss chard (see Table 1). No detected residues exceeded the FDA action levels or action levels we're proposing in this document.
- For 2005-2014, the highest percent of detects for PDP (in commodities likely to be sampled by CPRMP) were in kale, spinach, cilantro, and carrots. The single highest residue was 0.187 ppm in cilantro (see Table 2). No residues exceeded FDA action levels or action levels we're proposing in this document.
- HHAB recommends that EB use action levels for similar crops to evaluate DDT_r detected residues in commodities that are not covered by existing FDA action levels. Some of these proposed action levels are shown in Table 1 (attached). For example, HHAB proposes that an action level of 0.5 ppm should be used to evaluate residues on cilantro since FDA has assigned an action level of 0.5 ppm to other commodities in crop group 4, such as spinach, lettuce, and endive. The newly proposed crop groupings should be used to compare commodities. Until new federal regulations for crop groups are promulgated, these new crop group assignments can be found in the federal docket at this location:
<http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=10;po=0;D=EPA-HQ-OPP-2006-0766>
- For cases referred to HHAB for risk assessment, an aRfD of 0.0017 mg/kg will be used to evaluate risk. This endpoint is based on a LOAEL of 0.5 mg/kg for an increase in spontaneous motor activity in mice that were treated at 10 days of age and total uncertainty factors of 300X. The selection of this endpoint will be discussed in a separate memorandum "Toxicological Summary for DDT/DDE" by Dr. Qiaoxiang Dong.

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The HHAB Workgroup for the DDT project included: Rick Duncan (Lead for setting the action levels) and Qiaoxiang Dong (Lead on toxicology), Sheryl Beauvais, Mingzhang Guo, Svetlana Koshlukova, Carolyn Lewis, Peter Lohstroh, Andy Rubin and Leona Scanlan.

ATTACHMENT 1: Table 1: Summary of CPRMP DDT_r Detects (2006-2015) and Existing and Proposed Action Levels (a).

ATTACHMENT 2: Table 2: Total DDT_r Residues (ppm) on PDP Commodities Likely to be Sampled by CPRMP (2005-2014 data).

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Table 1: Summary of CPRMP DDT_r Detects (2006-2015) and Existing and Proposed Action Levels (a).

Commodities w/DDTr detects, 2006-2015	# detects	range (ppm)	FDA ACTION LEVEL	CURRENT CROP GROUP	DEEM4 CROP GROUP	PROPOSED CALIF ACTION LEVEL	SIMILAR CROPS W/FDA ACTION LEVELS
SPINACH	126	0.010 - 0.051	0.5	4A	4A	n/a	n/a
KALE	52	0.010 - 0.040	0.5	5B	4B	n/a	n/a
CILANTRO (CHINESE PARSLEY, CORIANDER LEAVES)	31	0.010 - 0.050	0.5	19A	4A	0.5	Spinach, lettuce, endive = 0.5
LETTUCE; HEAD, LEAF, ROMAINE	23	0.010 - 0.040	0.5	4A	4A	n/a	n/a
SQUASH; ALL, SUMMER, WINTER	23	0.010 - 0.030	0.1	9B	9B	n/a	n/a
CARROTS (ALL OR UNSPEC)	16	0.010 - 0.057	3	1AB	1AB	n/a	n/a
RADISH	15	0.010 - 0.043	0.2	1AB	1AB	n/a	n/a
BOK CHOY (WONG BOK)	12	0.010 - 0.070	0.5	5B	5	n/a	n/a
COLLARDS	7	0.010 - 0.050	0.5	5B	4B	n/a	n/a
POTATO (WHITE, IRISH, RED, RUSSET)	6	0.010 - 0.080	1	1C	1C	n/a	n/a
RADISH TOPS	4	0.010 - 0.042	0.2	2	4B	n/a	n/a
BEANS (GREEN, STRING)	3	0.010 - 0.023	0.2	6B	6B	n/a	n/a
SWISS CHARD (SPINACH BEET)	3	0.011 - 0.090	0.5	4B	4A	n/a	n/a
YAMS, TRUE (LISBON & WHITE YAM)	3	0.010	n/a	1CD	1CD	1	Sweet potato = 1
BEAN, BROAD (FAVA, HORSE BEAN) (ALL/UNSPEC)	1	0.020	0.2	6B	6B	n/a	n/a
BEETS, GENERAL	1	0.012	0.2	1	1	n/a	n/a
BEETS, TABLE, RED, OR GARDEN (ROOT CROP)	1	0.013	0.2	1AB	1AB	n/a	n/a
BROCCOLI	1	0.010	0.5	5	5	n/a	n/a
BROCCOLI RAAB (RAPA, ITALIAN TURNIP, RAPINI)	1	0.010	n/a	5B	4B	0.5	Brassica (cole) leafy vegetables (except broccoli raab, Chinese mustard cabbage, and rape greens) = 0.5
BURDOCK (ROOT CROP) (GOBO, HARLOCK, CLOTBUR)	1	0.020	n/a	1AB	1AB	0.2	Beet, parsnip, radish = 0.2
CELERY, GENERAL	1	0.010	0.5	4B	22B	n/a	n/a
CHINESE BROCCOLI (WHITE FLOWERING) (GAI LON)	1	0.015	0.5	5A	4B	n/a	n/a
CUCUMBER (PICKLING, CHINESE, ETC.)	1	0.070	0.1	9B	9B	n/a	n/a
MUSTARD GREENS, (LEAFY VEGETABLE)	1	0.013	0.5	5B	4B	n/a	n/a
ONIONS (GREEN)	1	0.060	n/a	3B	3B	0.2	Onion, dry bulb = 0.2
PARSNIP	1	0.010	0.2	1AB	1AB	n/a	n/a
PEACH	1	0.050	0.2	12	12B	n/a	n/a
SESAME (SEED & POD VEGETABLE)	1	0.010	n/a	20A	20A	0.1	Cottonseed = 0.1
TARO (DASHEEN) (ROOT CROP) (WETLAND, UPLAND, ETC.)	1	0.010	n/a	1CD	1CD	0.2	Beet, parsnip, radish = 0.2
TURNIP TOPS (FORAGE - FODDER)	1	0.021	0.2	2	4B	n/a	n/a

(a) Yellow shading indicates commodities without FDA action levels.

Table 2: Total DDT_r Residues (ppm) on PDP Commodities Likely to be Sampled by CPRMP (2005-2014 data).

YEAR	COMMOD_NAME	SampCt	HitsCnt	PctHit	MinConcen	MaxConcen	Actual or Proposed Action Level (a)
2006, 2007, 2008	KALE	215	77	35.81%	0.007	0.046	0.5
2006, 2008, 2009	SPINACH	1025	313	30.54%	0.003	0.052	0.5
2009-2010	CILANTRO	739	220	29.77%	0.002	0.187	0.5
2006, 2007, 2013, 2014	CARROTS	2907	798	27.45%	0.002	0.127	3
2006, 2007, 2008	COLLARD GREENS	214	38	17.76%	0.007	0.025	0.5
2007, 2008, 2013, 2014	CELERY	2896	369	12.74%	0.002	0.014	0.5
2005, 2009, 2010, 2011	LETTUCE INCL ORGANIC	2616	110	4.20%	0.003	0.034	0.5
2008, 2009	GREEN ONIONS	744	24	3.23%	0.003	0.003	0.2
2006, 2007, 2008, 2012, 2013, 2014	SUMMER SQUASH	2908	63	2.17%	0.003	0.030	0.1
2008, 2009	POTATOES	1488	32	2.15%	0.007	0.042	1
2005, 2006, 2011, 2012, 2013	WINTER SQUASH	2215	40	1.81%	0.003	0.014	0.1
2010, 2011, 2012	SWEET BELL PEPPERS	1671	28	1.68%	0.001	0.004	0.1
2009, 2010	CUCUMBERS	1488	16	1.08%	0.002	0.014	0.1
2006, 2007, 2008, 2013, 2014	BROCCOLI	2894	20	0.69%	0.002	0.003	0.5
2005, 2007, 2008, 2013, 2014	GREEN BEANS	1742	11	0.63%	0.003	0.009	0.2
2008, 2009, 2010	SWEET POTATOES	1476	4	0.27%	0.007	0.007	1
2011, 2012	SNAP PEAS	1487	2	0.13%	0.002	0.003	0.2
2005, 2006, 2010, 2014	WATERMELON	1493	1	0.07%	0.007	0.007	0.1
2008, 2009, 2010	ASPARAGUS	1466	1	0.07%	0.007	0.007	0.5
2005, 2006, 2011, 2012, 2013	CAULIFLOWER	2754	1	0.04%	0.003	0.003	0.5
2007, 2008, 2013, 2014	NECTARINES	2459	1	0.04%	0.003	0.003	0.2
2006, 2007, 2008, 2013, 2014	PEACHES	2253	1	0.04%	0.007	0.007	0.2
2006, 2007, 2008, 2012, 2013, 2014	BANANAS	2500	0	0.00%	n/a	n/a	n/a
2005, 2006, 2011, 2012, 2013	PLUMS	2435	0	0.00%	n/a	n/a	0.2
2005, 2009, 2010, 2014	APPLES	2408	0	0.00%	n/a	n/a	0.1
2005, 2006, 2009, 2010	ORANGES	2229	0	0.00%	n/a	n/a	0.1
2005, 2009, 2010	GRAPES	2228	0	0.00%	n/a	n/a	0.05
2007, 2008, 2014	BLUEBERRIES	2125	0	0.00%	n/a	n/a	0.1
2005, 2009, 2010	PEARS	2040	0	0.00%	n/a	n/a	0.1
2005, 2010, 2011, 2012	CANTALOUPE	1978	0	0.00%	n/a	n/a	0.1
2008, 2009, 2014	STRAWBERRIES	1661	0	0.00%	n/a	n/a	0.1
2007, 2008, 2014	TOMATOES	1658	0	0.00%	n/a	n/a	0.05
2011, 2012	CHERRY TOMATOES	1482	0	0.00%	n/a	n/a	0.05
2005, 2006	EGGPLANT	1476	0	0.00%	n/a	n/a	0.1
2011, 2012, 2013	MUSHROOMS	1462	0	0.00%	n/a	n/a	0.5
2008, 2009, 2010, 2014	SWEET CORN	1435	0	0.00%	n/a	n/a	0.1
2011, 2012	TANGERINES	1426	0	0.00%	n/a	n/a	0.1
2011, 2012	PAPAYA	750	0	0.00%	n/a	n/a	0.2
2011, 2012	ONION	744	0	0.00%	n/a	n/a	0.2
2010, 2011	HOT PEPPERS	739	0	0.00%	n/a	n/a	0.1
2013	RASPBERRIES	652	0	0.00%	n/a	n/a	0.1
2007, 2014	CHERRIES	647	0	0.00%	n/a	n/a	0.2
2012	AVOCADO	372	0	0.00%	n/a	n/a	0.2
2010	MANGOES	372	0	0.00%	n/a	n/a	0.2
2006	CRANBERRIES	316	0	0.00%	n/a	n/a	0.1

(a) Yellow shading indicates proposed Calif action level.

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