Summary

The Office of Environmental Health Hazard Assessment (OEHHA) conducted a screening analysis to evaluate the likelihood that chlorothalonil consumption from fresh tomatoes and tomato products by the average consumer would exceed the Proposition 65 No Significant Risk Level (NSRL) for the compound. The screening analysis derived an upper-bound estimate of chlorothalonil intake to compare with the NSRL. The analysis used the maximum residue concentration for chlorothalonil measured in recent US Department of Agriculture (USDA) surveys. Amounts of fresh tomatoes and other tomato products consumed by the average consumer on the day eaten were also calculated, using information from the National Health and Nutrition Examination Survey. Based on upper estimates for residues and tomato product consumption, upper-bound estimates of chlorothalonil consumption were calculated. These upper-bound estimates were lower than the NSRL. Thus, OEHHA found that consumption by the average consumer of fresh tomatoes and processed tomato products does not exceed the NSRL for chlorothalonil when tomatoes have residues at levels measured in recent USDA surveys.
Introduction

The Office of Environmental Health Hazard Assessment (OEHHA) has conducted an evaluation to determine whether exposure to chlorothalonil from consumption of tomatoes poses no significant cancer risk within the meaning of Proposition 65 when residues are at recent historical levels. This interpretive guideline provides the results of this analysis.

OEHHA may issue an Interpretive Guideline that interprets Proposition 65 and its implementing regulations, as applied to specific facts. The Interpretive Guideline reflects OEHHA’s scientific interpretation of the available information as the lead agency for implementation of the Act.¹

Proposition 65 Listing of Chlorothalonil and Its No Significant Risk Level

Chlorothalonil was listed as a chemical known to cause cancer under Proposition 65, effective January 1, 1989. An NSRL of 41 micrograms (µg) per day will be effective June 15, 2012.² Daily exposure to this level of chlorothalonil is estimated to cause a risk of one cancer per 100,000 people exposed. Businesses causing exposures at or below the NSRL are exempt from the Proposition 65 warning requirement.

Chlorothalonil Residues in Tomatoes and Tomato Products

The U.S. Department of Agriculture’s (USDA) Pesticide Data Program³ tests food commodities for pesticide residues. The U.S. Environmental Protection Agency (US EPA) uses the program’s results in its dietary assessments of pesticide exposure. OEHHA obtained USDA sampling data on residue levels for chlorothalonil in tomatoes for 2003, 2004, 2007 and 2008. These values are shown in Table 1. These are the most recent years that USDA reports sampling results for chlorothalonil in fresh tomatoes. USDA did not report sampling results for chlorothalonil in fresh tomatoes in 2005, 2006 or 2009.

Table 1 shows that in the 2967 samples of fresh tomatoes collected in years 2003-2008, chlorothalonil residues were not above the US EPA tolerance level of 5 parts per

¹ Health and Safety Code section 25249.12
million\textsuperscript{4} (ppm). The maximum concentration measured was 0.34 ppm. Residue concentrations were more than a factor of 10 below the tolerance. Over this period, chlorothalonil was detected in 10 percent of the samples. In 2007 and 2008, most of the samples in which chlorothalonil was detected had residue levels of 0.007 ppm.

\begin{table}
\centering
\caption{USDA Measured Concentrations\textsuperscript{5} of Chlorothalonil in Tomato Products}
\begin{tabular}{|c|c|c|c|c|}
\hline
Product & Year & Number of Samples & Detection Frequency (percent) & Concentration (ppm)\textsuperscript{a} & Limit of Detection (ppm) \\
\hline
Fresh tomatoes & 2003 & 742 & 6.5 & 0.013-0.29 & 0.008 \\
 & 2004 & 744 & 6.3 & 0.013-0.25 & 0.008 \\
 & 2007 & 741 & 15.7 & 0.007-0.34 & 0.004 \\
 & 2008 & 740 & 12.6 & 0.007-0.33 & 0.004 \\
Tomato paste & 2009 & 742 & 0 & -- & 0.014 \\
\hline
\end{tabular}
\textsuperscript{a} Concentrations measured when chlorothalonil was detected in the sample.
\end{table}

In 2009, USDA sampled for chlorothalonil in tomato paste. Chlorothalonil in all 742 samples taken was below the limit of detection for tomato paste, 0.014 ppm. With regard to chlorothalonil residues in other processed foods, there are data on the degradation of chlorothalonil with cooking and other food processing methods. The World Health Organization (WHO)\textsuperscript{6} discusses a study in which most of chlorothalonil was found to be lost during cooking in open containers:

\begin{quote}
“As much as 85-98\% of chlorothalonil added to tomatoes or green beans was lost during cooking in open vessels. Only 2.4\% was converted to the 4-hydroxy metabolite, which was stable to cooking (SDS Biotech Corporation, 1983a).”
\end{quote}

More recently, the WHO Food and Agriculture Organization’s Joint Meeting on Pesticide Residues evaluated the fate of chlorothalonil residues from storage and food processing

\textsuperscript{4} Code of Federal Regulations, Title 40, Part 180, Section 180.275
of tomatoes and developed “calculated food processing factors.” These factors represent “the concentration of pesticide after processing divided by the concentration before processing.”\(^7\) The WHO calculated food processing factors for a number of tomato commodities. These are provided in Table 2.

**Table 2. WHO Processing Factors for Chlorothalonil in Tomato Products**

<table>
<thead>
<tr>
<th>Tomato Commodity</th>
<th>Calculated processing factor (PF) Median or best estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crushed tomato</td>
<td>0.31</td>
</tr>
<tr>
<td>Wet pomace</td>
<td>0.32</td>
</tr>
<tr>
<td>Dry pomace</td>
<td>1.3</td>
</tr>
<tr>
<td>Raw juice</td>
<td>0.3</td>
</tr>
<tr>
<td>Bottled juice</td>
<td>0.11</td>
</tr>
<tr>
<td>Reduced tomato</td>
<td>0.005</td>
</tr>
<tr>
<td>Sieved tomato</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Puree, pre-sterilization</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Puree, post-sterilization</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Blanched tomato</td>
<td>0.1</td>
</tr>
<tr>
<td>Peeled tomato</td>
<td>0.03</td>
</tr>
<tr>
<td>Peel</td>
<td>2.9</td>
</tr>
<tr>
<td>Canned tomato</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Overall the information summarized above indicates that chlorothalonil residues in processed food should be at levels below those seen in the raw commodity. Dry pomace and tomato peels are the exception, with the pomace showing slightly elevated levels and the peel with levels roughly three times as large.

**Level of Exposure to Proposition 65 Chemicals that Cause Cancer**

Proposition 65 regulations address how to calculate the exposure to chemicals listed as known to cause cancer:

“For purposes of Section 25249.10(c) of the Act, the level of exposure to a chemical listed as causing cancer, assuming lifetime exposure at the level in question, shall be determined by multiplying the level in question (stated in terms

of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to the given medium of exposure measured over a lifetime of seventy years.”

The regulations give further guidance for calculating the reasonably anticipated rate of exposure for chemical exposures from consumer products:

“For exposures to consumer products, lifetime exposure shall be calculated using the average rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The average rate of intake or exposure shall be based on data for use on a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.”

**Chlorothalonil Intake from Tomato Consumption**

Table 3 provides estimates of mean intake for various tomato products by the consumer on the day the product is eaten. Values provided were calculated by OEHHA from the data collected in the National Health and Nutrition Examination Survey. This is a dietary survey of individuals throughout the US reported by the US Centers for Disease Control and Prevention. The values used to estimate average intakes were for any individual reporting they consumed the food either day of the 2 day study, for the years 2007-2008. Because people do not consume any particular tomato product every day for their lifetimes, this represents a substantial overestimate of intake by the average user of the product.

An upper-bound estimate of exposure of the average consumer to chlorothalonil can be calculated based on these average intake values for consumers of the food and the concentrations. These values are also provided in Table 3. In making these calculations for specific tomato products, OEHHA applied the processing factor calculated by the World Health Organization to estimate chlorothalonil residues in those products based on residues in fresh tomatoes.

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8 Title 27, Cal. Code of Regs., section 25721(c)
9 Title 27, Cal. Code of Regs., section 25721(d)(4); the National Health and Nutrition Examination Survey provides the functional equivalent of the USDA survey cited in this subsection
10 Data available at [http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm](http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm)
Table 3. Consumption of Tomato Products and Intake of Chlorothalonil

<table>
<thead>
<tr>
<th>Products</th>
<th>Mean consumption* of product on day eaten (gms/day)</th>
<th>Upper bound estimate of chlorothalonil concentration (µg per gm)</th>
<th>Mean chlorothalonil intake on day product eaten (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fresh Tomatoes</td>
<td>59.0</td>
<td>0.340</td>
<td>20.1</td>
</tr>
<tr>
<td>Ketchup</td>
<td>18.4</td>
<td>&lt;0.003</td>
<td>&lt;0.063</td>
</tr>
<tr>
<td>Canned Tomatoes</td>
<td>141.9</td>
<td>&lt;0.003</td>
<td>&lt;0.48</td>
</tr>
<tr>
<td>Salsa</td>
<td>48.5</td>
<td>&lt;0.003</td>
<td>&lt;0.16</td>
</tr>
<tr>
<td>Tomato Sauce</td>
<td>58.8</td>
<td>&lt;0.003</td>
<td>0.20</td>
</tr>
<tr>
<td>Spaghetti Sauce</td>
<td>68.4</td>
<td>&lt;0.003</td>
<td>&lt;0.23</td>
</tr>
<tr>
<td>Dried Tomato</td>
<td>7.3</td>
<td>0.440</td>
<td>0.032</td>
</tr>
<tr>
<td>Tomato Soup</td>
<td>298.6</td>
<td>&lt;0.003</td>
<td>&lt;1.02</td>
</tr>
<tr>
<td>Tomato Juice</td>
<td>297.1</td>
<td>&lt;0.003</td>
<td>&lt;1.01</td>
</tr>
</tbody>
</table>

*a Calculated by OEHHA using data from the NHANES 2007-2008 survey years (see text).

*b Maximum residue in fresh tomatoes (0.34 ppm) multiplied by processing factor (see Table 2).

Conclusion

Consumption of chlorothalonil residues by the average consumer of tomatoes does not result in exposures that exceed the Proposition 65 NSRL of 41µg/day for the chemical, where the residue levels in tomatoes are at recent historical levels measured for chlorothalonil in USDA surveys.

This interpretive guideline is intended to provide information for the general public and businesses to facilitate the implementation of Proposition 65. It is limited to the facts and assumptions contained herein. Further information can be obtained from the OEHHA website at: http://www.oehha.ca.gov/prop65.html