

# Are Organic Foods Safer or Healthier Than Conventional Alternatives?

## A Systematic Review

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**Background:** The health benefits of organic foods are unclear.

**Purpose:** To review evidence comparing the health effects of organic and conventional foods.

**Data Sources:** MEDLINE (January 1966 to May 2011), EMBASE, CAB Direct, Agricola, TOXNET, Cochrane Library (January 1966 to May 2009), and bibliographies of retrieved articles.

**Study Selection:** English-language reports of comparisons of organically and conventionally grown food or of populations consuming these foods.

**Data Extraction:** 2 independent investigators extracted data on methods, health outcomes, and nutrient and contaminant levels.

**Data Synthesis:** 17 studies in humans and 223 studies of nutrient and contaminant levels in foods met inclusion criteria. Only 3 of the human studies examined clinical outcomes, finding no significant differences between populations by food type for allergic outcomes (eczema, wheeze, atopic sensitization) or symptomatic *Campylobacter* infection. Two studies reported significantly lower urinary pesticide levels among children consuming organic versus conventional diets, but studies of biomarker and nutrient levels in serum, urine, breast milk, and semen in adults did not identify clinically meaningful differences. All estimates of differences in nutrient and contaminant levels in foods were highly heterogeneous except for

the estimate for phosphorus; phosphorus levels were significantly higher than in conventional produce, although this difference is not clinically significant. The risk for contamination with detectable pesticide residues was lower among organic than conventional produce (risk difference, 30% [CI, -37% to -23%]), but differences in risk for exceeding maximum allowed limits were small. *Escherichia coli* contamination risk did not differ between organic and conventional produce. Bacterial contamination of retail chicken and pork was common but unrelated to farming method. However, the risk for isolating bacteria resistant to 3 or more antibiotics was higher in conventional than in organic chicken and pork (risk difference, 33% [CI, 21% to 45%]).

**Limitation:** Studies were heterogeneous and limited in number, and publication bias may be present.

**Conclusion:** The published literature lacks strong evidence that organic foods are significantly more nutritious than conventional foods. Consumption of organic foods may reduce exposure to pesticide residues and antibiotic-resistant bacteria.

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Between 1997 and 2010, U.S. sales of organic foods increased from \$3.6 to \$26.7 billion (1, 2). Although prices vary, consumers can pay up to twice as much for organic than conventional foods (3–5).

Organic certification requirements and farming practices vary worldwide, but organic foods are generally grown without synthetic pesticides or fertilizers or routine use of antibiotics or growth hormones (6, 7). Organic livestock are fed organically produced feed that is free of pesticides and animal byproducts and are provided access to the outdoors, direct sunlight, fresh air, and freedom of movement (7). In addition, organic regulations typically require that organic foods are processed without irradiation or chemical food additives and are not grown from genetically modified organisms (6, 8). The International Federation of Organic Agriculture Movements endorses the principles of “health, ecology, fairness, and care” (9).

Consumers purchase organic foods for different reasons, including concerns about the effects of conventional farming practices on the environment, human health, and animal welfare and perceptions that organic foods are tastier than their conventional alternatives (2, 10–13).

The purpose of this study is to comprehensively synthesize the published literature on the health, nutritional, and safety characteristics of organic and conventional foods. Previous reviews comparing the nutritional content of organic and conventional foods have summarized studies narratively (13–18), reported differences in nutrient levels without assessing the statistical significance of those differences or weighting outcomes by sample size (19–22), or considered only harms (23).

## METHODS

### Data Sources and Searches

With a professional librarian, we developed search strategies for 7 databases: MEDLINE (January 1966 to May 2011), EMBASE, CAB Direct, Agricola, TOXNET, and Cochrane Library (January 1966 to May 2009) with such terms as *organic*, *vegetable*, *fruit*, and *beef* (Supple-

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ment 1, available at [www.annals.org](http://www.annals.org)) and reviewed bibliographies of retrieved articles.

### Study Selection

Peer-reviewed, English-language studies, regardless of design, were eligible for inclusion if they reported a comparative evaluation of populations consuming diets of foods grown organically and conventionally or a comparative evaluation of nutrient levels or bacterial, fungal, or pesticide contamination of fruits, vegetables, grains, meats, poultry, milk (including raw milk), or eggs grown organically and conventionally. We excluded studies of processed foods, those that evaluated samples from livestock feces or gastrointestinal tracts, and those that did not report information about variance or results of statistical tests (24–34). Organic practices included biodynamic farming and were defined by investigators' stated adherence. Studies merely comparing the effects of organic and nonorganic fertilization practices were ineligible unless they specified that the produce receiving organic fertilizer was grown by using organic farming practices (28, 32, 33, 35–47). Similarly, we excluded studies of such foods as recombinant bovine somatotropin-free milk and grass-fed beef unless the food production was reported to be organic.

### Data Extraction and Quality Assessment

One author abstracted data on study methods (for example, design; food tested; sample size; organic standard; testing methods; harvest season; and cultivar, breed, or population studied) and end points (Supplement 2, available at [www.annals.org](http://www.annals.org)). At least 1 additional author verified all abstracted data; discrepancies were resolved with discussion. If 2 or more studies presented the same data from a single population or the same farm experiment, we included these data only once in our analyses.

We defined quality criteria a priori and evaluated the extent to which included human population studies specified the organic standard used, evaluated the amount of organic foods consumed in diets, linked reported outcomes with health outcomes, obtained institutional review board approval and participant consent, and were not funded by an organization with a financial interest in the study outcome. For the studies that directly evaluated the study foods, we evaluated the extent to which each study specified the organic standard used, used the same harvesting or processing method for both groups, reported sample size, used equal sample size in both groups, and were not funded by organizations with a financial interest in the study outcome. We also evaluated the extent to which the organic–conventional comparison pairs were of the same cultivar or breed, grown on neighboring farms, and harvested during the same season.

### Data Synthesis and Analysis

We calculated summary effect sizes by using random-effects models for outcomes with at least 3 studies reporting data: summary risk differences (RDs) and summary prevalence rates for studies reporting the number of sam-

ples contaminated and summary standardized mean differences (SMDs) for studies reporting mean nutrient or harm levels. Differences were calculated as organic minus conventional (for example, a positive number indicates more contamination in organic). All RDs are absolute RDs.

We performed tests of homogeneity ( $Q$  statistic and  $I^2$  statistic) on all summary effect sizes. Homogeneity was indicated if  $I^2$  was less than 25% and  $P$  value for the  $Q$  statistic was greater than 0.010. If the 2 tests agreed, we report only the  $I^2$  statistic; otherwise, we report results for both. We used funnel plots to assess publication bias (48). We qualitatively summarized studies not reporting information on variance and excluded studies not reporting any information on variance or statistical testing. All analyses were completed by using Comprehensive Meta-analysis, version 2 (Biostat, Englewood, New Jersey). Because of the large number of comparisons (22 for produce and 31 for meat, poultry, milk, and eggs), we report adjusted  $P$  values for summary estimates using the Sidak formula for multiple comparisons. For each reported summary effect size, we omitted 1 study at a time to assess the influence of each individual study on summary effects and omitted outliers that were more than 1 order of magnitude larger or smaller than others. We explored heterogeneity by conducting subgroup analyses by food type, organic standard used, testing method, and study design when at least 3 studies examined these subgroups.

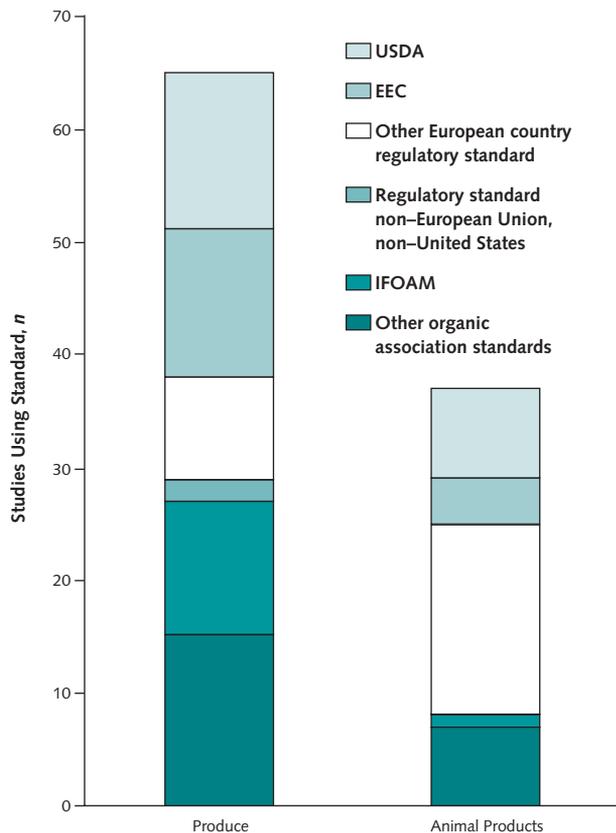
We limited our analyses of bacterial contamination to foodborne pathogens monitored by the Centers for Disease Control and Prevention's FoodNet (49) (for example, *Campylobacter*, *Listeria*, *Salmonella*, and *Escherichia coli*). However, given the potential for transfer of antibiotic resistance between species, we included all human pathogens (for example, *Staphylococcus aureus*) in the analyses of antibiotic resistance.

Studies frequently reported several results per outcome (for example, mean vitamin C level in years 1 and 2). To include such studies only once in our analyses, we combined the results within each study by using random-effects models and used this study-level summary effect in our overall summary calculation.

Similarly, several studies (50–53) reported multiple results for resistance to the same antibiotic by examining different bacteria (for example, *Salmonella* and *Campylobacter*). To include these studies only once in each effect size calculation, we used results for pathogens in the *Enterobacteriaceae* family (for example, *Salmonella*) for the main analyses and the alternate species (for example, *Campylobacter*) in sensitivity analysis.

Among the produce studies, several studies that otherwise could have been included in summary effect size calculations did not report sample sizes. To avoid discarding them, we assumed that they had a sample size of 3 (a common sample size among the smaller studies). In sensitivity analyses, we varied this to 10, the median sample size among studies. This alternate assumption did not change

**Figure 1. Organic standards used for studies of produce and animal products.**



Sixty-five produce studies and 37 studies of animal products reported the organic standard applied. EEC = European Economic Community; IFOAM = International Federation of Organic Agriculture Movements; USDA = U.S. Department of Agriculture.

conclusions, so we report the outcomes using a sample size of 3.

### Role of the Funding Source

This study did not receive external funding.

## RESULTS

Searches identified 5908 potentially relevant articles (Appendix Figure 1, available at [www.annals.org](http://www.annals.org)). Two hundred thirty-seven studies met inclusion criteria: 17 evaluated health outcomes among human populations consuming organic and conventional foods (54–70); 223 compared organic and conventional fruits, vegetables, grains, meats, poultry, milk, or eggs directly (50–53, 57, 65, 69, 71–286) (3 reported on both human and food outcomes). Supplement 2 lists all studies reporting each outcome and studies included in each subgroup analysis.

### Studies in Humans Consuming Organic and Conventional Foods

Seventeen articles describing 14 unique populations (13 806 participants) met inclusion criteria (Supplement

3, available at [www.annals.org](http://www.annals.org)). Study designs varied: 6 randomized, controlled trials (56, 57, 62, 65, 66, 69), 2 prospective cohort studies (54, 61), 3 cross-sectional studies (55, 64, 68), 4 crossover studies (describing 2 populations) (59, 60, 63, 67), and 1 case–control study (70). Only 3 studies (61, 64, 70) examined clinical outcomes (for example, wheezing, allergic symptoms, or reported *Campylobacter* infections), and the remaining studies examined health markers (for example, serum lipid or vitamin levels).

In general, the included studies were of fair quality (Appendix Figure 2 [top panel], available at [www.annals.org](http://www.annals.org)). Only 6 studies specified the organic standard used. Only 5 studies (54, 61, 64, 65, 68) evaluated participants who consumed a predominately organic diet; participants in the remaining studies consumed only certain organic foods (for example, apples [62], carrots [69], or meat or dairy products [68]). The sample sizes ranged from 6 to 6630, and duration ranged from 2 days to 2 years. Four studies were from the United States (55, 59, 60, 63), and all others were from Europe.

### Studies in Pregnant Women and Children

One prospective cohort study (61) and 1 cross-sectional study (64) of pregnant women and their children reported no association between diet type and the development of eczema, wheezing, serum IgE levels, or other atopic outcomes among children. Exploratory subgroup analyses found that children who consumed dairy products of which more than 90% were organically produced had a lower risk for eczema at age 2 years than children who consumed dairy products of which less than 50% were organically produced (odds ratio, 0.64 [95% CI, 0.44 to 0.93]) (61).

Three other studies examined markers of pesticide or insecticide exposure in children. One cross-sectional study (55) and 1 crossover study (59) examined urinary organophosphate pesticide metabolites, finding significantly lower levels among children on organic diets than those on conventional diets. Although these studies suggest that consumption of organic fruits and vegetables may significantly reduce pesticide exposure in children, they were not designed to assess the link between the observed urinary pesticide levels and clinical harm. One crossover study comparing urinary insecticide levels among children spending 5 days on a conventional diet followed by 5 days on an organic diet found household use of insecticides—but not diet—to be a significant predictor of urinary insecticide levels (60).

### Studies in Nonpregnant Adults

Eleven reports of 10 populations examined differences between adults consuming organic and conventional diets. Only 1 reported clinical outcomes: An exploratory case–control study (70) found consumption of organic meat in

**Table 1. Summary of Benefits: SMD of Nutrient Levels Found in Organic Versus Conventional Fruits, Vegetables, and Grains\***

Nutrient	Summary of All Identified Studies				Results of Meta-analysis										
	Studies, n	Comparisons, n	Comparisons Favor Organic, n†	Comparisons Favor Conventional, n‡	Studies, n§	Studies Describing Sample Size, n	Organic Sample Size, n	Conventional Sample Size, n	SMD (95% CI)	P Value¶	Heterogeneous (I <sup>2</sup> Statistic)				
Ascorbic acid	Foods studied: banana, berries, broccoli, cabbage, carrots, celery, eggplant, grapes, leafy greens, lettuce, oranges, peaches, pears, peppers, plums, potatoes, strawberries, and tomatoes				41	113	23	12	31	28	1141	1306	0.50 (0.05 to 0.95)	0.48	Yes (80%)
β-Carotene	Foods studied: eggplant, plums, carrots, tomatoes, sweet peppers, kale, and orange				16	23	6	3	12	6	114	114	1.14 (−0.13 to 2.42)	0.83	Yes (91%)
α-Tocopherol	Foods studied: peaches, pears, plums, corn, cabbage, carrots, and olive oil				8	19	3	2	5	5	60	60	−0.09 (−0.70 to 0.53)	1.00	Yes (26%)
Potassium	Foods studied: carrots, celery, corn, oranges, grapes, potatoes, peppers, plums, onions, strawberries, and wheat				37	108	18	18	14	9	300	315	0.45 (−0.30 to 1.20)	1.00	Yes (87%)
Calcium	Foods studied: carrots, celery, corn, oranges, peppers, plums, strawberries, onions, potatoes, and wheat				36	105	18	7	15	11	484	500	0.61 (0.01 to 1.22)	0.68	Yes (84%)
Phosphorus	Foods studied: carrots, celery, corn, plums, onions, and potatoes				30	82	24	12	7	6	353	374	0.82 (0.44 to 1.20)	<0.001	No (0%)
Magnesium	Foods studied: potato, plums, onions, peas, carrots, celery, corn, cabbage, strawberries, peppers, tomato, orange, and wheat				34	86	23	6	13	10	352	362	0.65 (0.01 to 1.30)	0.66	Yes (81%)
Iron	Foods studied: potato, plums, onions, peas, corn, cabbage, carrots, strawberries, peppers, wheat, oats, and tomatoes				24	77	10	12	12	9	350	300	0.30 (−0.47 to 1.08)	1.00	Yes (90%)
Protein	Foods studied: wheat, banana, plum, tomato, soybeans, grape juice, and eggplant				27	63	7	34	14	8	93	108	−1.27 (−3.20 to 0.62)	1.00	Yes (83%)
Fiber	Foods studied: banana, eggplant, plums, wheat, grape juice, and oranges				8	11	2	5	7	3	73	90	−0.79 (−1.87 to 0.29)	0.97	Yes (83%)
Quercetin	Foods studied: plums, tomatoes, bell peppers, grapes, grape leaves, lettuce, strawberries, and black currants				13	50	16	2	11	6	156	156	2.45 (0.20 to 4.69)	0.52	Yes (94%)
Kaempferol	Foods studied: plums, black currants, grapes, lettuce, bok choy, collard greens, tomatoes, bell peppers, strawberries, and tomatoes				9	18	6	2	9	5	96	96	2.64 (0.41 to 4.86)	0.36	Yes (93%)
Total flavanols	Foods studied: apples, grape leaves, strawberries, chicory, and black currants				5	22	7	6	5	3	96	96	−0.19 (−1.68 to 1.31)	1.00	Yes (59%)
Total phenols	Foods studied: apples, peaches, pears, plums, bell peppers, berries, tomatoes, chicory, olive oil, grape leaves, oranges, strawberries, bok choy, lettuce, leafy greens, tomatoes, and wheat				34	102	36	12	22	19	401	401	1.03 (0.47 to 1.59)	0.007	Yes (67%)

SMD = standardized mean difference.

\* All summary effect measures reported are results of random-effects models. Among studies examining nutritional content, studies with null findings tended to report results incompletely (hence, they were excluded from syntheses). The exception to this rule was among studies reporting on protein content of organic vs. conventional grain: Studies insufficiently reporting results (hence, they were excluded from summary effect calculation) tended to find significantly higher levels of protein in conventional vs. organic grains. In calculation of summary effect sizes, sensitivity analyses were performed, in which studies not reporting sample size were removed, and subgroup analyses were done by fresh vs. dry weight. Findings did not substantially change with the sensitivity analyses.

† The number of comparisons in which a statistically significant difference was identified with higher levels in the organic group.

‡ The number of comparisons with a statistically significant difference with higher levels in the conventional group.

§ Supplement 2 (available at [www.annals.org](http://www.annals.org)) lists the studies included for each statistical analysis.

|| The difference between mean nutrient level in organic minus that in conventional divided by the pooled SD; thus, a positive (negative) number indicates higher (lower) nutrient levels in organic.

¶ All summary *P* values are adjusted *P* values.

the winter (but not organic meat in general) to be a risk factor for illness due to *Campylobacter* infection (odds ratio, 6.86 [CI, 1.49 to 31.69]).

The remaining studies examined differences in the serum, urine, breast milk, and semen of persons consuming organic and conventional diets. We found no studies comparing pesticide levels among adult consumers of organic versus conventional foods. Seven studies evaluated serum and urine antioxidant levels or immune system markers; 6 of these found no consistent differences in plasma or urine carotenoids, polyphenols, vitamins E and C content, low-density lipoprotein cholesterol, antioxidant activity, ability to protect against DNA damage, immune system markers, or semen quality between participants consuming organic and conventional diets (54, 57, 62, 65, 66, 69). All were randomized, controlled trials except the study of semen quality (a prospective cohort study) (54). One prospective

crossover study reported a statistically significant reduction in serum total homocysteine levels, phosphorus levels, and fat mass after 2 weeks on an organic Mediterranean diet compared with a conventional Mediterranean diet but did not describe the magnitude or clinical significance of these reductions (67). Another crossover study found that organic diets were associated with higher urinary excretion of quercetin and kaempferol but not other polyphenols and found no difference in 7 of 8 serum markers of antioxidation (56).

Two cross-sectional studies examined the breast milk of women from the Dutch KOALA (Child, Parent, and Health: Lifestyle and Genetic Constitution) Birth Cohort consuming predominantly organic versus conventional meat and dairy products (58, 68). They found no difference in the amount of total fatty acids in the breast milk of mothers who consumed meat and dairy products of which

**Table 2. Summary of Harms: RD or SMD in Harms in Organic Versus Conventional Fruits, Vegetables, and Grains\***

Harm	Summary of All Identified Studies			
	Studies, <i>n</i>	Comparisons, <i>n</i>	Comparisons Favor Organic, <i>n</i> †	Comparisons Favor Conventional, <i>n</i> ‡
Any detectable pesticide residue contamination**	22	NA		
<i>E. coli</i> contamination	5	NA		
DON contamination	9	NA		
OTA contamination	7	NA		
Cadmium level	15	77	21	1
Lead level	11	49	9	7
Mercury level	3	34	0	0
Arsenic level	2	16	0	0
DON level	10	29	9	0
OTA level	4	15	3	2

*E. coli* = *Escherichia coli*; DON = deoxynivalenol; NA = not applicable; OTA = ochratoxin A; RD = risk difference; SMD = standardized mean difference.

\* All summary effect measures reported are results of random-effects models.

† The number of comparisons in which a statistically significant difference between organic and conventional was identified with lower levels in the organic group.

‡ The number of comparisons with a statistically significant difference with lower levels in the conventional group.

§ Supplement 2 (available at [www.annals.org](http://www.annals.org)) lists the studies included for each statistical analysis.

|| RD is calculated as the risk for contamination in the organic group minus that in the conventional group; thus, a positive (negative) number indicates more (less) contamination in organic. All RDs are absolute RDs. SMD is the difference between mean contaminant level in organic minus that in conventional divided by the pooled SD; thus, a positive (negative) number indicates more (less) contamination in organic.

¶ All summary *P* values are adjusted *P* values.

\*\* One of the studies included in the pesticide synthesis includes a data set (U.S. Department of Agriculture’s Pesticide Data Program) that oversamples products from sources with a history of violations. Hence, prevalence estimates may overstate prevalence of pesticide contamination in both organic and conventional products.

†† Result not robust to removal of 1 study at a time. Removal of 1 study (225) rendered results significant, suggesting higher contamination among organic produce (RD, 5.1% [95% CI, 2.92% to 7.18%]; *P* < 0.001; *I*<sup>2</sup> = 0%).

‡‡ For cadmium, lead, mercury, arsenic, DON, and OTA levels, these are the sample sizes instead of the number of contaminated samples divided by the total number of samples.

more than 90% were organically produced versus mothers who consumed meat and dairy products of which less than 50% were organically produced (58, 68). In subanalyses, they found higher levels of 2 beneficial fatty acids (conjugated linoleic acid and trans-vaccenic acid) in the breast milk of mothers consuming predominantly organic dairy and meat products versus mothers consuming conventional alternatives (58).

### Studies of Nutrient and Contaminant Levels in Organic Versus Conventional Foods

Two hundred twenty-three studies of foods met inclusion criteria: 153 studies of fruits, vegetables, and grains and 71 studies of meats, poultry, milk, and eggs (1 study reported on both types of foods [189]) (Supplement 4, available at [www.annals.org](http://www.annals.org)). Seventy percent (157 studies) were from Europe, and 21% (47 studies) were from the United States or Canada. Study methods varied: Among produce studies, 52% (80 studies) were on experimental farms in which potential confounders (for example, weather, geography, or plant cultivar) of the relationship between method of cultivation and nutrient levels were

controlled and 29% (44 studies) sampled food grown on commercial farms. Among animal product studies, 11% (8 studies) were conducted on experimental farms and 56% (40 studies) surveyed farms. Of the 37 milk studies included, 7 examined pasteurized milk and 30 examined raw milk (Supplement 4).

Forty-six percent (102 studies) of included studies specified the organic cultivation standard used (Appendix Figure 2 [bottom panel]). The most common standards were European Union or other European country-specific standards (43 studies), International Federation of Organic Agriculture Movements or other association standards (34 studies), and U.S. Department of Agriculture standards (22 studies). The most common standards among produce studies were from organic associations; country-specific European regulatory standards were most common among animal product studies (Figure 1).

Sixty-eight percent (151 studies) reported that harvesting or processing methods were the same for both groups; the remaining studies largely did not describe harvesting or processing methods (such as in studies that examined retail

Table 2—Continued

Results of Meta-analysis						
Studies, n§	Studies Describing Sample Size, n	Contaminated/Total Organic, n/N	Contaminated/Total Conventional, n/N	Difference (95% CI)	P Value¶	Heterogeneous (I <sup>2</sup> Statistic)
Foods studied: variety of fruits and vegetables 9	9	253/3041	45 184/106 755	RD, -30% (-37% to -23%)	<0.001	Yes (94%)
Foods studied: apples, bell peppers, berries, bok choy, broccoli, cabbages, carrots, cucumber, leafy greens, lettuces, spring mix, scallions, spinach, summer squash, tomatoes, and zucchini 5	5	63/803	39/1454	RD, 2.4% (-1.5% to 6.3%)††	1.00	Yes (58%)
Foods studied: barley, buckwheat, corn, mixed grains, rice, rye, and wheat 9	9	267/393	310/347	RD, -23% (-37% to -8%)	0.043	Yes (89%)
Foods studied: baby multigrain, baby rice cereal, baby semolina, barley, buckwheat, corn, maize/tapioca, oats, rice, rye, spelt, and wheat 7	7	384/713	791/1641	RD, 11% (-3% to 24%)	0.93	Yes (92%)
Foods studied: beet, bell peppers, cucumber, greens, green beans, lentil, oats, potatoes, purple 11	9	568††	470††	amaranth, strawberries, tomatoes, and wheat SMD, -0.14 (-0.74 to 0.46)	1.00	Yes (87%)
Foods studied: cucumber, greens, potato, strawberries, tomato, and wheat 8	7	207††	354††	SMD, 0.38 (-0.16 to 0.92)	0.98	Yes (75%)
Foods studied: results not synthesized 0	NA	NA	NA	NA	NA	NA
Foods studied: results not synthesized 0	NA	NA	NA	NA	NA	NA
Foods studied: oats and wheat 8	8	278††	275††	SMD, -0.82 (-1.19 to -0.45)	<0.001	Yes (69%)
Foods studied: corn and wheat 4	4	198††	214††	SMD, -0.21 (-0.13 to 0.54)	1.00	Yes (62%)

samples). Eighty-seven percent (194 studies) reported sample size; however, definitions of a sample varied (for example, 1 sample is 10 apples from 1 tree vs. 10 apples from 1 row of trees). Sixty-five percent (146 studies) had equal sample sizes in both groups, and 91% (204 studies) were not funded by an organization with an overt interest in the outcome. Eighty-six percent (61 studies) of animal product studies sampled animal products from the same season. Among produce studies, 59% (90 studies) and 65% (100 studies) compared food pairs from neighboring farms or the same cultivar, respectively.

### Vitamin and Nutrient Levels by Food Origin

#### Vitamins

We did not find significant differences in the vitamin content of organic and conventional plant or animal products (Supplement 5 [available at [www.annals.org](http://www.annals.org)] and Table 1). Produce studies reported on ascorbic acid (31 studies),  $\beta$ -carotene (12 studies), and  $\alpha$ -tocopherol (5 studies) content; milk studies reported on  $\beta$ -carotene (4 studies) and  $\alpha$ -tocopherol levels (4 studies). Differences were heterogeneous and not significant. Few studies examined vitamin content in meats, but these found no difference in  $\beta$ -carotene in beef (272),  $\alpha$ -tocopherol in pork (149) or beef (272), or vitamin A (retinol) in beef (272).

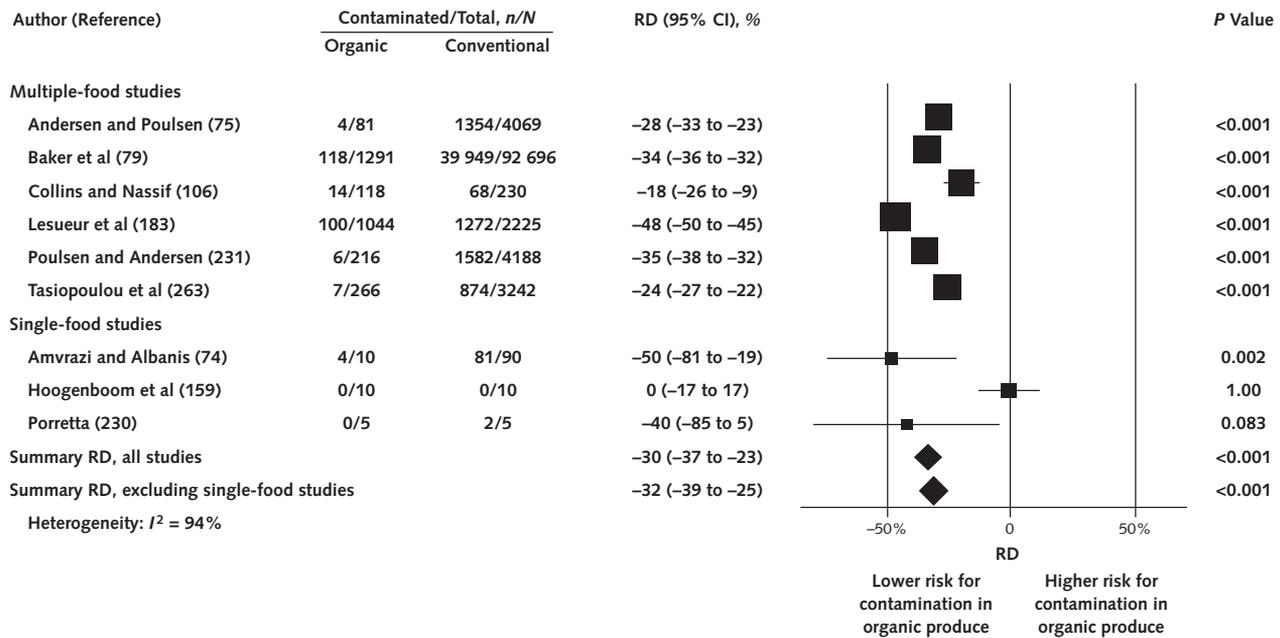
#### Nutrients

Summary SMDs were calculated for 11 other nutrients reported in studies of produce (Table 1). Only 2 nutrients were significantly higher in organic than conventional produce: phosphorus (SMD, 0.82 [CI, 0.44 to 1.20];  $P < 0.001$ ; 7 studies; median difference, 0.15

mg/kg [minimum difference, -18 mg/kg; maximum difference, 530 mg/kg]) and total phenols (SMD, 1.03 [CI, 0.47 to 1.59];  $P = 0.007$ ; 22 studies; median difference, 31.6 mg/kg [minimum difference, -1700 mg/kg; maximum difference, 10 480 mg/kg]). The result for phosphorus was homogenous ( $I^2 = 0\%$ ), but removal of 1 study (227) reduced the summary effect size and rendered the effect size statistically insignificant (SMD, 0.63;  $P = 0.064$ ). The finding for total phenols was heterogeneous ( $I^2 = 67\%$ ) and became statistically insignificant when studies not reporting sample size (95, 175) were removed ( $P = 0.064$ ). Too few studies of animal products reported on other nutrients for effect sizes to be calculated.

Few studies examined fatty acids in milk (Supplement 6, available at [www.annals.org](http://www.annals.org)). These studies suggest that organic milk may contain significantly more beneficial  $\omega$ -3 fatty acids (SMD, 11.17 [CI, 5.93 to 16.41];  $P < 0.001$ ;  $I^2 = 98\%$ ; 5 studies; median difference, 0.5 g/100 g [minimum difference, 0.23 g/100 g; maximum difference, 4.5 g/100 g]) and vaccenic acid than conventional milk (SMD, 2.62 [CI, 1.04 to 4.19];  $P = 0.031$ ;  $I^2 = 97\%$ ; 5 studies; median difference, 0.26 g/100 g [minimum difference, 0.11 g/100 g; maximum difference, 3.1 g/100 g]). All but 1 of these studies (212) tested raw milk samples. Results were robust to removal of 1 study at a time. Similarly, organic chicken contained higher levels of  $\omega$ -3 fatty acids than conventional chicken (SMD, 5.48 [CI, 2.19 to 8.76];  $P = 0.031$ ;  $I^2 = 90\%$ ; 3 studies; median difference, 1.99 g/100 g [minimum difference, 0.94 g/100 g; maximum difference, 17.9 g/100 g]). The differences between the remaining fatty acids examined in chicken and milk (Sup-

Figure 2. RD of detecting any pesticide residues in organic and conventional fruits, vegetables, and grains.



All studies sampled food from retail or wholesale settings except Hoogenboom and colleagues (159), which sampled directly from farms. Tasiopoulou and colleagues (263) did not specify the study design, but because the testing was part of a governmental monitoring program, we assume that samples were obtained from retail or wholesale settings, similar to the other government monitoring programs (75, 79, 231). We used a continuity correction of 0.5 (half a sample contaminated) for studies with 0 counts to allow RDs to be calculated. Removal of studies with 0 cells did not change results (see Appendix, available at [www.annals.org](http://www.annals.org)). All RDs are absolute RDs. Summary *P* values are adjusted *P* values. Funnel plots did not suggest publication bias, and results were robust to removal of 1 study at a time. RD = risk difference.

plement 6) were heterogeneous and statistically insignificant. Several included studies reported that the season of sampling and brand of milk affected fatty acid levels at least as much as the farming method (93, 94, 123, 125).

We found no difference in the protein or fat content of organic and conventional milk (Supplement 5). Results were robust to removal of 1 study at a time. Too few studies examined the protein and fat content of meats to calculate summary effect sizes.

### Contaminants

#### Pesticide Contamination

Detectable pesticide residues were found in 7% of organic produce samples (CI, 4% to 10%; 3041 samples) and 38% of conventional produce samples (CI, 32% to 45%; 106 755 samples) (9 studies) (Table 2). Studies of meats, poultry, eggs, and milk did not assess pesticide levels. Organic produce had 30% lower risk for contamination with any detectable pesticide residue than conventional produce (RD, -30% [CI, -37% to -23%]; *P* < 0.001;  $I^2 = 94\%$ ; 9 studies) (Figure 2). This result was statistically heterogeneous, potentially because of the variable level of detection used among these studies.

Only 3 studies reported the prevalence of contamination exceeding maximum allowed limits; all were from the European Union (159, 183, 263). One study was small (10 samples per group) and did not detect any pesticide resi-

dues exceeding maximum allowed limits in either group (159). Differences in prevalence of contamination exceeding maximum allowed limits were small among the other 2 studies (6% [60 of 1048 studies] for organic vs. 2% [179 of 2237 studies] for conventional [183], and 1% [1 of 266 studies] for organic vs. 1% [36 of 324 studies] for conventional [263]).

#### Bacterial Contamination

Prevalence of *E. coli* contamination was 7% in organic produce (CI, 4% to 11%; 826 samples) and 6% in conventional produce (CI, 2% to 9%; 1454 samples)—not a statistically significant difference (Figure 3) (RD, 2.4% [CI, -1.5% to 6.2%]; *P* = 1.00;  $I^2 = 58\%$ ), although only 5 studies examined this outcome. Four of these 5 studies found higher risk for contamination among organic produce. In sensitivity analyses, when we removed the 1 study (of lettuce) that found higher contamination among conventional produce, we found that organic produce had a 5% greater risk for contamination than conventional alternatives (RD, 5.1% [CI, 2.92% to 7.18%]; *P* < 0.001;  $I^2 = 0\%$ ). No study detected *Salmonella* (90, 159, 205, 206, 214), enterohemorrhagic *E. coli* (90, 159, 205, 206, 214), or *Listeria* (214, 226) among produce samples.

Bacterial contamination is common among both organic and conventional animal products; however, differ-

ences in the prevalence of bacterial contamination between organic and conventional animal products were statistically insignificant (Figure 4). For chicken, 67% (CI, 42% to 93%) of organic samples and 64% (CI, 40% to 90%) of conventional samples were contaminated with *Campylobacter* and 35% (CI, 8% to 63%) of organic samples and 34% (CI, 16% to 52%) of conventional samples were contaminated with *Salmonella* (3 studies). Pork was commonly contaminated with *E. coli* (65% of organic and 49% of conventional samples) (201), *Salmonella* (median, 5.1%; range, 0% to 39%) (282), and *Listeria monocytogenes* (3% of organic and 4% of conventional samples) (152). No studies compared the contamination of organic and conventional beef with human pathogens.

### Antibiotic Resistance

The risk for isolating bacteria resistant to 3 or more antibiotics was 33% higher among conventional chicken and pork than organic alternatives (CI, 21% to 45%;  $P < 0.001$ ;  $I^2 = 62%$ ; 5 studies) (Figure 5 [top panel] and Supplement 7, available at [www.annals.org](http://www.annals.org)). Results were robust to removal of 1 study at a time. Bacteria isolated from retail samples of organic chicken and pork had 35% lower risk for resistance to ampicillin (RD, -34.9% [CI, -56.2% to -13.6%];  $P = 0.031$ ;  $I^2 = 90%$ ; 5 studies) (Figure 5 [bottom panel]), although removal of 1 study rendered results statistically insignificant. Although comparisons for most of the remaining antibiotics suggest greater resistance among bacteria isolated from conventional compared with organic products, differences were statistically insignificant (Supplement 8, available at [www.annals.org](http://www.annals.org)). Few studies examined resistance to the same antibiotic on the same animal product, and effect sizes were heterogeneous.

### Fungal Toxin and Heavy Metal Contamination

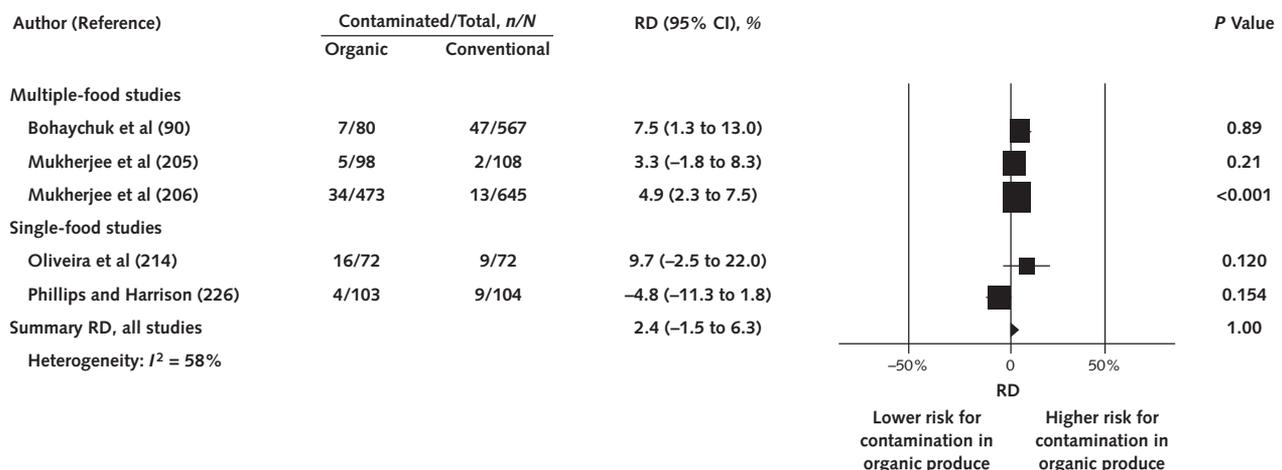
The included studies demonstrate mixed results about contamination of grains with fungal toxins. We found no difference in risk for contamination with or mean levels of ochratoxin A (Table 2). However, we found lower levels and lower risk for contamination with deoxynivalenol in organic grains than conventional alternatives (SMD, -0.82 [CI, -1.19 to -0.45];  $P < 0.001$ ;  $I^2 = 69$ ; 8 studies; median difference, -34  $\mu\text{g}/\text{kg}$  [minimum difference, -426  $\mu\text{g}/\text{kg}$ ; maximum difference, 72  $\mu\text{g}/\text{kg}$ ] (RD, -23% [CI, -37% to -8%];  $P = 0.043$ ;  $I^2 = 89$ ; 9 studies). Results were similar in subgroup analyses by grain type (Appendix, available at [www.annals.org](http://www.annals.org)). Among studies of produce, no significant differences in cadmium or lead content were identified (Table 2). All results were heterogeneous.

### Heterogeneity and Subgroup Analyses

To explore causes of heterogeneity, we conducted subgroup analyses by specific food, testing method (fresh vs. dry weight, and peeled and washed vs. unpeeled and unwashed), study design, and organic standard used. Results remained heterogeneous when analyzed by food: No significant differences were found in the ascorbic acid content of cabbage (3 studies), carrots (3 studies), potatoes (3 studies), or tomatoes (9 studies);  $\beta$ -carotene content of tomatoes (3 studies); or protein content of wheat (6 studies) when grown organically versus conventionally. Subgroup analyses by testing method, study design, and organic standard remained heterogeneous and did not change findings, although sample sizes were smaller, limiting our ability to detect significant differences.

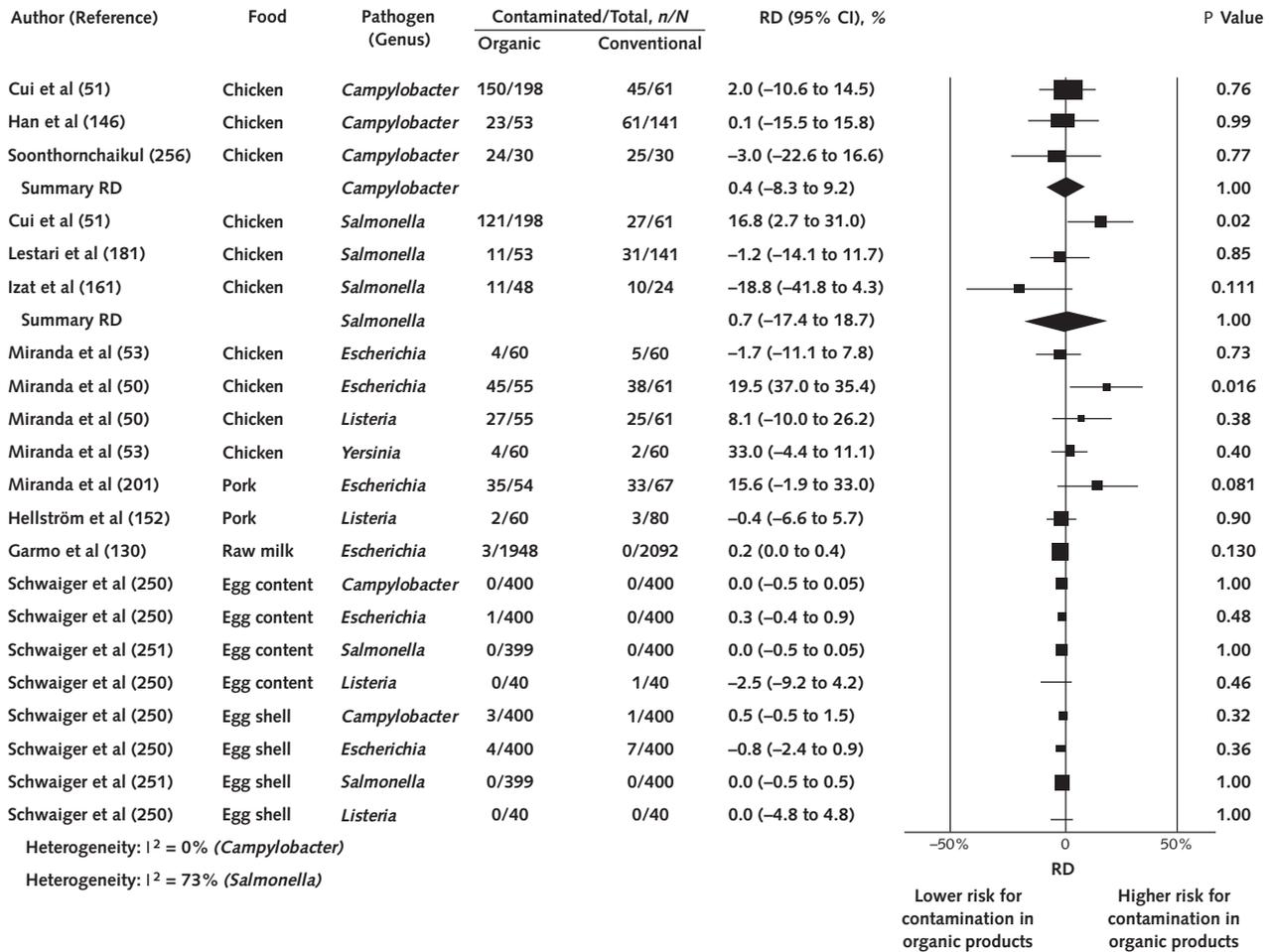
Only 1 data set reported peeling and washing produce before testing. However, the prevalence of contamination

Figure 3. RD of detecting *Escherichia coli* in organic and conventional fruits, vegetables, and grains.



All RDs are absolute RDs. Summary  $P$  value is an adjusted  $P$  value. Funnel plot did not suggest publication bias. Removal of 1 study (225) rendered results significant, suggesting higher contamination among organic produce (RD, 5.1% [95% CI, 2.92% to 7.18%];  $P < 0.001$ ;  $I^2 = 0%$ ). All studies sampled foods directly from farms, except Bohaychuk and colleagues (90), which sampled produce purchased in retail settings. RD = risk difference.

Figure 4. RD for contamination of organic and conventional meat products with bacterial pathogens.



Meat samples were obtained from retail stores, milk samples were raw milk obtained from farms, and all egg samples were obtained directly from farms. Risk difference is calculated as the risk for contamination in the organic group minus that in the conventional group; thus, a positive (negative) number indicates more (less) contamination in organic products. All RDs are absolute RDs. Summary effect measures reported are results of random-effect models.  $I^2 > 25\%$  suggests heterogeneity. Summary  $P$  values are adjusted  $P$  values. Funnel plots did not suggest publication bias, and results were robust to removal of 1 study at a time. All studies sampled products from retail or wholesale settings with 4 exceptions: Lestari and colleagues (181), Hellstrom and colleagues (152), Garmo and colleagues (130), and Schwaiger and colleagues (250, 251) sampled foods obtained directly from farms. Results for *Salmonella* in pork (282) are not reported in this figure because the authors reported only median prevalence of contamination. RD = risk difference.

in this study could not be compared with other studies because of use of different levels of detection (79). One study tested products for pesticide residues before and after peeling, finding that pesticide residues were undetectable in both organic and conventional samples once apples were peeled (203).

### Reporting and Publication Bias

Among nutrient studies of produce, those with null findings tended to report results incompletely (hence, they could not be included in summary effect size calculations), suggesting publication bias (Table 1). For example, among the 34 studies that evaluated phenol levels in produce, only 36 of the 102 comparisons (35%) found higher levels in organic produce. However, only 24 of the 34 studies re-

ported sufficient data for analysis, and among these, we found significantly higher levels of total phenols among organic produce (Table 1). In addition, for total phenols and several other nutrients in produce, funnel plots were asymmetric, raising concern for publication bias. Similarly, funnel plots of analyses of fatty acids in milk suggested possible publication bias.

We adjusted  $P$  values to assign significance to differences between organic and conventional foods due to the multiple statistical comparisons. It may be reasonable to use a less stringent criterion for the interpretation of contaminant results because consumers may have a lower threshold in their desire to avoid harms. However, examination of unadjusted  $P$  values changes the conclusions for

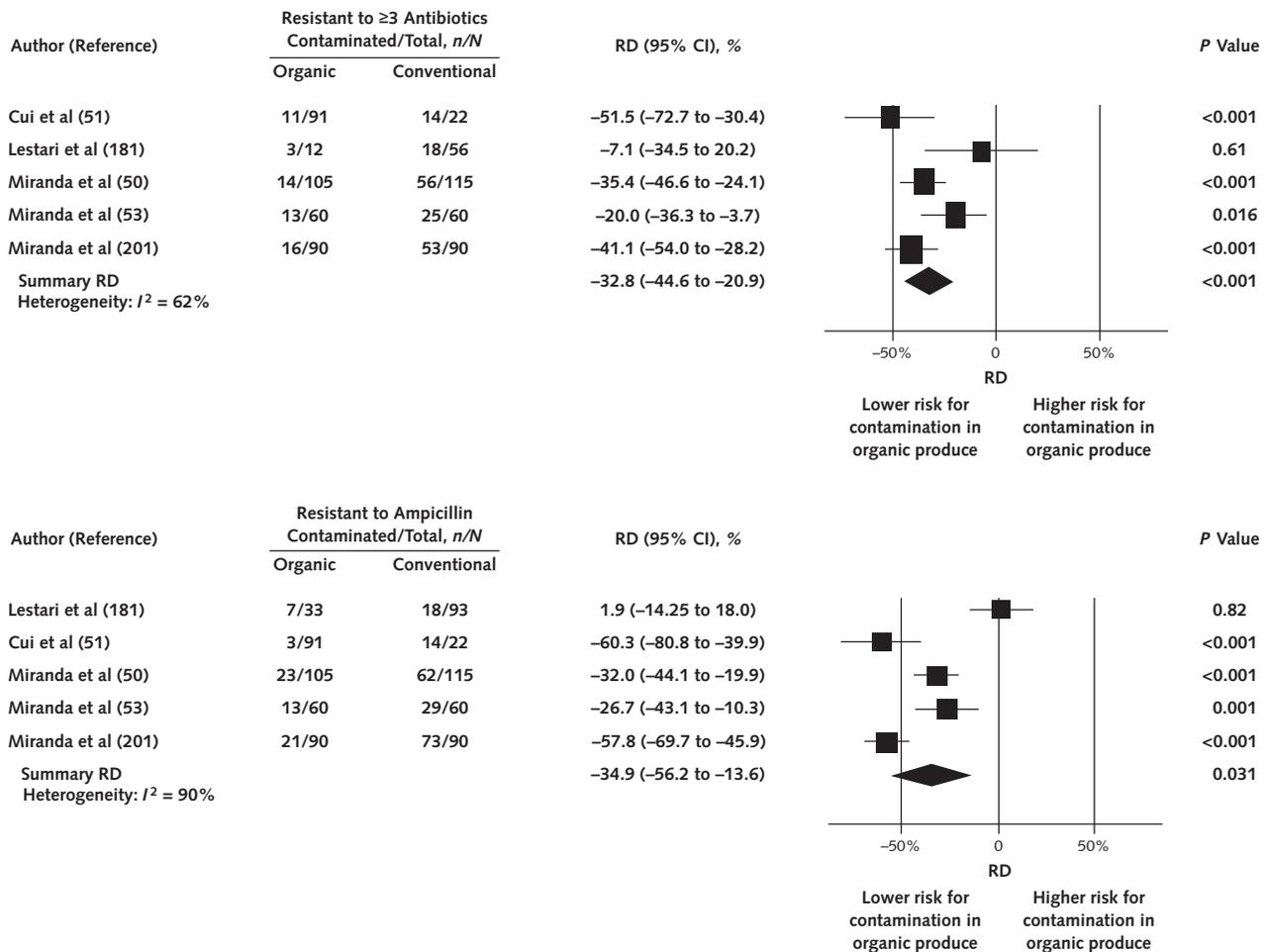
only a few outcomes: specifically, differences in contamination with bacteria resistant to cephalothin, sulfisoxazole, and tetracycline (Supplement 7).

## DISCUSSION

Consumers purchase organic foods for many reasons. Despite the widespread perception that organically pro-

duced foods are more nutritious than conventional alternatives, we did not find robust evidence to support this perception. Of the nutrients evaluated, only 1 comparison, the phosphorus content of produce, demonstrated the superiority of organic foods (differences were statistically significant and homogenous), although removal of 1 study rendered this result statistically insignificant. Higher levels of phosphorus in organic produce than in conventional

Figure 5. RD for isolating antibiotic-resistant bacteria in selected analyses.



Risk difference is calculated as the risk for contamination in the organic group minus that in the conventional group; thus, a positive (negative) number indicates more (less) contamination in the organic group. All RDs are absolute RDs. Summary  $P$  values are adjusted  $P$  values. The number of antibiotics tested in the included studies ranged from 8 to 15 (median, 9.5). All summary effect measures reported are results of random-effects models. Funnel plots did not suggest publication bias. All studies sampled food purchased in retail settings except Lestari and colleagues (181), which sampled animal products obtained directly from farms. The top panel shows the difference in risk for detecting *Escherichia coli*, *Salmonella* species, and *Enterobacteriaceae* resistance to at least 3 antibiotics in organic vs. conventional chicken and pork. One study (50) examined drug resistance patterns for 3 organisms (*E. coli*, *Listeria*, and *Staphylococcus aureus*) identified on organic and conventional products. To avoid entering the same study twice in the analyses, we included only the resistance patterns reported for *E. coli*. However, in sensitivity analysis, we included the results for *Listeria* instead of *E. coli*. The results did not substantially change. Two studies (52, 53) reported antibiotic resistance patterns for different bacteria (*Enterobacteriaceae* [53] and *Enterococcus* species [52]) obtained from the same population of retail packaged chicken. To avoid entering the same chickens in the synthesis twice, we included *Enterobacteriaceae* results in the syntheses (reported above) because it is the family to which *E. coli* and *Salmonella* belong. In sensitivity analysis, we used the *Enterococcus* results, which did not substantially change findings. Results were robust to removal of 1 study at a time from summary effect estimate. The bottom panel shows the difference in risk for detecting *E. coli*, *Salmonella* species, and *Enterobacteriaceae* resistance to ampicillin in organic vs. conventional chicken and pork. The result was not robust to removal of 1 study at a time from summary effect estimate. RD = risk difference.

produce is consistent with previous reviews (19, 20), although it is unlikely to be clinically significant because near-total starvation is needed to produce dietary phosphorus deficiency (287).

We also found statistically higher levels of total phenols in organic produce,  $\omega$ -3 fatty acids in organic milk and chicken, and vaccenic acid in organic chicken than in conventional products, although these results were highly heterogeneous and the number of studies examining fatty acids was small ( $\leq 5$ ). Our finding of higher levels of these beneficial fatty acids in organic than in conventional milk is consistent with another recent meta-analysis of these outcomes (288). One study examining the breast milk of mothers consuming strictly organic diets found higher levels of trans-vaccenic acid (58), similar to our findings among organic dairy products. Otherwise, studies measuring nutrient levels among humans consuming organic and conventional diets did not find consistent differences.

Our study has 3 additional key findings. First, conventional produce has a 30% higher risk for pesticide contamination than organic produce. However, the clinical significance of this finding is unclear because the difference in risk for contamination with pesticide residue exceeding maximum allowed limits may be small. One study found that children switched to an organic diet for 5 days had significantly lower levels of pesticide residue in their urine (55), consistent with our findings among the food studies.

Second, we found no difference in the risk for contamination of produce or animal products with pathogenic bacteria. Both organic and conventional animal products were commonly contaminated with *Salmonella* and *Campylobacter* species. The reported rates of contamination are consistent with published contamination rates of U.S. retail meat samples (289–291). However, with removal of 1 study, results suggested that organic produce has a higher risk for contamination with *E. coli*, a finding that was both homogeneous and statistically significant. Similarly, an exploratory case-control study suggested that human consumption of organic meat in the winter is associated with symptomatic *Campylobacter* infection (70). These preliminary findings need to be confirmed with additional research. A recent U.S. study found that produce from organic farms using manure for fertilization was at significantly higher risk for contamination with *E. coli* than was produce from organic farms not using animal waste (odds ratio, 13.2 [CI, 2.6 to 61.2]) (292).

Third, we found that conventional chicken and pork have a higher risk for contamination with bacteria resistant to 3 or more antibiotics than were organic alternatives. This increased prevalence of antibiotic resistance may be related to the routine use of antibiotics in conventional animal husbandry. However, the extent to which antibiotic use for livestock contributes to antibiotic-resistant pathogens in humans continues to be debated (293) because inappropriate use of antibiotics in humans is the major cause of antibiotic-resistant infections in humans. A previ-

ous review (23) reported that ciprofloxacin-resistant *Campylobacter* was more common among conventional than organic chickens, a finding that our study did not detect. Unlike the previous study, most of our included studies were done after bans on fluoroquinolone use and we excluded fecal samples. As a precaution, the European Union banned the use of some antibiotics in animal feed for growth promotion in 2006 (294), and the United States banned the use of enrofloxacin in 2005 (295).

Finally, there have been no long-term studies of health outcomes of populations consuming predominantly organic versus conventionally produced food controlling for socioeconomic factors; such studies would be expensive to conduct. Only 3 short observational studies examined a very limited set of clinical outcomes: 2 studies evaluating allergic outcomes of a cohort of children consuming organic versus conventional diets in Europe found no association between diet and allergic outcomes (61, 64).

Our results should be interpreted with caution because summary effect estimates were highly heterogeneous. Three potential sources of heterogeneity are study methods (for example, measurement and sampling methods, study design, or organic standard used), physical factors (for example, season, weather, soil type, ripeness, cultivar, or storage practices [14, 111, 165, 171, 296]), and variation within organic practices.

For example, heterogeneity among studies of pesticide contamination likely reflects variation in the sensitivity of testing methods and differences in pesticide contamination by food type and country of origin (75, 297). To explore causes of heterogeneity, we conducted subgroup analyses by study design, assay method (fresh vs. dry weight), and organic standard used in the study; however, these sub-analyses did not reduce observed heterogeneity.

Too few studies for any 1 outcome reported information about physical factors to conduct subgroup analyses, although many studies controlled for these factors (for example, 86% of meat studies specified sampling both production systems during the same season and approximately 60% of comparison produce pairs were of the same cultivar and harvested from neighboring farms). Many studies noted that season of sampling and brand of milk were important determinants of nutrient and fatty acid levels (93, 94, 123, 125) because organic and conventional cows may have similar diets in the winter but different diets in the summer when grass is available for organic cows.

Finally, variation within organic practices (even if certified under the same standard) may also explain heterogeneity. A review of organic practices concluded that “variation within organic and conventional farming systems is likely as large as differences between the two systems” (298). For example, the use and handling of manure fertilizers (a risk factor for bacterial contamination) varies among organic farms (292).

Our study has several additional limitations. First, produce studies, most of which were experimental field stud-

ies, may not reflect real-world organic practices. Subgroup analyses by study design did not change conclusions, although sample sizes were small. Additionally, studies with null findings frequently failed to adequately report results, potentially biasing our study to find differences where none exist. Finally, milk results should be interpreted with caution because most milk studies examined raw rather than pasteurized milk.

In summary, our comprehensive review of the published literature on the comparative health outcomes, nutrition, and safety of organic and conventional foods identified limited evidence for the superiority of organic foods. The evidence does not suggest marked health benefits from consuming organic versus conventional foods, although organic produce may reduce exposure to pesticide residues and organic chicken and pork may reduce exposure to antibiotic-resistant bacteria.

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## APPENDIX: SUPPLEMENTAL INFORMATION ABOUT STATISTICAL ANALYSES AND OUTCOMES THAT COULD NOT BE SYNTHESIZED

### Continuity Correction

In an effort to include all eligible studies, a continuity correction was applied for studies with 0 events in 1 or more groups. In practice, we applied the continuity correction in 2 analyses: contamination with any pesticide residues (**Figure 2**) and contamination of chicken or pork with bacteria resistant to ciprofloxacin.

Among the 9 pesticide contamination studies, 2 had 0 events (**Figure 2**). These were small, single-food studies. Removal of the small studies with 0 events did not substantially change results (**Figure 2**).

Among the contamination of chicken or pork with bacteria resistant to ciprofloxacin, removal of the 2 studies with 0 events (146, 256) did not substantially change results, although only 3 studies remained for analysis (RD,  $-4%$  [CI,  $-25%$  to  $17%$ ];  $P = 1.00$ ,  $I^2 = 93%$ ).

Results were not synthesized if the number of studies was less than 3 after those studies with 0 events were removed. This

was the case with pesticide residues exceeding maximum allowed limits (we report a range); contamination of milk with *S. aureus* resistant to erythromycin, oxacillin, and tetracycline; and contamination of chicken and pork with bacteria resistant to doxycycline and gentamicin.

### Other Nutrients in Produce

Too few studies evaluated selenium, manganese, zinc, and vitamins B, D, and K to be synthesized (**Supplement 2**).

### Other Nutrients in Animal Products

Only 3 studies (110, 129, 153) evaluated the calcium content of milk: 2 studies (129, 153) reported no difference by farming method and the other (110) reported significantly higher levels of calcium in organically produced milk ( $P < 0.010$ ). Two studies evaluated the lutein and zeaxanthin content of milk (93, 255), finding significantly higher levels of both antioxidants in organic than conventional milk. Two studies examined the zinc content of eggs (132) and beef products (216), finding significantly less zinc in organic egg yolks and beef kidney and significantly more zinc in beef muscle than their conventional counterparts.

Two studies compared protein content of chicken: 1 study found significantly more protein in organic than conventional chicken (160) and the other found no difference (192).

### Botanical Pesticides in Produce

Two studies (95, 172) tested for 2 botanical pesticides allowed in organic cultivation: Neither pesticide was detectable in organic or conventional produce samples.

### Antibiotic Resistance of Bacteria in Produce

Only 1 study examined the prevalence of antibiotic resistance in bacteria in produce, finding no difference between organic and conventional produce (245).

### Subgroup Analyses of Deoxynivalenol and Ochratoxin A in Produce

In subgroup analyses, we found a higher risk for ochratoxin A (OTA) contamination in organically grown rice (84, 133, 166) (RD,  $35%$  [CI,  $17%$  to  $53%$ ];  $P < 0.001$ ;  $I^2 = 22$ ) but not in wheat (84, 111, 164, 166, 189, 235) compared with conventional alternatives.

Seven studies examined deoxynivalenol levels in wheat (135, 150, 224, 235, 243, 249, 270), finding significantly lower levels of deoxynivalenol in organic wheat (SMD,  $-0.94$  [CI,  $-1.27$  to  $-0.62$ ];  $P < 0.001$ ;  $I^2 = 63$ ), although 1 large study, which did not report sufficient detail to be included in summary effect size calculations, found no significant differences in deoxynivalenol concentrations (122).

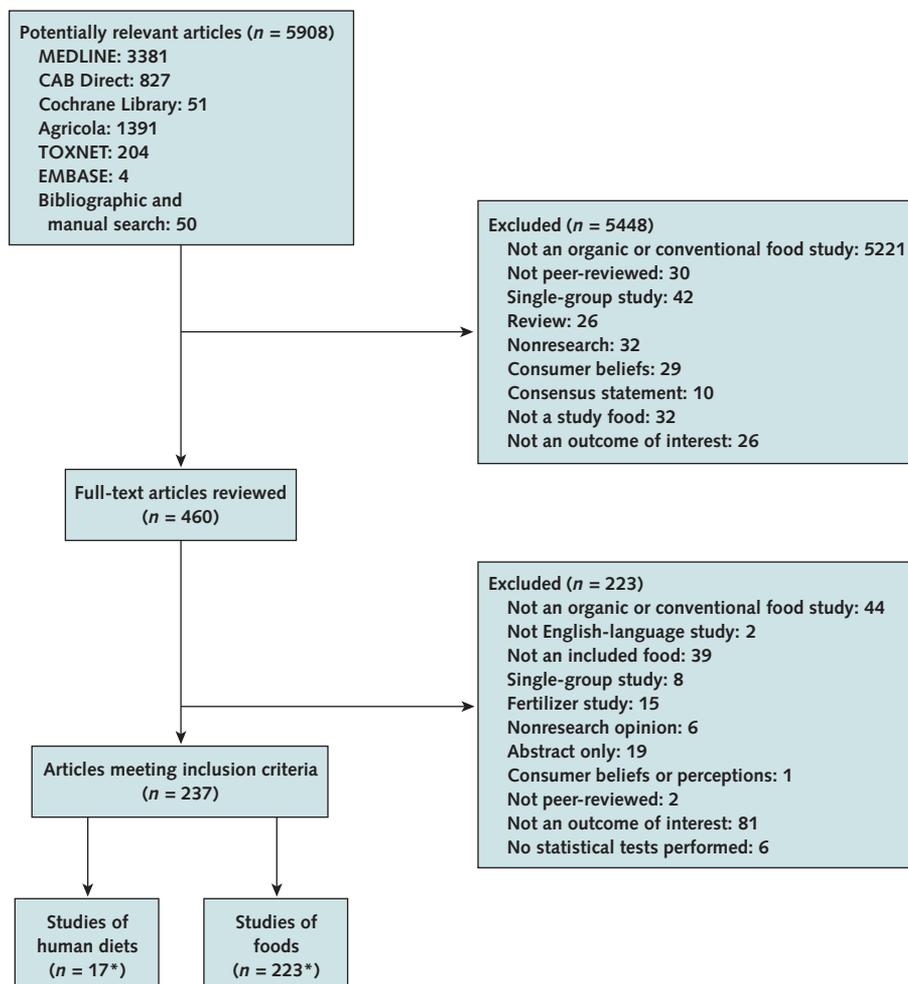
### Other Fungal Toxin Results in Milk and Meats

Two studies evaluated mycotoxin contamination of milk: 1 study found significantly higher levels of aflatoxin in organic than conventional milk (131), whereas another study found no difference in OTA contamination (253). One study found that OTA contamination of porcine serum samples was significantly higher among organic than conventional samples (1.32 vs. 0.16  $\mu\text{g}/\text{kg}$ ;  $P < 0.001$ ) (232).

Two studies evaluated mycotoxin contamination of milk: 1 study found significantly higher levels of aflatoxin in organic than conventional milk (131), whereas another study found no difference in OTA contamination (253). One study found

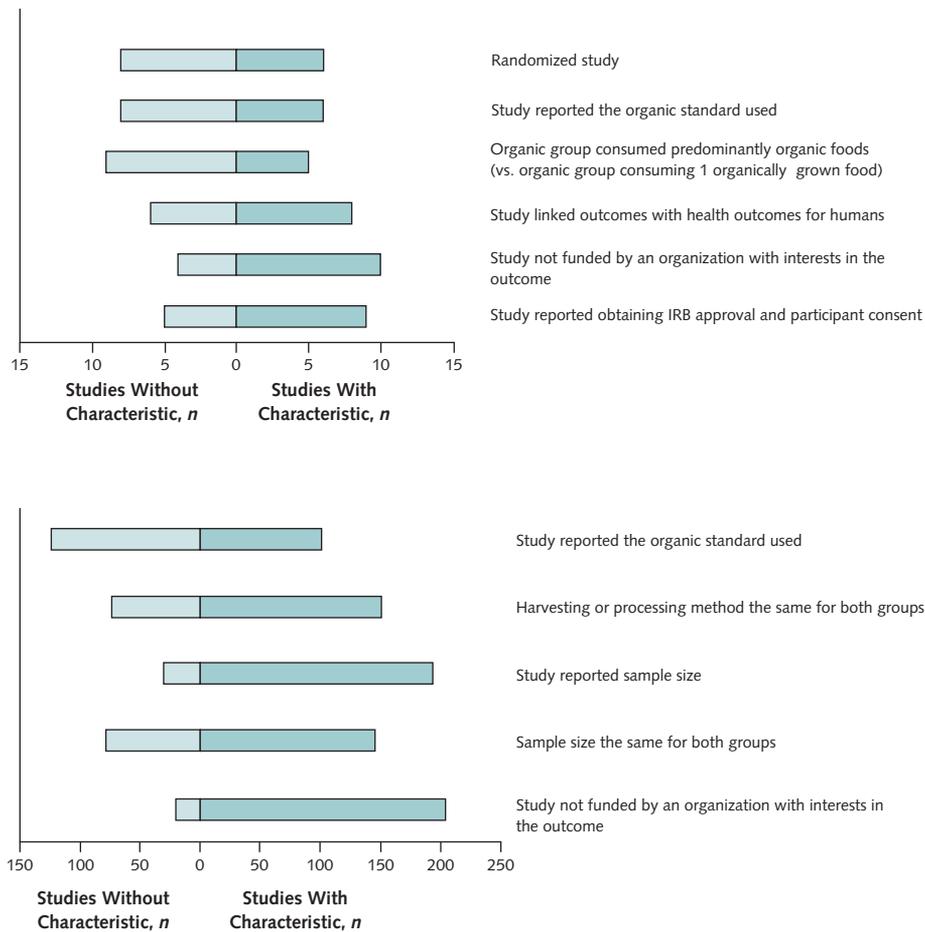
that OTA contamination of porcine serum samples was significantly higher among organic than conventional samples (1.32 vs. 0.16  $\mu\text{g}/\text{kg}$ ;  $P < 0.001$ ) (232).

Appendix Figure 1. Summary of evidence search and selection.



\* Three studies reported on human diets and on the foods themselves.

Appendix Figure 2. Selected characteristics of included studies.



The top panel presents the characteristics of the included human studies. Seventeen publications compared the human health effects of consuming organic vs. conventional food. Three publications report data from the same population and are counted only once in the figure. Hence, the number of studies sums to 14. The bottom panel presents the characteristics of the 223 included studies of food. IRB = institutional review board.