Analysis of JMPR Decisions to Reject Crop Pesticide Uses, 2010–2019

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Table of Contents

Summary ... 3
Analysis of JMPR Rejection Rate, 2010–2019 ... 6
Materials and Methods ... 6
Results and Discussion ... 11
Recommendations for JMPR/CCPR ... 17
Recommendations for Submitters ... 17
Analysis of JMPR Rejection Rate, 2010 ... 20
Analysis of JMPR Rejection Rate, 2011 ... 22
Analysis of JMPR Rejection Rate, 2012 ... 23
Analysis of JMPR Rejection Rate, 2013 ... 24
Analysis of JMPR Rejection Rate, 2014 ... 25
Analysis of JMPR Rejection Rate, 2015 ... 27
Analysis of JMPR Rejection Rate, 2016 ... 28
Analysis of JMPR Rejection Rate, 2017 ... 299
Analysis of JMPR Rejection Rate, 2018 ... 31
Analysis of JMPR Rejection Rate, 2019 ... 32
References ... 33
Tables ... 35
Table 1. Analysis of JMPR Rejection Rate, 2010–2019 ... 35
Table 2. Analysis of JMPR Rejection Rate, 2010 ... 366
Table 3. Analysis of JMPR Rejection Rate, 2011 ... 377
Table 4. Analysis of JMPR Rejection Rate, 2012 ... 388
Table 5. Analysis of JMPR Rejection Rate, 2013 ... 399
Table 6. Analysis of JMPR Rejection Rate, 2014 ... 40
Table 7. Analysis of JMPR Rejection Rate, 2015 ... 41
Table 8. Analysis of JMPR Rejection Rate, 2016 ... 42
Table 9. Analysis of JMPR Rejection Rate, 2017 ... 43
Table 10. Analysis of JMPR Rejection Rate, 2018 ... 44
Table 11. Analysis of JMPR Rejection Rate, 2019 ... 45
Figures ... 46
Figure 1. Annual JMPR Rejection Rate, 2010–2019 ... 46
Figure 2. Frequency of Reasons for Rejection ... 47

Summary

We have analyzed the decisions made by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to reject crop pesticide uses on the basis of residue data, in order to better understand the reasons for the rejections. Our analysis can help the crop protection industry improve data quality in order to fulfill JMPR's requirements and can ultimately lead to the development of Codex maximum residue limits (CXLs) to facilitate harmonized trade.

We examined information from a representative 10-year period, 2010–2019. For food commodities, an acceptance was indicated if a maximum residue level (MRL) estimation was made using the submitted data. For feed commodities, an acceptance was indicated if there was an estimation of the highest residue (HR) and supervised trials median residue (STMR). A rejection occurred if JMPR could not use any combination of the residue data for pesticide use on a particular crop to make an estimation of an MRL for food uses or an HR and STMR for feed uses.

During 2010–2019, JMPR evaluated residue data on 162 agricultural chemicals for 3,789 crop uses on raw agricultural commodities (including pre-harvest and post-harvest uses). Of these, 2,916 were acceptances (77.0%) and 873 were rejections (23.0%). The rejection rate was as low as 13.5% in 2011 and as high as 36.7% in 2010. During the 10-year period, 14.2% of the 863 rejected datasets were later re-evaluated and accepted after additional data were submitted or because of changes in acceptability criteria for the particular chemical. Most decisions were made about food commodities: there were 3,078 decisions on food crops during 2010–2019, including 2,377 acceptances (77.2%) and 701 rejections (22.8%). In 10 instances, JMPR made an estimation of an MRL, but the residues exceeded the acute reference dose, so a CXL could not be established.

The leading reasons for rejection were: residue data did not match the submitted good agricultural practice (GAP) from a registered label, or no GAP was available (50.6%); there were not enough independent field trials (34.0%); data on residues in rotation crops after previous uses were insufficient (4.5%); no data were obtained for some required analytes in the laboratory (3.8%); there were insufficient toxicological studies (3.4%); there were insufficient storage stability data to support the sample storage period (2.6%); or the results for storage stability were poor (1.8%). Some datasets were rejected for more than one reason.

We hope that this analysis will help the industry understand the reasons for these rejections, to improve the success of future data submissions and provide growers with timely access to appropriate new crop protection tools.

Keywords: Codex maximum residue limit (CXL), decisions, good agricultural practice (GAP), highest residue (HR), maximum residue level (MRL), pesticide residues, rejections, submissions, supervised trials median residue (STMR)

Abbreviations and Acronyms

ARfD	acute reference dose
CCPR	Codex Committee on Pesticide Residues
cGAP	critical GAP
CXL	Codex maximum residue limit
FAO	Food and Agricultural Organization of the United Nations
GAP	good agricultural practice
GEMS	Global Environment Monitoring System
HR	highest residue
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MRL	maximum residue level
OECD	Organization for Economic Co-Operation and Development
ppm	parts per million
RAC	raw agricultural commodity
STMR	supervised trials median residue
WHO	World Health Organization

About the Minor Use Foundation

The Minor Use Foundation, a nonprofit private foundation, was founded in 2018 to promote minor uses and specialty crop pest management solutions for growers globally. The Foundation hosts the Global Minor Use Priority Setting meetings, funds research to identify and develop pest control solutions, and provides training and capacity building globally. Together with its partners and cooperators, the Foundation identifies and implements work to expand uses, harmonize MRLs, and support grower needs. For more information, visit www.minorusefoundation.org.

Analysis of JMPR Decisions to Reject Crop Pesticide Uses, 2010–2019

Materials and Methods

This analysis covers decisions on residue data by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) between 2010 and 2019 on food and feed commodities. The data came from supervised residue trials conducted in various locations around the world by many different organizations. The analysis considers only decisions made on raw agricultural commodities. Pre-harvest and post-harvest application data were included, but processed commodity data and monitoring data on spices were excluded. Rotational crop data, analytical methods, and other types of supporting data were also excluded from this analysis, except as explanations for some of the rejections of residue data. The information used to determine the rejection rates was obtained from reports and evaluations posted online by the FAO. Understanding the reasons for these rejections is important because rejections delay grower access to appropriate new crop protection tools to address new pest problems or resistant pest species, which may be lower risk than the currently available agricultural chemicals.

In order to obtain a Codex maximum residue limit (CXL) for a new (or revised) pesticide use on a particular crop, submitters provide pesticide residue data to JMPR from supervised field trials on agricultural crops. JMPR reviews these data to ensure that they adhere to the requirements of the FAO Manual, *Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed*. In the present analysis, if JMPR made an estimation of a maximum residue level (MRL) based on the submitted residue data for a food commodity, we classified it as an acceptance. Each of these MRL estimations is forwarded to Codex, where a final decision is made regarding the establishment of a CXL. Forage crops are not items of international trade requiring CXLs (according to the FAO Manual cited above), thus no MRLs are estimated for these by JMPR. In this analysis, if JMPR made an estimation of a highest residue (HR) and supervised trials median residue (STMR) for a feed commodity, we considered it an acceptance. Meanwhile, if JMPR received residue data to support a specific crop MRL, HR, and/or STMR but could not use any combination of the data to make an estimation of an MRL for food uses or an HR and STMR for feed uses, it was considered a rejection.

The residue datasets submitted to JMPR are not always evaluated separately. For any single chemical/crop combination, JMPR may have received data from several sources, and it is difficult to determine from the JMPR reports how many distinct studies were involved. Studies that were conducted in different countries with applications made in accordance with the same use pattern may be evaluated together, unless it is known that cultural practices differ significantly among the locations. A single study may have an insufficient number of trials to support a positive decision by JMPR, but when it is combined with one or more additional studies, the aggregated data may be sufficient to support the estimation of an MRL, HR, and STMR. In some cases, additional data were reviewed at a later meeting after the original dataset was submitted, so there was an initial rejection and then an acceptance in a subsequent year.

JMPR can only release a positive decision or acceptance on the submitted residue data if a registered agricultural chemical label was also submitted to JMPR that has the same (or very similar) use pattern for that crop. The use pattern on the label, commonly referred to as a GAP (good agricultural practice), includes the application rate, number and timing of applications, and pre-harvest interval. A maximum deviation of 25% in one key parameter (application rate or pre-harvest interval) may be accepted between the use pattern in submitted residue data and in the GAP. If the only trial parameter that does not match the GAP is the application rate, and if there are quantifiable residues in the samples, then the proportionality principle may be used to scale the residue results, as long as the application rate in the submitted data was 0.3 to 4 times the GAP rate and the applications are all pre-harvest. Data from trials with more applications than are specified by the GAP may be accepted if the early application(s) are not expected to produce a significant difference in residue results, based on what is known about the persistence of the pesticide residues. A full residue dataset that does not have a corresponding label registered in at least one country will be rejected by JMPR, but it may be reconsidered and accepted in a later year when an appropriate registered label has been submitted.

Sometimes, multiple labels from different locations are submitted for a chemical/crop, with dissimilar application methods, rates, or intervals. In this case, one GAP is usually designated as the critical GAP (cGAP), the GAP that is expected to produce the highest residues. The submitted residue data are then considered in comparison with the cGAP. On occasion, JMPR has evaluated the residue data in comparison with two of the GAPs. For the purpose of this rejection rate analysis, a positive decision (one that supports estimation of an MRL, HR, and STMR) for any combination of residue data for any one GAP is considered an acceptance, whereas a rejection indicates that no combination of the residue data could be used to support any available GAP to make an estimation of an MRL, HR, and STMR.

Residue data for multiple crops in a crop group may be considered separately, to generate individual MRLs, or collectively, to generate a single MRL for the crop group. As reported by JMPR in 2013:

Group maximum residue levels are only estimated if the pesticide is registered for a group or sub-group of commodities, also allowing for the differences in Codex and national commodity group classifications.

Residue datasets reflecting cGAP will be compiled. Once the datasets have been established for individual commodities, the recommendations for residue levels for commodity groups would be considered according to the following principles.

The establishment of a commodity group residue level will generally be considered if the median residues of the commodities are within the 5 times range(.)

Where the residues in individual commodities in the commodity group are statistically not different...the residue data can be combined for the estimation of group residue levels(.)

Where the residue datasets in individual commodities are statistically different then the dataset leading to the highest maximum residue level would be used for the group, provided that sufficient residue data points are available(.)

If the dataset (that leads to the highest MRL) does not contain sufficient data points (preferably ≥8) required to estimate a group maximum residue level, the commodity should be considered an exception.

If the median of residues in an individual commodity dataset differs more than 5 times than those of other commodities, that commodity would not be included in the group and indicated as an exception.

If the medians of residues in more than one commodity of the group differ larger than five times, then recommending group residue levels may not be appropriate and would require decision based on all information available.

In the present rejection rate analysis, the number of acceptances or rejections is equal to the number of crops in the dataset that were evaluated in support of the same GAP, regardless of whether individual MRLs or a group MRL were estimated. For example, data from cherries, peaches, and plums that support a group MRL for stone fruit would count as three acceptances in this analysis. On the other hand, submitted data from various leafy vegetables may be too dissimilar to support a crop group tolerance. The data on head lettuce, leaf lettuce, and spinach may support individual MRL estimations (three acceptances), but the data on cos lettuce may have been rejected (one rejection) because of an insufficient number of field trials to support an MRL estimation.

We have quantified the reasons given for rejection of datasets. Some data were rejected for more than one reason, so the sum of the reasons for rejection is greater than the sum of the rejected studies. In a few instances, data that were accepted in an earlier year were re-evaluated even though there were no new residue data, because of a revised acute reference dose (ARfD) or a revised method of determining the residues for determining dietary exposure. These re-evaluations were not included in this analysis, because JMPR had already found all of the supporting residue data acceptable.

Results and Discussion

Using the criteria described above, JMPR made 3,789 decisions on food and feed uses, involving 162 agricultural chemicals, during the period 2010–2019. Of these, 2,916 were acceptances (77.0%) and 873 were rejections (23.0%) (Table 1). The lowest rejection rate was in 2011 (13.5%) and the highest was in 2010 (36.7%) (Figure 1). During the 10-year period, the data from 14.2% of the 873 rejections were later accepted during subsequent reviews because additional data were submitted or because there were changes in acceptability criteria. Most of the decisions (3,078) were made about food crops, including 2,377 acceptances (77.2%) and 701 rejections (22.8%). Decisions on major crops (Category 4 crops with worldwide consumption values above the threshold of 0.5% of the total daily consumption/capita), including animal feed commodities from these crops, constituted 1,473 decisions during 2010–2019, including 1,171 acceptances (79.5%) and 302 rejections (19.9%). The remaining crops constituted 2,318 decisions during this period, including 1,746 (75.3%) acceptances and 572 rejections (24.7%).

During this decade, JMPR made several changes to the acceptability criteria for submitted data. These included the adoption of the proportionality approach in 2011, the elimination of geographical location criteria in 2012, and revisions to the criteria for the minimum number of supervised field trials in 2016. JMPR discussed the proportionality approach in 2011:

> *The 2010 JMPR proposed an approach on the use of proportionality in maximum residue estimation (General Consideration 2.8 of the 2010 JMPR Report). This approach...could have recommended maximum residue levels for a number of commodities when the supporting residue data were from trials involving treatments more*

than 25% higher than the authorized GAP maximum rates... The 2011 JMPR made use of the proportionality approach to estimate maximum residue levels for dicamba in soya beans, etofenprox in grapes, flutriafol in grapes and hexythiazox in strawberries as well as of a median residue for diflubenzuron in almond hulls to estimate the animal dietary burden. Recommendations for these commodities could not have been made without using the proportionality approach.

A table in JMPR's 2011 report shows the results with and without scaling of residue data. Additional information was reported in 2012:

The 2012 JMPR decided to apply the principle of proportionality in several evaluations in order to make recommendations on commodities that were without sufficient supervised field trial data conducted according to the corresponding GAP: Ametoctradin (dried hops), Chlorfenapyr (tomato), Fluopyram (dry beans, cherries, dry chick peas, dry lentils, dry lupins, peaches, peppers, sugar beets, tomatoes), Imidacloprid (celery), Glufosinate-ammonium (sunflowers), MCPA (barley, oats, rye, triticale and wheat forage, barley, oats, rye, triticale and wheat straw and fodder), Methoxyfenozide (fruiting vegetables, cucurbits) and Spinetoram (brassica vegetables).

JMPR discussed changes to the geographical location criteria in the 2011 report:

At the 2003 JMPR, the Meeting considered the Zoning Report and agreed with the conclusion that the impact of climatic zones on pesticide residues is small, and residue *data derived from similar use patterns and growing conditions may be compared regardless of the geographical location of the trials. The JMPR has used trials complying with GAP irrespective of geographical location, but on a case-by-case basis. Recognizing the experience gained since 2003, the Meeting agreed that from 2012, geographical location should not be a barrier in selecting trials for estimation of maximum residue levels. However, the Meeting noted that there will be cases where regional differences in cultural practices will need to be considered.*

A table in the 2011 report shows the potential impact on decisions made on sulfoxaflor. Three of the decisions resulted in no MRL; two of these were overturned in 2013. All the other decisions resulted in MRL estimates, but more than half would have had different MRLs using the global dataset. The 2013 JMPR report gives additional details about this approach:

The present Meeting took into account the experience gained during previous years, and decided to build on the current practice and elaborated the following principles for utilizing the globally available supervised trial residue data for estimation of residue levels, provided that the growing and processing practices to produce RAC are comparable.

Step 1: Residues deriving from supervised trials reflecting the national or regional cGAP will be considered and the relevant residues selected.

If sufficient numbers of residue data are available from the country or region representing the cGAP, that dataset is used for estimating residue levels according to the current practice of the JMPR.

Where residue data from trials conducted in the country or region are not sufficient, then trials conducted with different application rates will be considered, and the residue values adjusted, based on the proportionality approach to obtain the largest possible residue dataset.

Step 2: Where sufficient residue data are not available from Step 1, then suitable residue data from the trials performed in other countries that meet cGAP, or can be adjusted using proportionality to the cGAP, the data can be considered with those from Step 1.

The datasets obtained in Steps 1 and 2 can be combined if the residue values are within 7 times the median of the newly combined dataset. (A survey of datasets between 1997 and 2011 revealed that about 90% of the residues were within 7 times median range, regardless whether the residue data was derived from a single country or countries in different regions.) Where the spread of residues exceeds the 7 times median range, the suitability of the dataset for estimation of residue levels would then need further careful examination, taking into account all relevant information.

The 2015 JMPR report explains the consumption criteria adopted for the minimum number of supervised field trials per crop:

Category 1 - No data in FAO Stat and no GEMS Food Cluster data; to be considered on a case by case basis

Category 2 - <0.5% worldwide and <0.5% in all of the clusters; minimum of 4 trials

Category 3 - <0.5% worldwide and >0.5% in one or more clusters; minimum of 5 trials

The Meeting welcomed the approach to harmonize the criteria on minor crops trial data needed for MRL setting. Beginning with the 2016 JMPR Meeting, a minimum number of four independent supervised field trials reflecting the respective GAPs for Category 1 and 2 crops and five trials according to Category 3 crops will be used as the basis for recommending maximum residue levels. On a case by case basis, fewer trials may be acceptable when additional circumstances can be taken into account; e.g. undetected residues following treatment at exaggerated rates.

Category 4 crops, with >0.5% worldwide consumption, require a minimum of 8 trials. “Independent” supervised field trials within a dataset are generally conducted at least 30 kilometers away from other trials within the set, or have pesticide application dates separated by at least 30 days among the trials.

The adoption of the proportionality approach and the global datasets expanded the criteria that JMPR could use to find residue data acceptable for estimating MRLs, HRs, and STMRs. The adoption of criteria for the minimum number of field trials had a mixed effect, possibly resulting in rejections of small datasets that had previously been accepted, and in the acceptance of data for certain crops that had previously been rejected because of insufficient number of trials and now qualified based on the number of trials.

There were two major reasons for the rejection of datasets (Figure 2). For approximately half of these rejections, the reason was the lack of a matching GAP. In more than a third of the rejected datasets, there were not enough independent supervised field trials. Among the 442 datasets that were rejected because of a mismatched GAP or no available GAP, 182 (41.2%) had no available GAP. More than half of these occurred in 2010, the earliest year covered in this analysis. Only 20 occurred in the last five years, and none occurred in the last two, indicating that the industry is adhering to the GAP requirement more successfully.

This analysis includes a brief discussion of the rejection rate for each year during 2010–2019, including the reasons for rejection and the number of rejected datasets that were subsequently accepted in a later year. For cases in which data were rejected for reasons other than no matching GAP or an insufficient number of field trials, we have identified the particular crop uses and provided some additional detail. We have also identified a small number of crop uses for which an MRL has been estimated but these residues exceeded the ARfD. These are counted as successes for the present analysis, but Codex will not establish a CXL that exceeds the ARfD.

Recommendations for JMPR and CCPR

We request that JMPR/CCPR consider the following in light of this report's findings.

1) Improved guidance for submitters may enhance the quality of submissions. It would be particularly helpful to have simplified and/or improved guidance in areas associated with comparable GAP and the recommended minimum number of trials. This guidance could include a pre-submission checklist to enhance the quality of submissions.

2) Eliminate the requirement that submissions include a registered pesticide label, on which the application instructions for each crop are the same as those followed in the submitted residue data (or are close enough for the application of the proportionality principle). This would allow the estimation of an MRL/HR/STMR for each crop solely on the basis of the application parameters and residue results in the submitted data. Regulatory agencies around the world would then be able to register pesticide uses based on CXLs regardless of whether a label has been registered in another country, as long as there are acceptable supporting residue data. The elimination of this requirement would greatly reduce the number of rejections that occur annually.

3) Annual training sessions, or opportunities for potential submitters to seek advice prior to submitting to JMPR, may enhance the quality of submissions. Training sessions could potentially be conducted in languages other than English and could be targeted specifically for infrequent submitters and those who have had many rejections.

4) Data submissions should be screened against set criteria before those submissions are accepted for review. Earlier rejections would save JMPR reviewers from having to review submissions that are clearly deficient, and it would provide faster feedback to failed submitters.

5) Allow insufficient (rejected) datasets to be resubmitted with additional data and receive a second review as soon as possible, rather than having to wait for a subsequent Meeting.

6) Consider whether the proportionality principle may be applied to post-harvest uses, or if a modification of the current principle could be applied to these uses.

7) The “results of supervised residue trials on crops” published in annual JMPR reports could be written in a more standardized manner that would indicate precise reasons for rejection under each crop (not in an introductory paragraph, as has sometimes occurred). In cases in which multiple datasets had been received and an MRL/HR/STMR was estimated, the explanations should give more detail about the acceptability of the datasets that were not used for these estimations.

8) Consider accepting electronic data submissions in the formats in which they had originally been prepared for their respective national agencies, without the requirement to reformat to a specific JMPR template, and consider also accepting the documented reviews from those countries, to eliminate the need for JMPR to start the review process from the beginning.

Recommendations for Submitters

We also encourage residue data submitters to ensure that their data meets JMPR standards, by following these recommendations.

1) For each dataset for a particular chemical/crop combination, there should be a sufficient number of independent trials conducted with the same application rate and timing (or within the range that will allow the application of the proportionality principle), proper sample handling, and a residue analysis that is in accordance with the requirements for that chemical.

2) The submission should include a registered label with a use pattern (GAP) that matches the residue data, or that is similar enough that the proportionality principle could be applied to residue results from trials in which the application rate or pre-harvest interval differs from the GAP. (If JMPR/CCPR accepts recommendation #2 above to eliminate the requirement to submit a registered label, then this recommendation to the submitters would no longer apply.)

3) Submitters should complete a checklist to ensure that the minimum standards have been met, and should resolve any deficiencies prior to submission.

Adoption of the recommendations listed above for dataset submissions will help to maximize the probability of acceptance by JMPR, improve the efficiency of the JMPR reviews, and facilitate the registration of needed pesticide uses in countries around the world.

Analysis of JMPR Rejection Rate, 2010

This rejection rate analysis covers evaluations by JMPR in 2010 for residue data on food and feed commodities. JMPR made 496 decisions on food and feed uses that year, involving 20 agricultural chemicals. Of these, 314 were acceptances (63.3%) and 182 were rejections (36.7%). The data from 53 of the rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: lack of a matching GAP (134 rejections), including GAP not matched by field trial use pattern (39) or no GAP available (95); insufficient number of independent trials (43); inappropriate treatment of samples during homogenization (10); storage stability data indicated substantial residue loss (9); inappropriate sample preparation issues noted in the field trials (6); insufficient storage stability data available to support the sample storage period (2); inadequate sample size (1); commodities had been cut in the field and there were no data to support residue stability in cut samples (1); and inconsistent recoveries during residue analysis (1) (Table 2).

A total of 72 reviews for fluopyram resulted in rejections because no registered uses were available (no GAP), but 46 of them were accepted in later years after GAPs were submitted. This was also true for bifenthrin data on barley, oats, triticale, and wheat. A total of 95 datasets among six compounds were submitted without a GAP in 2010, far more than any other year in this analysis. JMPR found that data to support chlorothalonil on pepper and thiamethoxam on mango and hops had insufficient trials, but these datasets were accepted in 2014 (thiamethoxam) and 2015 (chlorothalonil) after additional trial data were submitted. Also, 10 datasets supporting uses of chlorothalonil were rejected because the homogenization of samples did not include enzyme deactivation. Datasets supporting boscalid on lemon and grapefruit were rejected because data submitted were for whole fruit only, and data were needed for the edible portion of the fruits. Data supporting clothianidin on head cabbage were rejected because some of the samples had been collected as heads only (without wrapper leaves) and some samples had been collected as heads without cores. Similarly, data supporting clothianidin on broccoli were rejected because some of the samples had been collected as heads and stems, which was not in accordance with the Codex guideline requiring samples to be buds without leaves. Data supporting clothianidin on cotton were rejected because of insufficient sample sizes and because some samples had been stored at ambient temperature for an excessive period (one full day) prior to ginning. Data to support bifenazate on papaya were rejected because the harvested samples had been cut into fractions to reduce the sample size, which violated Codex standards on the recommended sampling method for this commodity. In the review for bifenthrin on strawberry, an MRL was estimated, but the residues exceeded the ARfD.

Analysis of JMPR Rejection Rate, 2011

This rejection rate analysis covers evaluations by JMPR in 2011 for residue data on food and feed commodities. JMPR made 371 decisions on food and feed uses that year, involving 21 agricultural chemicals. Of these, 321 were acceptances (86.5%) and 50 were rejections (13.5%). The data from eight rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: insufficient number of independent trials (26); lack of a matching GAP (19), including GAP not matched by field trial use pattern (11) or no GAP available (8); storage stability data indicated substantial residue loss (5); and no data obtained for some required analytes (1) (Table 3).

Data to support saflufenacil on sugar cane were rejected because of the lack of a GAP, but were accepted in 2016 when a GAP was also submitted. A total of eight datasets covering four compounds were submitted without a GAP. Datasets for sulfoxaflor on carrot, spirotetramat on avocado and guava, and emamectin benzoate on tree nuts and almond hulls were rejected because of an insufficient number of field trials, but were accepted in 2013 (sulfoxaflor), 2014 (emamectin benzoate), and 2015 (spirotetramat) along with additional data. Data to support sulfoxaflor on common bean were also rejected because of insufficient trials, and after being resubmitted in 2013 with additional data, were rejected again because of large differences in the residue results. Data supporting sulfoxaflor on dry bean were rejected because of an insufficient number of trials in any one region of the world, but the data were accepted in 2013 because JMPR had begun using global datasets (combining results from different locations). In the review of acetamiprid on spinach, an MRL was estimated, but the residues exceeded the ARfD.

Analysis of JMPR Rejection Rate, 2012

This rejection rate analysis covers evaluations by JMPR in 2012 for residue data on food and feed commodities. JMPR made 415 decisions on food and feed uses that year, involving 28 agricultural chemicals. Of these, 352 were acceptances (84.8%) and 63 were rejections (15.2%). The data from one rejection were later accepted when additional data had been submitted and another review was conducted for that chemical. The reasons for rejection included: insufficient number of independent trials (36); lack of a matching GAP (27), including GAP not matched by field trial use pattern (21) or no GAP available (6); and data from different countries could not be combined (1) (Table 4).

A total of six datasets covering four compounds were submitted without a GAP. Data to support the use of buprofezin on coffee from the USA and Brazil were rejected because no information was available on normal agricultural practices, so data could not be compared from the respective locations. The data were subsequently accepted in 2014 when additional information was submitted that allowed JMPR to conclude that the trials had complied with the GAP in the use of pesticides for coffee and processing practices used in the USA. In reviews for glufosinate on kiwifruit and on lettuce, an MRL was estimated, but the residues exceeded the ARfD.

Analysis of JMPR Rejection Rate, 2013

This rejection rate analysis covers evaluations by JMPR in 2013 for residue data on food and feed commodities. JMPR made 366 decisions on food and feed uses that year, involving 31 agricultural chemicals. Of these, 265 were acceptances (72.4%) and 101 were rejections (27.6%). The data from eight rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: lack of a matching GAP (46), including GAP not matched by field trial use pattern (11) or no GAP available (35); insufficient number of independent trials (32); insufficient data available on residues in rotation crops after previous uses (8); insufficient storage stability data available to support the sample storage period (7); no data obtained for some required analytes (5); commodities had been cut in the field and no data were available to support residue stability in cut samples (2); and unexplained large differences existed between the highest residue and other results (1) (Table 5).

A total of 35 datasets among six compounds were submitted without a GAP. Data to support cyantraniliprole on rice, tree nuts, cotton, rape seed, and sunflower were rejected because the data did not match the available GAP, but these datasets were accepted in 2015 (tree nuts, cotton, rape seed, and sunflower) and 2018 (rice) after matching GAPs were submitted. Datasets to support spirotetramat on pomegranate and pineapple were rejected because the collected fruits had been cut into smaller pieces in the field to reduce the bulk, and data to support the stability of spirotetramat residues in cut samples were not available. In the review of dithianon on pear, an MRL was estimated, but the residues exceeded the ARfD.

Analysis of JMPR Rejection Rate, 2014

This rejection rate analysis covers evaluations by JMPR in 2014 for residue data on food and feed commodities. JMPR made 354 decisions on food and feed uses that year, involving 31 agricultural chemicals. Of these, 262 were acceptances (74.0%) and 92 were rejections (26.0%). The data from four rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: lack of a matching GAP (48), including GAP not matched by field trial use pattern (30) or no GAP available (18); insufficient number of independent trials (33); insufficient storage stability data available to support the sample storage period (9); no data obtained for some required analytes (5); and commodities had been cut in the field and no data were available to support residue stability in cut samples (3) (Table 6).

A total of 18 datasets covering two compounds were submitted without a GAP. Data to support chlorantraniliprole on peanut were rejected because the data did not match the GAP, but the data were accepted in 2016 after an appropriate GAP was submitted. Datasets to support chlorantraniliprole on green onion and on barley, sorghum, and wheat were also rejected because of the absence of matching GAPs. The barley, sorghum, and wheat dataset was rejected again in 2016 because of insufficient trial numbers, and the green onion dataset was rejected again in 2017 because there was still no matching GAP. Data to support metrafenone on melon were rejected because the samples had been sliced in the field to reduce the bulk, and no data were available to support the stability of the molecule in cut samples. Datasets to support pymetrozine on cauliflower and on head cabbage were also rejected because the samples in these studies had been cut into smaller pieces in the field, and supporting stability data were lacking. Data to support emamectin benzoate on head lettuce, leaf lettuce, and cos lettuce were accepted in 2011 and re-evaluated in 2014 because the ARfD had been revised, resulting in a new calculation for the International Estimated Short Term Intake. New MRLs were estimated, but because the same data had previously been accepted, the 2014 decisions were not included among the totals in this rejection rate analysis.

Analysis of JMPR Rejection Rate, 2015

This rejection rate analysis covers evaluations by JMPR in 2015 for residue data on food and feed commodities. JMPR made 393 decisions on food and feed uses, involving 25 agricultural chemicals. Of these, 318 were acceptances (80.9%) and 75 were rejections (19.1%). The data from three rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: lack of a matching GAP (36), including GAP not matched by field trial use pattern (31) or no GAP available (7); insufficient number of independent trials (35); no data obtained for some required analytes (3); storage stability data indicated substantial residue loss (2); commodities had been cut in the field and there was no data on residue stability in cut samples (1); insufficient storage stability was available to support the sample storage period (1); and analytical method overestimates the level of parent compound (1) (Table 7).

A total of seven datasets covering three compounds were submitted without a GAP. Data to support difenoconazole on strawberry were rejected because there were insufficient storage stability data to support the sample storage period, but the residue data were accepted in 2017 after the needed storage stability data were submitted. Datasets to support fluxapyroxad on mango and quinclorac on rice were both rejected because of an insufficient number of trials, but they were both accepted in 2017 after additional data were submitted. Data to support quinclorac on rape seed were rejected because the analytical method used in the study potentially overestimated the level of the parent compound. Data to support chlorothalonil on pear were rejected because the stems and cores were removed in the field, which could have a significant influence on residue concentration of this molecule.

Analysis of JMPR Rejection Rate, 2016

This rejection rate analysis covers evaluations by JMPR in 2016 for residue data on food and feed commodities. JMPR made 398 decisions on food and feed uses that year, involving 23 agricultural chemicals. Of these, 323 were acceptances (81.2%) and 75 were rejections (18.8%). The data from four rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: lack of a matching GAP (38), including GAP not matched by field trial use pattern (34) or no GAP available (4); insufficient number of independent trials (32); no data obtained for some required analytes (6); common agricultural practices not used in trials (1); and no Codex classification available for the crop (1) (Table 8).

A total of four datasets for one compound were submitted without a GAP. Data to support flupyradifurone on hops were rejected because of an insufficient number of field trials, but were accepted in 2019 after additional trial data were submitted. Datasets to support sulfoxaflor on rice and sorghum were rejected because the data did not match the GAPs, but these datasets were accepted in 2018 with matching GAPs. Data to support fluensulfone on mizuna were rejected because no Codex classification was available for the crop. Data to support saflufenacil on olive were rejected in part because of an insufficient number of trials, but also because the hand-harvesting of the fruit was not in accordance with common agricultural practices and could have impacted the residue results.

Analysis of JMPR Rejection Rate, 2017

This rejection rate analysis covers evaluations by JMPR in 2017 for residue data on food and feed commodities. JMPR made 332 decisions on food and feed uses that year, involving 34 agricultural chemicals. Of these, 261 were acceptances (78.6%) and 71 were rejections (21.4%). The data from nine rejections were later accepted after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: residues were expressed as a molecule lacking toxicological studies (30); lack of a matching GAP (20), including GAP not matched by field trial use pattern (11) or no GAP available (9); insufficient number of independent trials (16); insufficient storage stability data to support the sample storage period (3); inadequate sample size (2); no data obtained for some required analytes (1); and inconsistent recoveries during residue analysis (1) (Table 9).

A total of nine datasets covering two compounds were submitted without a GAP. Data supporting azoxystrobin on guava were rejected because the GAP was not a match, but these data were accepted in 2019 with a matching GAP. Data to support fenazaquin on almond and almond hulls were rejected because there were insufficient storage stability data to support the sample storage period, but the data were accepted in 2019 after the needed storage stability data were submitted. Data to support fluensulfone on citrus fruit, sugar cane, and coffee were rejected because no GAP had been established for these uses, but these datasets were accepted in 2019 with GAPs. Data to support propylene oxide on tree nuts were rejected because of inadequate sample sizes. Data from just two field trials to support spinetoram on persimmon were accepted; JMPR determined that the submitted data supported the existing MRL. Data for 30 crop uses of thiophanate-methyl were rejected because of the absence of toxicological studies for carbendazim, the molecule in which residues of thiophanate-methyl are expressed. In the reviews of fenpyroximate on cherry, peach, and plum, an MRL was estimated, but the residues exceeded the ARfD. In the review of chlormequat on oats, one dataset matching one GAP produced residues that exceeded the ARfD for children, so a different dataset and GAP were used to estimate an MRL that would not exceed the ARfD.

Analysis of JMPR Rejection Rate, 2018

This rejection rate analysis covers evaluations by JMPR in 2018 for residue data on food and feed commodities. JMPR made 281 decisions on food and feed uses that year, involving 26 agricultural chemicals. Of these, 199 were acceptances (70.8%) and 82 were rejections (29.2%). The data from 34 of the rejections were accepted in 2019 after additional data were submitted and another review was conducted for that chemical. The reasons for rejection included: insufficient data on residues in rotational crops after previous uses (34), GAP not matched by field trial use pattern (25), insufficient number of independent trials (17), analytical method did not include all required steps (8), and no data obtained for some required analytes (1) (Table 10).

An MRL for chlorfenapyr on citrus fruit had been estimated in 2012. Using the same data, a new MRL was estimated in 2018 because the earlier estimation was not in line with the current procedure for crop group MRLs. Also, nine additional chlorfenapyr/crop datasets that had been accepted in 2012 were re-evaluated in 2018, because the 2012 data had not included residue results for the metabolite tralopyril, which had subsequently been determined to be necessary for estimating dietary exposure. A conversion factor of 1.44 was applied to the data that had been submitted to account for the metabolite, and new MRLs were estimated. These chlorfenapyr decisions were not included among the totals in this rejection rate analysis. Datasets supporting 24 crop uses of pydiflumetofen were rejected because there were insufficient data on residues in rotational crops after previous uses; all of these datasets were accepted in 2019 along with rotational crop data. Data to support the use of pyriproxyfen on mango were rejected because there were an insufficient number of trials to support a one-day pre-harvest interval, but the same data were accepted in 2019 to estimate an MRL in support of a 14-day pre-harvest interval.

Analysis of JMPR Rejection Rate, 2019

This rejection rate analysis covers evaluations by JMPR in 2019 for residue data on food and feed commodities. Some of the evaluations were summarized in a second report issued that year. JMPR made 383 decisions on food and feed uses that year, involving 45 agricultural chemicals. Of these, 301 were acceptances (78.6%) and 82 were rejections (21.4%). At the time of writing, this was the most recent year for which data were available, so the percentage of rejected data that were later accepted could not be quantified. The reasons for rejection included: GAP not matched by field trial use pattern (50), insufficient number of independent trials (27), no residue data submitted for some required analytes (11), no residue definition established for dietary risk assessment (1), insufficient storage stability data to support sample storage period (1), and validated limit of quantitation was not low enough (1) (Table 11).

An MRL was estimated for tolfenpyrad on tomato, but the residues exceeded the ARfD. An MRL was confirmed for a new GAP for bifenthrin on strawberry, but the ARfD was exceeded both for children and the general population.

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Tables

Table 1. Analysis of JMPR Rejection Rate, 2010–2019

	Total	2019	2018	2017	2016	2015	2014	2013	2012	2011	2010
Number of decisions	3789	383	281	332	398	393	354	366	415	371	496
Number accepted	2916	301	199	261	323	318	262	265	352	321	314
% accepted	77.0	78.6	70.8	78.6	81.2	80.9	74.0	72.4	84.8	86.5	63.3
Number rejected	873	82	82	71	75	75	92	101	63	50	182
% rejected	23.0	21.4	29.2	21.4	18.8	19.1	26.0	27.6	15.2	13.5	36.7
Reasons for Rejection or Other Decision[1]											
Data accepted at a later mtg. with additional data	14.2	---	41.5	12.7	5.3	4.0	4.3	7.9	1.6	16.0	29.1
Insufficient number of trials	34.0	32.9	20.7	22.5	42.7	46.7	35.9	31.7	57.1	52.0	23.6
GAP unmatched or no GAP available	50.6	59.8	30.5	28.2	50.7	48.0	52.2	45.5	42.9	38.0	73.6
Insufficient data on residues in rotational crops after previous uses	4.5	0.0	37.8	0.0	0.0	0.0	0.0	7.9	0.0	0.0	0.0
No data for some required analytes	3.8	13.4	1.2	1.4	8.0	4.0	5.4	5.0	0.0	2.0	0.0
Residues expressed as a molecule for which toxicological studies are lacking[2]	3.4	0.0	0.0	42.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Insufficient storage stability data	2.6	1.2	0.0	4.2	0.0	1.3	9.8	6.9	0.0	0.0	1.1
Poor storage stability results	1.8	0.0	0.0	0.0	0.0	2.7	0.0	0.0	0.0	10.0	4.9
Other[3]	4.2	2.4	9.8	4.2	2.7	2.7	3.3	3.0	1.6	0.0	7.1

[1]Some proposed crop uses were rejected for more than one reason.
[2]This reason for rejection was given only to submitted data for thiophanate-methyl in 2017.
[3]Other includes any reason for rejection that made up <1% of the rejections for the 10-year period. The table for each respective year lists all of the reasons for rejections for that year.

Table 2. Analysis of JMPR Rejection Rate, 2010

2010	Number	Percent
Decisions	496	
Accepted	314	63.3
Rejected	182	36.7
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	53	29.1
Insufficient number of independent trials	43	23.6
GAP unmatched (39) or no GAP available (95)	134	73.6
Inadequate sample size	1	0.5
Sample preparation issues in the field (other than cutting samples)	6	3.3
Commodities were cut in the field; no data on residue stability	1	0.5
Inappropriate treatment of samples during homogenization	10	5.5
Inconsistent recoveries during residue analysis	1	0.5
Insufficient storage stability data to support sample storage period	2	1.1
Storage stability data indicated substantial residue loss	9	4.9
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	1	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 3. Analysis of JMPR Rejection Rate, 2011

2011	Number	Percent
Decisions	371	
Accepted	321	86.5
Rejected	50	13.5
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	8	16.0
Insufficient number of independent trials	26	52.0
GAP unmatched (11) or no GAP available (8)	19	38.0
No data for some required analytes	1	2.0
Storage stability data indicated substantial residue loss	5	10.0
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	1	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 4. Analysis of JMPR Rejection Rate, 2012

2012	Number	Percent
Decisions	415	
Accepted	352	84.8
Rejected	63	15.2
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	1	1.6
Insufficient number of independent trials	36	57.1
GAP unmatched (21) or no GAP available (6)	27	42.9
Data from different countries could not be combined	1	1.6
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	2	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 5. Analysis of JMPR Rejection Rate, 2013

2013	Number	Percent
Decisions	366	
Accepted	265	72.4
Rejected	101	27.6
Reason(s) for rejection	Number	% of Total
Data accepted at a later meeting with additional data	8	7.9
Insufficient number of independent trials	32	31.7
GAP unmatched (11) or no GAP available (35)	46	45.5
Insufficient data on residues in rotational crops after previous uses	8	7.9
Commodities had been cut in the field; no data on residue stability	2	2.0
No data for some required analytes	5	5.0
Insufficient storage stability data to support sample storage period	7	6.9
Unexplained large difference between highest residue and other results	1	1.0
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	1	---

Table 6. Analysis of JMPR Rejection Rate, 2014

2014	Number	Percent
Decisions	354	
Accepted	262	74.0
Rejected	92	26.0
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	4	4.3
Insufficient number of independent trials	33	35.9
GAP unmatched (30) or no GAP available (18)	48	52.2
Commodities were cut in the field; no data on residue stability	3	3.3
No data for some required analytes	5	5.4
Insufficient storage stability data to support sample storage period	9	9.8
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	0	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 7. Analysis of JMPR Rejection Rate, 2015

2015	Number	Percent
Decisions	393	
Accepted	318	80.9
Rejected	75	19.1
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	3	4.0
Insufficient number of independent trials	35	46.7
GAP unmatched (31) or no GAP available (7)	36	48.0
Commodities were cut in the field; no data on residue stability	1	1.3
No data for some required analytes	3	4.0
Insufficient storage stability data to support sample storage period	1	1.3
Storage stability data indicated substantial residue loss	2	2.7
Analytical method overestimates the level of parent compound	1	1.3
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	0	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 8. Analysis of JMPR Rejection Rate, 2016

2016	Number	Percent
Decisions	398	
Accepted	323	81.2
Rejected	75	18.8
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	4	5.3
Insufficient number of independent trials	32	42.7
GAP unmatched (34) or no GAP available (4)	38	50.7
Common agricultural practices were not used in trials	1	1.3
No Codex classification available for crop	1	1.3
No data for some required analytes	6	8.0
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	0	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 9. Analysis of JMPR Rejection Rate, 2017

2017	Number	Percent
Decisions	332	
Accepted	261	78.6
Rejected	71	21.4
Reason(s) for rejection[1]	Number	% of Total
Data accepted at a later meeting with additional data	9	12.7
Insufficient number of independent trials	16	22.5
GAP unmatched (11) or no GAP available (9)	20	28.2
Inadequate sample size	2	2.8
No data for some required analytes	1	1.4
Inconsistent recoveries during residue analysis	1	1.4
Residues are expressed as a molecule lacking toxicological studies	30	42.3
Insufficient storage stability data to support sample storage period	3	4.2
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	3	---

[1]Some proposed crop uses were rejected for more than one reason.

Table 10. Analysis of JMPR Rejection Rate, 2018

2018	Number	Percent
Decisions	281	
Accepted	199	70.8
Rejected	82	29.2
Reason(s) for rejection	Number	% of Total
Data accepted at a later meeting with additional data	34	41.5
Insufficient number of independent trials	17	20.7
GAP unmatched (25) or no GAP available (0)	25	30.5
Insufficient data on residues in rotational crops after previous uses	31	37.8
No data for some required analytes	1	1.2
Analytical method did not include all required steps	8	9.8
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	0	---

Table 11. Analysis of JMPR Rejection Rate, 2019

2019	Number	Percent
Decisions	383	100
Accepted	301	78.6
Rejected	82	21.4
Reason(s) for rejection[1]	Number	% of Total
Insufficient number of independent trials	27	32.9
GAP unmatched (49) or no GAP available (0)	49	59.8
No residue definition for dietary risk assessment	1	1.2
No data for some required analytes	11	13.4
Validated limit of quantification (LOQ) not low enough	1	1.2
Insufficient storage stability data to support sample storage period	1	1.2
Residues exceeded Acute Reference Dose (ARfD) but MRL was estimated	2	---

[1]Some proposed crop uses were rejected for more than one reason.

Figures

Figure 1. Annual JMPR Rejection Rate, 2010–2019

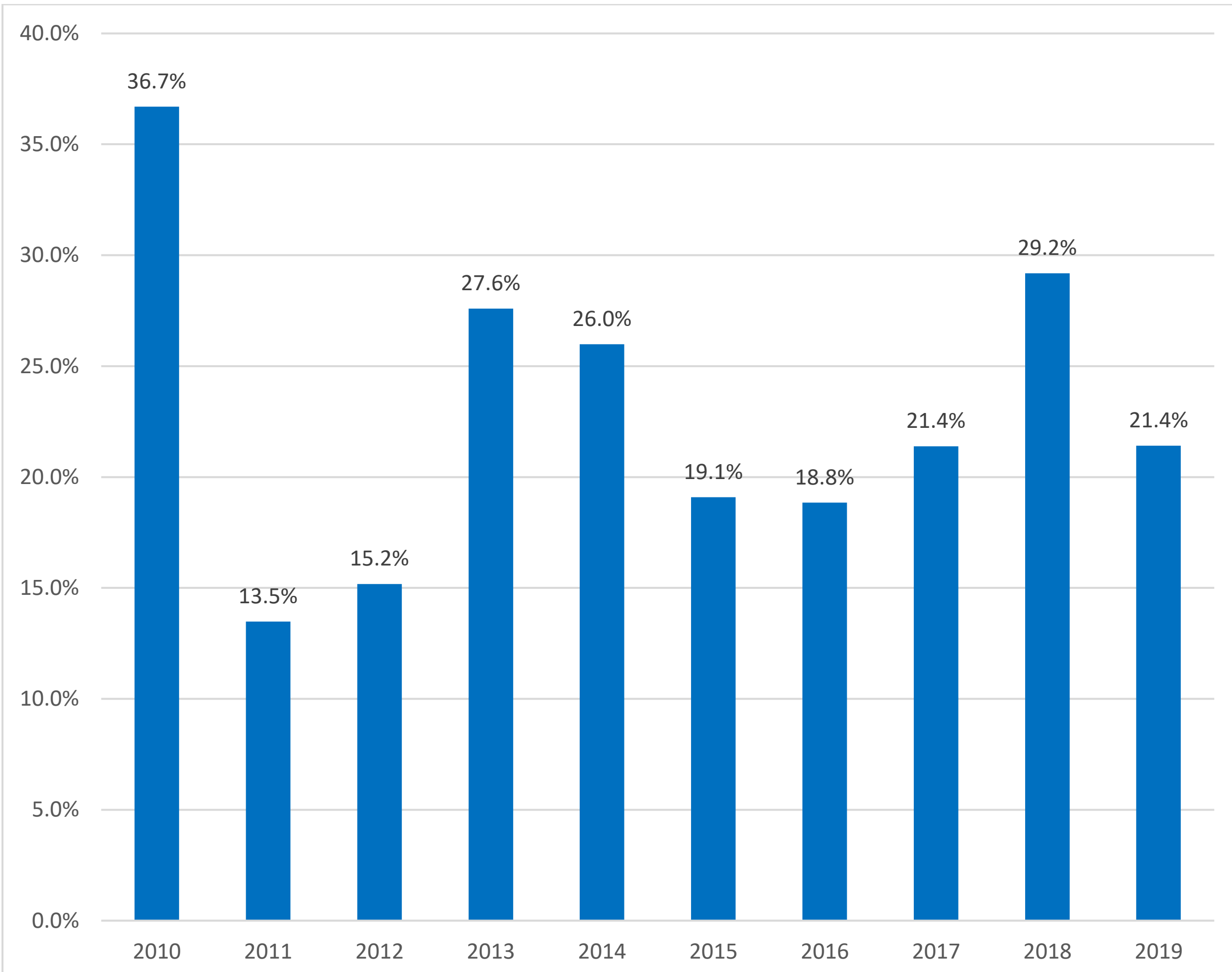
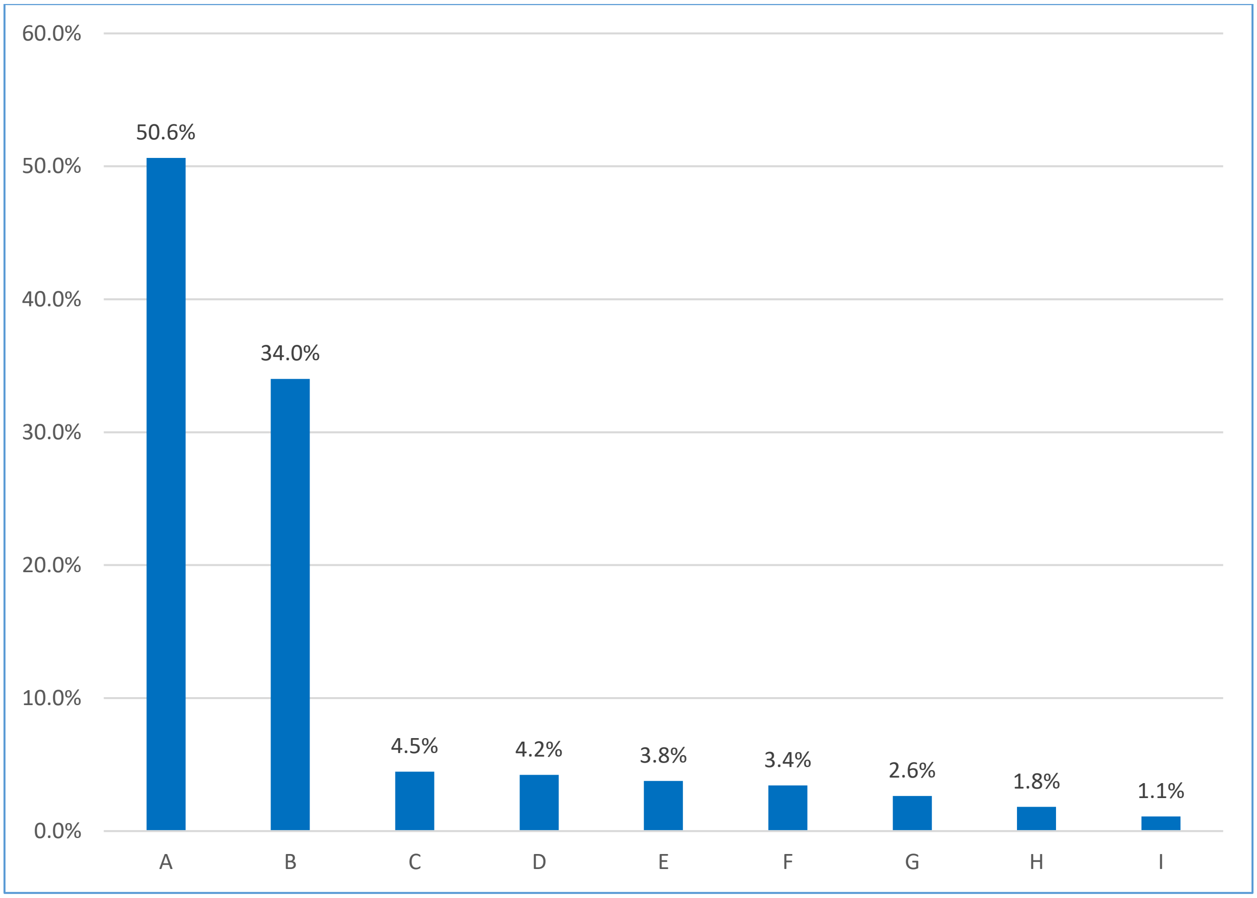


Figure 2. Frequency of Reasons for Rejection



Code	Reason for Rejection
A	GAP Not Matched by Field Trial Use Pattern (or no GAP)
B	Insufficient Number of Independent Trials
C	Insufficient Data on Residues in Rotational Crops After Previous Uses
D	Other
E	No Data for Some Required Analytes
F	Residues are Expressed as a Molecule for which Toxicological Studies Are Lacking
G	Insufficient Storage Stability Data to Support Sample Storage Period
H	Storage Stability Data Indicated Substantial Residue Loss
I	Inappropriate Treatment of Samples during Homogenization