

## *REGULATORY ACTIONS AFTER THE PRODUCT IS REGISTERED*

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## I. Payment of Mill Assessment

Registrants must, on a quarterly basis, pay an assessment per dollar sales on each registered pesticide product sold in California.

Exempted from this requirement are:

- Manufacturing-use only products
- Products sold at cost by government agencies

If another person, not the registrant, is the first person to sell the pesticide in California, they are subject to payment of mill assessment. For more information, refer to the Product Compliance website on [Mill Assessment](#).

## II. Renewal of Product Registration

A pesticide product certificate of registration (license) expires on December 31st of each year.

On approximately October 15 of each year, each registrant is mailed an Application for Renewal of Registration with a list of their currently registered pesticide products.

The registrant is required to:

- Line out the names of any products they wish to discontinue
- Sign and return the Application for Renewal with renewal fees for the remaining products
- Certify under penalty of perjury, that, prior to filing the renewal application the registrant has, to the best of the registrants knowledge based upon all information available to the applicant, complied with the provisions of FIFRA section 6(a) (2) and FAC section 12811.5..

A conditionally registered product will not be renewed if the registrant has not complied with the conditions of its time-limited registration.

DPR prepares a final notice for all renewed products. This is posted for public comment. Currently, DPR does not have the capability of sending or receiving renewal notices on-line.

## **A. Procedures for Renewal**

### **Initiating the Renewal Process**

The Licensing Technician sends each registrant an application for renewal listing the company's registered products. With the renewal request, DPR sends a letter outlining general requirements for renewal.

### **Applicant Sends in Renewal Form**

With each renewal request, the registrant must submit the following:

- The signed Application for Renewal of Registration form. A statement of compliance with the adverse effects disclosure provisions is included on the form.
- \$750 per product renewal fee and any applicable penalties. Exempt from fees are county, state, or federal agencies that sell pesticide at cost.
- Any data the registrant agreed to submit for a conditional registration or for an Interim registration. This data is processed separately from the renewal request. A progress report must be submitted with the renewal application if the time frame for submission of data is after December 31.

When a pesticide registration is renewed without reevaluation, DPR makes a written finding that information was not received necessitating reevaluation. Notice of the proposed decision to renew registration is posted for 30-day public comment.

Note: An Emergency Registration cannot be renewed for more than one year.

### **Processing the Renewal Request**

The Licensing Technician processes the Applications for Renewal of Registration.

If only an address change is made on the renewal request, the Licensing Technician will make the change to the license and to the computer database after confirmed with the company. If the address change includes an agent's name, the Regulatory Scientist (RS) should verify it.

The Licensing Technician should coordinate with the RS before proceeding if any of the following occur:

- The application for renewal shows a change in firm name, altered brand name, altered registration number, or additional brand name
- Data or an adverse effects disclosure is received

- An annual progress report is received in accordance with conditional registration, interim registration requirements, or any other time-limited registration
- Regulatory action against the product is being taken by DPR
- The registration is an Emergency Registration

If any of these things occur, the Licensing Technician will provide the RS with the application for renewal. The RS will determine the appropriate action to be taken and contact the registrant if necessary.

- If the Application for Renewal shows a change in a firm name, product name, additional brand name, or new registration number, the RS should contact the registrant and inform them that such regulatory actions are not part of the renewal process
- If the renewal contains a conditional registration progress report, forward the progress report to the Registration Resource Center with a note that it is to be filed in the product file and forward a copy of the report with the route sheet and instructions to the appropriate Evaluation Scientist
- Once all actions relating to the company license have been resolved, the RS should initial the Application for Renewal and return it to the Licensing Technician

Note: The RS may revise the Application for Renewal to reflect only those products to be renewed by confirming the revision with the company and initialing any revisions made to the license.

- After the records are updated, the Licensing Technician issues the Certificate of Registration listing the registrant's products registered for the current year. Licensing staff review the licenses for accuracy, distributes copies appropriately, and mails the original licenses back to the registrant.

## **B. Late Renewal**

DPR will only accept late registration renewals and requests for reinstatement of pesticide product registrations until December 31 of the current renewal year.

**P/P [2009-1](#)**

### **Procedure for Reinstatement of Registration**

If by April 1, a company does not submit its pesticide product renewal application, Licensing will issue a letter informing the company that DPR has not yet received its renewal application, and that as a result, its product(s) registration(s) is considered lapsed as of January 1 of the current calendar year. Once a product registration lapses it is illegal to sell the product in California. The letter will require the company to inform DPR by

June 1 if it intends to renew the registration(s) of its product(s). A copy of this letter will be sent to the Product Compliance Branch. If the company does not respond by June 1, Licensing will amend the database to list the company's product(s) as "inactive" effective December 31 of the previous year.

A request for late renewal or reinstatement of a pesticide product's registration must be accompanied by a \$750 renewal fee, and \$150 late fee for each product. The Licensing Technician will issue a Supplemental License, listing the product brand name, EPA Reg. No. (**with the same alpha code**), and the date of renewal. Licensing will amend the database to list the product as "active." The date of the Supplemental License will reflect the lapse in registration. However, the lapse will not show in DPR's database. If the product was inactive for a period, Licensing will send a copy of DPR's letter and the Supplemental License renewing the product(s) registration(s) to the Product Compliance Branch.

### C. Inactivation of a Product Registration

Inactivation of a product registration can occur for any of the following reasons:

- The applicant chooses to inactivate their product(s) and lines them out on their Application for Renewal
- The applicant does not submit the appropriate renewal fees
- The applicant does not submit the required data agreed upon when a conditional registration was issued or for any time-limited registration
- DPR cannot renew the product due to a regulatory action such as a cancellation order following a reevaluation

If any of the above shall occur, the RS should be provided a copy of the license and complete the following:

- Line out the product on the license (if the registrant has not already done so)
- Initial the application form and return it to the Licensing Technician
- Inform the registrant by letter that registration of the product will not be renewed and that the renewal fee, if paid, will be refunded

#### **Voluntary Cancellation**

A registrant may request voluntary cancellation at any time during the calendar year by filling out the "[Request for Voluntary Cancellation](#)" form found on-line and submit it to Licensing Technician. By signing the form, the registrant waives their right to a hearing. The form may be submitted by fax or e-mail but should be followed by a hard copy. If the RS receives the request, he/she should forward the form to the Licensing Technician.

Once received, the **Licensing Technician will**

- Prepare a letter to the registrant confirming that their product registration was inactivated
- Update the label file database showing "voluntary cancellation" as the reason for inactivation
- Line out the product brand name and registration number on the registrant's main license
- Create a supplemental license indicating that the product has been voluntarily canceled, and forward the supplemental license and other information to the Registration Resource Center
- Forward a copy of supplemental license to the Enforcement Branch

**The Label Resource Center will:**

- Mark the product file "inactive" and place into the inactive files area
- Line out the product name and registration number on the main license
- File the supplemental license and the voluntary cancellation form in the license file

#### **D. Lapsed Registration**

A registrant cannot legally sell a product once the renewal or registration of that product has lapsed.

Products whose registration has lapsed (become inactive) shall not be sold by the registrant, but may be possessed and sold by a dealer for two years after the last date of registration. It should be noted that products may not be sold or shipped into California once they are inactive; even to a licensed dealer. Therefore, the product must be shipped or sold into California prior to its inactivation to be legally possessed or sold by a dealer. **3 CCR [6301](#)**

If acquired while legally registered or within two years after the date of last registration, such products may be possessed and used according to the directions on the label.

### **III. Re-registering an Inactivated Product**

If a product has been inactive for more than a one-year time period, a registrant can no longer “renew” or “reinstate” the product’s registration. The registrant must apply to “register” the product again by submitting a new application for registration form, \$750 application fee, any other necessary documentation, and supporting data, if applicable. [P/P 2009-1](#)

If the product was inactivated within the last ten years, the Regulatory Scientist should obtain the inactive file and use it to process the newly submitted application. If the registrant has made no substantive changes to the proposed product formulation or label, or the proposed product label specifies uses previously approved by DPR for one or more pesticide products containing the same active ingredients, then under AB 1011, no scientific evaluation may be needed and the Regulatory Scientist may approve the application provided all other necessary items are provided. If the product was inactivated over ten years ago and/or DPR has not previously approved the proposed label claims, supporting data may be required. The Regulatory Scientist will assign the product a different alpha code. By assigning a different alpha code, the lapse in the product’s registration will be reflected in the DPR database for enforcement and product compliance purposes.

## IV. Extending a Conditional Registration

As discussed in Chapter 4, the director may waive specific data requirements for a period reasonably sufficient, not to exceed three years, for the generation and submission of the required data. [3 CCR 6200](#)

Upon registration, the time frame for submission of data is indicated in the letter to the applicant. If the conditional registration extends over January 1 of any year, each registrant is required to submit an annual progress report at renewal time for each item of the waived data.

If a registrant requests an extension of time to submit the required data, the RS will:

- Review the registrant's written request for an extension. To determine the validity of the extension request, the RS should consult with the evaluation scientist who recommended the conditional registration. If the scientist feels that an extension of time is acceptable, they should suggest a reasonable time extension to complete the studies.
- Consult with his/her supervisor before extending the time for the conditional registration.

If an extension is to be granted, the registration specialist will:

- Prepare the appropriate letter to the registrant indicating that the time frame has been extended. Include the new target date and a carbon copy to licensing.
- Print a yellow surname copy (to be returned to the RS)
- Prepare duplicate copies of the letter. Label one copy, "Licensing," one copy "Conditional Binder," and the other "Product File" in the upper right-hand corner. These copies should be placed behind the yellow surname copy of the letter and should be submitted to his/her supervisor for surname.

## V. Changing a Conditional Registration to a Full Registration

The following outlines the process for receiving data to satisfy a conditional registration:

### **The Mail Log and Intake Technician will:**

- Receive the submission and input the information into the database
- Forward the package to the Indexer who will process the data and enter the appropriate information into the database
- Receive the package back from the Index Technician, and create a status sheet. The tracking ID# on the status sheet will include an "EC" prefix to indicate that the package contains additional data submitted to satisfy conditions placed on the product registration.
- Forward the package to the RS

### **The RS will:**

- Review the data package for completeness and correctness (this does not include the contents of the data). This includes checking the status sheet to ensure there are no inconsistencies. If revisions are required, they should be made and a hard copy should be given to the Intake Technician. If the revision involves the firm name, firm number, product name, or chemical ingredient, a revised copy of the status sheet and the data should also be given to the Index Technician so that the appropriate revisions can be made.
- Obtain a copy of the currently registered label, CSF, and evaluation report(s) previously written that identifies the conditions. These documents must be routed with the package.

- If the package is complete and correct, complete the route sheet and forward the data package to the appropriate evaluation stations for review. The route sheet should contain as much detailed information as necessary for the reviewer to process the package. For detailed information on routing a package, review the appropriate procedures in Chapter 4. If more than one study is required, each study can be submitted and routed separately as it is completed.
- If the package is incomplete, it should be returned. Prepare a letter to the company explaining the deficiencies. A yellow surname copy should be printed and the RS' last name should be written in the upper right-hand corner. A white copy should also be printed and placed on the inside of the brown folder, on top of all other documents. Write "Return File" on the upper right-hand corner.

### **All Conditions Satisfied**

- If all conditions have been satisfied and the data found acceptable, prepare the appropriate letter to the registrant. The letter will state that submitted data supports full registration and the conditional registration has been changed to a full registration.

**Note: Packages submitted into evaluation to satisfy conditional registrations are not posted for public comment.**

- Prepare a letter to the registrant, one yellow surname copy for the product file, one copy for licensing, and one copy for the RS
- Submit the paperwork to his/her supervisor for sign off. The supervisor will review the letter, surname the yellow copy, and place in the licensing box.
- The Licensing Technician will amend the license to indicate full registration. Once the action is complete, the Licensing Technician will check the Conditional Binder and remove the letter/evaluation memo under the RS' name, and remove the "conditional date" from the label database.
- Once the action is complete and the RS has received a copy of the letter, he/she should place the tracking ID# on their action log.

### **Conditions Not Satisfied**

- If all conditions have not been satisfied and/or the data not found acceptable, the RS should prepare a letter detailing the deficiencies. The original date assigned to the conditional registration is kept unless DPR grants an extension.
- Print one copy for the registrant, one yellow surname copy for the product file (write “Product File” in the upper right-hand corner), and one copy for the RS (write the RS last name in the upper right-hand corner)

### **Archiving the Data**

Once the process is complete, all data submitted must be archived. The RS should:

- Write “Archive” on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

## **VI. Adverse Effects Disclosure**

If during the registration process, or anytime after registration, the registrant (or applicant) has evidence of an adverse effect or risk to human health or the environment, the registrant (or applicant) must immediately submit the information to DPR. This information includes, but is not limited to, that required by federal law FIFRA Section 6(a) (2).

Registrants were requested in CA Notice 92-5 to identify adverse effects disclosures in their cover letter with a citation referring to [FAC section 12825.5](#) or to [3 CCR section 6210](#). If there is reason to believe that use or continued use of the pesticide constitutes an immediate substantial danger to persons or to the environment, the director may, after notice to the registrant, suspend the registration pending a hearing and final decision.

### **Procedure for Processing an Adverse Effects Disclosure**

#### **The Intake Technician will:**

- Determine if the submission is an adverse effects disclosure. This is usually identified by the registrant in their cover letter. The cover letter will state that the submission is in compliance with either Section 6(a) (2) of FIFRA or 3 CCR section 6210.

- Give the submission a status sheet and tracking ID# with the suffix EA. If the submission involves SB950, also give the tracking ID# the prefix SBC.
- If data is submitted, route the submission to the Index Technician
- If no data is submitted, route the submission to the designated adverse effects disclosure staff person. If the submission involves SB950, and no data is submitted, route the submission to the designated SB950 staff person.

**The RS will:**

- Determine whether the submission must enter scientific evaluation or whether a letter of acknowledgement to the registrant is sufficient
- If scientific evaluation is needed, enter the submission into evaluation
- Review evaluators' comments after the scientific evaluation process is complete
- Write a letter to the registrant after the scientific evaluation summarizing the results of the evaluation
- If an adverse effect exists, forward the submission to the Reevaluation Coordinator, who will respond to the registrant

**Archiving the Data**

Once the registration process is complete, all data submitted must be archived. The RS should:

- Write “Archive” on the lower right-hand portion of the route sheet
- Arrange the data by volume (if more than one volume)
- Clip together the original route sheet, the status sheet with corrections made, the evaluation memo(s) and the data (in that order)
- Place the entire package in the designated area to be archived

If the submission does not contain data, archive the information as described above without the data. These documents should be placed in the designated area and sent to the Registration Resource Center (library). The RS should keep the remaining information and documents for 2 years in his/her workstation.

## VII. Reevaluations

California law requires DPR to continuously evaluate registered pesticides. DPR established the reevaluation process to implement this requirement. A number of factors may result in a registered pesticide product or group of products being reevaluated:

**3 CCR**  
[6220-6228](#)

**FAC** [12824](#)

- Public or worker health hazard
- Environmental contamination
- Residue over tolerance
- Fish or wildlife hazard
- Lack of efficacy
- Undesirable phytotoxicity
- Hazardous packaging
- Inadequate labeling
- Disruption of the implementation or conduct of pest management
- Other information suggesting a significant adverse effect

A reevaluation may be triggered by ongoing DPR registration reviews or by state and county pesticide use surveillance and illness investigations, pesticide residue sample analyses, environmental monitoring activities, and information submitted by other state or federal agencies, or other sources.

### **Receipt of a request for reevaluation**

Upon receipt of a request for reevaluation and supporting data/information, the Reevaluation Coordinator (RC) routes the request to all Branch Chiefs, Assistant Directors, Chief Deputy Director, and the Director for concurrence. If the Director chooses to pursue the reevaluation, the Reevaluation Coordinator identifies the products involved in the reevaluation and identifies the RS' whose registrants have products involved in the reevaluation.

1. The RC prepares a "Notice of Proposed Decision to Reevaluate Pesticide Products" and prepares individual letters to registrants whose products are to be reevaluated. The notice is signed by the Registration Branch Chief and routed for signature to the Assistant Director. The date the notice is signed is the initiation date of the reevaluation. A copy of the registrant letter is sent to the appropriate RS for that company.

2. The RC prepares a reference binder of reevaluation information. The binder includes:
  - All correspondence and memoranda regarding the reevaluation
  - Copies of letters notifying registrants of the reevaluation
  - A copy of the "Notice of Proposed Decision Concerning Reevaluation of Pesticide Products"
  - Concurrence form and all information relative to the basis of the reevaluation
  - Copies of labels (unless too numerous to be practical)
  
3. The RC informs the appropriate Branch Chief(s) that the reevaluation has been initiated and requests a list of data and/or information, if any, to be requested from the registrant. If the decision is to require additional data, the RC prepares letters notifying registrants of the data requirements. Copies of the letters are routed to the appropriate RS'. At this point, the reevaluation enters an inactive phase until the data are received.

During the reevaluation of a pesticide, data relevant to the focus of the reevaluation may be required. A reasonable time, not to exceed two years, is allowed for the development and submission of data.

Other ongoing registration actions continue independent of the reevaluation, but are included in consideration of the reevaluation.

### **Processing data submitted during reevaluation**

Once the data are received, the Intake Technician prepares a status sheet (the tracking ID# will have an ER suffix) and routes the data to be indexed. After indexing, the data are routed to the appropriate RC. The RC identifies the appropriate evaluator of the data and submits the package into the scientific evaluation process. Upon completion of the reviews, the Evaluation Tracking Technician gives the data package to the RC. The RC writes a letter to the registrant identifying the results of the review, with a copy routed to the Regulatory Scientist.

### **Conclusion of the reevaluation**

When the issues that caused the reevaluation to be initiated have been resolved, the RC prepares a summary and recommendation for review by the Branch Chief. The Registration Branch Chief forwards copies to the other Branch Chiefs, Legal Counsel, and if appropriate, to the PREC for comment. The Registration Branch Chief then makes the decision to modify, restrict, suspend, cancel, or continue registration.

There are several possible outcomes of a reevaluation. The data may demonstrate that the issue is resolved and that no significant adverse effect will occur. DPR may

determine that there is a need to adopt mitigation measures; or DPR may determine that the adverse effect cannot be mitigated in which case the pesticide product(s) must be suspended or canceled.

The RC prepares the "Notice of Final Decision Concerning the Reevaluation of Pesticide Products" and the individual letters to registrants informing them of the reevaluation final decision. The Registration Branch Chief signs the Notice, and routes it for signature to the Assistant Director, Chief Deputy Director, and the Director. The reevaluation is concluded on the date the notice is signed. A copy of the registrant letter is given to the RS for each affected company.

### **Semiannual Report**

A publicly available semiannual report is prepared describing the status of pesticides under reevaluation, or for which factual or scientific information was received, but no reevaluation was initiated. This is usually written by the RC.

## **VIII. Risk Assessments**

Upon registration of a new active ingredient, the active ingredient is prioritized for risk assessment. Risk assessment of currently registered active ingredients can be triggered by a number of different factors, including the identification of potential adverse effects. Risk assessments are generally related to chronic human health effects. The Adverse Effects Advisory Panel determines risk assessment prioritization. The Adverse Effects Panel is made up of representatives from the Medical Toxicology Branch (Med. Tox.), the Worker Health and Safety Branch (WHS), and the Office of Environmental Health Hazard Assessment (OEHHA).

Med. Tox. and WHS conduct risk assessments. The Registration Branch is responsible for data distribution and communication with registrants. For any data submitted relating to risk assessment, the Intake Technician prepares a status sheet using the prefix SBRA. The Intake Technician routes the data to be indexed. After indexing, the data is routed directly to Med. Tox. Copies of the status sheet are given to the SB 950 coordinator and the risk assessment coordinator. Med.Tox. indicates on the status sheet if the data package requires review by WHS and returns the data package to the evaluation clerk. Med.Tox. routes copies of the status sheets and review memos to the SB950 coordinator, who in turn gives them to the risk assessment coordinator. The risk assessment coordinator passes on the results of the data reviews to the registrant, with copies to the SB950 coordinator.

The risk assessment coordinator is responsible for notifying registrants at six different stages in the risk assessment/mitigation process. Notices are sent when:

- DPR first prioritizes a pesticide active ingredient for risk assessment
- DPR initiates the risk assessment process on a specific active ingredient

- DPR determines the endpoints of toxicological significance for a specific active ingredient
- DPR completes final drafts of the Risk Characterization and Exposure Assessment documents for a specific active ingredient
- DPR completes the final Risk Characterization and Exposure Documents for a specific active ingredient. If no mitigation measures are needed the process ends. If mitigation measures are needed, the notice provides registrants with an opportunity to propose risk mitigation measures.
- DPR completes the final Risk Mitigation/Risk Management documents

## IX. Data Call-ins

DPR may request additional data be submitted for currently registered products. This is referred to as a data call-in. Data call-ins are usually initiated through legislation and become part of law. These data call-ins differ from the reevaluation process that is initiated by DPR and is more fully described in the section on Reevaluation in this chapter. Two examples are described below.

### A. Birth Defects Prevention Act (SB 950)

The Birth Defects Prevention Act (Senate Bill or SB 950) of 1984 required a data call-in for multiple chronic (long term) toxicology studies and affected all products registered as of January 1, 1984. New active ingredients registered after that date also require submission of a complete set of chronic toxicology studies.

[FAC 13121-13135](#)

Spray adjuvants were (and are currently) not subject to the SB950 requirements. Antimicrobial and biopesticide products are subject to chronic toxicity testing but require only those tests outlined under the U.S. EPA tier system guidelines.

#### **Exemptions, Deferrals, and Waivers**

Registrants may request exemptions from the SB950 data requirements by complying with FAC section 13127. A data waiver request (which differs from an exemption request) may also be granted upon determination by the Medical Toxicology and the Worker Safety Branch, with communication through the Registration Branch.

Failure to comply with SB950 requirements can result in the issuance of suspension notices. Suspension indicates that the product may remain registered, but that the registrant cannot sell the product in California. If a suspension cannot be lifted, a cancellation may follow.

The data call-in process for the first 200 priority active ingredients has been completed. These were active ingredients currently registered in 1984 that posed the

highest risk to humans and the environment and were given the highest priority for review. All other active ingredients were deemed “other.” The data call-in and suspension process continues for the “other” active ingredients. The designated staff person is responsible for processing SB 950 data, waivers, or information received other than that submitted for new active ingredients. The RS assigned to new active ingredients should consult with the SB 950 staff person if they have questions regarding the subject matter.

## B. Pesticide Prevention Contamination Act (AB 2021)

<p>The Pesticide Prevention Contamination Act (Assembly Bill or AB 2021) of 1987 required a data call-in for environmental fate (groundwater protection) data on all agricultural use active ingredients registered as of January 1, 1987.</p>	<p><a href="#">FAC 13141-13152</a></p>
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New active ingredients registered after that date also require submission of environmental fate data (certain exceptions apply). Use of some active ingredients has been restricted as a result of the data call-in, requiring restricted materials permits and special reporting of sales and use. The designated staff person is responsible for processing AB 2021 data, waivers, or information received other than that submitted for new active ingredients or the first agricultural use of a product. The RS assigned to new active ingredients or such products should consult with the AB 2021 staff person if they have questions regarding the subject matter.

## X. Change of a Registrant’s Primary Address on File

If the primary address of a registrant changes, it is the registrant’s responsibility to inform DPR of the change. A change in the primary address of the registrant does not necessarily mean a change in address on the product label(s). The name and address on the product label may be different from that of the primary address. Neither California law nor regulations require that the primary address of the registrant be identical to that on the product label. Product labels that require changes of address must be submitted as label amendments. See Chapter 7 for processing a label amendment.

[3 CCR 6239](#)

[CA Notice 2002-1](#)

Since the Pesticide Registration Branch (PRB) is responsible for updating the registrant database for DPR, all primary address changes must be submitted in writing (hard copy letter, e-mail, etc.) by the registrant. All changes of address are handled by the lead Licensing Technician. In most cases, such address changes will be first submitted to the RS who is responsible for forwarding the request to

licensing. Verification of notification to U.S. EPA is not required.

If a company address change is submitted to another branch within DPR, the request must be forwarded to the lead Licensing Technician. If a request is forwarded by another branch, the lead Licensing Technician is responsible for contacting the company to verify the change of address is legitimate.

The primary address on file must be that of the registrant. Consultant addresses are not acceptable. The RS and the lead Licensing Technician should identify and decline consultant address changes to the extent possible.