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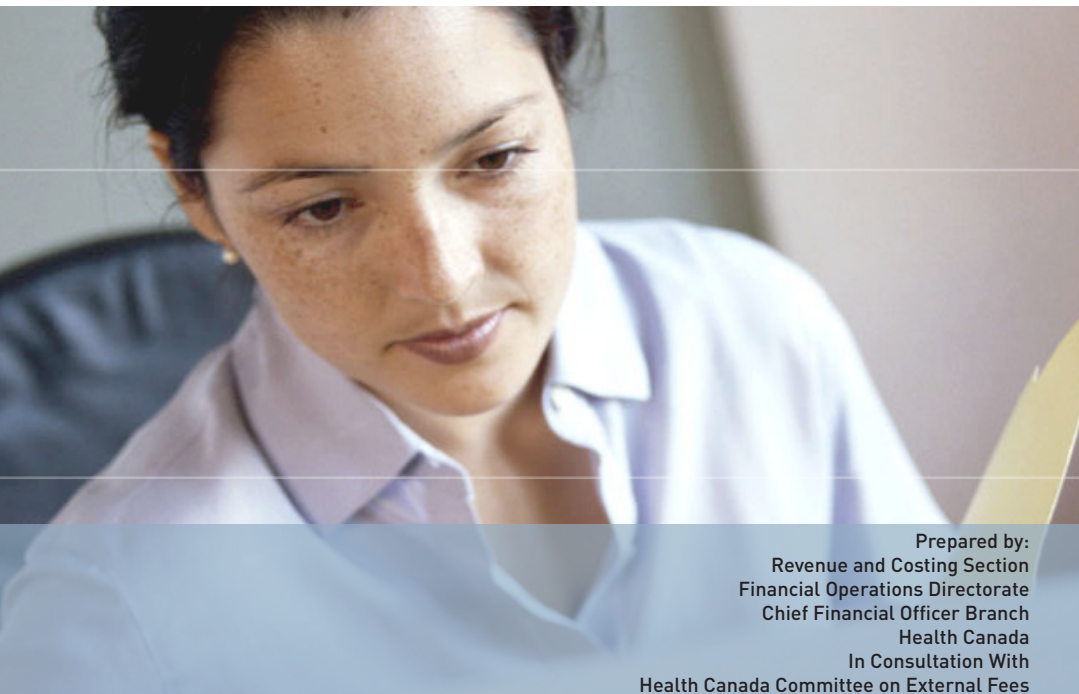
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HEALTH CANADA EXTERNAL CHARGING GUIDELINES

## Fee Structure

This is one in a series of documents developed to supplement the Health Canada External Charging Policy and provide Health Canada managers with guidance on issues related to the use of external charging.

**REVISED: April 26, 2007**



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Health Canada Committee on External Fees

Canada

*Health Canada is the federal department responsible for helping Canadians maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.*

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## FEE STRUCTURE

### 1. Purpose and Scope

- 1.1. This is one of a series of guidelines developed to provide Health Canada managers with guidance on issues related to the use of fees. The guidelines are intended to be applicable to most Health Canada programs, but it is the responsibility of the user to consider the specific circumstances in each case and adapt the guidance accordingly.
- 1.2. This guideline covers issues related to the establishment of a cost-based fee structure for external charging. Its primary focus is to identify elements and processes in developing appropriate fee structures, including the relationships with service standards and costs, level of complexity in design and fairness to the fee payers as well as taxpayers. The Guideline on Fee Structure should be read in the context of the Health Canada Policy on External Charging, related Health Canada guidelines, the Treasury Board Policy on Service Standards for External Fees and the *User Fees Act*.

### 2. Introduction

- 2.1. Once relevant activities and their service standards have been mapped out, the corresponding cost has been determined (or estimated)\* and the decision has been taken to pursue fees, it is then appropriate to consider the form or structure of the fee to be developed;
- 2.2. Determination of fees is a relatively complex task, involving consideration of a range of interrelated factors, including:
  - 2.2.1. The nature of the activity for which the fee will be charged (i.e., is it for a service, right or privilege, or regulatory process); and how much should be charged relative to cost;
  - 2.2.2. Legal authority to charge the fee;
  - 2.2.3. The expected service and performance standards of the activity;
  - 2.2.4. The cost behaviour or the manner in which a cost will react to changes in the level of an activity;
  - 2.2.5. The possibility of fee mitigation (e.g., exemptions, fee reductions)
  - 2.2.6. Existing structure and international comparison; and
  - 2.2.7. Internal considerations.

### 3. Discussion

- 3.1. Program and Public Policy Objectives
  - 3.1.1. Program objectives in Health Canada relate directly or indirectly to health issues (e.g., product or service availability / access, compliance with health regulations).
  - 3.1.2. Public policy includes such Government wide objectives as the economy, innovation, smart regulation, children's health, etc. Given the high priority Canadians place on health related issues, at any particular time a full list of Government wide policy objectives will include health related items;

\* Comment: In many cases, a constraint is being placed on the amount of the cost can incur (e.g. budgetary reason). Under such circumstances, performance standards will go as far as the costs allow.

- 3.1.2.1. These public policies are funded through appropriation. If these policies affect Health Canada's cost recovery programs, fee payers should receive a discount proportional to the amount of appropriation. This ensures cost recovery programs will not adversely affect a public policy objective and at the same time, demonstrates proper accountability and transparency for the use of public funds.
- 3.1.3. 3.1.3. Health Canada needs to assess whether program or public objectives could be compromised before introducing fees – it is a crucial factor in determining whether fees should cover the full cost of the service or activities. It is recognized that fee mitigation may also be required to further lower the fees during and after the fee has been designed, due to anticipated and unforeseen circumstances. Fee mitigation is a mechanism offered to specific groups or individual fee payers that are adversely affected by the fees but deemed eligible for monetary or non-monetary relief because certain criteria have been met. Fee mitigation is addressed in the Guideline on Fee Mitigation.

### 3.2. What is Fee Structure?

- 3.2.1. Fee structure is defined as the manner in which fees are being organized – for Health Canada; it may centre on an activity, a service or a right or privilege.
- 3.2.2. The fee structure can be equated to pricing. The objective of pricing or designing a fee structure in the federal government is to recover in a fair and consistent manner and to the extent possible, the identifiable full cost of services or activities that benefit an identifiable group or individual.

### 3.3. Principles of Fee Structure

- 3.3.1. As a general rule, fee proposals should begin with the full cost<sup>1</sup> of the relevant activities, given a specific set of service and performance standards;
- 3.3.1.1. Generally, cost is a function of service (performance) standards and the fee is a function of cost. In other words, fees are a function of service standards (see also Guideline on Service Standards);
- 3.3.1.2. As per the Health Canada Policy on External Charging, fees cannot be more than full cost (except in the case of rights and privileges) and may be set below full cost due to program or public policy objectives or if costs outweigh potential monetary and non-monetary benefits. They should **not** be less than the incremental cost for providing the product or service<sup>2</sup>, although it is recognized that there may be policy reasons for recovering less than incremental/marginal costs. In any case, alternative sources of funding for the difference in fees and full cost for net-voted activities should be explicitly identified and reported.
- 3.3.2. Fees should be based on costs that are distributed fairly to all fee payers;

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1 Full Cost is defined as all identifiable cost captured by Health Canada's information system for carrying out the relevant activity, including the start-up costs such as development work and consultations. This is consistent with TBS' definition in its Guide to Costing (currently in Discussion Draft) – The full cost of a cost object includes "all" the costs that can be reasonably attributed to it.

2 Incremental/marginal costs are defined as the change in total costs arising when the quantity increases by one additional unit. If possible, fees should at least cover the marginal cost of the service or activities the Department provided. Otherwise, a situation is created in which the Department will suffer monetary consequences in proportion to the success of carrying out its services and activities. (i.e., the more units of service the department provides, the higher the funding deficits the department will incur as a result).

- 3.3.3. One group or class of fee payer should not be given undue or unreasonable preference over another.
- 3.3.4. Fees should be reviewed once every five years and, more frequently if necessary. The level of fees for a good or service should reflect changes to cost in a timely manner;
  - 3.3.4.1. Contributing factors to the frequency and depth of review include:
    - 3.3.4.1.1. Ability of information systems to identify and capture relevant, specific cost drivers;
    - 3.3.4.1.2. Changes to service standards;
    - 3.3.4.1.3. The alignment of fee and cost structures - the more aligned the fee and cost structures, the less depth or need for a review; or
    - 3.3.4.1.4. Changes to operating environment.
- 3.4. Recoverable Cost
  - 3.4.1. Current legislation allows for fees to be charged up to the full cost of providing a service. Full cost recovery should apply if it can be demonstrated that all costs are associated with the services providing a direct benefit to the fee-payer;
  - 3.4.2. A discount to full cost may be considered at the discretion of the Department if such service also provides public benefits. The amount of discount should be determined on a case-by-case basis and in consultation with stakeholders.
    - 3.4.2.1. For net-voted activities, TBS should be fully engaged as soon as possible since the discount to full cost will need to be covered by another source of funding or else the feasibility of offering the service or activities could be in jeopardy.<sup>3</sup>
    - 3.4.2.2. Fee payers and central agencies, specifically TBS, should be advised that any possible fee discount for net-voted activities is contingent upon another source being found to fund the gap in cost.
- 3.5. Fair Distribution of Costs
  - 3.5.1. Fee structures should reflect, as close as possible, the cost of the underlying activity for which the fees are charged;
    - 3.5.1.1. For example, a simple flat fee based on the average cost of an activity element or service may not be appropriate if the actual cost of such activity varies greatly from one task to another. It can result in a financial gain for the fee payer requiring the larger amount of time, and an unfair situation for the fee payer requiring the small amount of work. In essence, the latter is subsidizing the former.
  - 3.5.2. Fee structures should be designed to avoid or reduce obvious unfairness;
    - 3.5.2.1. For example, flat fees can be designed to have an escalated structure based on components and steps (Drug Evaluation Fees Regulations and Authority to Sell Drugs Fees Regulations) or a structure built on different service levels (National

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<sup>3</sup> For example, Section 5.1 of the User Fees Act states that the Department will be penalized if it does not meet service standards. Given the fact that service standards drive or contribute to costs, but funding determines how much cost can be incurred, service standards will not be met if appropriate (replaced) funding is not provided. In such case, it would be unfair to ask the Department to deliver the service with the discount.

Dosimeter Services Schedule - Bronze, Silver and Gold). The modifications could alleviate concerns of some activities that vary in degree of efforts. 3.6.

### 3.6. Factors To Consider in Determining Fee Structure

#### 3.6.1. Impact of the Nature of the Activity

3.6.1.1. The starting point for determining a fee structure is usually to consider the nature of the activity to which the fee will apply. In turn, this dictates the authority by which the fee may be established;

#### 3.6.2. The advice of Legal Services should be obtained regarding authority to charge fees;

3.6.2.1. If the activity or service is mandatory (e.g. based on a requirement under regulations administered by the Program), fee regulations will be required;

3.6.2.2. Depending on the advice of Legal Services, authority for fee regulations will likely be ss 19.1 or 19(1) of the *Financial Administration Act* (FAA), or ss 6, 7 or 8 of the *Department of Health Act* (DHA). In both *Acts*, the sections are specific to the type of activity for which the fee will be charged. For example, s 8 of the *DHA* relates to regulatory processes or approvals.

3.6.2.3. In general, fee regulations are unnecessary for voluntary or discretionary activity and service (i.e. fee payers have a choice whether or not to request the service, good, etc.). Fee schedules can simply be published (e.g. in Canada Gazette, Part I) under the authority of the Minister's right to contract;

3.6.2.4. There are different rules around fees for services and fees for rights or privileges. In the case of services, the fee must relate to - but not exceed - the full cost of the service, while fees for rights or privileges should reflect the value of the right or privilege.

3.6.2.5. In establishing and amending fees, the start-up cost and process for mandatory activity are assumed to be higher, lengthier and more complex than non-mandatory activity. All fees for mandatory activities are under the purview of the *User Fees Act*.

3.6.3. Fee structures should reflect or take into account the different level of services being provided, including a portion for corporate services;

3.6.4. Fee payers should be explicitly made aware of the trade-off between affordability and service standards. This is particularly important with services and activities that are under the purview of the *User Fees Act*.

3.6.5. The process diagram in Figure 1 outlines the series of steps required in the development of a fee.

### 3.7. Form of the Fee

3.7.1. In designing a fee, the full cost of the activity or service should be forecast over several, but no more than five years. This should lead to a fee structure that will provide a reasonable financial base for Health Canada and some predictability to assist the fee payer with its business planning. Inflation and other cost factors should be built into the fee to ensure viability of the cost recovery program where the legislation allows.

- 3.7.2. The structure of a fee depends on a number of factors, including the cost structure of the activity, the ability of information systems to capture relevant data to isolate specific cost drivers, the exchange of fee simplicity for fee equality, the availability of historical cost behaviours, the capacity to forecast service levels and the predictability of the process being carried out.
- 3.7.3. Ideally, the form of a fee should ensure the fair distribution of costs (or value) of government activities to the specific payer. In the case of services, this means that the fee charged should be proportional to the amount of activity required to provide the service to the specific recipient.
- 3.7.4. A single flat fee is the default for simplicity. It works best in an environment where the activity is relatively homogeneous from one job to the next, cost is relatively fixed and the volume of work is stable (e.g., assembly lines). It does not require an elaborate information system;
  - 3.7.4.1. A single flat fee may not be the most appropriate in an environment where an activity requires various levels of effort, time, resources and/or expertise between different requests for services, right or privileges.
  - 3.7.4.2. A “stepped” approach may address some of the inherent weaknesses of flat fees.
    - 3.7.4.2.1. An extra “flat” fee may be charged for each additional “step” of activity or level of service that needs to be undertaken.
    - 3.7.4.2.2. The challenge of a stepped fee structure is defining the number of distinct fee steps that cover all possible jobs and that are consistent in level of effort within each of these steps.
    - 3.7.4.2.3. The more steps in a fee structure, the closer it is to becoming a variable fee (see below).
    - 3.7.4.2.4. A step increment may add or reduce a “flat” amount if the volume of activities reaches a pre-determined number to take into account capacity.
    - 3.7.4.2.5. When taken to the extreme, a “stepped” fee approach becomes a variable fee approach.
- 3.7.5. A variable fee is the default for fairness, which is based on estimated levels of effort. It is most useful in an environment where the process of an activity may change or the level of effort varies substantially from one job to another.
  - 3.7.5.1. To function effectively, a variable fee structure requires increased inputting of financial and process data and there is an increase in complexity in the related costing model(s). Consideration needs to be given to whether the benefits of such a system outweigh its costs (administration).
  - 3.7.5.2. Variable fees usually take the form of “Rate x Hour”. There may be either a standard rate or standard hour for a particular job. There may also be additional charges such as out-of-pocket expenses included in the variable fee structure
- 3.7.6. A fee may be comprised of both flat and variable components depending on the activity.

- 3.7.7. Consideration should be given to defining a fee structure that reflects compliance or enforcement costs in regulatory activities. This would mean that those in greater compliance with regulations would pay less than those in a lower state of compliance. (See fee structure of Canadian Nuclear Safety Commission and the Fee and Service Standards Policy of Competition Bureau)
- 3.8. Consideration for Existing Fee Structure
  - 3.8.1. Consideration should be given to take advantage of an existing fee structure, providing one is available;
    - 3.8.1.1. To ensure relevancy and compatibility, there should be an assessment of the context in which an existing fee structure was established versus the structure being proposed;
    - 3.8.1.2. Short-term savings should also be weighed against the present value of additional maintenance and possible loss of potential revenue, if applicable.
- 3.9. Inter-departmental and International Comparisons
  - 3.9.1. Stakeholders will expect Health Canada's fee structure approach to be comparable and consistent within the Department, with those of other government departments and agencies within Canada as well as internationally, where relevant;
    - 3.9.1.1. Where relevant comparison is not possible, the reasons should be justified and documented;
  - 3.9.2. For fees that are under the purview of the User Fees Act, there is a legislative requirement to compare the amount (rather than the structure) of fees against Canada's relevant international trading partners;
  - 3.9.3. As the definition of "relevant" may change from case to case, it should be explicitly documented and justified every time international comparison is being initiated.
- 3.10. Internal Considerations
  - 3.10.1. Many issues need to be addressed to implement fees, and the details of some will be influenced by fee structure. These include changes to information systems, design of invoices and invoice cycle, preparations of guidance documents and the dispute management process (see Guideline on Complaint Resolution and Dispute Management for External Fees);
  - 3.10.2. Consideration should be given to s.s. 5.1 of the User Fees Act at the time of designing the fee. Program managers should ensure that the Department will not be unduly penalized because of the way the fee is structured, should there be a requirement to activate s.s. 5.1.
    - 3.10.2.1. 3.5.2.1. In cases where cost recovery is less than full and there is a pre-determined sharing arrangement ratio (i.e., appropriation and external fees) established to cover the full cost of the service, it would be prudent to have a contingency plan to deal with possible changes (e.g., unexpected revenue shortfalls, penalty provision of the User Fees act, etc.). This is a funding issue that pertains to all cost recovery issues, which are currently based on modified cash accounting as required by Treasury Board.



## 4. Summary

- 4.1. Steps to consider in developing Fee Structure:
  - 4.1.1. Determine activity;
  - 4.1.2. Define service standards;
  - 4.1.3. Déterminer le coût total.
    - 4.1.3.1. Identify full cost;
  - 4.1.4. Identify portion that is recoverable;
  - 4.1.5. Determine if there should be a discount or if mitigation is required;
  - 4.1.6. Determine form of fees;
    - 4.1.6.1. Consider flat fees or its derivative(s), variable fees, or a combination of the two;
    - 4.1.6.2. Conduct intra- and inter-departmental as well as international comparisons;
  - 4.1.7. Forecast full costs (and fees) up to maximum of 5 years;
    - 4.1.7.1. Include inflationary factors where the legislative authority allows.

## 5. References

- 5.1. *User Fees Act*
- 5.2. *Financial Administration Act*
- 5.3. *Department of Health Act*
- 5.4. Health Canada Policy on External Charging
- 5.5. Health Canada Guideline on Navigating the Fee Process
- 5.6. Health Canada Guideline on Service Standards
- 5.7. Health Canada Guideline on Fee Mitigation
- 5.8. Health Canada Guideline on Complaint Resolution and Dispute Management
- 5.9. Treasury Board Policy on Service Standards for External Fees
- 5.10. TBS Guide to Costing and Toolkit for Government Costing
- 5.11. Canadian Nuclear Safety Commission Fee Structure
- 5.12. Competition Bureau Fee and Service Standards Policy

## 6. Enquiries

- 6.1. Enquiries on this guideline should be directed to:

Revenue and Costing Section  
Chief Financial Officer Branch  
[rca\\_src@hc-sc.gc.ca](mailto:rca_src@hc-sc.gc.ca)  
Tel: (613) 952-9936  
Fax: (613) 957-2292

**Figure 1: Fee Development Diagram**

Reference	Steps in the Fee Process	
Departmental Policy on External Charging; <i>User Fees Act</i>	Identify service/activity for possible charging	
Guideline on Navigating the Fee Process; Guideline on Fees vs. Appropriation (development pending)	Determine that cost recovery is applicable	
Legal Services	Determine Legislative Authority	
Guideline on Service Standards	Develop Service Standards	
	Compare Service Standards to other countries with which comparison is relevant	
Departmental Policy on Costing; Corporate Cost Allocation Model; Branch Activity Full Costing Models (development pending) TBS Guide on Costing of Outputs (draft) TBS Costing Toolkit (currently in draft)	Conduct costing of service/activity, including corporate service component	<b>COSTING</b>
	Determine amount that is recoverable	
Guideline on Fee Structure	Design Fee Structure	<b>PRICING</b>
Guideline on Fee Mitigation	Identify potential unintended consequences of the fee	
	Design fee mitigation mechanisms	
	Identify alternative sources for funding any shortfalls	
	Develop Issue Analysis for internal discussion and approval	
	Internal sign-off	
	Prepare Impact Analysis for External Review	
Guideline on Consultation (development pending)	Undertake Consultations with Stakeholders	
Guideline on Complaint Resolution and Dispute Management	Establish independent advisory panel to address complaints/disputes	
	Develop Proposal	
	Table in both Houses of Parliament	
	Fee approved	<b>FUNDING</b>

Fee mitigation for unforeseen circumstances	Inflation factor update where allowed by legislation	Periodic review of fees in accordance with pre-established timetable	Assessment of department's performance against standards	Annual Report (DPR)	Revenue Tracking
			Fee reductions, if required		

**Figure 2: Fee Types**

Activity Characteristics	Fee Type	Advantages	Disadvantages												
<p>Activities do not vary</p> <p>Cost is fixed</p> <p>Volume of work is stable</p>	<p>Flat Fee</p> <p>Example:</p> <table border="1" data-bbox="548 327 859 506"> <thead> <tr> <th>Activity</th> <th>Hours</th> <th>Fee</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>9.5</td> <td>\$100</td> </tr> <tr> <td>B</td> <td>10</td> <td>\$100</td> </tr> <tr> <td>C</td> <td>10.5</td> <td>\$100</td> </tr> </tbody> </table> <p>Fee remains the same and is not affected by the required level of effort.</p>	Activity	Hours	Fee	A	9.5	\$100	B	10	\$100	C	10.5	\$100	<p>Does not require elaborate information system</p> <p>Simple and straightforward</p> <p>Easily understandable by fee payers</p>	<p>May not be fair to all fee payers or the Department in that the fee may not always be proportional to the amount of effort required to provide the service/activity.</p>
Activity	Hours	Fee													
A	9.5	\$100													
B	10	\$100													
C	10.5	\$100													
<p>Professional expertise is required for different jobs</p> <p>Different level of effort and skills required for different activities</p> <p>There are logical steps between the level of effort and skills required for each activity</p>	<p>Stepped Fee</p> <p>Example:</p> <table border="1" data-bbox="548 774 859 953"> <thead> <tr> <th>Activity</th> <th>Hours</th> <th>Fee</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>9.5</td> <td>\$100</td> </tr> <tr> <td>B</td> <td>10.0</td> <td>\$105</td> </tr> <tr> <td>C</td> <td>10.5</td> <td>\$110</td> </tr> </tbody> </table> <p>Fee varies in pre-determined increments, no matter what the level of effort.</p>	Activity	Hours	Fee	A	9.5	\$100	B	10.0	\$105	C	10.5	\$110	<p>Fee is more proportional to level of effort required to perform a service or activity</p> <p>Ensures a fairer distribution of costs</p>	<p>More complex to administer</p>
Activity	Hours	Fee													
A	9.5	\$100													
B	10.0	\$105													
C	10.5	\$110													
<p>Process of an activity varies</p> <p>Level of effort varies substantially</p>	<p>Variable Fee</p> <p>Example:</p> <table border="1" data-bbox="548 1266 859 1444"> <thead> <tr> <th>Activity</th> <th>Hours</th> <th>Fee</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>9.5</td> <td>\$95</td> </tr> <tr> <td>B</td> <td>10.0</td> <td>\$100</td> </tr> <tr> <td>C</td> <td>10.5</td> <td>\$105</td> </tr> </tbody> </table> <p>Fee varies in direct proportion to the level of effort.</p>	Activity	Hours	Fee	A	9.5	\$95	B	10.0	\$100	C	10.5	\$105	<p>Most proportional to level of effort required to perform a service or activity</p> <p>Most fair distribution of costs of government activities</p>	<p>Requires increase in data entry and costing requirements/models.</p> <p>Potentially complex for fee payers to understand</p>
Activity	Hours	Fee													
A	9.5	\$95													
B	10.0	\$100													
C	10.5	\$105													

**Examples:**

**Flat Fee – Canadian Authority to Sell a Drug:** The fee payer is required to pay an annual set fee per each schedule type that has been assigned a Drug Identification Number (DIN). The fee is not altered by the level of effort required in confirming the existence of the DIN, the current ownership, location, etc.

**Stepped Fee – Australian Government Registration of Non-Prescription Medicines Evaluation Fees:** Imposes a page count fee: 1-50 pgs. = \$ 6,300, 51-250 pgs. = \$8, 100 and the fee continues to be stepped to the maximum fee of \$44,200 for > 3,000 pgs. There is an impact on the fee with each step; however, the fee is impacted by the additional step associated with the work and not the experience/ability of the person doing the work.

**Variable Fee- A submission fee – New Zealand Food Safety Authority:** Charges an hourly rate for the issuing or renewing of food import permits and inspecting of prescribed foods, tableware, etc. as well as other related permits/services. The level of effort as well as the experience and ability of the inspector can directly impact the amount of the fee.